



Environmental
Defense
Fund

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October 4, 1977

Mr. Donald R. Goodwin
Director
Emission Standards and
Engineering Division
Office of Air Quality Planning
and Standards
U.S. Environmental Protection
Agency
Research Triangle Park, NC 27711

Re: Supplemental Comments to Proposed Amendments to the Final
Emission Standard for Vinyl Chloride

Dear Don:

Attached is an article from this month's issue of the Journal of Occupational Medicine, entitled "Mortality Among Employees of PVC Fabricators" by Drs. Leonard Chiazze, Jr., William E. Nichols, and Otto Wong, which reports on the results of a study of cancer in employees of polyvinyl chloride fabrication plants. Also attached is the study on which the article was based. Because this study contains potentially significant new information on the health effects of vinyl chloride, EDF requests that it be included as part of the Agency's public record on the proposed amendments to the vinyl chloride standard. EDF scientists have analyzed the study and we would like to bring the following points to the Agency's attention.

Although the study did not uncover any deaths from angiosarcoma within the group of employees studied, it did uncover "an important excess in mortality from cancer among both white males and white females." This conclusion is based on an analysis of proportionate mortality ratios for both males and females for various types of cancer. The proportionate mortality ratio is the ratio of observed deaths to expected deaths where the expected number is calculated on the basis of distribution of deaths for the total United States. Thus, a proportionate mortality ratio larger than one indicates excess cancer deaths over that expected in the U.S. population at large.

Perhaps the most significant finding of the study is an excess rate of cancer of the digestive system for both male and female employees. In males, 209 cases of cancer of the digestive system were diagnosed as opposed to an expected number of 162.143. This excess produced a proportionate mortality ratio of 1.29 for males. Specifically, stomach cancer, cancer of the intestine, of the

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rectum, and the liver were all in excess in males. Although the sample size was smaller, the same excess showed up in females -- indeed was even more pronounced. For females, 53 deaths for cancer of the digestive system were diagnosed whereas only 35.342 were expected, producing a proportionate mortality ratio of 1.50.

In males, potentially significant excess rates were also found for cancer of the lungs and respiratory system, and the urinary system. The excess in lung cancer death rates appears to be particularly significant because a relatively large sample was involved. 193 deaths from lung cancer were diagnosed whereas only 165.566 were expected.

In females, the authors of the study reported that "there seems to be a great excess in urinary cancer and mortality from breast cancer also appears to be in excess." (Study, p. 44). Forty-four deaths were observed from breast cancer in female employees whereas only 32.397 were expected, producing a proportionate mortality ratio of 1.36. Although the sample was relatively small, the proportionate mortality ratio for cancer of the urinary organs in female employees was 2.42.

EDF believes that these findings are potentially significant because vinyl chloride levels in fabrication plants are generally believed to be quite low, and in the range of concentrations to which members of the general public would be exposed as the result of emissions from polyvinyl chloride and vinyl chloride monomer plants.

Although the authors did not indicate whether these findings are statistically significant, they did conclude that:

The current study would seem to indicate that excesses of mortality from cancer of the digestive system are not sex-specific and are not limited to liver cancer. The majority of the PMRs for cancer among both white men and white women are in excess of unity. Such results must be interpreted with caution but, since they appear to be consistent with previously studied workers, they suggest the need for continued investigation. (Article, p. 628).

In the article the authors discuss two earlier studies which showed excess cancer rates in vinyl chloride workers. To quote the authors once again (pp. 627-628):

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Monson, et al., provided a proportionate mortality analysis of 161 deceased workers (all presumably white males) in two plants, one where vinyl chloride monomer is produced and one where it is polymerized into polyvinyl chloride. Results of that study suggest a possible excess in total cancer mortality, primarily cancer of the liver. However, there was a suggestion that cancers of the lung and brain also appeared with excess frequency. (Citing Monson, R.R., Peters, J.M., and Johnson, M.N.: Proportional mortality among vinyl chloride workers. Lancet 2:397-398, 1974).

