MANUFACTURING CHEMISTS ASSC
1825 CONNECTICUT AVENUE, N.W. WASHINGTON, D.C. 20009 (202) 483-6126

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February 5, 1974

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MEDICAL DEPT.

To: AIR QUALITY COMMITTEE
LABELS AND PRECUATIONARY INFORMATION COMMITTEE
OCCUPATIONAL HEALTH COMMITTEE
SAFETY AND FIRE PROTECTION COMMITTEE
SOLID WASTES MANAGEMENT COMMITTEE
TECHNICAL TASK GROUP ON VINYL CHLORIDE RESEARCH
WATER RESOURCES COMMITTEE

Subject: NIOSH Investigations and Recommendations with Regard to Vinyl Chloride (VC) and Polyvinyl Chloride (PVC)

Gentlemen:

The attached correspondence from NIOSH Director Dr. Marcus Key reports their activities consequent to the report by the B. F. Goodrich Chemical Company of four cases of angiosarcoma of the liver among the employees of their Louisville, Kentucky vinyl chloride operations. At Dr. Key's request, we are helping to provide wide distribution of NIOSH's recommendations among those industries handling vinyl chloride.

As you may know, a group of PV/PVC companies has been supporting MCA-administered studies involving chronic inhalation exposures of laboratory animals to vinyl chloride monomer vapors, and a mortality study of workers in the industry. Both programs are as yet incomplete, and MCA will continue to cooperate with NIOSH as it seeks to resolve the questions raised by these events.

The Occupational Safety and Health Administration will hold hearings, starting February 15, 1974, to determine whether an emergency standard should be promulgated for vinyl chloride,

631030

or whether it should proceed directly to develop a permanent standard pursuant to section 6(b) of the Act. MCA plans to submit a statement.

Sincerely,

Kenneth D. Johnson, Ph.D.
Secretary, Technical Task Group
on Vinyl Chloride Research

KDJ:mb

Distribution "C"

cc : Medical Contacts
Management Contacts of Companies Supporting the Vinyl Chloride Research Program
D. P. Duffield, M.D.
Mr. D. M. Elliott
Dr. Tiziano Garlanda

and the National Institute for Environmental Health Sciences (NIEHS), as to the results of the initial survey of the Louisville plant and also review the results of the investigation thus far. Subsequent to this meeting, NIOSH will develop a protocol for further field studies as well as recommendations for medical diagnosis and follow up.

At this time the etiologic role of vinyl chloride in the induction of the observed liver tumors is not certain. The occupational exposure of the deceased workers to over 50 other chemicals at the Louisville facility precludes a clear definitive role for this substance as a carcinogenic agent until the degree of exposure to other chemical substances and work histories of deceased employees can be evaluated. However, the implication of vinyl chloride as the possible etiologic agent is not readily dismissable and, unless an association with another of the chemical substances is revealed, vinyl chloride must remain as the principal etiologic agent of suspicion.

Until well-documented recommendations to OSHA can be developed, we are recommending that the preliminary work practices and monitoring and control procedures for the polymerization of vinyl chlorides (Enclosure 1) be instituted as interim measures. These preliminary procedures are based, in part, on the information on hand concerning the operation of the Louisville facility and on the results of the walk-through survey conducted by members of the Institute's staff. These recommendations in more specific detail have been transmitted to the B. F. Goodrich Chemical Company for implementation at their Louisville facility.

Mr. Vernon E. Rose, Acting Assistant Institute Director for Research and Standards Development will provide NIOSH coordination in development of controls and/or standards to be recommended to OSHA. Mr. Rose or members of his staff may be reached by telephone at (301) 443-3680. They will insure that all requests for technical information or assistance concerning this situation are directed to appropriate NIOSH staff or members of the other Federal agencies involved with the ongoing study.

The possible significance of vinyl chloride as a carcinogenic substance requires close cooperation between the vinyl chloride industry and State and Federal agencies. Consequently, it is my hope that through your organization the above information and

enclosed recommendations can receive the widest distribution to other companies using these processes.

Sincerely yours,

Marcus M. Key, M.D.
Assistant Surgeon General
Director

Enclosure

Enclosure 1

NIOSH Recommended Precautionary Monitoring and Control Procedures for Polymerization Processes Involving Vinyl Chloride

I. General Housekeeping Procedures

A. The spillage of Vinyl Chloride and ~~Polyvinyl Chloride~~ in and around the production facilities should be controlled as follows:

1. Housekeeping procedures should be implemented to assure immediate removal of VC and PVC material around polymerization operations including drying, packaging and loading operations.

2. Recovered PVC material which is to be packaged should be stored in closed containers.

3. Waste PVC material should be stored in closed containers and consideration should be given to the adequacy of its disposal and/or destruction. Care should be taken in the storage of closed containers to insure that unsafe conditions do not result from an internal build-up of pressure in the container.

B. Inventories of beginning and recovered quantities of VC and quantities of PVC produced, packaged and recovered should be made to determine losses and probable areas affected.

C. PVC material should be removed from overhead structures and conduits where it tends to collect.

D. Consumption of food should be permitted only in separate facilities provided for this purpose, and no food products should be permitted elsewhere in the polymerization facility.

II. Protective Clothing

A. A daily change of protective clothing including full coveralls, or the equilvalent, should be provided each employee in areas where possible exposure to VC [redacted] could occur. Clothing contaminated by accidental spills should be changed as soon as feasible.

B. Protective gloves and footwear, or footcovers, should be worn as appropriate in those ~~PVC~~ operations where exposure to ~~PVC~~ material is possible.

C. Protective head covers should be worn during ~~PVC~~ operations as appropriate (e.g. hard hats in those areas where physical protection of the head is necessary and hair coverings, or the equilvalent, in

2. Breathing zone samples should be obtained to complement environmental monitoring program for VC, and similar samples should be obtained for PVC.

V. Respiratory Protection

Because VC is a gas under ambient conditions and PVC is a solid under these conditions, it is recommended that respiratory protection for employees take these circumstances into consideration.

A. Where employees are engaged in cleaning and maintenance operations inside polymerization reactors they should be equipped with an atmosphere-supplied respirator in order to protect against both VC vapor and PVC particulates.

B. During housekeeping procedures and packaging operations where the possibility of PVC dust inhalation is a factor, it is recommended that an air-purifying respirator equipped with a mechanical filter designed to remove particulate material be worn. Respiratory protective devices which meet this requirement, as well as protect against VC vapors in concentrations less than 0.1% have been approved by the NIOSH Testing and Certification Laboratory and bear the numbers: TC-23C-40, TC-23C-47, TC-23C-48.

C. Where employees are engaged in transfer operations of VC from railway tankcars to storage facilities or at any similar transfer point which requires manual operations, they should wear a self-contained breathing apparatus (SCBA) during such operations to guard against unexpected release of VC during such operations.

D. Other operations involving possible exposure to VC or PVC should be evaluated as the individual situation exists and respiratory protection provided as appropriate.

(36)

MANUFACTURING CHEMISTS ASSOCIATION

1825 CONNECTICUT AVENUE, N.W. WASHINGTON, D.C. 20009 (202) 483-6126

1977

September 27, 1977

TO: Vinyl Chloride Technical Panel

SUBJECT: I. The Chemistry and Biogenesis of the S-Containing Metabolites of Vinyl Chloride in Rats

II. Comparative Mammalian Metabolism of Vinyl and Vinylidene Chlorides in Relation to Oncogenic Potential

Gentlemen:

Mr. R. N. Wheeler has thoughtfully made available the subject technical papers which he received from Mr. J. Stafford of ICI. Your copies of these papers are enclosed.

The contribution by Dr. David E. Hathway on the elucidation of the role of vinyl chloride metabolites in the various reaction sequences which comprise the metabolic pathway (reference Subject II) was well received at the Symposium on Comparative Metabolism and Toxicity of Vinyl Chloride Related Compounds (NIEHS, Bethesda, Maryland).

Sincerely,

J. T. Seawell
Project Manager
Vinyl Chloride Research

JTS:ec
Enclosures

631035.1

VINYL CHLORIDE (26)

1625 I Street, N.W.
Washington, DC 20006
202-872-1080

Organization Resources Counselors, Inc.

Memorandum

February 14, 1980

To: ORC Occupational Safety and Health Group
ORC Occupational Safety and Health Physicians Group
ORC Occupational Safety and Health Lawyers Group

From: Richard F. Boggs

The following is reproduced with the author's permission and provides an interesting assessment of the impact that OSHA's vinyl chloride actions have had on the business community.

Enclosure

RFB:shb

SAFE AND HEALTHFUL WORKING CONDITIONS: THE CASE OF VINYL CHLORIDE

Charles R. Perry, Associate Professor of Management,
University of Pennsylvania Senior Faculty Research Assoc.
Industrial Research Unit
The Wharton School.

The Occupational Safety and Health Act was passed less than ten years ago with an apparent ease and unanimity uncharacteristic of major labor legislation in this country. The Occupational Safety and Health Administration created by the Act, however, has not enjoyed the blessings of its noble birthright. Indeed, OSHA, almost from its inception, has been the target of public criticism and private conspiracy typically reserved for the mad or illegitimate progeny of royalty.

The fall from grace of the highborn is fascinating to observe and intriguing to explain. The "downfall" of OSHA began with the requirement of "inflation impact statements" for major regulatory actions and has been carried on in the "regulatory reform" and "regulatory analysis" movements. These movements are the product of a perception that OSHA, like an unwise monarch, is imposing substantial and oppressive new taxes to support personal adventures which provide or promise little tangible benefit to an already overtaxed populace which, per force, must indulge the king's whims.

There can be no doubt that OSHA regulations impose a tax on the producers and consumers of American-made goods and services. There is, however, considerable latitude for debate over the magnitude of that tax both in absolute terms and in relation to the benefits purchased by the tax. This debate over the absolute and relative impact of OSHA regulation on productivity and cost may never be subject to definitive resolution, but it should be possible to gain some perspective on the issue by analysis of the results of specific

OSHA regulatory initiatives. The OSHA standard governing worker exposure to vinyl chloride provides an excellent vehicle for such an analysis because it was one of the first major new health standards promulgated by OSHA and one whose impact was concentrated in a single easily studied industry.

The Feasibility of Compliance

The battle over the permanent standard for permissible levels of worker exposure to vinyl chloride was beset with the predictions of dire economic consequences which have become commonplace in the standard setting process. Such consequences clearly have not come to pass, a fact which prompted some to conclude that the industry "cried wolf."[1] That conclusion, strictly speaking, is not justified. But, justified or unjustified, it has had the effect of tempering the industry response to other proposed regulations.

The permanent standard initially proposed by OSHA called for a "no detectable" exposure level. The industry responded that such a standard "is not technologically feasible and, if adopted, would shut down the industry."[2] Interestingly, this claim was supported by the conclusion of a feasibility study commissioned by OSHA.[3] The consequences of a possible industry shutdown were detailed in a separate study which indicated that $65 to $90 billion in GNP and $1.7 to 2.2 million jobs were dependent on the production of PVC resins.[4]

The industry argued for a standard which would set a time weighted exposure limit of 10 ppm for polyvinyl chloride resin plants and 5 ppm for vinyl chloride monomer plants[5] based on feasibility considerations. Organized labor endorsed the "no detectable level" standard and disputed the infeasibility of such a standard. The results of its own feasibility study

forced OSHA to withdraw from the no detectable level standard and to adopt in its place a 1 ppm standard. The industry challenged both the necessity for and feasibility of this stringent limit in the courts with a notable lack of success, particularly since the court of appeals specifically ruled that

> the secretary is not restricted to the status quo. He may raise standards which require improvements in existing technologies or which require the development of new technology . . . .[6]

The actual economic consequences of this technology-forcing standard for the viability of PVC plants and the availability of jobs in those plants were remarkably modest. A few older PVC plants were shutdown, in whole or substantial part, because of the projected cost of bringing those facilities into compliance with the requirements of the standard. These shutdowns resulted in the loss of about 325 million pounds of production capacity and 375 jobs--approximately 5 percent of the industry total. Much of the credit for the modesty of these adverse effects now is attributed by the industry to the reasonableness of the standard itself as is evident in the following confidential statement of one company representative.

> The OSHA-VCM program was, in the end, a real success story for both OSHA and the VCM-PVC industry. By fighting the "absolute zero" concept originally proposed, industry achieved a more practical 1 ppm standard that allowed it to continue to operate and grow. And, apparently the standard has protected the workers . . . so at least in this case we have a government regulation that has been practical and beneficial to all concerned.

The Cost of Compliance

The vinyl chloride standard may not have been catastrophic for the industry, but it was expensive. The first public estimate of the cost of compliance with the 1 ppm standard indicated that the industry would have to

invest $200 million (excluding development costs) in immediate process improvements to satisfy the requirements of the standard.[7] The VCM-PVC industry actually invested about $130 million in such process improvements to bring existing production facilities into compliance with the standard. More than 90 percent of this total was accounted for by PVC plants which employ only about 75 percent of the workers in the industry.

