

UNITED STATES DEPARTMENT OF LABOR
Occupational Safety and Health Administration

In the Matter of:

PROPOSED PERMANENT STANDARD FOR) DOCKET: OSH-36
OCCUPATIONAL EXPOSURE TO VINYL)
CHLORIDE)

POST-HEARING MEMORANDUM OF
THE SOCIETY OF THE PLASTICS INDUSTRY, INC.

PROPOSED FINDINGS OF FACT AND
CONCLUSIONS SUPPORTED BY THE RECORD

In accordance with the provisions made for supplementing
the Record in the above-referenced matter ^{1/}, The Society of the
Plastics Industry, Inc. (SPI) through its Vinyl Chloride and
Polyvinyl Chloride Resin Producers Committee ^{2/} hereby respectfully

1/ Occupational Safety and Health Administration Hearings, In
the Matter of: PROPOSED PERMANENT STANDARD FOR OCCUPATIONAL
EXPOSURE TO VINYL CHLORIDE, Prehearing Conference, remarks of
Administrative Law Judge Gordon J. Myatt Transcript at 3, June
25, 1974, and Occupational Safety and Health Administration
Hearings, In the Matter of: PROPOSED PERMANENT STANDARD FOR
OCCUPATIONAL EXPOSURE TO VINYL CHLORIDE, Transcript at 1247,
July 8, 1974 and at 1975, 1978, July 11, 1974. (Hereinafter,
the main body of the Hearing Transcript will be cited in the
text as: (Tr. _____).)

2/ The Society of the Plastics Industry, Inc. (SPI) is a Cor-
poration organized under the Not-for-Profit Corporation Law
of the State of New York. It is composed of approximately
1400 member companies and individuals who supply raw materials;
process or manufacture plastics or plastics products; engineer
or construct molds or similar accessory equipment for the plas-
tics industry; and engage in the manufacture of machinery used
to make plastics products or materials of all types. SPI is
the major national trade association of the plastics industry. (cont'd)

submits for the consideration of the Assistant Secretary and the Occupational Safety and Health Administration's Office of Standards Development, its synopsis and analysis of the evidence presented by SPI witnesses at the Hearing and otherwise contained in the Record, and urges the adoption in substance of the conclusions we submit are justified thereby.

I
INTRODUCTION

In the development of a standard such as is being contemplated here, the Assistant Secretary must reach his decisions on the facts and evidence available to him which "...shall be based upon research, demonstrations, experiments, and such other information as may be appropriate."^{3/} To aid the Secretary in the decision making process, the purpose of this filing is to summarize the probative evidence in the Record in a form that permits ultimate findings and conclusions to be drawn accurately and readily.

It is respectfully suggested that the main issues presented in this case are (1) whether the proposed Permanent Standard is technologically achievable, (2) whether the known

2/ (cont'd) Its membership is responsible for an estimated 75% of the total dollar volume of sales of plastics in this country. A more complete discussion of the interest of the Society in this entire matter is set forth in the Transcript at 330 et seq.

3/ Occupational Safety and Health Act Section 6(b)(5), 29 USC §655(b)(5).

hazards associated with occupational exposure to vinyl chloride justify the extreme reduction in exposure levels proposed, (3) whether the proposal is too broad in scope with reference to its coverage of PVC processors and fabricators, and (4) whether the compliance mechanics and safety measures detailed in the proposal are responsive to and reflective of realistically achievable working conditions and practices.

It is the position of the Society that a careful evaluation of the Record can only lead to the conclusions that the proposed Permanent Standard is technologically infeasible to meet, that the alternative plan relative to exposure reduction over a three year period as advocated by SPI in the Hearings is at least potentially achievable by most of the industry, and that a level of exposure lower than proposed by industry, or the indiscriminate imposition (i.e. on fabricators or processors) of the proposed or reasonably amended work rules and record-keeping concepts would give rise to serious adverse social and economic effects unjustified by the hazard presented.

The following sections of this Memorandum set forth (1) a detailed summary of the probative evidence presented, (2) a recitation of the ultimate findings considered warranted by this evidence, and (3) the ultimate conclusions SPI submits are fully supported by the facts in evidence.

II
EVIDENCE PRESENTED

The main facts at issue are (a) whether the proposed Permanent Standard is technologically achievable in terms of compliance, (b) whether the occupational exposure levels to vinyl chloride contained in the proposed Permanent Standard are justified as rationally related to the toxicological and medical-epidemiological data, (c) whether the scope of the Proposal is too broad with reference to its coverage of PVC processors and fabricators, and (d) whether the various provisions of the Proposal accurately reflect possible working conditions and practices; and whether the compliance mechanics are responsive to the goal of protecting employees from excessive exposure to vinyl chloride monomer.

A. Feasibility

The Hearing Record presents a very complete picture with regard to the question of whether compliance with the Proposal is technologically feasible.

