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28 April 1978

Joseph E. Hadley, Jr., Esquire
Keller & Heckman
Suite 1000
1150 17 Street N.W.
Washington, D.C. 20036

Dear Joe:

This letter will update you on our activities since the March 23 meeting at EPA where we prepared the testimony for the American Industrial Health Council (AIHC) and SPI.

Testimony for California Air Resources Board Hearing

During the week of April 3, 1978, we were advised by Messrs. Nuechterlein, Savage, Barr and Becker that problems were developing in the State of California regarding the desire of the Air Resources Board (Board) to regulate the emissions of vinyl chloride. There is a concern that California may adopt a more stringent standard for vinyl chloride which could set an unfortunate precedent. Action such as this could, of course, have a negative impact on all members of the PVC Safety Group.

On April 12 we were advised that we should draft testimony which summarized the submissions SPI had presented to EPA during the last three years. The primary purpose of the testimony is to convince the Board that the U.S. Environmental Protection Agency (EPA) has adequately reviewed the information relating to vinyl chloride and is regulating it appropriately.

During the week of April 17 Messrs. Barr, Savage and Beveridge prepared the testimony to be presented to the Air Resources Board. (Copy attached.) It was discussed with other members of the PVC Safety Group Steering Committee but due to time constraints a comprehensive review and comment period could not be conducted.

The testimony has the following goals:

- (1) Demonstrate that there are infinitesimal risks to the public from exposure to vinyl chloride;
- (2) Convince the Board that EPA already has an effective emission control strategy under the existing regulations;

VEV-261314

Mr. Hadley
28 April 1978
Page Two

- (3) Convince the Board that its proposal has not been sufficiently analyzed to determine the costs involved and benefits achieved; and
- (4) Correct and clarify observations made in the Staff Report to the Board.

The testimony was presented by Mr. Barr on April 27, 1978. In addition, other companies with affected plants in California also made presentations.

Vinyl Chloride Amendment

Regarding the proposed amendment to the Vinyl Chloride Standard, we have been advised that EDF will attempt to force EPA into some action within the next 30 to 45 days. If there is none, EDF plans to return to court.

Enforcement Memorandum

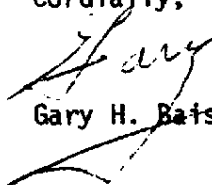
We have had several requests for the enforcement memorandum. I had indicated at the last PVC Safety Group meeting that it would be available around April 15, 1978. We have encountered some delay but I hope to have it out in the next 10 days.

AIHC

As you know, we have been working with the American Industrial Health Council (AIHC) on SPI's behalf. After the March 23 meeting, we were asked to quickly review the transcript and suggest to AIHC/SPI what issues which were raised during the meeting should be responded to by industry. The AIHC Executive Committee has reviewed the list but we have not initiated any work on the list of issues.

If you have any questions, please advise.

Cordially,


Gary H. Baise

Enclosure

Testimony of

John T. Barr

for the
Society of the Plastics Industry, Inc.

Regarding

Proposal To Establish State Ambient
Air Quality Standards And/Or Significant
Harm Levels For Vinyl Chloride

Before

State of California
Air Resources Board

April 27, 1978

STATE OF CALIFORNIA

AIR RESOURCES BOARD

Proposal To Establish State Ambient
Air Quality Standards And/Or Significant
Harm Levels For Vinyl Chloride

Statement of John T. Barr
for the
Society of the Plastics Industry, Inc.

Ladies and Gentlemen:

I am John T. Barr, Assistant Director of Research for Plastics, Air Products and Chemicals, Inc. I am appearing before you on behalf of The Society of Plastics Industry, Inc. (SPI), the principal trade association of the plastics industry. My testimony represents the position of industry as a whole and not necessarily the position of any individual member of SPI.

INTRODUCTION

Our 1400 member companies and 49 operating units include producers of plastics raw materials, resins, modifiers, adjuvants, machinery and mold builders; the majority of members are processors and converters of the resins into end products. We estimate that SPI membership represents 95% of the plastics materials and machinery produced in the USA and about 75% of the domestic processing volume. The Society's concern with vinyl chloride begins with the manufacture of vinyl chloride monomer (VCM) and carries forward through its polymerization into polyvinyl chloride (PVC) and the various conversion processes to its multitude of end uses and ultimately to its recycling or disposal.