The apparent $70 million cost "saving" recorded by the industry is an attractive focus of attention but in no way offsets the $130 million actual invested in compliance with the standard. It is difficult to identify the sources of the saving without knowledge of the basis of the original $200 million cost estimate, but three possibilities deserve note. First, part of the savings may be attributable to the decision to close rather than modify some older PVC plants. Assuming that these plants had the most acute and expensive compliance problems, they may well have accounted for as much as 10 percent of estimated compliance cost, although they represented only 5 percent of PVC capacity, and for as much as $20 million of the $70 million saving. Second, part of the savings may have stemmed from miscalculation of the significance of the relative cost advantage of VCM facilities in complying with the standard. For example, there was an almost $4000 per worker difference between average compliance cost for PVC and for VCM-PVC plants which, if not accounted for in industry cost projections, would have added another $25 million to those estimates. Finally, the industry was able to find more efficient means to achieve compliance than were foreseen at the time the standard was adopted. The largest producer in the industry reported it had been able to reduce its projected $42 million compliance costs by 10 to 15 percent through technological developments.[8]

If other producers were able to realize similar economies, the total saving for the industry would have been another $25 million.

Compliance with the vinyl chloride standard entailed incremental operating as well as capital costs. Data on incremental operating costs are limited, but the data which are available suggest that compliance probably cost the industry close to $10 million per year or $100 million in present value terms, assuming a 10 percent interest rate and infinite time horizon. Approximately 70 percent of this incremental operating cost was attributable to added activity and staff in two areas--exposure monitoring and equipment maintenance.

The incremental operating costs associated with compliance are noteworthy for three reasons. First, they were not included in public estimates of compliance costs. Second, they were sizeable both in absolute amount and in relation to the capital costs of compliance. Finally, they appear to have been primarily a product of exposure control, per se, rather than the more peripheral requirements of the standard such as record-keeping or medical surveillance.

The incremental capital and operating costs associated with compliance constitute the most visible dimension of the economic impact of regulation. A much more subtle and surprising economic impact of the vinyl chloride standard was a significant reduction in effective production capacity and output per man-hour in the industry.

Compliance with the exposure limits set by the standard required substantial changes in work procedures in the industry. These changes resulted in less efficient utilization of existing equipment and manpower which lowered effective capacity by approximately 15 percent. The actual

loss of product and productivity immediately after the standard became effective was slightly less than 15 percent because there was some temporary excess capacity in the industry. Over the longer run, however, the loss of product and productivity in then existing facilities has approached the full 15 percent for two reasons. First, industry sales generally have been capacity limited. Second, little progress has been made in eliminating the need for modified work procedures which limit capacity.

The Price of Compliance

There is every reason to expect that the compliance cost of regulation will be borne by the consuming public. This clearly appears to have been the case for the regulation of worker exposure to vinyl chloride. In the year following implementation of standard, the price of PVC resins increased by $.02 to $.03 per pound. OSHA regulation appears to have accounted for approximately 20 percent of this price increase.

The incremental capital and operating costs for compliance with the vinyl chloride standard represent the equivalent of a $23 million increase in annual production cost. That $23 million, in turn, is the equivalent of a $3000 per year or $1.50 per hour wage premium for the approximately 7000 workers employed in the VCM-PVC industry. Assuming average hourly compensation of $10 for those workers, the OSHA vinyl chloride standard mandated a 15 percent increase in effective wage rate in the industry. That 15 percent increase coupled with a 15 percent drop in productivity suggests that compliance resulted in a 35 percent increase in unit labor costs. Labor costs, however, is only a small percentage of total cost in the VCM-PVC industry

and probably accounts for no more than 10 percent of total operating cost. Thus, OSHA regulation added no more than 3.5 percent to cost of PVC resins--about $.005 per pound. Assuming production from then existing facilities of 4.5 to 4.8 million pounds the cost to consumers would be about $23 million per year.

It is highly unlikely that any industry will passively accept increases in wage rates and labor costs of the magnitude imposed by OSHA on the VCM-PVC industry, except in the short run. Over time, one must expect changes in basic patterns of resource use which permit a more efficient and less costly accommodation to the requirements of regulation. In this context, three possibilities deserve attention: 1) technological change; 2) economies of high safety; and 3) shock effects.

The development and application of labor-saving technology is the classic mode of industry adaptation to rising relative labor cost. The process improvements undertaken in immediate response to regulation clearly were not labor-saving in character. Subsequent process improvements instituted as old production capacity is replaced and new capacity added, however, generally have been labor saving in character. Most notable among these process improvements has been the construction of computer-controlled facilities which has enabled at least one firm to increase its production capacity by 10 percent with no change in total employment. The cost savings resulting from this favorable productivity trend, however, have been far more modest than 10 percent due to the greater capital investment and the higher ratio of high wage workers required by computer-controlled operations.

The possibility that a substantial increase in real wages will elicit

a long-run increase in the productivity of labor is recognized in economic theory. This "economy of high wages" generally has been regarded as a phenomenon to be found in developing rather than mature economies. It is possible, however, that in an affluent society and economy such as ours there are substantial "economies of high safety and low risk." The early experience of the industry provided little evidence to support the existence of such "economies of low risk." Subsequent experience provides little additional evidence that the "health premium" paid by the industry has yet significantly enhanced its ability to recruit or retain qualified labor or reduced the relative wage rates it must pay to do so. The possibility of economies of low risk which are, in a broader sense, a basic economic justification for the OSHA regularity effort remains an open question deserving of further research.

The possibility that a dramatic rise in wage rates and labor costs will elicit offsetting savings through more intensive efforts by management to control and reduce the non-labor costs of production is also recognized in economic theory. The experience of the VCM-PVC industry provides some limited evidence of such a "shock effect." One effect of the standard was to encourage development of new technology to permit more complete reaction of VCM or recovery of unreacted VCM in the process of manufacturing PVC resins. The incentive for this effort was twofold: 1) to reduce the level of VCM emissions in plant; and 2) to reduce the potential level of VCM emissions from PVC resins at the fabrication stage in order to permit the purchasers of those resins to escape regulation. The industry response to these cost/sales incentives ranged from changes in reaction formula to development of new stripping technology and resulted in an increase

of the overall reaction/recovery rate for VCM in the PVC industry by 3 to 5 percent. This improvement in raw material usage has produced cost savings for the industry which have grown in value over time as VCM prices have risen. Those cost savings, however, are not yet judged by the industry to be of sufficient magnitude to provide a competitive rate of return on the investment required to achieve the improvement in reaction/recovery rate.

The Divine Right of the King

The court test of the vinyl chloride standard confirmed that OSHA enjoyed almost unlimited taxing power in the exercise of its authority and responsibility to promulgate standards. The vinyl chloride standard itself represented a classic case in what can be characterized as a heavy-handed use of that power. The result was a substantial, multi-faceted tax on the production of VCM and particularly PVC involving a one-time license tax (the incremental capital cost for old and new facilities), an annual operating tax (the incremental operating costs for an old and new facilities), and a direct tax or tithe on output (the loss of production capacity). The net effect of these taxes has been a downward shift in the industry's production function for positive outputs (products) hopefully accompanied by a comparable downward shift in its production function for negative outputs (problems).

Is the king insane? There are many who would say that he is, but the vinyl chloride experience suggests the contrary. The tax imposed on the industry was substantial, if not staggering, in terms of its impact on effective unit labor costs; however, it was not lethal and even proved to be less than was predicted, at least with respect to the most visible

regulatory tax--initial capital investment. Whether by accident or design, the taxes imposed on the industry had little obvious effect on either the price or availability of PVC resins. This "fortunate" result is not inevitable, but is not improbable in the case of a single regulation. The cumulative effects of multiple kingly mandates or mandates by multiple kings (OSHA and EPA) may be quite different but equally difficult to detect until or unless there is another "Chrysler crisis" or worse.

If not insane, is the king profligate? The answer to this question depends strictly on viewpoint. The vinyl chloride standard was very conservative with respect to the level of risk assigned to workers, but equally liberal with respect to the level of cost assigned to the industry. The dramatic difference in the initial capital investment required to achieve compliance between the VCM and PVC segments of the industry at least suggests that OSHA may have been profligate in not adopting a two-tier standard. Similarly, the paucity of evidence "economies of low risk" suggests that the industry in general may have been overtaxed in relation to the desires of its own current and prospective workers in whose name the tax was levied.

If the king is not insane or profligate, is he a fool? The answer to this question, again, is a matter of perspective. Politically/bureaucratically, it is difficult to fault OSHA's desire to probe the frontiers of feasibility as it did in the vinyl chloride standard. Economically, however, the taxes necessary to indulge that desire are open to serious question. At the present time, it is impossible to measure and difficult to predict the reduction in negative output resulting from the regulation of worker exposure to vinyl chloride. However, neither the historical nor

the recent record of the industry offer solid evidence that the benefits of regulation will prove to be substantial. After 30 years of operation with worker exposures many times that mandated by the standard, fewer than 25 deaths from angiosarcoma of the liver were attributed to occupational exposure to vinyl chloride. Even more disturbing is the report from one industry source that the last confirmed case of angiosarcoma of the liver in the industry was discovered in early 1976, despite the fact that during the 1974 crisis,

> . . . We observed workers contracting angiosarcoma only after 10 to 20 years of high exposure. So there were predictions that because of a latency period, no matter what [OSHA or the industry] did, cases of angiosarcoma might continue to surface at the rate of two or three a year for ten years or more.

Should the king be deposed for his possible economic folly? The answer to this question ultimately will depend on the willingness to pay a tax to insure ourselves against the risk of collective guilt for occupational injury and illness. To date that willingness has been strained but not broken, at least in part due to the intervention of the courts and the White House to restrain the king in the exercise of his power to tax. Perhaps this form of constitutional monarchy will suffice to serve the public interest in these inflationary times. Only time will tell, and there may be little of that left given the mounting chant of "down with the king" and our tradition of changing rules if not rulers in the labor field every twelve years.

FOOTNOTES

1. Steven Rattner, "Did Industry Cry Wolf? Polyvinyl Chloride Health Rules Can Be Met," New York Times, December 28, 1975, p. C-5.

2. "Post-Hearing Memorandum of the Society of the Plastics Industry, Inc. --Proposed Findings of Fact and Conclusions Supported by the Record," (Memorandum presented to the U.S. Department of Labor, Occupational Safety and Health Administration, in the matter of proposed permanent standard for occupational exposure to vinyl chloride, Washington, D.C., August 22, 1974), p. 5.

3. "Showdown on Vinyl Plant Rule Presages Shutdowns," Chemical Week, September 25, 1974, p. 15.

4. Arthur D. Little, Inc., United States Polyvinyl Chloride Industry Impact Analysis (Cambridge, Mass: Arthur D. Little, Inc., 1974), p. 5.

5. "Showdown on Vinyl Plant Rule Presages Shutdowns," Chemical Week, September 25, 1974, p. 16.

6. Brief for SPI at 39, Society of the Plastics Industry, Inc. v. Occupational Safety and Health Administration, 509 F. 2d 1309 (2nd Cir. 1975).

7. "PVC Plants are Ready to Pass First Test," Chemical Week, May 7, 1975, p. 49.

8. "Goodrich Cuts Cost of Meeting VCM Limits," Chemical Week, December 10, 1975, p. 59.

MCA-EPA-SPI
1976

December 6, 1976

Messrs: F V Prus
E J Burkett
W L Cox
F A Cox
J M Gilmore
W Ito

Attached are the details of the EDF Suit. We have agreed -

(1) Support SPI in their intervention

(2) Support SPI in a request for stay.

Goodyear needs to determine whether they as an individual want to file for either of the above.

No further detials are known on the "ozone technology."

Director
Domestic Chemical Production

D H Francis
J

attach

631035.15

BEVERIDGE, FAIRBANKS & DIAMOND

MEMORANDUM

November 30, 1976

TO: Mr. Jerome Heckman

FROM: Beveridge, Fairbanks & Diamond

RE: EDF Petition to Review EPA Vinyl Chloride Standard

Factual Background

Pursuant to our meeting on November 23, 1976, we have reviewed the background of the Environmental Defense Fund (EDF) Petition in greater detail. In addition, we have generally examined the legal options available to SPI.

On November 22, 1976, Gary Baise advised you that EDF believes EPA did not use "best available technology" in setting the Vinyl Chloride Standard. Based on further discussion, we have determined that the technology referred to by EDF involves the oxidation of vinyl chloride by ozone in the presence of ultra-violet light. This technology, according to EPA, has been successful in the laboratory but has not been used on a commercial basis.

EPA is seeking a demonstration project for the ozone technology and will be ready to supply equipment for such a project to one or more companies in a couple of months.

This technology was brought to the Agency's attention by Houston Research Corporation, Houston, Texas; Westgate Research Corporation, California and General Electric. G.E. is apparently using this technology for solving its PCB problem. At least one firm has tried to sell this technology to a producer of polyvinyl chloride but was turned down.

Notwithstanding the development of this new technology, the EPA staff at Research Triangle Park, North Carolina, believes that best practicable, demonstrable technology was used and they stand behind their decision. One note of caution: Bernard J. Steigerwald, Deputy Assistant Administrator for Air Quality Planning and Standards, who was in overall charge of the Vinyl Chloride Standard, has resigned his post and he has been replaced by Walter Barber. The impact of this change cannot be underestimated.