The authors also point to the Tabershaw and Gaffey study of workers engaged in the manufacture of vinyl chloride and its polymers. Although they point out that that study concluded that no specific cause of death was statistically significantly greater than expectations based upon standard mortality ratios, the authors did conclude that "there may be an excess risk for mortality from digestive cancer, respiratory cancer, cancer of other and unspecified sites, and lymphomas. At lower exposure levels, they suggest some excess for cancers of the buccal cavity and cancers of the other and unspecified sites." (Citing Tabershaw, I.R. and Gaffey, W.R.: Mortality study of workers in the manufacture of vinyl chloride and its polymers. Journal of Occupational Medicine 16:509-518, 1974).

The fact that Dr. Chiazzi found similar excesses in cancer rates among employees who were exposed to presumably much lower levels of vinyl chloride we believe is quite significant. It suggests that angiosarcoma is not the only type of cancer caused by vinyl chloride and that there are numerous other forms of cancer which are also of concern. Although the data is certainly not conclusive, it strongly suggests that the Agency should continue its efforts to reduce vinyl chloride emissions to the lowest levels possible.

This conclusion is also supported by other evidence which EDF has just obtained. The Center for Disease Control in Atlanta has just completed its preliminary survey of deaths from angiosarcoma which occurred in the United States from 1964 to 1974. The CDC has identified approximately 225 to 250 cases of hepatic angiosarcoma. Ten additional cases have been identified from 1975 to the present time. Of the cases which have been confirmed up to this point, approximately 10% of them, or 26 cases, have been diagnosed as resulting from the administration of thorotrast which had been used in hepatolienography until the early 1950s. Another 10% of the cases have been definitely linked to occupational exposure to vinyl chloride. This leaves 175 to 200 cases which could have resulted from community exposure or some other cause. EDF has asked the Center for Disease Control whether

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there are other probable causes of angiosarcoma other than vinyl chloride and thorotrast. The Center has indicated that arsenic could also be another source of angiosarcoma, although the evidence is not yet conclusive. Even if arsenic is included as a possible cause, there is still a large number of cases which could have been caused by community exposure to vinyl chloride. Unfortunately, Center officials have been unable to reconstruct the histories of the deceased individuals in enough detail in order to determine whether community exposure could have played a significant role in the development of the disease.

The possibility that low level exposures to vinyl chloride from vinyl chloride monomer and polyvinyl chloride plants could produce angiosarcoma in the general population is supported by some recent findings on the latency of angiosarcoma as a result of the administration of thorotrast. Originally, thorotrast was given in relatively high doses. Later, however, the dosage was severely reduced as a result of growing concerns about the toxic effects of the chemical. What is interesting is that the Center for Disease Control is still finding cases of angiosarcoma as a result of relatively low exposure to thorotrast, but the latency period is substantially greater than that for higher dose individuals. Dr. Henry Falk, the Deputy Chief of the Cancer Branch of the Chronic Diseases Division, Bureau of Epidemiology at the Center for Disease Control, has concluded that:

One of the important epidemiological questions to answer in coming years relating to vinyl chloride induced angiosarcoma is whether a similar type of dose-response relationship exists. Is it possible or likely that people who had lower doses of vinyl chloride (for example, fabricating workers or people who lived near polymerization plants) will also develop angiosarcoma, but only after a longer latent period than was seen with the PVC polymerization workers? This question cannot be fully answered until after more time has elapsed. (Letter to Marcia Fine, EDF, dated Sept. 29, 1977).

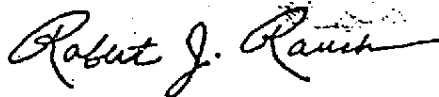
If Dr. Falk's hypothesis is correct, it would not be surprising that Dr. Chiazze and his associates did not find any cases of angiosarcoma among the fabrication workers studied. the workers in the study may have died from other forms of cancer before angiosarcoma itself appeared. Furthermore, there is a serious question as to whether the size of the sample used in the study is adequate to conclude that fabrication workers have no increased risk of death from angiosarcoma. The authors point out on p. 18 of the study itself that "it would be necessary to follow a cohort of 260,416 workers 12 years to have an expected

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one death (from angiosarcoma)." The study only examined death certificates for 4,592 employees who died during the period 1964 to 1973, and the authors concede that the 18 companies studied employed only approximately 65,000 to 70,000 workers at the end of 1973. Thus, there is a serious question as to whether the finding of no angiosarcoma deaths is significant at all. The study population may simply be too small. Furthermore, as indicated above, other causes of death may have intervened before the angiosarcoma would have actually appeared.