An important witness discussing the details of technological feasibility was Mr. Anton Vittone, President of the B. F. Goodrich Chemical Company, testifying on behalf of The Society of the Plastics Industry, Inc. (SPI) and the Society's Vinyl Chloride and Polyvinyl Chloride Resin Producers' Committee. Speaking for this Committee, which

represents over 90% of the current United States capacity for the production of vinyl chloride and polyvinyl chloride resins, Mr. Vittone stated that "[T]he Committee is unanimous in its position that the proposed Permanent Standard is not technologically feasible and, if adopted, would shut down the industry." (Tr. 351)

Mr. Vittone noted that the history of worker exposure to vinyl chloride is one of a high degree of exposure in the 1940's decreasing to far lower exposures in the current time period. Nevertheless, on the basis of background information available, he pointed out that "it is only prudent that we continue to decrease the level of exposure of our workers." But, because "the development of technology [is] not currently in hand", it would seem that the "only practical way of accomplishing [compliance with the proposal] is to shut the PVC industry down or to impose work practices which will create a greater immediate risk to health and safety than exposure to low levels of vinyl chloride." (Tr. 353, 361)

Mr. Vittone concluded:

"...the producers have stated that a 'no detectable level' for vinyl chloride, as defined, would shut down the industry. As stated earlier, it is not feasible to require workers to continually use self-contained breathing apparatus [required when exposure exceeds the permitted level]. Therefore, there are only two

ways to seek a 'no detectable level': to eliminate all losses of vinyl chloride or to dilute losses through ventilation. Neither of these alternatives are feasible, in our judgment, because losses from processing equipment will always occur. Some are identifiable and others are fugitive losses." (Tr. 357)

In setting forth the industry recommended standard for vinyl chloride exposure, Mr. Vittone pointed out that these recommendations represent "the maximum reduction which a majority of the industry believes feasible" (Tr. 358 [Emphasis supplied]), qualified, of course, by a previous statement that the industry proposals had "already taken into consideration projections for improvement which are not in hand but depend on new developments and additions to facilities." (Tr. 354)

This industry proposal reads as follows:

Polyvinyl Chloride Resin Plants

October 5, 1974	40 ppm ceiling 25 ppm maximum daily time weighted average (TWA)
October 5, 1975	25 ppm ceiling
October 5, 1976	25 ppm ceiling 10 ppm TWA

Vinyl Chloride Monomer Plant

October 5, 1974	25 ppm ceiling 10 ppm TWA
October 5, 1975	10 ppm ceiling 5 ppm TWA

(Tr. 358-362)

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Mr. Joseph Fath, Vice President of Tenneco Chemicals and General Manager of its Organics and Polymers Division, testified that "[T]he standard of no detectable amount of ambient vinyl chloride is not feasible." (Tr. 686) "Adoption of the proposed OSHA Standard", Mr. Fath maintained, "would leave Tenneco with the following options: (1) We would have to place all our operating and support personnel at our PVC manufacturing sites in respirators all of the time; or (2) Tenneco would have to cease to manufacture PVC...." (Tr. 686-687)

"The only conceivable course of action for industry is the maximum feasible reduction of human exposure to airborne concentrations of vinyl chloride monomer" since "it is neither safe nor feasible to place vinyl chloride workers in respirators for the full duration of the work shift." According to Mr. Fath, a no detectable standard is therefore technologically infeasible. (Tr. 686-687) Mr. Fath also testified that "technological advances have enabled automation of some manual operations, ventilation has improved, leaks have been subjected to greater controls, and work practices have improved materially" but, nevertheless, "compliance with the proposed standard cannot be accomplished as a practical matter." (Tr. 689-691)

Dr. Paul Lobo, Director of the Technical Group for the Organics and Polymers Division of Tenneco Chemicals, added

to Mr. Fath's testimony that "based on presently available technology, it is not feasible for existing polyvinyl chloride facilities to meet the proposed OSHA Standard through engineering changes...[and] there exists no practical, quick corrective means to bring these facilities into conformance with a standard of no detectable level of VCM in the plant areas. In this conclusion, I include even our most modern facility that is expected to begin operation in Texas this coming fall." (Tr. 696-697)

After a discussion of the details of Tenneco's effort to reduce vinyl chloride in the workplace, Dr. Lobo remarked that "because of the factors I have just described, it is not feasible by engineering changes using presently available technology, to modify our existing plants to meet the proposed standard, nor can a combination of work practices and engineering changes achieve that result. Steps can be taken to reduce employee exposure to vinyl chloride. With these steps, Tenneco hopes by October, 1976 to reduce vinyl chloride monomer exposure levels [to those levels recommended by SPI]". (Tr. 698, 701-702)

With respect to the SPI proposal relative to vinyl chloride exposure levels, Air Products and Chemicals Incorporated Group Vice President Richard Fleming maintained that the enunciated 1974 levels are "feasibly attainable, though