Mr. Barber has already determined that the Vinyl Chloride Standard and the events leading up to its promulgation should be re-examined and has advised EDF accordingly. Furthermore, we have been advised that Mr. Barber would like to see this case settled. He believes the case will cause a manpower drain and if an acceptable solution to the law suit can be devised, he would welcome one.

One option which may be considered by Mr. Barber is to apply the present Standard to existing plants and the new ozone technology, if proven practicable, to new sources. This might be acceptable to EDF because it believes that the two year period in the Clean Air Act allowed for installation of controls is intended to give adequate time in which to develop new technology to virtually prohibit emissions.

It is also known that Mr. Barber is concerned over the fact that the Maltoni data submitted by Ralph Harding to Messrs. Talley and Strelow was not formally brought to the attention of the Administrator by these EPA officials or their staffs before he signed the Standard.

Regarding the Maltoni data, the EPA staff does not seem to be overly concerned. They believe it would be an error to change the Standard because these new data have not been replicated, are not statistically significant; and as Dr. Maltoni admitted, are inconclusive. Therefore, the Standard can be defended from a medical standpoint. One word of caution: this view is not official and has not been reviewed by the policy makers in the Agency.

It is clear that the EDF Petition has created uncertainty with respect to the Vinyl Chloride Standard, and creates problems for the enforcement of the Standard. Because of the statutory 90 day waiver period and the requirement in EPA's regulations for a compliance schedule, contractual commitments and installation of control technology, the EPA General Counsel is reviewing the question of waivers.

Discussion

There is uncertainty as to what position EPA will adopt with respect to: (1) defending the Standard in the face of the EDF challenge; (2) enforcement of the current Standard; (3) the waiver process with its 90 day deadline. In light of these considerations, we have reviewed the legal issues and conclude that there are only two which require a decision by SPI. They are whether to move to intervene and whether to seek an order from the Court staying the effective date of the Administrator's final action.

1. Intervention

We believe the advantages of intervention are: (a) EPA may not adequately defend the Standard; (b) even if it does so, SPI may wish to argue different issues; (c) SPI will be in a better position to protect its interests in settlement discussions; (d) SPI will have the opportunity to ensure that the record on appeal is complete and (e) it will be in a better position to protect its interest in any further appeals. The major objection to interventions is that by defending the Standard, SPI might appear to compromise EPA by giving the impression that the Standard is an "industry standard".

On balance, we believe the reasons for intervention clearly outweigh the reason against and that papers should be prepared as promptly as possible pursuant to Rule 24(a), F.R.C.P. Although EDF has not decided whether to oppose such a motion, we believe that the motion will be granted even if opposed.

2. Stay

Under the Act, the filing of a petition for review does not automatically stay the proceedings and the statutory time limits for waivers (90 days) and final compliance with the Standard (two years after the effective date) continue to apply. This creates serious practical problems for the industry.

We recommend the following:

(1) SPI file as promptly as possible a motion to stay the effective date of the Administrator's final action. The Clean Air Act, unlike other statutes, e.g. the Occupational Safety and Health Act, does not contain an explicit provision authorizing a court to order such a stay. However, we believe that in a case of this importance, that the Court will consider such a request.

(2) Each company which intends to seek a waiver should continue to follow the statutory and regulatory requirements currently in effect, but as previously advised, should not enter into any binding contractual obligations.

(3) SPI should continue its efforts to negotiate with EPA a practical solution to the problems created by EDF's petition and the statutory deadlines.

EJ Bartlett

12/6

JOSEPH E KELLER
JEROME H HECKMAN
CHARLES M MEEHAN
WILLIAM H BORGHESANI JR
ROBERT R TIERNAN
WAYNE V BLACK
DAVID L HILL
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12/10

December 3, 1976

DH Francis (PLAN
cc FA Cox
A Gilmore W.
T. Ito

TO: All Members of:

VCM/PVC Producers Group
VCM/PVC EPA Technical Committee
Attendees at October 26, 1976 Meeting

Gentlemen:

Following our standard procedure we are forwarding herewith a copy of a self-explanatory letter and attachments received today from Associate Counsel, Beveridge, Fairbanks & Diamond. That letter is concerned with disclaimer statements (vis a vis the potential effects of the EDF Petition to Review) that could be used by member companies intending to file waiver requests with the Environmental Protection Agency.

Should you have questions about any aspect covered in this communication, please do not hesitate to contact us.

Cordially yours,

Joseph E. Hadley, Jr.

Enclosures

631035.20

LAW OFFICES
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JONATHAN Z. CANNON
ANDREW E. MISHKIN
CHRISTOPHER H. BUCKLEY, JR.
CHARLES A. PATRIZIA
SUEDEEN M. GIBBONS *

* NOT A MEMBER OF D. C. BAR

CARL EARDLEY
OF COUNSEL

CABLE ADDRESS
"INDLAW"

December 3, 1976

Jerome H. Heckman, Esquire
Keller and Heckman
Suite 1000
1150 17th Street, N.W.
Washington, DC 20036

Dear Jerry:

Since the VCM/PVC Producers' Group meeting of November 30, 1976, we have been requested by several members of SPI to suggest appropriate language to be added to their waiver requests filed under EPA's Section 112 regulations currently applicable to vinyl chloride, for the purpose of protecting their rights in light of the filing of the EDF challenge to the final Standard.

Enclosed are two suggested drafts. Draft "A" would cover those situations where a company must shortly execute major contracts in order to meet compliance requirements. Draft "B" is designed to cover situations where future contractual problems are anticipated.

In recent conversation with EPA officials, I have learned that the Agency's tentative inclination, in light of the EDF challenge, is to consider treating interim compliance steps required under Section 112 and the regulations (Part 61.10) and final compliance (two years after the effective date) differently. The Agency may be willing, until there is some clarification of the legal challenge, to permit a company to defer signing substantial contractual agreements implementing interim compliance steps if the contract lead time is not so great that there will be any difficulty complying with the Standard as presently published by October 21, 1978. On the other hand, EPA would probably not be inclined to permit deferral of execution of any contract if a delay might result in the company being unable to meet the present Standard within the two-year statutory time limit.

631035.21

This policy may be of some assistance to certain companies but we recognize it probably does not help others. We are, therefore, continuing to discuss with EPA other ways to alleviate the serious problems facing the industry because of the recently-filed legal challenge.

Because of the relative uncertainty still surrounding these issues, it would be advisable for member companies applying for waivers to proceed as they had originally planned but to review carefully their contractual commitments along the lines suggested in the enclosed draft disclaimer statements. We hope that each company will tailor its disclaimers to its own specific circumstances so that these drafts do not assume the appearance of a "form" letter. Each should also keep in mind the distinction EPA may draw during the current uncertainty.

Although we believe it would be prudent for companies to submit disclaimer statements, we cannot give any assurance at the present time that EPA will consider waivers containing such requests as meeting the requirements of the Agency's regulations. It should also be kept in mind that each regional office may reach its own decisions on all waiver-related issues notwithstanding the view of EPA in Washington. You may wish to have regional actions reported to you so that any problems can be taken up with the appropriate regional officials or with EPA officials here.

Please let me know if you have any questions.

Sincerely yours,

Harold Himmelman

HH/ap

cc: John R. Lawrence
Robert Laundrie

DRAFT "A"

(SUBSTANTIAL CONTRACTS NEEDED IMMEDIATELY)

PROPOSED DISCLAIMER IN VINYL CHLORIDE WAIVER REQUESTS FILED UNDER SECTION 112

EPA regulations under Section 112 of the Clean Air Act require a compliance schedule to be submitted with this waiver request including the dates each step toward compliance will be reached, contracts for installation of equipment awarded, orders issued for purchase of equipment, construction or installation initiated and completed, interim emission control steps taken, and final compliance achieved (40 C.F.R. Section 61.10).

While we herein submit a compliance schedule in conformity with Section 61.10, we wish to notify EPA that because of the legal challenge to the validity of the final Vinyl Chloride Standard filed in the U.S. Court of Appeals for the District of Columbia by the Environmental Defense Fund (Environmental Defense Fund v. Train, No. 76-2045, November 19, 1976), and the uncertainty created as to whether the Standard as published will be the final standard, we wish to defer formally executing the following contracts until the legal situation is clarified, notwithstanding our continued full intent to comply with the current Standard under Section 112:

The reason for our decision is that these particular contractual agreements, if executed now to implement the current Standard, may have little relevance to a new Standard, thus subjecting us to potential substantial legal liability for cancelling the contracts. We are continuing efforts to comply with the Standard in all other respects.

[redacted]

DRAFT "B"

(SUBSTANTIAL CONTRACTS NOT NECESSARY NOW)

PROPOSED DISCLAIMER IN VINYL CHLORIDE WAIVER REQUESTS FILED UNDER SECTION 112

In the event the status of the final Vinyl Chloride Standard is not clarified by the time it is necessary for us to enter into final contractual arrangements in conformity to our compliance schedule, we will wish to defer formally executing the following contracts pending clarification of the legal challenge to the final Standard filed by the Environmental Defense Fund in the U.S. Court of Appeals for the District of Columbia (Environmental Defense Fund v. Train, No. 76-2045, November 19, 1976):

The reason is that these particular contractual agreements, if executed at a time when there is still uncertainty whether the Standard as published will be the final Standard, may have little relevance to a new Standard, thus subjecting us to potential substantial legal liability for cancelling the contracts. In the meantime, we are fully complying with the current Standard under Section 112 and we plan to continue our efforts in this regard.

631035.24

MT 1-12-77
SHK 1/12/77
RHLeC
EMG

bl cc: *H S Sell
F C Betzhold
J R Purdon
F M Matthews
D H Francis
J M Gilmore (attachment)
F A Cox (attachment)
M E Evelsizer (attachment)
T Ito

* Please route

January 10, 1977

Mrs Juliette Lang Cahn
Staff Director
SPI, Inc
355 Lexington Avenue
New York, New York 10017

Dear Mrs Cahn:

On January 5, 1977, Goodyear sent the attached letter to CHEMTREC advising that we will assist shippers of vinyl chloride in emergency situations. Although there is a termination date on the agreement, we will extend our participation if the team response experience is favorable.

Thank you for your assistance in organizing the response program.

Very truly yours,

W D Davis

W D Davis, Section Head
Chemical Development Services

WDDslak

Attachments

631035.25

The Goodyear Tire & Rubber Company

Akron, Ohio 44316

November 15, 1976

CHEMTREC
Manufacturing Chemists Association
1825 Connecticut Avenue, NW
Washington, D C 20009

Attention: Mr Dewey A Kunze

Re: Response Teams

Dear Mr Kunze:

This is to advise that The Goodyear Tire & Rubber Company (Goodyear) will assist shippers of vinyl chloride who are members of CHEMTREC in the event of an emergency involving vinyl chloride. You may release our name, telephone numbers and the locations of our response teams to such CHEMTREC member shippers. CHEMTREC will contact the shipper of the vinyl chloride tank car involved in an emergency situation, and said shipper will contact our plant listed below should it be determined that emergency assistance is needed, provided, however, that said plant's response personnel are in the CHEMTREC designated geographic location to render such emergency assistance:

The Goodyear Tire & Rubber Company
Niagara Falls, New York Vinyl Chloride Plant
5408 Parker Avenue
Niagara Falls, New York 14302
Phone: (716) 283-7682

The Goodyear Tire & Rubber Company
Plaquemine, Louisiana Vinyl Chloride Plant
P O Box 578
Plaquemine, Louisiana 70764
Phone: (504) 687-2041

Our participation shall be limited to an advisory capacity covering the following:

631035.26

HAZARDS

FIRE: Extremely flammable gas transported as a liquid under pressure. It can be ignited by heat, sparks or open flame. Fire may cause violent rupture of the tank.

EXPOSURE: MAY EXPLODE IF INVOLVED IN FIRE. Vapor from the burning material is harmful. It is mostly Hydrogen Chloride. There is little likelihood of Phosgene being present Although chronic long term exposure may cause cancer in humans, nothing has been observed to indicate any carcinogenic effect for acute short term exposures. As with any chemical material, minimum exposure is recommended.

IN CASE OF ACCIDENT

SPILL OR LEAK: If there is a leak but no fire, DO NOT ignite the gas. Use self contained breathing apparatus and protective clothing. Clear the area, keep upwind and use water spray to disperse vapor and protect men attempting to shut off leak. Keep low behind the spray and avoid entering vapor area as it may ignite and flash back to source. If leak cannot be shut off, it would be best to consult shipper prior to taking any further steps.

FIRE: LET IT BURN - STAY AWAY FROM ENDS OF TANKS. If massive fire, evacuate area for one-half mile, but on-the-scene judgment will be necessary. If large volume of water is available, use water spray from monitor nozzles to cool tanks that may have flame impinging from the fire; otherwise, STAY AWAY. Clear area immediately in case of high rising sound from venting safety device.

EXPOSURE: Remove to fresh air. If unconscious, call a physician. If not breathing, apply artificial respiration, oxygen. In case of contact with the liquid, thaw frosted parts with water. In case of exposure to gas from fire, administer oxygen, if breathing is difficult.

PRECAUTION: If Vinyl Chloride gets into sewer, flush sewers with fire hoses and copious amount of water.