Total plastics production in 1977 was approximately 29 billion pounds of which polyvinyl chloride accounts for 5.25 billion. In the United States there are 16 ethylene dichloride (EDC) plants, 17 vinyl chloride monomer producing plants and 41 polymerization plants. Twenty-two companies representing over 95% of VCM and PVC capacity are active members of SPI's PVC Safety Group.

Polyvinyl chloride is the second most widely used plastics product in the United States. It is a solid, produced by several polymerization processes from the gaseous vinyl chloride monomer. PVC is used in a vast array of industrial and consumer products including pipe, conduit and fittings, flooring and siding, wire and cable insulation, home furnishings, automobile and transportation, textiles, packaging, adhesives, and film and sheeting. For some of the more critical uses of PVC such as in medical applications there are no substitutes available, and for most other applications, if there are potential substitutes, it is not known what their costs might be, whether they possess the same valuable characteristics as PVC or what threat their manufacture or use might pose to public health.

POSITION

We agree that emissions of vinyl chloride should be reduced to a level that represents a negligible risk. However, we disagree with the Staff's recommendation relative to the strategy to be used to show this has been attained.

We urge this Board to adopt a policy of enforcing the emission regulations for vinyl chloride promulgated by the Environmental Protection Agency (EPA) on October 21, 1976 pursuant to Section 112 of the Clean Air Act, and to defer

any state regulatory action until the NESHAP emission regulations are fully implemented in October 1978 and the results can be evaluated.

We urge you to adopt this position for the following reasons: First, there are less than six months until EPA's vinyl chloride regulations, ("NESHAP") must be implemented. Within a relatively short time thereafter this Board should be in a position to know the ambient air concentrations which will result from compliance with that standard. The only logical course is to see how NESHAP works before embarking on an entirely new regulatory scheme.

Second, there is no evidence that vinyl chloride in the ambient air concentrations which existed even before NESHAP had any adverse effect on the general public. Epidemiological evidence does not support the suggestion that vinyl chloride is unsafe at ambient levels which have existed in the past, even though the precise threshold level has not yet been determined experimentally.

Third, the emission regulations promulgated by EPA were the result of an intense two-and-one-half year analysis of the health effects of vinyl chloride and possible control strategies. Government agencies, environmental groups and industry participated in that analysis and the result, we believe, represents the most stringent reasonable control strategy, entirely in keeping with an attainment of the ambient level standard being considered by this Board.

Fourth, EPA's regulations are based on the use of best available control technology (BACT) for each emission source in VCM and PVC plants. As a practical matter, reductions below the emissions levels established by EPA, if possible, could only be accomplished by the installation of unproven experimental control systems which may not be effective, or the use of extremely expensive and high-energy consuming controls. EPA estimated and studies commissioned by SPI

confirm, that NESHAP will reduce ambient air concentrations by about 95% from earlier levels. Any additional point source reduction would have a negligible effect on ambient air concentrations since point sources are estimated by EPA to account for less than 20% of predicted future emissions, and the Staff has assumed them to be negligible¹. Accordingly the cost of additional control equipment would clearly be grossly disproportionate to any benefit that might be achieved.

Finally, to rely on essentially a "nondetectable" standard is a step backward in regulatory policy. We urge this Board to adopt a risk/cost/benefit analysis instead of returning to an outmoded and rejected regulatory scheme. By analyzing the risks involved and the benefits to be achieved for the costs incurred, this Board can have some measure of the consequences of its regulatory activity before those consequences are realized -- something it cannot do under the approach suggested by its staff.

BACKGROUND

EPA's existing vinyl chloride emission regulations are the result of a two-and-one-half year analysis of the health effects of vinyl chloride, possible control technologies, and the effect of those controls on the plastics industry and the general public.

In February 1974, EPA initiated an intensive study of the possible health hazards of vinyl chloride in the ambient air and of the environmental effects resulting from its

¹Report of Research Division, California Air Resources Board, March 27, 1978 (hereafter referred to as "Staff Report") p. 30.

manufacture and use. The Agency reviewed in detail relevant health data and the technological feasibility of various methods of control. It produced: (1) a "Preliminary Assessment of the Environmental Problems Associated with Vinyl Chloride" in September 1974; (2) a "Scientific and Technical Assessment Report on Vinyl Chloride and Polyvinyl Chloride" in June of 1975; (3) an extensive "Standard Support and Environmental Impact Statement" in October 1975; (4) a "Quantitative Risk Assessment for Community Exposure to Vinyl Chloride" in December 1975; and (5) a second volume to the "Standard Support and Environmental Impact Statement" in September 1976.

