Vinyl Chloride and Community Safety

In February 1974, following the discovery that heavy, long-term occupational exposure to vinyl chloride gas had resulted in an excess of worker deaths from angiosarcoma of the liver, a rare form of cancer, the Environmental Protection Agency (EPA) began investigations to determine if any hazard existed for people living in the vicinity of vinyl chloride or PVC resin plants. After years of intensive investigations, on October 21, 1976, EPA promulgated regulations to reduce community exposure to vinyl chloride by approximately 95 percent. These regulations were immediately challenged in court by the Environmental Defense Fund (EDF), an environmentalist group, with the eventual result that in June 1977 EPA proposed a series of revisions in the existing standards. To date, no final action by EPA has been taken on these proposed revisions.

The controversy over vinyl chloride air emissions has now been going on for more than four years. During this time period, much speculation and misinformation regarding this issue has been generated, with resulting confusion and apprehension in the public mind. It is the purpose of this paper to state the facts regarding vinyl chloride air emissions and to place the issue in its proper perspective.

This paper documents four key points:

- There is no evidence, despite years of investigation, of an excess number of angiosarcoma cases among people living in the vicinity of vinyl chloride or PVC resin plants.

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- There is no credible evidence linking vinyl chloride emissions with an excess of birth defects in communities surrounding vinyl chloride plants.
- Recent studies conducted for The Society of the Plastics Industry, Inc. (SPI) show that implementation of the 1976 EPA standards will result in a reduction in ambient concentrations of vinyl chloride even greater than that projected by EPA, but that the imposition of the proposed amendments would result in little additional reduction.
- There is no evidence that the public health will be materially improved by any further tightening of the EPA standards limiting vinyl chloride emissions, as proposed in the June 1977 amendments.

Background

In January 1974 three cases of angiosarcoma of the liver, an extremely rare type of cancer, were discovered among long-term workers exposed to high concentrations of vinyl chloride monomer (VCM), the gaseous industrial chemical used to produce polyvinyl chloride (PVC) resin. Ultimately, it has been determined through extensive research that over the past 16 years there have been a total of 23 deaths from angiosarcoma in six U.S. PVC plants, and approximately 48 in other countries. The workers' jobs principally involved cleaning residue of PVC resin from the polymerization reactors in which it was produced from VCM.

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As a result of these findings, the U.S. Occupational Safety and Health Administration in late 1974 announced standards to drastically reduce worker exposure to vinyl chloride. These standards have now been in effect for three years, and VCM exposures in the workplace have been reduced a hundred-fold or more. The Food and Drug Administration is currently considering regulations on the use of PVC food and beverage packaging materials, but the industry has already developed new and better PVC packaging materials to eliminate the possible migration of detectable residual vinyl chloride into finished food and beverage products.

EPA Investigations

Acting under its authority under the Clean Air Act, the Environmental Protection Agency, almost as soon as the then tentative link between vinyl chloride exposure and angiosarcoma was made public, began investigations into whether VCM concentrations in community air constituted a hazard to the health of individuals living in the vicinity of vinyl chloride and PVC resin plants.

As a first step, EPA established a vinyl chloride task force in February 1974. On May 31, 1974, EPA requested emission control data from manufacturers, and on June 11 of that same year the agency announced that preliminary monitoring test results showed "no scientific evidence to indicate that these emissions pose an imminent hazard to people living near these plants..."

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EPA said, nonetheless, it would propose regulations to reduce VCM emissions drastically from 1974 levels, even though monitoring results showed only a handful of measurements above 1 part per million, the level eventually established by OSHA for worker exposure.

Ultimately EPA's extensive investigations into vinyl chloride resulted in the publication of four major documents on the subject: (1) a 67-page Preliminary Assessment of the Environmental Problems Associated with Vinyl Chloride -- September 1974, (2) a Scientific and Technical Assessment Report on Vinyl Chloride and Polyvinyl Chloride -- June 1975, (3) a Quantitative Risk Assessment for Community Exposure to Vinyl Chloride -- December 1975, and (4) an extensive two volume Standard Support and Environmental Impact Statement -- September 1976.