The terms of this letter agreement may be terminated by Goodyear by written notice being given to CHEMTREC, and the date of said termination shall be the date appearing on said notice.

Further, unless terminated as provided hereinabove, the conditions and terms of this letter agreement shall expire on November 15, 1978.

THE GOODYEAR TIRE & RUBBER COMPANY

By: _____
F V Prus, Vice President

Attest: _____
J Davies, Assistant Secretary

631035.28

JMG 1
cc: FHC
EJB

2/9

JOSEPH E. KELLER
JEROME H. HECKMAN
CHARLES M. HERMAN
WILLIAM J. BOROUSANI, JR.
[illegible]

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TELEPHONE
202 457-1100
CABLE ADDRESS "KELMAN"
WRITER'S DIRECT DIAL NUMBER
202-457-1116

February 7, 1977

To: VCM/PVC Producers Group
VCM/PVC EPA Technical Committee
Attendees at October 26, 1976 Meeting

Re: SPI-VCM/PVC--EPA

Gentlemen:

Enclosed herewith is a copy of a communication we have received from Harold Himmelman of Beveridge, Fairbanks & Diamond, Associate Counsel for Environmental Protection Agency (EPA) matters. It explains the current status of all known waiver applications on both a national and regional basis.

As Harold reports, the Agency is now beginning to act on waiver applications. The current prognosis is for EPA to take final action on as many as half the pending applications within the next few weeks.

If, prior to our next progress report, you should have any question or comments regarding any aspect of the waiver process, please do not hesitate to let us know.

Cordially yours,

Joseph E. Keller, Jr.

Enclosure

631035.29

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KEVIN M. FOLEY
JONATHAN Z. CANNON
ANDREW E. MIEMIEC
CHARLES A. PATRIZIA
SUEDEEN M. GIBSONS
SCOTT W. BOWEN

CARL EARDLEY
OF COUNSEL

February 4, 1977

Jerome H. Heckman, Esquire
Keller & Heckman
Suite 1000
1150 Seventeenth Street, N.W.
Washington, D.C. 20036

Dear Jerry:

I want to report to you on the results of my recent discussions with all EPA regional enforcement officers concerning their progress in processing waiver applications.

It appears that while the regions are making some progress, they are still a long way from completing the waiver review process. In the seven regions where there are vinyl chloride, polyvinyl chloride, or ethylene dichloride plants, there are approximately 60 formal waiver applications pending. (Many of these applications contain numerous specific waiver requests.) To date, on a national basis, only approximately six applications have been finally acted upon by EPA, all of them affirmatively. With respect to several applications, the regions are awaiting additional information requested from the companies involved. EPA estimates that within the next two weeks approximately two dozen applications will be through the paper-work stage with approvals, denials, or letters requesting additional information having been issued. No real progress has been made on the balance of the applications and none is expected for several weeks.

On a region-by-region basis the breakdown is roughly as follows:

Region I — Boston. There are two requests pending. EPA has completed the review process and is attempting to negotiate tighter compliance schedules with the companies involved.

Region II — New York. There are eight applications pending; the paper work has not yet been completed on any

631035.30

of them. However, EPA reports that it is close to completion on all applications and anticipates no special problems. Regional officials are attempting to negotiate any differences with companies through informal phone contacts rather than [illegible].

Region III -- Philadelphia. There are six waiver applications pending in this region. Four have been granted and are supposed to have been mailed. Two others have been delayed, but EPA anticipates they will be issued within the next two weeks.

Region IV -- Atlanta. There are between seven and nine applications pending in this region; enforcement officials are unsure as to the precise number. To date, two applications have been approved. It is anticipated that reviews of all applications will be completed within two weeks. We have been advised that the region currently intends to deny some of the applications because of questions over compliance time schedules. The Agency does not currently plan to issue formal denials, but rather "letters of intent" to deny as a vehicle for resolving any problems.

Region V -- Chicago. There are seven waiver requests pending in this region. This week consultants for the region have completed visits to certain plants. Decisions on how to proceed on waiver applications will be made during the week of February 7. EPA officials indicate that it is not likely that any applications will be acted upon for at least a couple of weeks and that six weeks to three months will be required to complete all work. Region V is behind the others in considering waiver applications.

Region VI -- Texas. There are between 20 and 22 waiver applications. Two have been issued. Three or four companies have received letters requesting more information, but in those cases EPA expects to issue the waivers soon. Six other waivers are almost completely processed and EPA expects to complete work on them within two weeks. The remaining applications have been delayed and EPA estimates that it may be four or six weeks before its work is completed; this may turn out to be a conservative estimate. Region VI reports that while some requests for equivalent methods have been denied, no major problems have been encountered with respect to waiver applications.

Region IX — San Francisco. There are four applications pending in this region. Two waivers have been tentatively approved and are expected to be mailed within two weeks. The other two applications are in need of further work and it may be four to six weeks before final decisions are made.

I will continue to keep you apprised of these and related developments.

Sincerely yours,

Harold Himmelman

HH:cl

cc: John R. Lawrence
Robert Laundrie

JOSEPH E. KELLER
JEROME H. HECKMAN
CHARLES M. MERHAN
WILLIAM H. BOROHESANI, JR.
ROBERT R. TIERNAN
WAYNE V. BLACK
DAVID L. HILL
MARTIN W. BERCOVICI
PETER M. NEMKOV
JOSEPH E. HADLEY, JR.
CAROLE C. HARRIS
PETER THOMAS SMITH
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JOHN B. DUBECK
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WRITER'S DIRECT DIAL NUMBER
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March 4, 1977

cc: JMG
FAC
V.P.
EJB

To: VCM/PVC Producers Group
VCM/PVC EPA Technical Committee
Attendees at October 26, 1976 Meeting

Re: SPI-VCM/PVC--EDF v. Train

Gentlemen:

Enclosed herewith is a communication just received from Gary Baise of Beveridge, Fairbanks & Diamond, Associate Counsel for Environmental Protection Agency (EPA) matters. It concerns the pending dismissal of the above referenced action, now expected to be filed on approximately April 15, 1977. Under the terms of the dismissal agreement, EPA will propose amendments to the existing Vinyl Chloride Standard at that time. A public hearing on the proposed amendments will probably be held about June 15, 1977.

Although we believe Mr. Baise's letter to be self-explanatory, should you have any questions, comments or suggestions about it, please do not hesitate to contact us.

Cordially yours,

P.S. Subsequent to the preparation of this letter, we were informed that the U.S. Court of Appeals has now denied the SPI Motion to Expedite Briefing and Oral Arguement in EDF v. Train. This is an expected result of the settlement negotiations.

631035.33

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CARL EARCLEY
OF COUNSEL

March 3, 1977

Jerome H. Heckman, Esq.
Keller and Heckman
1150 17th Street, N.W.
Suite 1000
Washington, D.C. 20036

Dear Jerry:

This letter will further update you with respect to Environmental Defense Fund v. Train (C.A.D.C 76-2045).

The Environmental Defense Fund (EDF) continues to advise that it will seek to dismiss the above entitled action; however, the Motion to Dismiss will not be filed until approximately April 15, 1977. On or about the 15th, the Environmental Protection Agency (EPA) will propose the amendments to the existing Vinyl Chloride Standard. **EDF's dismissal is contingent on the publishing of the proposed amendments.**

Discussions are continuing on how to handle the public comment and hearing regarding the proposed amendments. At this time we should assume there will be a public hearing on June 15, 1977. If this schedule remains unchanged, EPA would promulgate an amended Vinyl Chloride Standard by October 1, 1977. EDF and the Department of Justice (DOJ) both predict there will be some slippage in this schedule.

One final note. DOJ and EDF report that if a new petition to review the amended standard is filed by EDF, the petition will be limited to only those issues raised by the amendments. EDF claims it does not want to disturb the existing standard.

General

In discussing Section 112 of the Clean Air Act with the EDF attorneys, we are advised that they are pushing EPA to regulate Benzine under 112. Section 109 is another provision that could be used, but it would take too long to implement. Therefore, even though the health data is not as strong as EDF would like, it appears that EDF is ready to take EPA to court if the Agency refuses to list Benzine as a hazardous pollutant.

If you have any questions, please advise.

Cordially,

Gary H. Baise

GHB/sm

February 21, 1977

D H Francis
Director
Domestic Chemical Prod

Re: EDF vs Russell Train (USEPA)
Vinyl Chloride Regulations
U S Circuit Court - District of Columbia

Pursuant to a settlement meeting between USEPA and EDF (held 18 February 1977), the following conceptual agreement, without specific details, was reached by EPA and EDF (SPI and Goodyear were not invited nor participated in the 18 February settlement meeting):

1. EPA proposes a lower standard be attained in five years. A variance from the lower standard would be allowed companies showing that they are unable to meet said standard. A specific lower numerical standard has not been agreed upon.

2. EPA will agree to review the standard in five years, including all available technical and medical data.

3. EPA will propose more restrictive new source performance standards. What limits will be proposed or what technology said limits would be based upon has not yet been decided upon.

Under the conceptual agreement, no final standards would be agreed upon at this time. The agency would propose regulations consistent with the above discussed framework. The industry would retain its rights to contest any portion of the proposed regulation which it felt was unreasonable. Also, under the proposal, EPA will not suggest any immediate revision of the standards for existing plants.

EPA and EDF have indicated a desire to reach a more detailed agreement within the next three to four weeks. A stipulation would be prepared, and Goodyear and SPI would have an opportunity to review the stipulation and submit suggestions or objections.

631035.36

I will advise you of any future developments.

Attorney

T (Wally) Ito
dsp
cc: F V Prus
F R Tully
T W Leary
E R Moats
E J Burkett
W B Hirsch
J M Smerglia

JAP

The Society of the
Plastics Industry, Inc.

355 Lexington Avenue
New York, New York 10017
(212) 573-9400

TO: PVC SAFETY GROUP
VOTING REPRESENTATIVES

SUBJECT: PHYSIOLOGICAL EFFECTS OF VINYL CHLORIDE AND POLYVINYL CHLORIDE

The enclosed reports represent the results of the work sponsored by the PVC Safety Group to identify and abstract technical literature relative to the Physiological Effects of Vinyl Chloride and Polyvinyl Chloride. This project was carried out by Daniel P. Boyd and Co. under the direct supervision of the Health Subcommittee.

We have created a work product here which has cost the members approximately $50,000. The enclosed material should be carefully reviewed by appropriate representatives in your company in order that we may have answers to the questions raised in the last two paragraphs of this letter.

These reports are broken down as follows:

1) The Users Manual for "The Physiological Effects of Vinyl Chloride and Polyvinyl Chloride"

2) Volume I - "The Physiological Effects of Vinyl Chloride and Polyvinyl Chloride" - contains abstracts for numerically identified documents 1 through 99

3) Volume II - "The Physiological Effects of Vinyl Chloride and Polyvinyl Chloride" - contains abstracts for numerically identified documents 100 through 433.

In addition to these reports, all of the material in these abstracts is being held in a computer file held by Daniel P. Boyd and Co. for the exclusive use of the PVC Safety Group. Access to this computer record of these abstracts can be made by member companies by direct contact with Daniel P. Boyd.

By use of selected key words it is possible to have the computer rapidly search these abstracts and identify sources for particular information. This system has already been used by several members in connection with certain workplace health concerns.

We must make a decision as to what we do with this information as far as: 1) keeping it up-to-date and 2) keeping it available for computer searches.

We would like to have you review this material and respond to both of these questions by the end of December, at the latest. Please use the attached response form for this purpose.

631035.38

cc: J M Gilmore

The Society of the
Plastics Industry, Inc.

355 Lexington Avenue
New York, New York 10017
(212) 573 9400

rec'd
1/18/77

January 11, 1977

TO: THE VCM AND PVC PRODUCERS GROUP
VOTING REPRESENTATIVES

Gentlemen:

On January 10th representatives of the EPA Committee of the VCM and PVC Producer Group met with Mr. Michael Lamorte of Research Triangle Institute (RTI) who is preparing the EPA Inspection Manual for the enforcement of the Standard on Vinyl Chloride. This meeting had been set up at his request to give the industry an opportunity to work with them on their preparation of this Manual.

As a result of this meeting, there are several actions that will occur involving various member companies, therefore, it is important for you to review the contents of this letter and take appropriate action.

The industry representatives meeting with Mr. Lamorte were as follows:

Mr. Robert Laundrie - General Tire & Rubber Co.
Mr. W. C. Holbrook - B. F. Goodrich Chemical Co.
Mr. J. R. Lawrence - SPI

Messrs. John Barr of Air Products & Chemicals and Harold Himmelman of Beveridge Fairbanks & Diamond were unable to attend because of the weather.

Mr. Lamorte indicated his plans involving industry's assistance as follows:

1 - Plant visits for information gathering

(a) EDC/VCM Plants
- Isolated plant
- Integrated plant

(b) PVC Plants
- Suspension plant
- Dispersion plant
- Bulk plant
- Solution plant

2 - Preparation of Inspection Manual

(a) Initial draft of Inspection Manual
(b) Distribute draft for SPI's review (late April or early May)
(c) Meet and discuss draft Manual with SPI representatives (3-4 weeks after (b) above)
(d) Revise Manual accordingly

3 - Plant visits to test Manual as required.