In addition to these studies, the Agency offered interested parties, including environmental groups, and industry, the opportunity to discuss alternative methods of controlling vinyl chloride emissions and weighed objections to control techniques which were considered impracticable or disproportionately expensive relative to the expected benefits. The proposed standards also were discussed before the National Air Pollution Control Techniques Advisory Committee (NAPCTAC). Thus, there was a full airing of all of the consequences of the proposed standard.

After 22 months of extensive study and discussion with all interested parties, on December 24, 1975, the Agency proposed a standard to regulate emissions of vinyl chloride into the ambient air (40 Fed. Reg. 59532). A public hearing was held on February 3, 1976, at which EDC, VCM and PVC producers, SPI, environmental groups, and other parties appeared. During the comment period the Agency received 50 comment letters on the proposed standard. The Certified Index to the Record, lists 699 documents which were considered in the development of the standard; this attests to the care with which the Agency proceeded up to promulgation of the final standard on October 21, 1976 (41 Fed. Reg. 46560).

The final standard was calculated by the Agency to result in the reduction of vinyl chloride emissions of approximately 95% and to provide at least a corresponding percentage reduction of any health risks which might be attributable to exposure to vinyl chloride. EPA diffusion modeling estimated that the annual average exposure to vinyl chloride for persons within five miles of a vinyl chloride or polyvinyl chloride plant was only 17 ppb before the industry initiated its program to reduce vinyl chloride emissions. The Agency recognized in the preamble to the final standard that its estimate was based on 1974 data and that if 1976 emission data had been used the average concentration would be lower. Using EPA's own calculations, implementation of the present standard could be expected to result in a lowering of vinyl chloride exposure in the five mile area surrounding a plant from 17 ppb to less than 1 ppb.

This expectation, and the predictions of ambient concentrations made for SPI by Dames and Moore², has been confirmed by the monitoring studies conducted in this State by your staff. The measurements set forth in the Staff Report for the Long Beach--Carson and Saugus areas, are consistent with EPA and Dames and Moore predictions.

Considering the substantial effort and thought that went into the development of NESHAP and the short time period remaining until it is fully implemented, it would seem only reasonable to review the results of the Standard before embarking on a new regulatory path.

²See Appendix I.

Even if one is not completely satisfied with NESHAP, it seems only sensible to determine if the regulations work before rejecting them.

HEALTH EFFECTS

The staff recommendations which are the subject of this hearing are premised on the assumption that exposure to vinyl chloride at any level involves a significant risk to public health. To the contrary, we submit that on the basis of existing studies, the evidence does not indicate adverse health effects from exposure to vinyl chloride in concentrations which presently exist in the ambient air or even ambient concentrations which existed before industry began to reduce emissions of vinyl chloride.

A. Epidemiology

1. Occupational Exposure in the Manufacture of Vinyl Chloride Monomer and Polyvinyl Chloride.

Published epidemiological evidence indicates that the adverse health effects alleged to result from exposure to vinyl chloride have been observed only in groups of workers with the greatest levels of exposure, levels which OSHA estimated exceeded 1,600 ppm for many years.³ Studies on populations of workers with exposure to low concentrations of vinyl chloride have shown the absence of such health effects. These studies present a consistent pattern of epidemiological evidence that deserves considerable weight.

³Vinyl Chloride, Job Health Hazard Series, OSHA 2225, U.S. Department of Labor, June 1975.

Although angiosarcomas of the liver were found among employees subject to high exposure over long time periods none were found in the lower exposure groups. In a study published in 1975, Ott, Langner and Holder⁴ included 594 workers and found no angiosarcomas of the liver. Equitable Environmental Health, Inc. recently prepared an expanded and updated final report based on the Manufacturing Chemists Association-administered epidemiological study which included mortality data on 10,173 workers with a history of occupational exposure to vinyl chloride.⁵ The Equitable and Ott studies also reported no significant excess of tumors in the lower exposure groups.

A recently published study by Fox and Collier⁶ reported on studies of 7,717 workers who had been exposed to vinyl chloride in the manufacture of polyvinyl chloride in Great Britain. Two cases of angiosarcoma were found. These cases of angiosarcoma "were associated with exposures to very high concentration of [vinyl chloride monomer]." With respect to whether vinyl chloride exposure causes cancers other than those of the liver, the study found "no evidence to support this suggestion."