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difficult" but that "lower levels proposed for later achievement by SPI are much more difficult and much more speculative as to achievement at this time, in our view." (Tr. 789-790)

The main obstacle in meeting even the future SPI recommendations, according to Mr. Fleming, is that the "replacement of older equipment with newer types, which are designed with minimum leakage in mind, depends upon the availability and deliverability of such replacements. Delivery of even an exhaust fan takes months in the current high capital spending environment. Major equipment takes many more months." (Tr. 791-792)

Further details about equipment ordering and delivery lag times were offered by Mr. John T. Barr, Technical Manager-Manufacturing of Air Products. He stated that "even standard equipment such as pumps and valves run several months to a year for delivery, and as all industry knows, it is impossible to get early delivery on monitoring equipment, apparently because of large orders placed by Government agencies. Other quoted delivery times for the types of equipment which we will need are: [in the range of a minimum of 12 to 24 months after order acceptance.] This situation will deteriorate rather than improve as more companies move to reduce their exposure, and we can expect that at least two years will be necessary for any major capital improvements." (Tr. 800, 801)

Mr. Barr concluded that "we can support the SPI proposal [for the first year] as a goal that we have a reasonable hope of achieving by October, 1974. Beyond that, we cannot say with certainty the results of technology which is yet to be applied." (Tr. 801)

Mr. Karl Oelfke, Production Manager at the Texas Division of Dow Chemical, USA, and the individual responsible for the coordination of vinyl chloride production techniques and technology for The Dow Chemical Company on a worldwide basis, also addressed engineering controls and manufacturing practices involved in the reduction of vinyl chloride exposure in the production of vinyl chloride monomer. He explained why Dow, the acknowledged leader in reducing vinyl chloride exposure, supports the SPI recommendation for monomer plants. (Tr. 899, 901) Although Dow is generally operating at or lower than the proposed SPI levels for monomer plants (Dow is not a PVC resin producer (Tr. 1022)), its data showed occasional, unpredictable excursions well above such levels. (Tr. 884-892)

Additionally, Mr. Oelfke stated, in response to questions from the Solicitor, that he had "tried to demonstrate the complexity of the production plant, what we have done in the past, and the problems that we face in the future, to get down to OSHA's proposed permanent standard of one part per million, at 'no detectable'...But when we get down to the

bottom [very low concentrations], then it becomes more and more difficult. Right now, I think it [the proposal] is technically not feasible." (Tr. 899, 900)

Diamond Shamrock Chemical Company also testified in support of the SPI proposed exposure levels because, as Mr. Harry E. Connors, Jr., Vice President and General Manager of the Plastics Division of Diamond noted, his company is "convinced that the Standard as now proposed cannot be complied with....In fact, if the proposed Standard is placed into effect in its present form, our entire PVC operations [including resin manufacture and processing/fabrication] would almost certainly have to be shut down." (Tr. 1030, 1031 and 1054)

Mr. John L. Nelson, Vice President-Manufacturing of B. F. Goodrich Chemical Company also testified about feasibility. After extensive review of Goodrich exposure levels, its current programs to reduce these exposure levels, and its research and development programs to further reduce exposure levels in the future, Mr. Nelson summarized the Goodrich position by saying that his company generally supported the position outlined by The Society of the Plastics Industry and that "[a]chievement of [a] no detectable level of VCM exposure is not technically feasible....Thus, if the proposed standard is adopted, Goodrich would have no alternative but to shut

down its monomer and PVC resin operations." (Tr. 1127)^{4/}

In response to a direct question from the Solicitor about a new Goodrich PVC plant not yet in operation, Mr. Nelson stated that "there is just no way of projecting what exposure levels will be in this plant." (Tr. 1148) In other words, despite the new engineering controls and work practices that will be instituted in that plant, even though it is expected to be more proficient in all aspects, vinyl chloride exposure levels cannot be predicted.

There was testimony by the ACS representatives which appeared to contradict the position of industry witnesses on technological feasibility. The facts are, however, that:

(1) ACS submitted no data on this issue of feasibility; (2) the ACS witnesses conceded that no studies of any type had been undertaken relative to the feasibility issue (Tr. 1339 et seq.); and (3) there is now available evidence that the only members of the ACS Committees here involved who were truly familiar with the vinyl chloride and polyvinyl chloride industries were uninformed, inadequately informed, or objected to the position that the ACS witnesses advanced at the Hearing, and these members now vigorously oppose that position.

^{4/} Accord, Borden Chemical (Exhibit 71), Continental Oil (Exhibit), General Tire (Exhibit), Goodyear (Exhibit 56), Hooker (Exhibit 55), Olin (Exhibit 61), Pantasote (Exhibit), Stauffer (Exhibit 92) and Union Carbide (Exhibit 94).