631035.39

The industry representatives indicated a willingness to cooperate with the Research Triangle Institute in this endeavor in order to develop a product that will be useful and practical for EPA Inspectors. Mr. Lamorte indicated he would like to have plants identified which would cover all of the operations involved in the Standard with variations as to age, size, and specific technologies practiced. He likewise indicated his desire to obtain photographs of emission sources for inclusion in the Final Manual.

In discussing the plants to be included in the desired visits, the group selected a number of companies with operations representing the range of activities RTI desires to become acquainted with. This list is attached for your review and consideration. If your company is not designated in this tabulation, there is no need to feel left out. However, if you feel that you would like to have your plant included in this visitation, you may so indicate, particularly if you feel your operations are in any way unique compared to those that are otherwise designated. Mr. Lamorte is anxious to visit all plants with important variations in the basic manufacturing procedures. However, he would like to complete this assignment with a minimum possible number of plant visits.

Mr. Lamorte will make direct contact with the companies to be visited to arrange appropriate time schedules. During his visitation, he would like to designate equipment he would like to have photographed for inclusion in the Inspection Manual. If he requests photographs of equipment while visiting each of your facility, you would be expected to supply an appropriate photograph of such equipment. These photographs will not identify the company from which they have been obtained.

The attached response form should be used to indicate your willingness to take part in this program and also to indicate variations that you feel should be considered before Mr. Lamorte works out his specific plans. If you have any questions on this subject, please feel free to write or give me a call.

Very truly yours,

John R. Lawrence

John R. Lawrence
Technical Director

Attachments

cc: Messrs - R. Harding
S. Nuspliger
T. McGrath
R. Laundrie
J. Barr
R. Ferrante
J. Heckman
J. Hadley
M. Swetonic
G. Baise
H. Himmelman
W. Holbrook

631035.40

ROPOSED PLANT VISITS
RESEARCH TRIANGLE INSTITUTE

		PVC PROCESS			
	EDC-VCM	LATEX	SUSPENSION	DISPERSION	BULK	SOLUTION
3. F. Goodrich Chemical Co	X		X			
Dow Chemical USA	X					
Shell Chemical Co	X					
PPG Industries	X					
Firestone Plastics Co		X		X		
Union Carbide Corp		X		X		X
General Tire & Rubber Co			X			
Tenneco Inc.			X			
The Pantasote Co. of N.Y.			X			
Borden Chemical Corp				X		
Goodyear Rubber & Tire Co					X	
Hooker Chemical Corp					X	
Air Products & Chemicals			X			

631035.41

PLEASE RETURN BY JANUARY 25, 1977

TO: Mr. John R. Lawrence
Technical Director
The Society of the Plastics Industry, Inc.
355 Lexington Avenue
New York, New York 10017

1 - We agree X do not agree _____ that it is appropriate for the VCM/PVC Producers Group to cooperate with the Research Triangle Institute in the preparation of the Inspection Manual on the EPA Vinyl Chloride Standard.

COMMENTS:
* The licensor of the bulk process requires us to obtain a confidentiality agreement for plant visits which may reveal proprietary information. We would expect RTI to execute such an agreement.

FOR THOSE COMPANIES DESIGNATED IN THE PROPOSED PLANT VISITATION SCHEDULE.

2 - We are willing X are not willing _____ to have a representative from the Research Triangle Institute vist the plants representing the processes designated in the plant visitation schedule. *

3 - We will X will not _____ be willing to cooperate with the Research Triangle Institute in supplying photographs of certain phases by the processors.

4 - The contact for Mr. Lamorte in scheduling visits is:

NAME Mr F A Cox
The Goodyear Tire & Rubber Company
ADDRESS P O Box 578
Plaquemine, Louisanna 70764
TELEPHONE NO. (504) 687-2041

5 - We would like the Research Triangle Institute to vist our plant producing _____ at _____ (location) for the following reason:

631035.42

Signed D H Francis
Voting Representative D H Francis

Company The Goodyear Tire & Rubber Company

The Goodyear Tire & Rubber Company

Akron, Ohio 44316

July 29, 1977

Mr D R Goodwin
Emission Standards and Engineering Division
Environmental Protection Agency
Research Triangle Park, North Carolina 27711

Subject: Proposed Vinyl Chloride Emission Standard
40 CFR Part 61 as published in the Federal Register Vol. 42, No. 106, June 2, 1977

Dear Sir

The Goodyear Tire and Rubber Company has expended a considerable amount of time, manpower and money to meet the vinyl chloride standards that were promulgated in 1976. Although we had reservations about the stringency of the regulations, we have expended our maximum effort to meet the regulations. We were therefore quite disturbed when the EPA proposed these revisions to the regulations without giving industry the time or opportunity to properly evaluate the changes. Goodyear strongly supports the position of the Society of the Plastics Industry (SPI) that was presented at the EPA's July hearing.

In addition to the comments of the SPI, Goodyear believes that there is a serious omission in all of the statements and discussions presented in the proposed regulation. Bulk resins are not specifically included but previous interpretations classify bulk resins as "all others" in part 61.61 e(1)(i)(B). The proposed regulation would then require that "new resins" not exceed 100 ppm (61.61 e(1)(ii)(B). This is unacceptable as the present technology indicates that it is not possible to meet this limit for bulk resins without seriously degrading the polymer. It is, therefore, requested that this limit be maintained at 400 ppm for bulk resins, both new and existing, since this level is actually marginal according to present technology. No other method is presently known that can be used to reduce the VCM levels of the resins.

Very truly yours

E J Burkett, Manager
Environmental Engineering

jlc

cc: P D Fahrenthold, USEPA
Region VI

631035.43

C 410

The Society of the Plastics Industry, Inc.
355 Lexington Avenue, New York, New York 10017
(212) 573-9400

VCM-PVC MANAGEMENT SUMMARY

Vol. II, No. 7

ON THE REGULATORY FRONT

EPA:

SPI Submits Comments on Proposed Revisions to VC Standard

On September 27, SPI submitted additional written documents to the Environmental Protection Agency (EPA) on the proposed revisions in the VC air emissions standard ... commenting on the health-related issues raised by the proposed amendments, the SPI stated ... "we know of no information, old or new, that would justify lowering the existing standard ... the existing standard provides at the very least an ample margin of safety to protect the public health."

The SPI document pointed out that in a recent study of 7717 workers exposed to vinyl chloride in the manufacture of PVC in Great Britain, four cases of liver cancer were found, only two of which were angiosarcoma and these cases "were associated with exposure to very high concentrations of VC" ... as to whether vinyl chloride exposure causes cancers other than those of the liver, the study found "no evidence to support this suggestion."

In an analysis of the EPA's "Risk Assessment Document," the SPI filing pointed out that a modeling study by Dames and Moore which it submitted to the agency on August 9, confirmed EPA's estimate that "implementation of the existing standard would result in roughly a 95 percent reduction in ambient vinyl chloride concentrations" ... that study indicated the mean vinyl chloride concentrations within five miles of EPA's typical vinyl chloride plant in compliance with the existing standard would be "on the order of 0.15-0.25 ppb." and that the proposed amendments would further reduce ambient concentrations by less than 0.1 ppb ... the average ambient exposure before installation of controls was about 17 ppb, according to EPA estimates.

Stating that the calculated risk of getting cancer from the emissions is extremely small, the SPI paper reported that Professor Richard Wilson of Harvard, in a document already submitted to the EPA, said the risk of living within five miles of the polyvinyl plant for one year is "equivalent to the risk of contracting cancer from eating one-half tablespoon of peanut butter, or the risk of contracting cancer from increased cosmic radiation during a three-day visit to Denver, Colorado, or the hazards from smoking 1/15 of a cigarette."

SPI Meets With EPA on VC Standard

On September 29, SPI again met with officials of EPA to determine if the agency would consider withdrawing the proposed "zero emission" goal and the proposed offset requirements ... EPA indicated no willingness to drop the "zero emission" goal ... SPI now is seeking a personal meeting with EPA Administrator Douglas M. Costle.

SPI Renews Request For "Hybrid" Hearing on VC Standard

On August 19, SPI renewed its request to the EPA to provide "hybrid" public hearings which would provide more opportunities for the industry to present its case with greater accuracy ... EPA replied on September 13 that the request was being evaluated and a reply would be forthcoming.

MCA Challenges EPA on VC "Zero Emission" Approach

On September 23, The Manufacturing Chemists Association (MCA) challenged the EPA's "zero risk/zero emission" approach to regulation of vinyl chloride emissions as being "contrary to nature's laws of conservation of mass and energy" ... in a letter to EPA Administrator Costle, MCA President William J. Driver said EPA's reasoning that the only "adequate margin of safety" for vinyl chloride is zero emission was spurious ... better approach would be close cooperative monitoring and continued exchange of scientific, engineering and economic data ... in meanwhile MCA recommends that proposal be withdrawn.

SPI Receives Documents Under Freedom of Information Act

On August 30, SPI received from the EPA a number of documents that had been submitted to or produced by the Agency in the period when the revised vinyl chloride standards were being considered ... documents requested by SPI were obtained under provisions of the Freedom of Information Act ... the papers are now being analyzed for possible use by the SPI in opposing the proposed revisions in the VC air emission standard.

EPA Names Toxic Substances Advisory Committee

On September 28, EPA announced the appointment of 16 members to the Agency's newly-created Toxic Substances Advisory Committee ... three industry representatives are from Du Pont, Eastman Kodak and Hardwicke Chemical Company ... others are from conservation and environmental groups, medical schools and institutes, local government agencies, the League of Women Voters and the AFL-CIO.

FDA:

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FDA Issues Final Order Banning AN Beverage Containers

On September 19, the Food and Drug Administration (FDA) issued a final order banning the use of acrylonitrile (AN) in the fabrication of beverage bottles ... ban takes effect 90 days after its September 23 publication in the Federal Register

order signed by FDA Commissioner Donald Kennedy said that contention that packaging material was not a "food additive" is inconsistent with the statute's language and the Congressional purpose in enacting the food additive provisions ... also that the statutory language "does not require the amount of the migrating substance be analytically detectable or quantifiable or exceed some minimum threshold level before the substance can be considered a component of food".

Hardline AN Ruling by FDA May Presage PVC Action

Hardline action by FDA Commissioner Donald Kennedy in banning the use of acrylonitrile (AN) beverage bottles on the "migration issue" may lead to rapid action on FDA's PVC proposal, the September 26, Food Chemical News reports.

OSHA:

SPI Calls OSHA Proposal on Carcinogens a "Quick Fix"

On October 3, SPI President Ralph L. Harding, responding to a 278-page proposal announced by the Occupational Safety and Health Administration earlier that same day, said that SPI "is in fundamental disagreement with OSHA's apparent intent to rush unequivocal enforcement judgments on the basis of limited scientific knowledge of carcinogens" ... the OSHA plan for controlling worker exposure to toxic materials would set up a procedure for identifying, classifying and regulating various types of carcinogenic substances posing hazards to workers ... SPI said "we feel OSHA ... is placing undue reliance on limited animal tests to demonstrate carcinogens ... also OSHA assumes there is no safe threshold for potential carcinogens -- a premise with which we totally disagree."

OSHA Safety and Health Committee Members Named

On September 23, OSHA announced the appointment of five new members to the National Advisory Committee on Occupational Safety and Health (NACOSH) ... among the new members were Andrea Hricko, formerly with the Health Research Group and now with the University of California in Berkeley, and Marcus M. Key, formerly director of NIOSH and now with the University of Texas ... also named were Dr. Ernest M. Dixon of Celanese Corporation, Professor Don B. Chaffin of the University of Michigan and Claudia Miller, a private consultant ... the other industry member of the Committee is Dr. Paul Kotin of Johns-Manville Corporation.

ON THE LEGISLATIVE FRONT

In the States

In New Jersey, the Cancer Control Bill (S.3035), which would have banned 14 known chemical carcinogens, plus asbestos and vinyl chloride, was amended to delete the ban provision.

ON THE TECHNICAL FRONT

Employees of PVC Fabricators Studied for Angiosarcoma

A cross-section mortality study of 4,341 deaths among current and former employees of 17 PVC fabricators during 1964-73, revealed "no angiosarcoma deaths were found among the study group," it was reported in the September 1977 Journal of Occupational Medicine ... in a proportionate mortality analysis -- the ratio of "observed" to "expected" deaths for the total U.S. specific for color, sex, cause and age -- the study found that excesses in cancer mortality appear concentrated in "cancers of the digestive system and, in particular, in cancers of the intestine for both men and women."

The article's authors warn that while the current study suggests an excess in total cancer ... it does not point to marked excesses for cancers of the liver, lung, and brain among white men, although the PMR's (proportionate mortality ratios) for these cancers are greater than one ... such results, the authors say, must be interpreted with caution, but since they appear to be consistent with previously studied workers, they suggest the need for continued investigation.

EDF Submits PVC Study to EPA

On October 4, the Environmental Defense Fund (EDF) submitted a copy of the PVC Mortality Study to the EPA with a covering letter containing EDF's interpretation of the findings ... the study was being submitted, the EDF said, because it contains potentially significant new information on the health effects of vinyl chloride" and the EDF requests that "it be included as a part of the Agency's public record on the proposed amendments to the vinyl chloride standard."