In conclusion, EDF believes that the foregoing studies strongly suggest that vinyl chloride exposure should be reduced to the lowest level possible. We now have both animal evidence and human evidence which suggest that exposure to even very low levels of vinyl chloride can induce cancer. In the face of this evidence, there is no reason to conclude that a threshold exists below which adverse health effects do not occur.

Sincerely,



Robert J. Rauch
Staff Attorney

RJR/jkr
Enc.

cc: David Hawkins
Robert McGaughy

RECEIVED SEP 8 1977

COMMENTS OF THE ENVIRONMENTAL DEFENSE FUND
ON THE PROPOSED AMENDMENTS TO
THE FINAL EMISSION STANDARD FOR
VINYL CHLORIDE
(42 Federal Register 28154, June 2, 1977)

*I made
this note
show what
are my
amendments*

On October 21, 1976 (41 Fed. Reg. 46560), pursuant to §112 of the Clean Air Act as amended, the Administrator promulgated National Emission Standards for the hazardous air pollutant vinyl chloride. On November 19, 1976 the Environmental Defense Fund (EDF) filed a petition in the U.S. Court of Appeals for the D.C. Circuit for review of these standards. As part of a settlement which led EDF and EPA to move to dismiss the review petition on March 24, 1977, the amendments under consideration were proposed.

The proposed amendments represent a true compromise between what EDF could have pressed for in court and the existing standard. Section 112 of the Clean Air Act requires that emission standards for hazardous air pollutants, such as vinyl chloride, be set "at a level which in the judgment of the Administrator provides an ample margin of safety to protect the public health from such hazardous air pollutants." It clearly requires a health-linked, not a technology-based standard. Yet, inconsistent with the statutory requirement, the original standards were based on what EPA believed industry could accomplish with best available technology. In the Standard Support and Environmental Impact Statement, EPA

recognized that vinyl chloride is an "apparent non-threshold pollutant" which creates a risk to public health at all levels. Had the case gone to trial, EDF would have taken the position that §112 required a zero emission standard, the only standard adequate to provide the required margin of safety for a non-threshold pollutant. Instead, EDF settled for a compromise which establishes a goal of zero emissions and requires industry to move one step closer to that goal.

The new standard would not require the installation of completely new technology. Industry is not being asked to scrap existing technology. The revised limits can be achieved through the improved operation of existing technology permitting full amortization of the industry's investment in control technology. This should be viewed in contrast with the proposal of the New Jersey Commission on the Incidence of Cancer that any industry emitting one of some seventeen substances reduce emissions to zero or stop producing. Not only will there be no shut-downs required by these amendments, but the industry will be able to continue its growth under this compromise.

The Society of the Plastics Industry, Inc. (SPI) has attempted to portray this settlement as some sort of private agreement between EPA and EDF to promulgate a revised emission standard, largely because they were excluded from the settlement negotiations. There is no legal requirement that an intervenor in a case be permitted to participate in settlement

negotiations. Industry searched for such a legal precedent but was unable to find one. Industry has now had ample opportunity to comment on the proposed amendments at a meeting from which EDF was excluded, a public hearing, and through written comments. It should be noted that EDF was also excluded from the industry-EPA sessions which led to promulgation of the original standard. It should also be noted that despite industry's exclusion from settlement negotiations, EDF's attorney kept industry well informed of the outline of the proposed settlement at all stages. Finally, if SPI and its members are unsuccessful in persuading EPA to revise the proposed standards before promulgation, they can always petition the Court of Appeals for review of the standards.