2. Other Types of Exposure.

NESHAP is premised on EPA's calculations that average ambient exposure within five miles of vinyl chloride plants before installation of controls to meet the existing Standard

⁴M. Ott, R. Langner and B. Holder, Vinyl Chloride Exposures in a Controlled Industrial Environment, 30 Archives of Environmental Health, pp. 333-39 (July, 1975).

⁵Epidemiological Study of Vinyl Chloride Workers, Final Report, prepared by Equitable Environmental Health, Inc., for the MCA (January, 1978).

⁶A. Fox and P. Collier, Mortality Experience in Workers Exposed to Vinyl Chloride Monomer in the Manufacture of Polyvinyl Chloride in Great Britain, 34 British Journal of Industrial Medicine, pp. 1-10 (1977).

was about 17 ppb. Even this calculation does not square with that Agency's own actual monitoring observations which demonstrate that ambient concentrations are really far less than EPA's calculated predictions. The monitoring results here in California contained in the Staff Report also confirm, we believe, the fact that concentrations are lower than EPA predictions.

Despite this, EPA estimated that the ambient annual average vinyl chloride concentrations remaining after implementation of the existing standard would be only 5% of the unregulated levels,⁷ or less than 1 ppb. The diffusion modeling study prepared by Dames and Moore, and submitted to EPA by SPI on August 9, 1977, confirmed EPA's estimate that implementation of the existing standard would result in roughly a 95% reduction in ambient vinyl chloride concentrations. That study indicated the mean annual average concentration within 5 miles of a vinyl chloride plant in compliance with the existing standard would be "on the order of 0.15-0.25 ppb."⁸

The public health risk from such exposure is infinitesimally small. Using animal data as the basis, plus the conservative linear extrapolation method, the EPA found a risk of 7×10^{-5} /yr. per ppm of vinyl chloride. Adjusting this to the predicted 0.2 ppb for the annual average concentration around a plant in compliance with NESHAP, and the approximately 700,000 persons reported to live within 5 miles of the California plants, the conservatively calculated risk is about one case of angiosarcoma per hundred years. We can not believe that this is a significant danger to anyone.

⁷ 41 Fed. Reg. 46560 (1976).

⁸ Appendix I, p. 2.

Organization Resources Counselors, Inc. (ORC) administered⁹ an epidemiological study of the employees of 17 PVC processing plants, whose occupational exposure we estimate to be in the range of 1-15 ppm for many years. ORC found no evidence of angiosarcoma in this work population whose exposures were approximately a thousand times that which could be expected by the general population.

Furthermore in assessing risk to public health, the actual population involved must be considered. EPA reports no residences within a half-mile of any of the California PVC production plants, and the majority of those in the 5-mile area living more than three miles away. The Staff Report also shows that the predicted and measured concentrations drop sharply with distance¹⁰, suggesting any risk to the actual population in California is further minimized.

There is, of course a background incidence of angiosarcoma that is unrelated to vinyl chloride. This rate is about 20-25 cases per year in the U.S., and the Center for Disease Control (CDC) recently reviewed over 250 such cases collected over a 10 year span without finding any relationship to vinyl chloride exposure.

In February, 1976, for example, the CDC reported the occurrence of four angiosarcomas in Wisconsin residents in a 2-1/2 year period and a total of 10 angiosarcomas since 1974, roughly twice as large as expected.¹¹ There are no vinyl chloride emitting facilities in Wisconsin and the cases presumably reflect a fluctuation in the background cases of angiosarcoma.

⁹ Report on a Mortality Study Covering Employees of PVC Fabricators, Organization Resources Counselors, Inc., Washington, D. C., February, 1976.

¹⁰ Staff Report, p. 37.

¹¹ Center for Disease Control, 25 Morbidity and Mortality No. 8, for week ending February 28, 1976 (released March 5, 1976).

Although a latency period exists for angiosarcoma, in some areas vinyl chloride plants have been in operation for long periods of time, more than long enough to have covered a sufficient latency period. SPI pointed out in its comments to the existing standard that at least 3 vinyl chloride monomer and seven polyvinyl chloride plants have been in operation for a period of 25-30 years. Thus, in spite of this extensive production which occurred over this extended period no adverse health effects from exposure to low vinyl chloride concentrations have been demonstrated even at levels higher than will exist after NESHAP is implemented.