ON THE MEDIA FRONT

Ten Groups of Chemicals Face EPA Tests

The Interagency Testing Committee, an eight-agency task force set up under the Toxic Substances Control Act (TSCA), has recommended immediate testing of 10 widely used groups of chemicals "because they pose a potential threat to human or environmental safety" the October 6 Washington Post reports ... among the chemicals and chemical groups on the list are toluene and xylenes ... selected groups are to be listed for possible cancer-causing properties, mutagenic effects and the potential of possible embryonic malformations in women exposed to them ... the task force is working its way through a list of 330 chemical substances singled out for study in July.

If Money Causes Cancer .... Ban It?

Two medical doctors from Denver General Hospital concerned about the "inane pronouncements" by the FDA on cancer dangers, report on an unusual experiment they conducted in a letter to the editor in the August 1, Journal of the American Medical Association (JAMA) ... ten months after inserting sterilized dimes into the peritoneal cavity of 35 rats the first cancer was noted ... by 14 months nine rats had cancer and nine had distinct abdominal masses ... based on their findings, the doctors estimated that "malignant neoplasms will develop in more than 50 percent of the rats."

In view of their findings, the doctors said "the FDA and Consumer Products Safety Commission (CPSC) "should convene an emergency meeting for the purpose of removing all coins from circulation" .... since there is an excellent probability that folded paper money, government paychecks, bills and credit cards will produce cancer," the doctors said, "they should be banned immediately" .... stating that a proper grant request for cancer research was being prepared, the doctors concluded, "We hope that no political demerits will be associated with our use of the Roosevelt dime."

# # #

October 1977

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Gilmore, J.	11-4	11-4
~~Hunsaker, R.~~		
~~Trowbridge, M.~~	11-7	11-8
~~Husband, L. D.~~		
~~Blickley, J.~~	11-9	11-9
~~Kernaghan, S.~~	11-9	11-9
~~Gilmore, T.~~	NOV 11 1977	11-10
~~Evans, R.~~		11-11
LeCain, R.	11-10	11/14

Return to: J M Gilmore

MCA-EPA-SPI
1976.

February 19, 1976

P M
RHE
TMG

To: C A Johnson, M.D.
D H Francis
E J Burkett
W L Cox
D R Martin
J N Gilmore (N.F.)
F Cox (Plaq.)

REPORT OF MEETING
ORC VINYL CHLORIDE TASK FORCE
Washington, D.C. - February 10, 1976

R N Wheeler (Union Carbide) attended recent EPA Hearings and reviewed these for the group.

1. Results of the Pottstown study will be published in the near future.
2. Deadline for submission of comments to EPA is February 23rd.
3. The final EPA Standard will be in effect by June 15, 1976, or sooner. Anticipated that a 90 day compliance period will be allowed.
4. Standard calls for a 10 ppm emission limit. SPI, Union Carbide and others will try to get this maximum limit changed to allow for averaging over a 30 day period, or longer.

Tenneco representatives believed there is no way to meet requirements of the Standard within the allotted time fame. Some specific areas of concern were:

1. What type of information will be necessary to support request for waiver. Environmental monitoring data necessary?
2. Need for standby power source at Plants.
3. EPA attitude on "manual venting" of reactors.
4. Page 59539——"operator errors are considered to be preventable".

Repercussion of low EPA emission level may be lowering of OSHA personnel xposure levels within the Plants.

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Though OSHA is not currently intending to rewrite or modify the existing Vinyl Chloride Standard they have expressed intention to rewrite the Field Directive (200-35), covering interpretation of the Standard. Leo Teplow will determine if OSHA has any interest in cooperating with the ORC Task Force in rewriting this Directive.

Definition of "fabricated product" discussed. This is a product that will not produce atmospheric vinyl chloride concentrations in excess of the "action level". There are dispersion, solution and bulk resins now manufactured by Union Carbide that are considered "fabricated products", and not labelled.

Other areas requiring clarification are massive release, emergency, record keeping requirements, medical surveillance.

Some companies are regarding tank car unloading areas as "hazardous" areas, not "regulated" areas.

Panasote has stopped charcoal tube monitoring of personnel and performs only area monitoring. This has apparently been approved by letter from OSHA.

An OSHA citation was received by one company for failure to provide adequate employee training under the Vinyl Chloride Standard.

Italian studies on hazard of PVC dust are continuing but no new information available.

R. W. Modrell

Manager,
Corporate Industrial Hygiene

R W Modrell
cr

631035.51

MCA-VCM Study

The Society of the Plastics Industry, Inc.

355 Lexington Avenue
New York, New York 10017
(212) 573 9400

Route: ~~C A Johnson~~
F R Tully
S Hanway
R Hehir
W Davis File

TO: THE VINYLS TOXICOLOGY SUBCOMMITTEE

FROM: H. P. TONER, ASSISTANT TECHNICAL DIRECTOR

DATED: NOVEMBER 1, 1978

For your reference, attached is a copy of a translation of the German Epidemiology study that was mentioned at the October 12 meeting.

HPT:ale
ENC.

cc: Mr. J. R. Lawrence
Mr. T. Torkelson

631035.52

meeting

PVC SAFETY GROUP — HEALTH COMMITTEE

New Orleans Marriott Hotel
New Orleans, LOUISIANA

Thursday, February 7, 1980
1:00 P. M.

In response to the OSHA request for information relative to health hazards from over exposure to vinyl chloride and polyvinyl chloride, there will be a meeting of the PVC Safety Group's Health Committee on Thursday, February 7, 1980 at the New Orleans Marriott Hotel, New Orleans, Louisiana, from 1:00 p.m. through 5:00 p.m. This meeting is being held in the Chartres Room of the hotel.

This location and time has been set up to coordinate with the meeting of the PVC Safety Group's Steering Committee on February 8 and in conjunction with the Chlorine Institute Annual Meeting occurring in New Orleans earlier that week.

The principle items on the agenda will be as follows:

- Review and critique of the 12 documents cited in the December 18, 1979 Federal Register (copy attached).
- Discussion on new industry studies. (Attendees should come prepared to present any new company data or data from other sources which should be considered for submission to OSHA).
- Recommendations for industry response to the OSHA request.

Please call Mrs. Gloria Pyne (212/573-9437) as soon as possible indicating your plans for attending this meeting.

Very truly yours,

John R. Lawrence

John R. Lawrence
Technical Director

JRL:gp
Attachment

631035.53

PVC INHALATION STUDY

PO Box No 6
Bessemer Road
Welwyn Garden City Hertfordshire AL7 1HD
Telephone Welwyn Garden 23400 (STD Code 07073)
Telex 264251

RECEIVED
OCT 27 1978
R N. WHEELER, JR.

Imperial Chemical Industries Limited
Plastics Division

FEB 23 1979

From J Stafford
Division Manager
Health & Environment Protection

To
See Circulation Below

Copies to

TO: SPI VINYL SUBCOMMITTEE

FROM: W D Davis/R N Wheeler
November 28, 1978

Your ref.	Our ref	Tel ext	Date
	JS/AMB/DSO-107	3162	17 October 1978

PVC DUST

You may care to see the attached letter and NIOSH report I have received from Dr Douglas of EMAS. This report seems reassuring but I would welcom the opinion of our Medical Committee who have been considering how to design a good PVC dust inhalation study. Has the need for such a study disappeared as a result of the NIOSH work? Dr M N Johnson of B F Goodri h, when he saw us on 9 October, knew of these results but was critical that the rodent species were sacrificed at 12 months (monkeys 22 months). Dr Johnson thought that a well conducted full life study on PVC dust inhalation should still be considered and the possibility of Transatlantic cooperation explored to derive both protocol and funding.

Circulation

Dr W G F Adams
Dr D P Duffield
Dr G Pigott
Dr B W Duck
Dr M Sharratt
Dr P Grasso
Dr J T Carter
Dr D W Plester
Dr G Paddle
Dr K S Williamson
Dr I F H Purchase
Sir C Lawrence Jones
Dr F W Best
Mr G J Sleddon
Mr W Adams
Mr R Hards
Mr P H M Sharrock
Mr T L Phillips
Mr B N P Hutcheson
Mr H M Clayton
Mr T W Moffitt
Dr L de Boer
Dr J G Kammuller
Mr J C Thomas
Mr M Bonnefoy
Dr T Garlanda
Dr M N Johnson
Dr T R Torkelson
Mr R N Wheeler (Jr)
JS (2)

Dr R E Davies, ICI Melbourne
Mr K H White, Duperial SAIC
Chief Medical Officer, AECI

631035.54

Health & Safety Executive

Baynards House
1 Chepstow Place
London W2 4TF
Telephone 01-229 3456
ext

Dr J Stafford
Division Manager
Health & Environment Protection
ICI Limited, Plastics Division
P O Box No 6
Bessemer Road
Welwyn Garden City AL7 1HD

Your reference

Our reference
1/MS/406/225/78

Date
6 October 1978

Dear Dr Stafford

PVC DUST

Thank you for sending me a copy of Waxweiler's report on PVC dust and the item from Tox-Tips. Both will be discussed at the next tri-partite medical meeting which should take place in late November. Dr Elliott Harris the head of the Division of Bio-Medical and Behavioural Science, NIOSH, was here on Tuesday 3 October and told me that the study by Dr Trent Lewis had been completed and no evidence of carcinogenicity or pneumoconiosis had ... been found in any of the animal species. I enclose copies of the reports given to me by Dr Harris.

Yours sincerely

D B Douglas
Deputy Director of Medical Services

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cc: Dr R Gwyn

PVC Chronic Inhalation Toxicology Study

Polyvinyl chloride (PVC) is widely used in various forms. Rigid PVC is used for tubing and fittings (insulation material and drainage pipe), foils, films and sheeting (packaging, recording tapes), profiles (blinds, window frames), tiles, sound records, and fibers. Flexible PVC is used for cables, foils (decoration, roof covering), tubing, artificial leather, flooring, foam rubber, paint, varnish (lacquer), and toys.

Reports of pulmonary dysfunction and pneumoconiosis in PVC workers and dust exposed animals point to the need for further studies on the toxicological properties of the polymer. Also, cases of still-births, miscarriages and malformations among workers engaged in the polymerization of vinyl chloride have aroused great interest in the toxicological properties of PVC. Since PVC is a fine volatile dust, pathogenic effects of the lungs may be anticipated.

B. F. Goodrich Company is a supplier of resins for vinyl dispersions using the trade name "Geon." The dispersions are fluid suspensions of special fine particle-size polyvinyl chloride resins in plasticizing liquids. When the system is heated to about 148 to 177°C (300 to 350°F), fusion (mutual solubilization of resin and plasticizer) takes place. The dispersion turns into a homogeneous hot melt. When the melt is cooled below 50 to 60°C (122 to 140°F), it becomes a tough vinyl product.

The term "plastisol" is used to describe a vinyl dispersion which contains no volatile thinners or diluents. Plastisols often contain stabilizers, fillers, and pigments along with the essentials, dispersion resin and liquid plasticizer, but all ingredients have very low volatility under the processing and use conditions.

Geon 121 is a high molecular weight resin. It has been the standard of the plastisol industry for over 25 years and is an excellent resin for starting point formulations. Currently, it is being used in dip, slush and rotational molding, spread coating, foam coating and molding, crown and jar seals, and caulks and sealants.

In light of the relationship unequivocally established between occupational exposure to vinyl chloride monomer and liver angiosarcoma, and the concern expressed on potential risks to human health from exposure to polyvinyl chloride (PVC) dusts manufactured and used from polymerization of the vinyl chloride monomer, DBBS in FY'75 in its project plan on "Chronic Exploratory Toxicology Studies and Test of Validity of Industrial Air Standards" proposed an inhalation exposure study with PVC dust. Actual exposures to a representative material (B. F. Goodrich Company, Geon 121) began in February 1976 utilizing three species of animals -- monkey, guinea pig and rat -- a 6-6-1/2 hours per day, 5 days per week exposure regimen, and at a 10 mg/m^3 respirable PVC dust concentration. Exposure duration was for 22 months. The following table summarizes the above data.

Selected Data from PVC Chronic Inhalation Exposure Study (Geon 121)

Animal Species	No. per Group		Duration of Exposure			Mean PVC Conc.	Mean Range of Conc.	CT Values (mg/m^3-Hrs.)	
	Exposed	Control	Calendar Days	Exposure Days	Exposure Hrs.	mg/m^3	mg/m^3	Intended	Actual
Monkey	10	10	690	464	2818	10.8	4.65-9.25	28,180	30,510
Guinea Pig	40	40	379	245	1428	10.6	-	14,700	14,698
Rat	80	80	376	244	1424	10.6	-	14,640	14,627

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Particle size analysis of collected exposure chamber samples indicated that the generated PVC dust was of a geometric mean diameter of 0.53µm with more than 99% of the sampled particles below 5.0µm; 82% below 1.0µm. The manufacturer's specifications data states a particle size range for Geon 121 of between 0.5 and 1.5µm.