Attached hereto is (a) a copy of a letter and enclosures dated July 31, 1974 from Dr. Zeb G. Bell, Jr. to Assistant Secretary Stender (Exhibit 122 in the Record, Appendix A, hereto) and a copy of a letter addressed to Mr. Stender by Mr. Paul D. Halley on behalf of Committee E-34 of the American Society for Testing and Materials (ASTM) on August 19, 1974 (Exhibit in the Record, Appendix B, hereto). These statements make it quite clear that one of the members of the ACS Committees most knowledgeable about the industry never saw the actual testimony presented by the Society and neither of them support its substantive conclusions.

Mr. Martin J. Kleinfeld, Commercial Planning Director of the Chemical Division of Uniroyal, Inc., stated that Uniroyal supported a 50 ppm TWA for both monomer and polymer operations, until such time as further evidence requires its reduction, with the total exclusion of processing and fabricating plants. (Tr. 1488-1500) Uniroyal characterized the proposal as technologically infeasible and stated that, upon the adoption of such an infeasible standard "Uniroyal, for one, would have to close down." (Tr. 1494)

Mr. Todd C. Walker, President of Firestone Plastics Company, agreed with other industry witnesses that the proposed Standard is "technologically unachievable [but that] a technologically and economically feasible standard is that which provides for a 25 parts per million TWA-time weighted average--

and 40 parts per million ceiling exposure level." (Tr. 1682, 1683)

Characterizing the 25 TWA and 40 ceiling as a standard "which is not immediately achievable nor a level which can be accomplished without the expenditure of millions of dollars at Firestone alone," Mr. Walker disagreed with the SPI position on setting in futuro levels and said that the exposure level recommended by Firestone "should be maintained as the permanent standard until further ongoing medical experimentation and study--of the human as well as the animal experience--is completed and more definitive conclusions have been reached concerning the nature and consequences vinyl chloride may have on industry employees." (Tr. 1683-1684)

Mr. Walker further reported that Firestone's engineering studies and studies conducted by independent consultants, lead to the conclusions that:

"It is impossible on the basis of the present state of technology and the engineering art to predict with any degree of certainty that the reduced levels suggested by SPI can be achieved in existing facilities..." (Tr. 1684-1685)

"The clear conclusion resulting from the studies carried out by the Firestone engineering staff in conjunction with [the consultants] is that Firestone would have no alternative but to cease all polyvinyl chloride manufacturing operations if the proposed Standard is adopted....it is

not possible to achieve the drastic non-detectable exposure levels required by the proposed Standard based on engineering controls and process modifications...."
(Tr. 1696-1697)

Representatives of Calgon Corporation testified that experiments showed that virgin vinyl chloride monomer could be absorbed out of air when passed through a granular, activated carbon bed. However, Calgon had no suggestions as to how the air in which the vinyl chloride was dispersed could be gathered and evacuated from the breathing zone and then forced through the carbon bed to eliminate the vinyl chloride. (Tr. 1905, 1946)

In sum, the Calgon testimony seemed more applicable to air pollution control problems and technology than the essence of the instant proceeding. Specifically, the only practical situation to which the Calgon representatives would refer was one where activated carbon was employed at the pilot plant level to evaluate its effectiveness in controlling vinyl chloride emissions, resulting from the venting of certain small process streams to the atmosphere. (Tr. 1889, 1890) Although the Calgon witnesses were not at liberty to discuss or did not have detailed knowledge of the pilot plant experiments, new information now available in a post-Hearing comment by Tenneco, the company whose experiments were referred to in the Calgon testimony, substantiates doubts raised during cross-examination. First, these pilot plant tests did not deal with the large volumes

of air and dilute concentrations of vinyl chloride which would be involved in major plant activities, and second, the pilot plant tests show that vinyl chloride may polymerize on the charcoal. Thus, these tests cast doubt on the commercial plant-scale feasibility of activated carbon as a means of recovering VCM from polymerization systems.^{5/}

With further regard to the question of the technological feasibility of controlling vinyl chloride in-plant concentrations, the National Institute for Occupational Safety and Health (NIOSH), in its comments on the "Draft Environmental Impact Statement on the Proposed Regulation for Vinyl Chloride" has now stated:

"...we question the extent to which OSHA has demonstrated that 'technology appears to be readily available' for engineering controls. We certainly don't have the data to support such a strong statement....In general, the broad statement [referenced to in the single quotes above] appears too unsubstantiated and should be at least modified to more accurately reflect the state-of-the-art. Unfortunately, the state-of-the-art for engineering control techniques for vinyl chloride has not, in our opinion, really been established and this is a sizeable gap in the proposed Standard." ^{6/}

^{5/} See Exhibit 127(a), a post-Hearing filing by Tenneco relating to Calgon testimony.