To assist you in evaluating this rapidly developing scientific frontier, we have included in the materials submitted to you a copy of a volume of expert testimony and the Alternative Proposal of the American Industrial Health Council. These were prepared for the forthcoming OSHA hearing on its proposed carcinogen policy, but the underlying principles are equally applicable to all areas of enforcement. We hope that these documents will be of use to you in your deliberations on this important matter.¹²

3. Conclusion

The absence of evidence suggesting vinyl chloride-related angiosarcomas at low exposure levels is striking. Epidemiological evidence indicates an absence of angiosarcoma in workers exposed to low concentrations of vinyl chloride.¹³ In comparison to those low levels to which these workers were exposed, the ambient vinyl chloride concentrations around a vinyl chloride or PVC

¹² Appendix II.

¹³ For some of the possible reasons for this phenomenon see P. Gehring, P. Watanabe, and C. Park, Resolution of Dose-Response Toxicity Data for Chemicals Requiring Metabolic Activation: Example -- Vinyl Chloride (July 12, 1977) (unpublished, available upon request from SPI). See also Zapp, "An Acceptable Level of Exposure, Herbert E. Stokinger Lecture, 1977, Appendix III.

plant are dramatically low. There is no credible evidence that exposure to such infinitesimal concentrations has resulted in angiosarcoma or other adverse health effects in the general population.

b. Non-Carcinogenic Effects

The suggestion that vinyl chloride might possibly be a mutagen and/or a teratogen, prompted SPI to seek independent evaluation and interpretation of the available information.

Dr. Brian MacMahon, Professor and Chairman of the Department of Epidemiology of Harvard University's School of Public Health, was asked to perform one such review. A copy of Dr. MacMahon's report is attached as Appendix IV. Dr. MacMahon expresses concern regarding the potential mutagenic and potential teratogenic aspects of vinyl chloride, but he concluded:

"[E]xcept for the evidence of chromosome breakage in heavily exposed workers -- evidence which itself cannot be regarded as definitive -- the literature to date contains no credible evidence that vinyl chloride has actually caused mutations, fetal anomalies or fetal death in humans." (emphasis supplied)

A separate and independent review and evaluation was performed by Drs. Thomas D. Downs, Revel A. Stallones, Ralph F. Frankowski and Darwin R. Labarthe of the School of Public Health at the University of Texas' Health Science Center at Houston. The authors are, respectively, a Professor of Biometry, The Dean and Professor of Epidemiology, the Associate Dean and Professor of Biometry, and a Professor of Epidemiology. A copy of this report is attached as Appendix V.

One recently published article, by Picciano, Flake, Gay and Killian¹⁴ was not available for inclusion in Dr. MacMahon's review. That article reported on new cytogenic studies on 209 vinyl chloride production workers who had up to 28 years of exposure. Chromatid aberrations, chromosome aberrations and the proportion of abnormal cells were analyzed. No significant differences were observed between the group of workers exposed to vinyl chloride and a control group.

Another recent study, not yet published, retested the workers in a Norwegian plant that was reported in 1974 to have experienced higher than normal chromosome breakage. The 1977 study found that the test group did not differ from a control group. This indicates either that the 1974 report was in error, or that the recently reduction of exposures to 1 ppm allowed natural reversal of the chromosome breakage.¹⁵

Conclusion

Existing studies do not support a conclusion that no exposure level above zero can be considered safe. To the contrary, although the precise level has not yet been determined the evidence suggests that exposure to small concentrations of vinyl chloride in the ambient air presents no risk of adverse health affects to the general public. Certainly the evidence does not support the establishment of a "significant harm level" of a few ppb.

¹⁴D. Picciano, R. Flake, P. Gay and D. Killian, Vinyl Chloride Cytogenetics, 19 Journal of Occupational Medicine, pp. 527-30 (August, 1977).

¹⁵Effects of Vinyl Chloride in Man, Cytogenic Followup Study, I. L. Hansteen, L. Hillestad, E. Phiis-Evensen, and S. Heldaaf, Mutation Research in Press (1978).

REGULATORY SCHEME

NESHAP

We believe the Staff Report is unduly critical of NESHAP for the reasons discussed below. Even accepting some of the criticisms, however, NESHAP is not so deficient that it should not at least be evaluated before it is rejected in favor of an entirely different and additional regulatory program.