In addition to these studies, the agency offered interested parties the opportunity to meet with appropriate EPA officials to discuss proposed methods of controlling VCM emissions. Proposed standards were also discussed before outside groups such as the National Air Pollution Control Techniques Advisory Committee. In summary, there was a full airing of all relevant health data and the technological feasibility of various methods of control.

Finally, after 22 months of extensive study and discussion, the agency officially proposed on December 16, 1975, a standard regulating emissions of vinyl chloride into the ambient air. A public hearing was held on February 3, 1976, at which SPI, the Environmental Defense Fund and other parties appeared. During the comment period, EPA received 50 comment letters on the proposed standard.

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The official record of the agency's investigation of vinyl chloride listed 699 documents totaling some 9,000 pages, thus attesting to the extreme care with which EPA went about developing and promulgating its standard on VCM air emissions.

Community Health Risks Extremely Low

In developing its proposed standard, EPA calculated, based primarily on a series of animal studies plus some epidemiological data, that the levels of vinyl chloride existing around VCM and PVC resin plants in 1974, if left uncontrolled, would result in "somewhere between less than one and 10 cases" of angiosarcoma per year among the nearly five million people living within five miles of such plants.

EPA further calculated that the average yearly vinyl chloride exposure of those five million people was 17 parts per billion.

In order to test its risk assessment hypothesis, EPA conducted a survey of all angiosarcoma deaths in the United States between 1964 and 1974. Based on national mortality rates, EPA calculated that there should have been six cases of angiosarcoma among the people living near vinyl chloride plants during that ten-year period "if the presence of the vinyl chloride plant contributed no risk factor pre-disposing people to the disease."

Instead of six cases, EPA found only three. In short, not only was EPA unable to confirm an excess number of cases among people living in proximity to vinyl chloride plants, but the number found was actually less than would have been expected had no vinyl chloride plants existed in those communities at all.

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EPA concluded, therefore, that "this survey has produced no evidence that living around vinyl chloride plants is a risk factor in the occurrence of liver angiosarcoma."

In addition, at the EPA public hearing, Dr. William Marcus of EPA's office of toxic substances, stated that there is no evidence "that angiosarcoma has been produced by vinyl chloride monomer in the general population."

Data on community cases of angiosarcoma are supported by a series of epidemiological studies of workers exposed to far greater amounts of vinyl chloride than that to which the general public could ever possibly be exposed. Research by Tabershaw and Gaffey; by Ott, Langer and Holder; by Equitable Environmental Health, Inc.; and by Fox and Collier, involving nearly 18,000 workers, found no evidence of an increased risk of angiosarcoma at low levels of exposure.

Furthermore, a study by Organization Resources Counselors of more than 4,100 deaths among PVC fabrication workers discovered not a single case of angiosarcoma. Accusations by the Environmental Defense Fund that this study demonstrated an excess risk of breast cancer from low level vinyl chloride exposure were proven false when it was found upon re-examination that only two of the 44 cases of breast cancer in the study had "definite exposure" to vinyl chloride.

While the available evidence should be reassuring to those people living near vinyl chloride installations, the possibility cannot be totally ruled out that one or more cases of this disease will not occur at some time in the future due to past uncontrolled community exposures or to pure chance. Nonetheless, the human evidence is strong that the original EPA estimates were far too pessimistic and need to be drastically revised downward.

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Professor Richard Wilson of Harvard University, for example, has calculated that the risk of living within five miles of a PVC 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 1/15th of a cigarette.

In addition, a report from Ohio that vinyl chloride emissions might result in an excess of birth defects in communities adjacent to VCM or PVC resin plants was proven false by a series of studies conducted by the U.S. Center for Disease Control. Dr. Brian MacMahon, chairman of the department of epidemiology at the Harvard University Graduate School of Public Health, dismissed the Ohio study findings as resulting "from a combination of chance, reporting differentials and epidemiologic gerrymandering." Dr. Thomas D. Downs of the University of Texas Health Science Center was even more emphatic, stating that "it does not seem possible to salvage anything from this study."