At SPI's request, a public hearing was held by EPA on July 19, 1977 to receive public views and suggestions on the proposed amendments. EDF would like to address the major points in opposition to the proposal raised by SPI at that hearing. The primary areas of interest seemed to be: (1) the absence of new data since the existing standard was promulgated to justify a revision of that standard, (2) the offset policy, (3) the cost of compliance, and (4) the degree of improvement resulting from the amendments. In addition some inapposite comments were made concerning the energy consequences of certain emission reductions. EDF believes these amendments are sound, representing progress toward EPA's goal of zero emissions, and urges their promulgation.

I. Absence of New Data

The most prevalent comment by industry has been, "How could EPA change the vinyl chloride standards when no new information has been developed?" There are several responses to this. First, EDF believes the original standards did not comply with the law, §112 of the Clean Air Act, and so no new information is required to amend the standard to bring it in closer compliance with the law. Second, some significant test data was either not available at promulgation or, as with Dr. Cesare Maltoni's latest experiments, only became available shortly before promulgation, not allowing time for full consideration.

EDF would like to retrace and update the state of medical knowledge concerning vinyl chloride which, under the Clean Air Act, is to serve as the basis for EPA's regulatory actions. It should be noted that no data, developed either before or after promulgation of the existing standard, indicates that any level of exposure to vinyl chloride but zero ppm is safe.

In 1970 Professor Viola presented the results of a pilot experiment which showed that rats exposed to extremely high concentrations of vinyl chloride (30,000 ppm) developed tumors and carcinomas.^{1/} Four years later the B.F. Goodrich Company provided the first report, based on employee deaths from angiosarcoma (liver cancer), which confirmed that vinyl chloride was a human carcinogen. Significantly, not all of

the vinyl chloride/polyvinyl chloride plant employees who have died from angiosarcoma were exposed to high concentrations of vinyl chloride. Of the fifteen occupation cases confirmed as angiosarcoma of the liver by pathologists at the National Cancer Institute, one worker was an accountant employed at a vinyl cloth plant and another operated a machine which applied polyvinyl chloride to electrical wires as insulation.^{2/} These two workers were exposed to levels between 1 and 12 ppm, significantly lower than levels to which other polyvinyl chloride workers were exposed.

There have also been two confirmed cases of angiosarcoma in individuals who had resided in the vicinity of industrial vinyl chloride emission sources, and were probably-exposed to levels lower than those to which workers were exposed. They signify the risk associated with living near a vinyl chloride plant, but for two reasons they may underrepresent the total number of community cases. First, they both lived in Connecticut, a state which probably has the best cancer detection program in the country. Hence, it is very possible many more cases exist which have been either undiagnosed or misdiagnosed. Second, one must consider the latency period of 10-20 years for angiosarcoma^{3/} in light of the fact that not only is the plastics industry only seventy years old, but a great deal of its growth has come recently -- at ten percent a year from 1969 to 1974. We may only be seeing the beginning of a cancer epidemic.

There is also evidence which indicates angiosarcoma is not the only health risk associated with vinyl chloride.

Angiosarcoma served as a "marker disease," its rarity allowing a causal connection with vinyl chloride to be easily drawn. Studies also point to vinyl chloride as the causal agent in the development of cancer of the lung, the lymphates, and the central nervous system as well as the liver.^{4/} In addition, Dr. Peter Infante, currently with NIOSH, has observed an excess rate of serious birth defects (teratogenesis) in residents in Ohio counties with plants emitting vinyl chloride.^{5/} Also, mutagenicity was indicated in studies by Dr. F. deSerres of NIEHS, on the effect of vinyl chloride on *Salmonella* -- liver microsome systems. A higher-than-normal rate of stillbirths and miscarriages among the wives of vinyl chloride workers and a high incidence of abnormal chromosomes among the workers themselves have been observed.^{6/}