^{6/} Memorandum to David R. Bell, Office of Standards Development, OSHA from Vernon V. Rose, Director, Office of Research and Standards Development, NIOSH, dated July 16, 1974, (Exhibit) p. 2.

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Similarly, the comments of the United States Department of Commerce point out that in OSHA's Draft Environmental Impact Statement:

"The feasibility of compliance is implicitly assumed and no consideration is given to the possibility that efforts at compliance may engender unlimited capital and operating costs and still fail of achieving their goal....The concluding section of this statement 'that a preliminary assessment of the cost of compliance indicates that expenditures required will not be prohibitive' is completely unsupported by evidence in this document." 7/

With respect to the economic impact of the standard, Arthur D. Little, Inc., representatives testified on the consequences which a shut-down of the industry would have. They testified that 25% of PVC resin was used for extruded pipe and conduit, 15% for film and sheet for packaging and coated fabric applications, 10% each for wire and cable insulation and flooring, and 5% for phonograph records. (Tr. 458) They also testified that the building and construction industry is the largest consumer of PVC end products, accounting for about 43% of all PVC consumption. The four other major industrial segments that consume PVC are listed by A.D.L. as: (1) motor vehicles, (2) wearing apparel and home furnishings, (3) the telephone,

7/ Letter to David R. Bell, Office of Standards Development, OSHA from Sidney R. Galler, Deputy Assistant Secretary for Environmental Affairs, Office of the Assistant Secretary for Science and Technology, United States Department of Commerce, dated August 1, 1974, (Exhibit) pp. 6 and 7.

telegraph, lighting, wiring equipment and record industries, and (4) industries manufacturing such products as luggage, handbags, toys, sporting goods, footwear, garden hose, packaging, credit cards and medical equipment. (Tr. 458-459) A.D.L. concluded that "an immediate shutdown of all polyvinyl chloride (PVC) resin plants in the U.S. and the subsequent unavailability of PVC resin could result in a loss of 1.7 to 2.2 million jobs in consuming and related industries and a loss of domestic production value of \$65 to \$90 billion annually." (Tr. 456)^{8/}

8/ In Exhibit 85, General Motors Corporation indicates, at page 4, that a "severe reduction in the production of vinyl chloride" would directly affect 450,000 GM employees. GM also estimates that the ripple effect, that is, the GM-related layoffs alone, could possibly reach 1.8 million workers. This indicates that the A.D. Little conclusions are most conservative. See also Exhibit ____, a letter to David R. Bell, OSHA Office of Standards Development from Sidney R. Galler, Deputy Assistant Secretary of Environmental Affairs, U.S. Department of Commerce dated August 1, 1974 where, in commenting on the OSHA Draft Environmental Impact Statement on the Proposed Regulation of Vinyl Chloride, it is stated at page 6 that:

"Termination of production of VCM and PVC resin, and replacement of PVC products with other material, is not a viable option. In many cases, there is no reasonable substitute material which can serve as a replacement material. In many cases, the required quantity of replacement material would not be available on short notice. Hence, the economic impact on downstream industries would be very significant if PVC resins were not available." (Emphasis supplied.)

B. Toxicological and Medical-
Epidemiological Considerations

Considerable evidence was presented relating to the toxicological and medical-epidemiological ramifications of vinyl chloride in the air.

1. Toxicological Evidence

Dr. M. L. Keplinger, who is the director of the animal experiments involving VCM exposure at Industrial Bio-Test Laboratories, appeared as a witness at the Hearing. Dr. Keplinger reported his results to date and labeled them "tentative." Specifically, Dr. Keplinger reported that in his experiments two cases of angiosarcoma of the liver had been observed in mice at 50 parts per million, 11 cases at 200 ppm and 28 at 2500 ppm, with none being observed as yet in the controls. (Tr. 442)

He also reported that "in addition to the tumors in mice, a few tumors have been observed in rats and hamsters, but the diagnosis at this time must be considered tentative. It appears that angiosarcomas have been observed in one male hamster and one male rat exposed to 2500 parts per million, and in one female rat exposed to 200 parts per million." (Tr. 442)

"Since these data are preliminary in nature," Dr. Keplinger testified:

"conclusions from the results of the study are even more preliminary . . . In comparing our results from mice, rats and

hamsters, it does appear that the mouse is more susceptible than the other two species. The relevance of these data in mice for prediction or extrapolation to effects on man at the same concentration, same durations of exposure, are quite conjectural. It is now known that mice are very different from man in size, life span, respiratory rate, respiratory volume, metabolic rates, metabolic pathways, absorption, excretion, distribution and many others. These facts should be considered when evaluating animal data for predicting effects in man, particularly when, as here, there has been considerable human experience, and the data in some respects still are inconclusive." (Tr. 443-444)