New Standards Promulgated

On October 21, 1976, after more than two and a half years of intensive investigation, EPA promulgated national emission standards for vinyl chloride gas and PVC resin plants. EPA also decided, on the basis of extensive research, that emissions from PVC fabricating plants were so minimal to begin with that no restrictions on these operations were necessary.

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The EPA standards were designed to reduce emissions by approximately 95 percent of 1974 levels. Since EPA had estimated that concentrations within five miles of vinyl chloride plants had averaged 17 parts per billion (ppb) in 1974, the standards would theoretically reduce these exposure levels to less than one ppb as a yearly average. Based on EPA's own calculations, this could result at a maximum in approximately one case of angiosarcoma every two years among the five million people living in the vicinity of these plants. Considering that more than 80,000 of these people could be expected to die from other causes during that same two-year period, the theoretical one angiosarcoma case was considered an acceptable risk by EPA.

The available evidence, however, shows that the EPA "worst case" estimate is far too high so that, in practical terms, the risk of contracting VCM related angiosarcoma from living within five miles of a controlled vinyl chloride facility is essentially zero.

Upon promulgation of the standards, SPI, speaking on behalf of the entire vinyl chloride industry, declared that while it doubted such a severe standard was necessary in view of the lack of evidence of adverse health effects at such low concentrations, it nonetheless pledged industry cooperation in meeting the standard and expressed its belief that the agency had acted openly and responsibly in a good faith attempt to deal with a difficult problem.

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EDF Challenges Standard

On November 19, 1976, the Environmental Defense Fund filed suit in the Court of Appeals in Washington challenging the effectiveness of the standards. SPI, and certain individual companies, subsequently filed routine motions to intervene in these court proceedings to protect their interests. Astoundingly, EPA, through its lawyers, opposed industry participation in the case.

Despite an eventual ruling by the court that SPI and the other companies had a legitimate right to intervene in the case, EDF and EPA continued to negotiate in private meetings from which the industry was excluded.

The result of those secret negotiations was a formal agreement on March 24, 1977, between EPA and EDF to propose amendments to the existing vinyl chloride standard which had been promulgated only five months previously. The proposed amendments were published in the Federal Register on June 2, 1977.

Through a series of Freedom of Information Act petitions, SPI obtained documents from EPA showing that since the promulgation of the original standard in October 1976, the agency had received or obtained no new medical or technical information that would justify any changes in the standard. In fact, preliminary results of a new animal inhalation study by Dr. Cesare Maltoni of Italy -- the main reason given by EDF for opposing the standards -- were not only given to EPA by the industry prior to the promulgation of the original standard, but were subsequently described by top EPA medical experts as "not cause for a change in the regulatory approach taken by the agency."

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In simple terms, EPA, faced with a lawsuit by an environmentalist group, decided to disregard nearly three years of its staff's painstaking research and evaluation, including the results of open public hearings and numerous meetings and field trips. EPA -- with admittedly no medical or technical justification for its reversal of position -- accepted almost without change revisions in the standard as proposed and written by EDF.

SPI, seeking to bring these issues into the open, requested a formal public hearing on the proposed revisions at which cross-examination of EPA, EDF and industry witnesses would be permitted. EPA rejected this request, but did agree to hold an "open meeting" on July 19, 1977. Cross-examination was not permitted and no questions were asked of any witnesses by the EPA panel.

Since the EPA "open meeting," SPI and various companies in the vinyl chloride industry have submitted a vast amount of medical, technical and legal data to EPA in support of the industry's position that a further tightening of the standard is unjustified.

Community Exposures Lower than Estimated

One major report submitted to EPA by SPI was a two volume dispersion analysis study conducted by the nationally renowned environmental consulting firm of Dames & Moore. Using actual meteorological readings plus sophisticated computer programs, some of them developed by EPA itself, Dames & Moore established that the original EPA estimate of 17 ppb of vinyl chloride as a yearly average exposure within five miles of uncontrolled vinyl chloride

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