Some important test data was made public just as EPA was promulgating the original standard and may not have been fully considered. Other data not available at the time the regulations were promulgated has come to light and serves as an additional basis for EPA to amend the existing standard to reflect the health risk posed by lower levels of vinyl chloride. Each group of tests indicates vinyl chloride induces cancer at extremely low concentrations. Professor Viola first noted these effects at 30,000 ppm.^{1/} By June of 1974, Dr. Cesare Maltoni, in the

experiments which originally established the link between vinyl chloride and cancer, reported that angiosarcoma had been produced in rodents by inhalation of as little as 50 ppm in air.^{7/} Just as the original vinyl chloride regulations were promulgated, Dr. Maltoni reported the induction of mammary carcinomas in rodents at levels of 1 ppm.^{8/} All of this data was at least available to EPA prior to promulgation, though there was probably not enough time for EPA to fully consider Dr. Maltoni's data. Completely new data has since become available from tests performed by Professor F. Kaloyanova at the Institute of Hygiene and Nutrition in Sofia, Bulgaria. Professor Kaloyanova found that vinyl chloride exposure at 1 ppm induced carcinomas in both rats and mice.^{9/}

Rather than pointing toward the existence of a threshold for harmful effects, each test with vinyl chloride indicates that almost any level of exposure contributes to the development of cancer. The addition of the new scientific evidence further justifies the amendment of the existing standard. It might even be said EPA has a duty under the law to amend the existing standard to reduce the level of vinyl chloride to which the public is exposed, based on evidence which continues to indicate vinyl chloride is a non-threshold carcinogen.

II. Offset Policy

Under the proposed amendments, before an existing plant could expand or a new plant locate near an existing site,

reductions would have to be achieved so there would be no net increase in total vinyl chloride emissions. This offset policy is necessary because, as EPA recognized in the background documents,^{10/} an emission standard by its very nature cannot prevent the total amount of vinyl chloride released from a particular facility from increasing over time should there be expansion or a new plant built. About 4.6 million people live within five miles of existing plants^{11/} and would not be adequately protected if no thought were given to overall levels of exposure. A clustering of large plants on the same site could triple or even quadruple the ambient air concentration produced by just one plant. Another objective is to provide an incentive for industry to develop new technology, which will be rewarded by permitting expansion and new construction.

The offset policy also represents a compromise. An alternative approach could have been a no growth policy within a given radius. EDF, however, felt this was an unreasonable position and did not pursue it, though we believe it could have been legally supported.

It should be emphasized that this "trade-off" approach is not new. EPA has already developed a similar policy for regulating new construction in areas which have not yet attained the primary air quality standards.^{12/} In both cases, the objective is the same: no increase in ambient levels of

a pollutant which presents a health threat at existing levels. SPI suggests that applying this policy to a single chemical would be substantially different without saying in what ways. EDF feels the major difference, that this policy involves a single, confirmed human carcinogen, offers more support than even non-complying air quality regions for pollutants which are not necessarily carcinogenic.

As a first step in implementing this trade-off approach, a facility which planned to expand would have to calculate the total emissions from the existing operation. If the existing plant were not already in compliance with the present standard, the total emission figure would have to be adjusted to reflect permissible emissions from the existing facility once it is in compliance. If, however, the emissions from the plant are below the emission limit applicable to it, the proposed rules would give the source credit if it maintains its emission levels at the time a new plant is added or expansion undertaken. It is through early compliance and continued reductions that additional capacity can be added in a given geographic area. Of course, degradation from levels for which credit was given will erase the credit and prevent expansion or new construction.

A major source of emissions from controlled vinyl chloride and polyvinyl chloride plants are fugitive emissions. The original standards require either specific emission limits or

the use of certain technology to control these sources. Reductions in fugitive emissions will offer a means of earning credit under the offset policy in the same way reductions in other areas would.

Two methods of calculating credit would be available to each plant. If a baseline level for fugitive emissions could be measured or estimated, assuming compliance with existing standards, any demonstrated reduction could be used as credit under the offset policy. Deference should be given to industry's estimates of fugitive emissions because of the great incentive to be accurate. A low estimate would hinder future expansion and a high estimate of emissions would be harmful publicly. Alternatively, the operator of a plant should be able to isolate a particular source or sources of fugitive emissions, demonstrate that they comply with existing standards, measure or estimate emissions from them, and proceed to reduce those emissions. Any such reduction would be transformed into credit.