1. Best Available Control Technology

NESHAP was based on the Best Available Control Technology (BACT). The Staff Report suggests that this was not the case since "some California VC processors are currently installing equipment that provides far more effective control of VC emissions than is called for under NESHAP."¹⁶

We believe the Staff may have misunderstood the basic concept of BACT as used in NESHAP. The point source emission levels established by NESHAP represent emission levels which may never be exceeded. The emission limits are such that the only abatement technology practically available to the producer limits emissions far below the established maxima. For example, incinerators which are one control method being used to achieve the 10 ppm stack limit produce exit VCM emissions well below 1 ppm. Similarly, slurry stripping methods that yield below 400 ppm for all suspension resins will give results below 50 ppm for many. Thus, in many cases BACT will yield the results observed by the staff, which is one of the purposes of such a standard.

¹⁶Staff Report, p. 4.

The basic philosophy underlying BACT is that it "will produce the most stringent regulations of hazardous air pollutants short of requiring a complete prohibition of all cases."¹⁷ The ambient air standard advocated by Staff does nothing to improve upon that goal.

In Table IV Staff has made certain suggestions on possible improvements for the control methods required under NESHAP. Many of these have already been achieved by the application of BACT under the existing standard. Others are dangerous and/or impracticable such as ducting of relief valve discharges to an incinerator. This particular method was discussed at length by industry and EPA, and finally rejected by the Agency.

2. Fugitive Emissions

The staff recognizes that "The air quality impacts of controlled point sources (stack) are insignificant in relation to the impact from fugitive sources."¹⁸ And its recommendations appear in part at least to be based on the assumption that setting an ambient air concentration limit is the most effective way to force producers to limit fugitive emissions. We don't know whether this will work or not because there is no discussion of the technology necessary or available to achieve Staff's target level of 0.5 kg/hr. The most significant criticism of this approach, however, is the Staff's own observation of the dramatic drop in ambient levels of vinyl chloride, which suggests, first, that NESHAP is working and, second, that EPA's fugitive emission factor may be too high.¹⁹ We agree and suggest that the logical conclusion of this observation is to review the results of NESHAP when fully implemented and, perhaps, as

¹⁷40 Fed. Reg. 59534.

¹⁸Staff Report, p. 30.

¹⁹Ibid. at 31.

suggested by the Staff, perform "a more refined emissions inventory"²⁰ before initiating an entirely new and additional regulatory scheme.

3. Regulatory Complexity

One of the proposed benefits of Staff's proposal is regulatory simplicity. The Staff suggests the NESHAP "would appear to place inordinate demands upon the regulatory agency charged with ensuring compliance".²¹ We disagree on two counts.

First, NESHAP is largely self enforcing since producers are required to keep extensive records and make regular reports which will be the principal enforcement mechanism. Staff has not suggested why a technique which is used extensively by the Federal Government and other state authorities is not appropriate.

Second, affected plants and the authorities which regulate them must still follow NESHAP. At the present time any regulations of this Board will be in addition to Federal regulation and will not replace it.²² Therefore both the California regulatory authorities and industry would under present circumstances be required to perform duplicate tasks in order to arrive at an end result that will not be significantly different from that to be achieved by NESHAP alone.

4. Miscellaneous

The Staff Report makes a number of observations which we believe need clarification:

²⁰Ibid. at 33.

²¹Ibid. at 4.

²²We know of no delegation by the Administrator pursuant to Section 112(d)(1) of the Clean Air Act. We are not speculating as to whether such a delegation might be made.

(1) NESHAP places no upper limit on the total emissions from the stacks of a VC facility.²³

As the Staff Report notes, not only are the fugitive emissions substantially below that expected, but the point source emissions are negligible relative to the fugitives. Thus, setting a limit on emissions that requires the use of BACT results in an effective practical limit on all emissions and, therefore, indirectly on mass emissions. At the concentrations being encountered here of fraction of a ppm, no significant mass can be emitted. This is confirmed by Table IV-3 which lists a total mass flow from the stacks at Long Beach of only 0.16 g/sec.

(2) NESHAP does not deal adequately with the critical upset/breakdown question.²⁴

To the contrary, the preamble to the standard and a statement by EPA's Division of Enforcement take the position that upset discharges are set at zero. Only discharges which cannot be avoided by taking preventative measures, such as those caused by natural disasters are exempt from the zero limitation. Any case of malfunction of abatement equipment requires immediate shutdown of that part of the facility. It is difficult to understand how NESHAP could deal more adequately or stringently with the upset/breakdown question.