Dr. Perry Gehring of the Toxicology Research Laboratory of The Dow Chemical Company, USA, reported on studies he had undertaken to gain an understanding of the metabolism of vinyl chloride. In essence, Dr. Gehring testified that his preliminary results suggest that vinyl chloride may be metabolized in more than one way depending upon the magnitude of exposure. Dr. Gehring testified that the primary metabolic pathway may not produce a carcinogen, but if this primary metabolic pathway is "swamped," a secondary pathway may be established, and this pathway may produce a carcinogen. Dr. Gehring's preliminary observations led him to express the opinion that the primary metabolic pathway may become "swamped" at levels greater than 200 parts per million. (Tr. 969-970)

Most importantly, Dr. Gehring's expert opinion was as follows: "In my opinion, if I examine the toxicological data

available, as well as the human data which has been shown here, there is not any discernible indication or any, at least, specific indication that 50 parts per million, for example, constitutes an unreasonable risk [to man]." (Tr. 1023)

2. Medical-Epidemiological Evidence

Testifying on behalf of SPI, Mr. John E. Ertel, General Manager of Robintech Incorporated, reported on a three-day problem analysis conference which utilized the Kepner-Tregoe problem solving and decision making analysis procedure in an attempt to categorize and analyze information available on the known cases of human angiosarcoma. The conference reached the following conclusions:

1. All 13 individuals [who had angiosarcoma of the liver] had been exposed over long periods of time to continuous high levels of VCM. These levels, frequently above the odor threshold, were estimated to be a minimum of 500 ppm TWA and may have exceeded 2000 ppm TWA. 9/
2. The Maltoni toxicological studies indicate that disease in rats is dose related.
3. The Industrial Bio-Test Laboratory studies support Maltoni but also suggest a difference in species response.
4. The animal data also indicates that the test animals are significantly more sensitive

9/ See Exhibit 94(b), a statement filed for the Record by Richard J. Hughes of Union Carbide Corporation. Appendix C to that statement contains the results of a recently conducted olfactory detection study which validates the fact that odor detection of vinyl chloride is likely to begin only at 1960 ppm or higher, depending on individual worker smelling sensitivity.

to the development of angiosarcoma than humans.

5. The Emergency Temporary Standard set at 50 ppm maximum exposure to vinyl chloride in the workplace appears to assure that employees will no longer be exposed to any undue occupational hazards. (Tr. 501-506)

The SPI sponsored health survey of polyvinyl chloride producers with plants reporting no cases of angiosarcoma was the subject of testimony by Dr. Carl U. Dernehl, M.D., Associate Medical Director at Union Carbide Corporation. In summarizing the results of this study, Dr. Dernehl stated that the:

"[E]xaminations of these men have failed to show the existence of abnormal liver function tests in greater proportion than would be found in a control population. There is no case of angiosarcoma of the liver among these 1,402 men, even though their exposure time is sufficient for disease to have occurred and exposures are believed to have been in excess of 50 ppm....The fact that not one case was found cannot be ignored....This suggests that the difference lies in the degree of exposure which in the survey group is estimated at more than 250 ppm in early years and about 50 ppm in recent years. We submit that these data fail to support the need for an exposure level as drastic as that proposed in the Standard...." (Tr. 513-514) 10/

As a witness for Air Products and Chemicals Incorporated, Paul Kotin, M.D., formerly Director of the National Institute of

10/ It should be noted that the estimate of 250 ppm exposure in early years was based on the belief that the odor threshold for vinyl chloride was "...in the vicinity of 225 parts per million." (Tr. 510) This estimate was made prior to the recent olfactory detection study confirming odor detection of vinyl chloride at 1960 ppm. See note 7, supra.

Environmental Health Sciences of the National Institute of Health (NIH) testified that, as a consultant, he had conducted health examination programs at two Air Products' plants. After detailing his findings, he testified:

"I would conclude at this time that except for the case of acroosteolysis discovered in an employee in the Florida plant, the results...findings or diagnoses which point to VCM as a causative agent or mechanism were not identified. More specifically, we can state at this time that no cases of angiosarcoma have been identified." (Tr. 811-812)

Similarly, Ralph Cook, M.D., Midland Division of Dow Chemical, USA conducted a medical surveillance program and reported an analysis of selected health surveillance data gathered from Midland Division employees. Based on 20 years of industrial hygiene records and medical surveillance data combined with recent examinations, Dr. Cook reported that "Above 200 ppm, some deviations were noted in various health parameters; below 200 ppm nothing of statistical significance has been observed." (Tr. 932-938)

Ben Holder, M.D., Medical Director of Dow's Midland Division lent further weight to Dr. Cook's report on living employees with a report on a study of the mortality experience of workers exposed to vinyl chloride dating back to 1942. Dr. Holder testified that he had found no cases of angiosarcoma

or other liver malignancies. More important, Dr. Holder concluded:

"...overall mortality experience of the population was better than the expected for the U.S. white male population....No adverse effect from malignancy was demonstrated in the population where exposures to vinyl chloride were controlled below 200 parts per million time weighted average. In workers exposed above 200 parts per million, time weighted average, an increase in overall malignancy experience was noted." (Tr. 955)

Richard W. McBurney, M.D., Medical Director of Diamond Shamrock Corporation which has had no angiosarcoma cases, testified that, based on a comprehensive review of the medical condition of present and past employees combined with data indicating that for over 20 years the Diamond Shamrock worker population had "been exposed to VCM levels substantially in excess of the current emergency standard of 50 ppm," (Tr. 1043) the proposed limitation on vinyl chloride exposure "may be unnecessarily restrictive and not yet supported by available medical evidence." (Tr. 1033) "Taking into account the clear dosage-response effect of VCM in the rodent population, the present good health of our workmen... the tremendous reduction in exposure levels Diamond Shamrock has already achieved and plans to achieve in the future," Dr. McBurney said that he was "of the opinion that our workers are now at low risk insofar as VCM hazard is concerned." (Tr. 1039)^{11/}

^{11/} Accord, Comments by J. Wister Meigs, M.D., Associate Clinical Professor, Occupational Medicine, Yale University in Appendix C (cont'd)

C. Scope of Regulation

Extensive information by both large and small companies involved in processing or fabricating PVC into intermediate and/or final end products indicated that occupational exposure to vinyl chloride in these facilities was, in most cases, very low or not detectable.

A myriad of witnesses have now provided data demonstrating that both the sources and amount of vinyl chloride exposure have, in large part, been pinpointed in processing and fabricating plants. In most instances where exposure was detected, it was stated that engineering and work practice techniques are available to reduce and, in most cases, eliminate this exposure completely.

The smaller companies made a special point of objecting to many of the compliance mechanisms and safety regulations on the basis that they are inappropriately severe for the types of facilities to be regulated and beyond economic feasibility.

Specifically, the PVC processor and fabricator witnesses whose companies provided monitoring data showing occupational exposure stated that they were already committed to new and improved engineering techniques such as increased area and

11/(Cont'd) to Exhibit 92, a statement filed for the Record by Stauffer Chemical Company. Dr. Meigs concludes his remarks on page 6 by stating that "based on the available medical evidence and human experience data, it is my opinion that the worker exposure levels proposed by Stauffer [much the same as those proposed by SPI] are reasonable."

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point ventilation systems in order to reduce or eliminate the exposures. However, many such processors and fabricators objected strenuously to the expense and complexity of instituting monitoring systems and fitting out employees with sophisticated respiratory protective equipment. In their view, because of the impossibility of occurrence of very large exposures, such requirements are inappropriate and would be financially ruinous with no concomitant benefit to the work population or the public interest.

In such operations the only vinyl chloride exposure that could occur is that which might emanate from polyvinyl chloride resins during storage and mixing. In these operations no bulk VCM is handled so there is no possibility of a significant release of monomer. It is on these grounds that most witnesses who presented information for the Record strongly suggested the exclusion of processing and fabricating operations from the proposed Standard.

It was repeatedly pointed out that such processing operations are already subject to the OSHA Clean Air Regulations (29 CFR 1910.93) and that the additional burdens in the proposed Standard were simply not germane to their type of operation. When queried by the Solicitor, the consensus of processors and fabricators seemed to be that, if a Standard for them is deemed necessary by OSHA, any such Standard should be independent from

the Standard applicable to vinyl chloride and polyvinyl chloride resin producers and should be based upon performance-type requisites that would eliminate the need for other than known engineering and work practice solutions.

D. Safety Regulations-Compliance Mechanics

1. Respiratory Protection

Based on industry testimony that compliance with exposure levels set under the proposed Standard would be infeasible and require the full-time use of respiratory protective devices, the consensus of those presenting evidence on respiratory protection was that such full-time use of respirators was impractical to the extent that it would be infeasible to continue manufacturing operations under such conditions.

All witnesses testifying on the topic indicated that respiratory protection devices were designed for short-term use. (Tr. 92/9, 92/10, 92/14, 316, 580, 917) One expert witness defined short-term as 15 to 60 minutes use. (Tr. 329)

Addressing the specifics of the proposed Standard, the expert witnesses testified that self-contained breathing apparatus and airline-type respirators were designed for and are typically used in situations where there is an immediate hazard to life. (Tr. 86) The consensus was that air-purifying-type respirators should be considered if it can be shown that they are capable of adequate performance and a sufficiently long service life.

Generally, the use of self-contained or airline-type respirators was considered by the experts to be impractical and hazardous because of the inherent limitations of the equipment and the type of work being performed. (Tr. 87-90) It is on this basis that the use of air-purifying equipment was recommended by the experts. Despite the limitations of this type of equipment, the thrust of the evidence was that if adequate protection could be provided with their use, most of the extreme hazards and limitations of the other types of equipment would be circumvented. Nevertheless, Dr. Hyatt testifying for OSHA at the Hearing said that "[a]t best, any of these devices is an instrument of torture." (Tr. 92/14)

Agreeing that in emergency situations self-contained and air-fed devices should be employed, the expert testimony favored the use of air-purifying-type devices for exposure levels in excess of the limits proposed by SPI.