Exposure System: Chambers used in the study were five feet square, stainless steel, and featured a dynamic airflow system of 40 cubic feet per minute under a negative chamber pressure of approximately 0.2" H_2O. The PVC aerosol was generated by means of a Wright Dust Feed Mechanism and the dust dispersed into the chamber at a rate sufficient to maintain the desired 10 mg/m^3 concentration. Gravimetric analyses were made four times per day on collected membrane filter samples for total dust concentrations, and once per day for respirable dust (10-plate horizontal elutriator sample).

Biological response data evaluated from the exposed and control animals at time of serial sacrifice/evaluation included:

Biochemical/Clinical Chemistry (Guinea Pig, Rat only): (SGOT, SGPT, alkaline phosphatase, gamma glutamyl transpeptidase, total protein and serum protein electrophoresis). No significant differences were indicated in rats for any parameter. Guinea pig data showed controls with higher SGOT, SGPT, and alkaline phosphatase. It was concluded that no extensive liver damage was detected by any of the liver clinical indicator tests used. However, a sizable amount of liver damage must occur before these tests would indicate abnormalcy. One cannot conclude that there is no liver damage; but only that there is no extensive liver involvement.

Pathology (All species): No significant alterations in liver tissue. The only contribution of the inhaled PVC dust deposition and retention to pulmonary tissue morphology was aggregation of PVC-containing macrophages (refer to attached pathology reports and to report on Amorphous Silica exposed and control monkeys).

Pulmonary Function (Monkey only): Fasted, exposed and control monkeys were tested for pulmonary function one day following their last exposure. Evaluations were accomplished through use of a variable pressure, whole-body plethysmograph. Tests evaluated were: Total lung capacity (TLC); vital capacity (VC); inspiratory capacity (IC); residual volume (RV) divided by total lung capacity (RV/TLC); forced expiratory volume in 0. 5 seconds (FeV 0.5); forced expiratory volume in 1.0 seconds (FeV 1.0); peak expiratory flow (PF); maximum mid expiratory flow (MMF); maximum expiratory flow volume curves (MEFV) at 50%, 25% and 10% of vital capacity; resistance; and compliance.

A summary of the extensive pulmonary function evaluations indicated some signs of loss of lung recoil pressure, probably a result of the animals' aging process. In most cases differences were noted during the second and third testing periods (exposure months 6 and 14) and were indicative of some small airway obstruction. At this time, however, these differences were not statistically significant. At the last evaluation (month 22) compared with baseline (pre-exposure) data there were no significant differences for any parameter tested. Impairment of respiratory function does not appear to be indicated under the conditions of this study from exposure to respirable PVC dust.

Attachments

MEMORANDUM

PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

TO : Chief, BSB
THROUGH: Chief, Pathology Section _____

DATE: May 5, 1977

FROM : Veterinary Pathologist, Pathology Section

SUBJECT: Pathology Report on Rats Exposed to PVC

Male rats were exposed by inhalation to polyvinyl chloride (PVC), respirable concentration 10 mg/m^3, for 6 hours/day for 5 days/week for a period of 12 months. The animals were sacrificed immediately after 12 months of exposure to PVC. The following tissues on each animal were saved at necropsy for histopathology evaluation: lungs, liver, heart, spleen, kidney, pancreas, adrenal, thyroid, testis, and urinary bladder. The histopathology evaluation was performed on a total of 121 (exposed 57, control 64) male rats.

1.1 Rats exposed to PVC 10 mg/m^3 for 6 hours/day for 5 days/week by inhalation.

Path. Accs. No.: 76-1329, 76-1337, 76-1338, 76-1340 to -1393.

Gross pathology:

Lungs: Multiple white foci of varying size either in one or more lobes of the lungs were seen in 76-1337, -1338, -1344, -1345, -1347, -1348, -1350, -1353, -1354, -1363, -1367, -1369, -1373, -1379, -1385, and -1387. "Abscess" was seen in the lungs of each of 76-1346, -1351, -1352, -1363, and -1378. "Tumor" measuring 1.5 x 2.0 cm and weighing 2.90 gm was seen in 76-1375.

Liver: Enlarged dark red liver was seen in 76-1337.

Kidney: Small mineralized areas (stones) were seen in the kidneys of 76-1363 and 76-1366.

Pituitary gland: Enlarged (10X) pituitary was seen in 76-1338.

Histopathology:

Lungs: The lesions commonly associated with the chronic murine pneumonia (bronchiectasis, peribronchial, and perivascular accumulations of lymphocytes, focal chronic active bronchitis and bronchiolitis, focal atelectasis) were seen in all rats. Vascular (arterial) wall mineralization was seen in all rats. Focal intense macrophage accumulations (solid sheets), sometimes displacing the normal structures, were seen. Most of these macrophages had varying size globular to spherical structures in the cytoplasm (foam cells).

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These dense conglomerations of macrophages were occasionally associated with mild blue staining (mucin?) fluid material. The above-mentioned macrophages or macrophages surrounded by fluid when accumulated at the periphery of the lung probably imparted the appearance of "white foci" grossly seen in the lungs. The intracellular material in these macrophages was probably particles of the PVC. No birefringence was seen among these. Dr. Stettler and Mr. George Mackay informed me that these, indeed, were PVC particles, based on electron probe analysis of some lungs from the rats exposed to PVC by inhalation as well as by intravenous injection. The macrophage accumulations apart from physical displacement of the lung parenchyma do not seem to bestow any deleterious effects on these rats. No alterations (hyperplasia, etc.) of the alveolar or bronchial epithelium attributable to treatment were seen in these rats.

Tracheobronchial lymph nodes (TBLN): Macrophage accumulations as seen in the lungs were seen in the medulla and cortex of all the TBLNs examined. Reactive hyperplasia of germinal centers was also seen.

Liver: Mild fatty infiltration of hepatocytes was seen in 76-1338. Extra medullary hematopoiesis (mild) was seen in 76-1364 and 76-1371.

Spleen: Macrophages containing yellow granular material in the cytoplasm and extramedullary hematopoiesis were seen in all the spleens examined.

Heart: Mild focal myocarditis was seen in 76-1337, -1363, and -1377.

Kidney: Multifocal mineralized areas of the tubules or the transitional epithelium of the kidney pelvis were seen in 76-1348, -1353, -1356, -1363, and -1366. Focal tubular dilatation, focal tubular epithelial degeneration and regeneration and mild lymphocyte accumulations were seen in 76-1351, -1356, -1357, -1363, -1370, -1376, -1381, -1382 to -1384, -1387, -1388, -1390 to -1392.

Pancreas: Mild hyperplasia of the islets of Langerhans was seen in 76-1355, -1361, -1363, -1364, -1367, -1368, -1370 to -1372, -1376, -1377, -1379 to -1381, -1385 to -1389, and -1391 to -1393.

Adrenal: Moderate fatty infiltration of the epithelium of the cortex was seen in 76-1341 to -1344, -1348 to -1350, -1369, -1370, -1378, and -1381. An adrenal cortical adenoma was seen in each of 76-1365 and 76-1371. A pheochromocytoma was seen in 76-1358.

Thyroid: Cyst(s) containing keratin was seen in 76-1337, -1338, -1341, -1342, -1345, -1346, -1353, -1355 to -1357, -1360, -1361, -1364, -1365, -1370, -1372, -1374, -1375, -1379 to -1382, -1388, -1391 to -1393.

Testis: Vessel (artery) wall mineralization was seen in 76-1358, -1378, -1385, and -1390. Mild hyperplasia of interstitial cells and atrophy of seminiferous tubules were seen in 76-1347, -1353, -1358, -1361, -1365, -1370, and -1378.

Lymph node: Chronic lymph adenitis was seen in 76-1375. The lymph node was adjacent to a major artery suggesting it to be a mediastinal lymph node.

Pituitary: A chromophobe adenoma was seen in 76-1338.

All the other organs examined were unremarkable.

1.2 Untreated Male Rats

Path. Accs. No.: 76-1394 to -1431, 76-1510 to -1520, 76-1523 to -1537, 76-1539 to -1548.

Gross pathology: A cataract of the right eye was seen in 76-1396. Consolidation of lung lobes was seen in 76-1395, -1400, -1416, -1527, -1530, -1537, -1540, -1546, and -1547. Brown discoloration (76-1405) and an abscess was seen in the lungs (76-1418). A multiloculated mass 2.5 x 3.0 cm was seen attached to mesentery in 76-1427. Renal calculi were seen in 76-1518.

Histopathology:

Lungs: The morphological changes associated with the chronic murine pneumonia and pulmonary vascular wall mineralization as seen in 1.1 were seen in all rats. Macrophage accumulations of far lesser degree in intensity were seen in all rats. These macrophages did not congregate in a solid sheet as seen in 1.1. The cytoplasm of most of these macrophages contained granular eosinophilic material. No alveolar or bronchial epithelial hyperplasia was seen in any rat.

TBLN: Chronic reactive hyperplasia was a common finding in all rats.

Liver: A single cyst was seen in each of 76-1397 and 76-1399.

Spleen: The changes seen were similar to those seen in 1.1 in all rats.

Heart: Mild focal myocarditis was seen in each of 76-1401, -1402, -1405, -1407, and -1415.

Pancreas: Mild hyperplasia of endocrine elements was seen in 76-1395 to -1399, -1402, -1404 to -1410, -1414 to -1418, -1420, -1421, -1424 to -1426, -1428, -1429, -1510, -1511, -1514, -1515, -1518 to -1523, -1532, -1539 to -1542, and -1545.

Kidney: Tubular epithelial degeneration and regeneration, occasional tubular dilatation and focal mild lymphocytic accumulation were seen in 76-1394, -1396, -1397, -1399, -1401 to -1403, -1405, -1409, -1412, -1417 to -1419, -1421, -1422, -1425, -1431, -1515, -1524, -1527, -1534, -1546, and -1548. Focal mineralization of tubular epithelium and/or the transitional epithelium of the renal pelvis was seen in 76-1518, -1527, and -1533.

Adrenal: Adenoma of the adrenal cortex was noticed in 76-1400, -1518, -1523, and -1544. Pheochromocytoma was seen in 76-1548. Moderate fatty infiltration of the cortex was seen in 76-1410 and 76-1544.

Thyroid: Cyst(s) containing keratin was seen in 76-1395, -1397, -1399, -1402, -1403, -1406, -1410 to -1412, -1416, -1417, -1419, -1420, -1422, -1423, -1425 to -1427, -1429, -1510, -1512 to -1515, -1517, -1519 to -1527, -1529, -1530, -1532 to -1534, -1536, -1541, -1543 to -1548.

Testis: Atrophy of seminiferous tubules and Leydig cell hyperplasia was seen in 76-1395, -1400, -1514, -1516, -1533, -1541, and -1548. Vessel (artery) wall calcification was seen in 76-1398 and 76-1533. Focal moderate mineralization of seminiferous tubules was seen in 76-1418, -1510, and -1517.

Eye: 76-1396: Retinal atrophy - unilateral. Adhesions between the retina and lens with dystrophic calcification at some foci. The lens protein was well oriented with occasional basophilic bodies, probably nuclei from decidual lens cells. The calcific deposits coupled with the hyalinization of sclera imparted the opacity to the lens; cataract seen grossly.

Mass: 76-1427: Granuloma of mesenteric fat.

Comment: For comparison, this comment shall include rat and guinea pig data. Both the rats and the guinea pigs exposed to PVC by inhalation exhibited the presence of PVC particulates in the pulmonary macrophages, although the pattern of macrophage accumulation between the two species differed. There was no inflammatory or any other deleterious effect seen in the lungs of these animals that could be attributable to PVC inhalation.

The incidence of perivascular lymphoid aggregations in the lungs of guinea pigs was similar in both exposed and controls. The presence of bony spicules in the lungs of exposed and control guinea pigs was observed. The pathogenesis of these two conditions is not known (Thompson, S. W., Hunt, R. D. et al: Am. J. Path. 40:507-517 (1962); Kaufmann, A. F.: Lab. Anim. Care 20:1002-1003 (1970)) and is worth exploring as NIOSH uses guinea pigs as

one species of animals in biological experiments. The nephrocalcinosis seen in the exposed and control guinea pigs may be related to diet (J. C. Woodard: Am. J. Path. 65:253-268 (1971) and 65:269-278 (1971)). Corollary to the above observation was the finding of invariable fatty infiltration of exocrine and endocrine elements of the pancreas in both the exposed and control guinea pigs and the hyperplasia of islets of Langerhans seen in both the rats and the guinea pigs employed in this experiment. In addition, the vascular wall calcification in the pulmonary vessels of rats is disturbing. All of these "incidental" findings strongly suggest that these animals had metabolic problems probably related to the animal diet. The changes seen in the testes of rats were non-specific and probably not related to treatment. The incidence of neoplasms in the adrenals of rats is within the normal range observed for Sprague-Dawley rats of this age.

Choudari Kommineni, D.V.M.