5. Conclusion

There is no doubt that NESHAP is a complex regulation. However, most of the criticisms of NESHAP in the Staff Report are either misplaced or inappropriate.

Furthermore, whether NESHAP is inadequate can only be determined after it has been implemented. All we urge upon this Board is to wait and determine the adequacy of NESHAP.

²³Staff Report, p. 5.

²⁴Ibid. at 5.

AMBIENT AIR CONCENTRATION REGULATION

1. Lowest Detectable Level

The Staff recommendations that the Board has been asked to adopt are essentially a variant of the "nondetectable" standard used at one time in the regulation of pesticides but since rejected as vague and unscientific. Originally, pesticides manufacturers could submit registration applications claiming that their pesticide has no detectable residue. As early as 1966 this practice came under attack in a Congressional committee report:

"The rapid advances in analytical chemistry have made it possible to detect such minute amounts of residue [that] the registration of pesticides on a nonresidue or zero tolerance basis has become scientifically and administratively untenable."²⁵

Current pesticide registration procedures require pesticide manufacturers to submit actual residue levels for their products.

Regulations based upon a "nondetectable" standard ignore the continuing advances in analytical technique which can identify substances in infinitesimal amounts. More importantly, such a standard merely avoids the difficult questions regarding the amount of risk and what society is willing to do to reduce that risk to a given level.

2. Risk/Benefit

We urge this Board to adopt the first alternative given in the meeting notice, to support NESHAP, and not to establish an arbitrary ambient level based on detection techniques.

²⁵S. Rep. No. 1379, 89th Congress, 2d Sess., p. 62 (1966).

A risk/cost/benefit analyses should be applied to the Board's deliberations. Such an analysis first, weighs the risks and then determines whether the benefits to be achieved are worth the cost.

a. Risk

The maximum risks to the general public from exposure to vinyl chloride can be calculated.

Even using EPA's very conservative linear dose response model, the calculated risk associated with ambient air exposures to vinyl chloride is so small that it is difficult to comprehend without comparing it to other risks existing in everyday life. Such a meaningful risk comparison has been prepared by Professor Richard Wilson of Harvard University.²⁶

Professor Wilson has compared the yearly risk associated with various events with the average yearly risk of living within five miles of a polyvinyl chloride plant, calculated as 5×10^{-8} , a number which he says "uses EPA numbers in EPA calculations and is probably pessimistic."²⁷ Based on this, Professor Wilson estimates that risk associated with living within five miles of a polyvinyl chloride plant for one year is equivalent to the risk of contracting cancer from eating 1/2 of a tablespoon of peanut butter, or to the risk of contracting cancer from increased cosmic radiation during a three-day visit to Denver Colorado, or to the hazards from smoking 1/15 of a cigarette.²⁸

²⁶Comments on Proposed Rule for Vinyl Chloride Emissions, August 1, 1977, EPA, by Prof. Richard Wilson (unpublished, available on request to SPI.)

²⁷Ibid. at 14.

²⁸Appendix VI.

Professor Wilson also makes another important point. The calculated risk of living near a source of vinyl chloride emissions is so small that steps to eliminate that theoretical risk could give rise to greater public risks. Based on EPA's estimate of capital expenditures needed for compliance with NESHAP and Professor Wilson's estimate of one death per \$30 million of capital expenditures (averaged over all industries), one can predict six lives will be lost merely to comply with NESHAP. Already two lives are known to have been lost in connection with the NESHAP compliance effort.

b. Cost/Benefit

Judged by any standard any risk to public health from exposure to vinyl chloride at existing levels is infinitesimal. The Staff document contains no cost analysis and no supportable benefit analysis. We do not know the costs which would be involved in complying with the proposed ambient air concentration limit. However, even without such knowledge, it would not appear reasonable to require additional expenditures until the practical results of implementing NESHAP are known.

CONCLUSION

We believe the record demonstrates the following:

- (i) There is only an infinitesimal risk to the general public from exposure to vinyl chloride
- (ii) NESHAP is an effective emission control strategy
- (iii) The Staff proposal for an ambient air concentration has not yet been sufficiently analyzed to determine the costs involved and the benefits achieved.

On the basis of the foregoing we have what we think is an entirely reasonable request. Let NESHAP be fully implemented in the next six months; then monitor the results. Whether NESHAP is inadequate can only be determined after it has been implemented.

Thank you.