In reporting on experiments conducted by the B.F. Goodrich Chemical Company, Dr. Strassburg reported that experience with canister respirators demonstrates that they can provide adequate, short-term protection against exposure to vinyl chloride above the levels recommended by the industry. (Tr. 585)

Specifically, he reported findings that, at concentrations of 100 parts per million in the air, the canister-type equipment he tested had a service life of 11 hours. As the

concentration in the air rose, the service life of this equipment decreased. On the basis of the data he gathered, Dr. Strassburg reported that the demonstrated effectiveness and service life of this equipment should permit the short-term use of canister respirators under normal operating conditions. Additionally, Dr. Strassburg indicated that the long service life of the canister equipment he tested obviated the need for an indicator that the canister's life had been exhausted, if canisters are replaced after each day's use. (Tr. 586)

2. Monitoring

Dr. Rudolph Stehl, a Senior Analytical Specialist with Dow Chemical, USA, recommended a departure from the proposed requirement of personnel monitoring. He recommended continuous sequential area monitoring as a system for determining vinyl chloride concentrations in work areas. He noted, and many other witnesses concurred, that personnel monitoring should be employed as a back-up to area monitoring. Changes in vinyl chloride monomer concentrations could be observed and corrected promptly with the use of the area systems; personnel monitoring, on the other hand, will give a historical record of exposure.

In short, Dr. Stehl's recommendation was that continuous sequential area monitoring be employed, supplemented by periodic personnel monitoring. (Tr. 555-557)

Subsequent to the Hearing, the Vinyl Chloride and Polyvinyl Chloride Producers Committee appointed a working group to consider specifics of sequential area monitoring. The report of this working group is attached hereto as Appendix C.

It will be noted that this group of specialists has recommended, as did Dr. Stehl, that continuous sequential area monitoring be employed as an early warning system for indicating potential exposure to vinyl chloride in VCM and PVC plants. The working group recommended that the area monitoring system be backed-up with periodic personnel monitoring, and that gas chromatography with flame ionization detectors should be the "referee" method used to validate the detection sensitivity of any fixed point area system.

3. Medical Surveillance

The proposed Standard addresses itself to medical surveillance of employees in paragraph (c) of the proposed Section 1910.93q. However, the procedures set forth in the Standard have deficiencies. First, the medical examination concept is directed only to the detection of liver diseases whereas. Maurice N. Johnson, M.D., Director of Environmental Health for the B.F. Goodrich Company, stated, in his testimony on behalf of SPI, that the examination should not be directed exclusively toward liver pathology. Second, the proposed Standard attempts

to define which tests should be performed to discover liver angiosarcoma, but it is generally recognized that none of the proposed tests are definitive for this purpose. Finally, the proposed Standard leaves little room for the clinical judgment of the examining physician for evaluating the total health status of the employee in recommending the advisability of his working in any given environment. (Tr. 552, 553)

It was recommended by Dr. Johnson that a more general standard be set for medical surveillance with provision made for periodic up-dating of an examination protocol as new information or experience may dictate. (Tr. 554)

No contrary testimony was presented at the Hearing.

II ULTIMATE FACTS

A. Feasibility

(1) Historically, occupational exposure to vinyl chloride was quite high, in excess of 2000 parts per million, based on the most recent reports regarding VCM olfactory detection capability of human beings.

(2) Over the years the vinyl chloride monomer and polyvinyl chloride resin manufacturers have reduced the exposure to vinyl chloride to the extent that the industry is in compliance with the requirements of the Emergency Temporary Standard--some

segments doing better and others indicating some compliance difficulties.

(3) The most dramatic improvements in occupational exposure to vinyl chloride have by and large been accomplished quite recently.

(4) The testimony at the Hearing demonstrated that VCM and PVC plants are quite complex and that, because of this, not all vinyl chloride losses are identifiable. A considerable amount of known losses are "fugitive".

(5) Information available concerning the newest facilities coming on line indicates that, because these plants employ the latest in technology, exposure levels will probably be reduced, but they cannot be reduced to the point where there is either a non-detectable or zero exposure to vinyl chloride.

(6) The industry is unanimous that it is impossible to achieve compliance with the proposed Standard. Based on internal studies and judgment, and externally obtained reports from consultants, it is evident that the advanced technology, sophisticated leak-proof equipment, and new engineering techniques required to reduce occupational exposure to a no-detectable level are not available. The industry position is that imposition of the proposed Standard would leave it two options: one, the cessation of operations or, two, operation with all employees making constant use of respiratory protection devices.