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

TO : Chief, ETB
Through: Director, DBBS
Chief, BSB

DATE: September 6, 1978

FROM : Research Veterinary Medical Officer

SUBJECT: Pathology Report on Monkeys Exposed to PVC

Ten male Cynomolgus monkeys were exposed to PVC at 10 mg/m^3 by inhalation for 6 hours/day, 5 days/week for almost 22 months. Control male monkeys (10) were maintained in an open animal room in their individual cages. The monkeys were killed within 48 hours after the final exposure. At the time of autopsy, tissues from the lungs (all lobes with trachea), thyroid, heart, tracheobronchial lymph nodes (TBLN), mesenteric lymph nodes (MLN), liver, spleen, kidney, urinary bladder, prostate, testis, stomach (pylorus), duodenum, pancreas, adrenals, and skin from the abdomen were saved for histopathology.

1.1 Control Monkeys
Path. Accss. #77-2975, 77-2979, 77-2981, 77-2983 to 77-2986, 77-2991, 77-2993 and 77-2994.
Gross and histopathology: See the pathology report on monkeys exposed to Silica-F.

1.2 Monkeys Exposed to PVC
Path. Accss. #77-2974, 77-2976, 77-2980, 77-2982, 77-2988, 77-2989, 77-2995, 77-2996, 77-2997 and 77-2999.
Gross Pathology: Adhesions between the lobes of the lung and the thoracic wall were seen in 77-2980, 77-2995 and 77-2997. Multiple black areas were seen in the lungs of 77-2976, 77-2980, 77-2982, 77-2988, 77-2989, 77-2996, 77-2997 and 77-2999. Enlarged and black MLNs were seen in 77-2974 and 77-2976.
Histopathology:
Lung: Macrophages with anisotropic particles as in the controls were similarly present in all these monkeys. Admixed with these macrophages were other macrophages with spherical material (PVC) of varying size in the cytoplasm. About 15% of the total macrophage aggregates (macules) in 77-2997, 77-2988 and 77-2980 contained black to brown anisotropic particles of the same degree of deposition as in the controls. In the rest of the PVC exposed monkeys 20 to 22% of

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the macules had these black to brown particles. A total of 110 macrophage aggregates were seen at 25X magnification in most of the lungs. The diameter of many of these aggregates varied from 100 to 200μ while the largest, present in the alveolar region, measured 475μ. The macrophage aggregates were present in the alveolar walls, alveoli, partially obstructing the alveolar lumens. They were also present around tertiary bronchioles and in some alveolar ducts without causing observable obstruction. A few places showed submucosal accumulations with no polypoidal projections. With phase contrast illumination these macrophage accumulations appear as blue aggregates. This tinctorial character is distinct from the macrophage aggregates seen in amorphous silica (F, G and P) exposed monkeys.

Focal hyperplasia of type II cells was present in 77-2989. Smooth muscle hyperplasia was seen around blood vessels and alveolar walls in 77-2996. Acute bronchopneumonia was seen in 77-2988. Plant material was present in a bronchus in 77-2999. Multiple gaint cells away from the plant material were seen in the 77-2999. Non-inflammatory arteriopathy as in the controls was present in all these monkeys.

TBLN: As in the controls the medulla contained macrophages with anisotropic particles. In addition, other macrophages with cytoplasmic material (PVC - blue in color - see lung) were present. Together, these macrophages replaced most of the medulla of the TBLNs in all monkeys.

Liver: Diffuse fatty infiltration of the hepatocytes was present in 77-2982 and 77-2996.

Kidney: Multifocal calcification of cortical tubules was seen in 77-2995.

MLN: See the controls.

The other tissues examined were unremarkable.

Comment: A slightly higher number of macrophage aggregates containing black and brown birefringent particles were seen in PVC exposed than in the control monkeys. The pattern of distribution of the macrophage accumulations in the PVC exposed and the amorphous silica (F, G and P) exposed monkey lungs and the TBLNs was similar. The macules were smaller in size in PVC exposed than those seen in the amorphous silica (F, G and P) exposed monkeys. The monkey lung reaction suggests that it may be a

non-specific one, inasmuch as these materials (PVC and amorphous silicas-F, G and P) show diverse chemical composition. The second paragraph under "Comment" in the pathology report on monkeys exposed to amorphous silica-F also applies here. The influence of the brown and black particles on the biologic effects of PVC are hard to define but should be carefully considered. The only contribution of the inhaled PVC dust deposition and retention to pulmonary tissue morphology was numerous aggregations of PVC-containing macrophages.

Choudari Kommineni, Ph.D., DVM

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

TO : Chief, BSB
THROUGH: Chief, Pathology Section

DATE: May 10, 1977

2-4

FROM : Veterinary Pathologist, Pathology Section

SUBJECT: Pathology Report on Guinea Pigs to PVC

Male guinea pigs were exposed by inhalation to polyvinyl chloride (PVC), respirable concentration 10 mg/m^3, for 6 hours/day for 5 days/week for a period of 12 months. The animals were sacrificed immediately after 12 months of exposure to PVC. The following tissues on each animal were saved at necropsy for histopathology evaluation: lungs, liver, heart, spleen, kidney, pancreas, adrenal, thyroid, testis, and urinary bladder. The histopathology evaluation was performed on a total of 75 (exposed 36; control 39) male guinea pigs.

2.1 Guinea pigs exposed to PVC 10 mg/m^3 for 6 hours/day for 5 days/week by inhalation.

Path. Accs. No.: 76-1432 to 76-1467.

Gross pathology: Yellow specks were seen in the lungs of 76-1434, -1436, -1459, and -1464. Consolidation of lungs was observed in 76-1435, -1437, -1439, and -1449. Small areas of necrosis in the liver of 76-1443 were seen. Mesenteric fat necrosis was found in 76-1438 and 76-1441.

Histopathology:

Lungs: All guinea pigs exhibited moderate amount of eosinophilic serous exudate mixed with mild to moderate numbers of epithelial cells (decidual showing varying stages of degeneration) in the bronchial lumens. Another common finding among all guinea pigs was the presence of multiple aggregates of lymphocytes. Most of these lymphoid aggregates were oriented around or near small arteries or veins, thus giving an appearance of lymphoid follicles. The interstitium of all the lungs showed numerous macrophages. These macrophages contained spherical to globular hollow structures in the cytoplasm. These macrophages did not aggregate in the same fashion as those seen in rat lungs (1.1). Plant material with or without associated inflammation was seen in bronchioles of 76-1432 and 76-1435. Bone formation (small spicules) in alveolar area was seen in 76-1434, -1435, -1438, -1446, -1452, -1453, -1455, and -1456. Focal atelectasis was seen in the lungs of all guinea pigs examined.

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Liver: Mild fatty infiltration of hepatocytes was seen in 76-1432, -1441, and -1467. The histology slides from 76-1443 did not show any hepatic necrosis. Search for liver tissue with necrotic areas from "wet tissue" was not fruitful.

Heart: Focal mild myocarditis was seen in 76-1441, while 76-1449 showed focal mineralization of myocardial muscle bundles.

Spleen: Macrophages with yellow granular pigment in the cytoplasm were seen in all guinea pigs.

Kidney: Multifocal mild mineralization of tubular epithelium was seen in 76-1432, -1437 to -1448, -1450 to -1460, -1462 to -1465, and -1467.

Pancreas: Fatty infiltration of the endocrine and exocrine elements was seen in 76-1439, -1442, -1444, -1447 to -1456, -1458 and -1461. Fatty infiltration of only exocrine elements and moderate hyperplasia of the endocrine elements were seen in all guinea pigs excluding the nes given above.

Adrenal: Yellow granular pigment in the cytoplasm of the cortical epithelium was seen in all guinea pigs. Focal mild mineralization of the cortical epithelium was seen in 76-1435 and 76-1455.

Urinary bladder: Mild focal hyperplasia of the transitional epithelium was seen in 76-1444. Mineralization of surface epithelial cells was seen in 76-1452, -1453, and -1462 to -1465.

2.2 Untreated guinea pigs

Path. Accs. No.: 76-1470 to 76-1508.

Gross pathology: Consolidation of lungs was seen in 76-1488, -1490, -1506. Small necrotic foci were seen in the livers of 76-1486, -1488, and -1491. A contracted kidney was seen in 76-1493. Necrotic fat (mass) was found attached to mesentery of 76-1475 (3.57 gm), -1477 (3 x 2 cm), -1480 (4.5 x 2.5 cm), -1486 (1.0 x 2.0 cm), -1494 (1 x 2 cm), -1495, and -1496.

Histopathology:

Lungs: The presence of eosinophilic fluid exudate with cellular debris and the lymphoid aggregation in all guinea pigs was the same as seen in 2.1. The interstitium of all the lungs contained lesser number of macrophages than those seen in 2.1. The cytoplasm of these macrophages was granular and eosinophilic. Plant material with or without inflammatory infiltrates was seen in 76-1488 and -1490. Bone formation in the alveolar region was seen in -1474, -1475, -1476, -1478, -1490, -1493, -1499, -1501, and -1506. Focal consolidation of all lungs was seen.

Liver: Fatty infiltration (mild) of hepatocytes was seen in 76-1472 and 76-1478. Moderate hyperplasia of bile ducts was seen in 76-1474. A myxoliposarcoma was seen in the liver of 76-1470.

Spleen: Macrophages with yellow granular material in the cytoplasm were seen in all guinea pigs.

Kidney: Multifocal mild to moderate mineralization of tubular epithelium was seen in 76-1470, -1471, -1473 to -1483, -1487 to -1508.

Pancreas: Fatty infiltration of exocrine and endocrine elements was seen in 76-1470 to -1475, -1478, -1480, -1482, -1486, -1488, -1490, -1492, -1494, -1495 to -1497, -1501, -1502, -1503, and -1507. The pancreas from the remaining guinea pigs showed fatty infiltration of exocrine elements and hyperplasia of endocrine elements.

Adrenal: Yellow granular pigment in the cytoplasm of the epithelium of the cortex of all guinea pigs was seen.

Urinary bladder: Mineralization of the surface epithelium was seen in 76-1472, -1475, -1480, -1495, -1497, -1498, and -1504. Subacute cystitis was seen in 76-1470 and 76-1494.

Mesenteric masses: 76-1473: Granuloma of mesenteric fat. Entrapped pancreatic exocrine elements were present.
76-1475: Granuloma of mesenteric fat.
76-1477: Thrombosis of veins with degenerative fat.
76-1480: Thrombosis of veins and degenerating fat.
76-1486: Granuloma of mesenteric fat; polarising yellow material seen.
76-1494: Degenerating fat.
76-1496: Granuloma of mesenteric fat.

Comment: For comparison, this comment shall include rat and guinea pig data. Both the rats and the guinea pigs exposed to PVC by inhalation exhibited the presence of PVC particulates in the pulmonary macrophages, although the pattern of macrophage accumulation between the two species differed. There was no inflammatory or any other deleterious effect seen in the lungs of these animals that could be attributable to PVC inhalation.

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to the above observation was the finding of invariable fatty infiltration of exocrine and endocrine elements of the pancreas in both the exposed and control guinea pigs and the hyperplasia of islets of Langerhans seen in both the rats and the guinea pigs employed in this experiment. In addition, the vascular wall calcification in the pulmonary vessels of rats is disturbing. All of these "incidental" findings strongly suggest that these animals had metabolic problems probably related to the animal diet. The changes seen in the testes of rats were non-specific and probably not related to treatment. The incidence of neoplasms in the adrenals of rats is within the normal range observed for Sprague-Dawley rats of this age.

Choudari Kommineni, D.V.M.

PLASTICS DIVISION

NOTE ON A TELEPHONE CONVERSATION WITH DR M N JOHNSON OF BF GOODRICH, 20 OCTOBER 1978

PVC DUST - NIOSH STUDIES

Dr Johnson 'phoned to say he had now had a talk with Dr Trent L wis of NIOSH on the 3 mammal study. Dr Lewis emphasised that this was in no sense a carcinogenicity study. It was a study aimed at ascertaining about pulmonary function and fibrosis. Dr Lewis was happy with the outcome of the work in that nothing happened and there was nothing to comment on the subject of pulmonary function and fibrosis. He thought the study was totally unsuited to gauge carcinogenecity.

In Dr Lewis's view an inhalation study of PVC dust on animals to demonstrat carcinogenicity is a very difficult undertaking. He would be very unwilling to tackle it unless there was something equivocal in the epidemiology that needed to be resolved. Even then he would advocate expanding the epidemiology to get a more positive answer. If there is a positive answer from the epidemiology no amount of animal work would mak any difference and again he stressed that dust inhalation tests f r carcinogenicity on animals are long, tedious, difficult and uncertain.

J Stafford
Division Manager
Health & Environment Protection

JS/MJE/DSO-107
23 October 1978

Circulation

Dr W G F Adams
Dr D P Duffield
Dr G Pigott
Dr B W Duck
Dr M Sharratt
Dr P Grasso
Dr J T Carter
Dr D W Plester
Dr G Paddle
Dr K S Williamson
Dr I F H Purchase
Sir C Lawrence-Jones
Dr F W Best
Mr G J Sleddon
Mr W Adams
Mr T L Phillips
Mr B N P Hutchesson
Mr H M Clayton
Mr T W Moffitt
Dr L de Boer
Dr J G Kammuller
Mr J C Thomas
Mr M Bonnefoy
Dr T Garlanda
Dr M N J hnson
Dr T R Torkels n
Mr R N Wh eler (Jr)
JS (2)
Dr R E Davies, ICI Australia
Mr K H White, Duperial SAIC

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