Fugitive emissions have become the primary source of emissions from vinyl chloride plants. Yet EPA has been unable to tackle the technical problem of how these can be further reduced. One of the principle benefits of the offset policy will be to force industry to address the problem of how to control fugitive emissions. Any technical innovation will be rewarded by permitting further expansion. It is likely, in

fact, that fugitive emissions reductions will be the major source of such credit. Once new technology has been developed and tested, it could be mandated for the whole industry, thus moving one step closer to the purpose of §112 of the Clean Air Act -- protection of the public health.

Of course, a developer always has the option of constructing a "green field" plant, that is, a plant at an entirely new site. This would prevent further concentration of vinyl chloride emissions in an area where such emissions are recognized as currently posing a potential health risk. Naturally, the new "green field" plant would be subject to the standards for brand new facilities.

Unfortunately, SPI has taken a fairly negative attitude about improving the level of vinyl chloride emitted from plants. Rather than attempting to move toward the lowest possible levels, it has opposed any changes. The offset policy will provide industry the incentive it is obviously lacking to improve control technology. That is why the offset policy is central to these proposed amendments. It will also provide the incentive for industry to offer economic support to firms, such as the Houston Research Company, which are capable of developing new control technology, like the ozone-UV process. Without economic and technological support from industry, firms such as Houston Research cannot afford to develop new technology.

III. Cost of Compliance

SPI attempts to make cost a central issue, even though the statute EPA operates under requires regulations based on protection of health and not cost and technology concerns. To say that Congress did not intend §112 to force plants to close, as SPI contends, does not necessarily imply no economic burdens should be placed on industry. In fact, industry has offered no cost estimates, possibly because the proposed amendments were designed to make use of existing technology and equipment for the most part, making additional costs minimal. In their July 19, 1977 statement, SPI estimated that vinyl chloride emissions will be reduced by 0.1 lb/hr for typical suspension plants and 0.02 lb/hr for typical dispersion resin plants, citing Table 4.3 of the Standard Support Document. SPI goes on in a footnote to mention that the Table referred to does not actually use those figures. The footnote indicates the Table actually lists emissions as zero (in which case no new controls would be required and so the cost would be zero as well). We do not see either figure supported by the Table. In fact, the Table suggests a minimum of 4.4 lb/hr and a maximum of 7 lb/hr subject to further reductions. These figures would suggest that instead of costing \$12.20 per pound of vinyl chloride removed per \$10,000 expended, it would only be \$.61 maximum. These are both nice, but meaningless figures. The only relevant figure is the

increase in the cost per pound of polyvinyl chloride. An additional expenditure of \$10,000 in a typical size polyvinyl chloride plant only represents seven one-thousandths of a cent increase in the cost per pound of producing vinyl chloride.^{13/} In the past, the plastics industry has demonstrated its ability, in complying with emission regulations, to pass on costs without any significant economic harm to the industry. There is every reason to believe this will be the case with these regulations.

Without any support, Mr. Holbrook of SPI states that the cost of building a new plant, required by the offset policy if existing emissions cannot be reduced, will be \$10 million greater than expanding output at an existing plant. This figure might contain unnecessarily negative assumptions, such as locating plants in isolated areas as opposed to existing industrial parks where non-plastic industries are located. This difference could result in exaggerated shipping costs and omission of additional economies. In the absence of further documentation and comparison of costs, these figures are without value. For instance, an investment of considerably less than \$10 million in control technology may be able to reduce existing emissions enough to add the additional capacity needed under the offset policy.

IV. Energy Consumption

EDF has taken an active role in the problems of energy supply, supporting conservation and increased efficiency as methods of assuring a continuous supply of energy in the future. We are somewhat confused by SPI's use of the FEA industrial energy efficiency targets^{14/} as an excuse for not adopting control technology for the oxychlorination process. FEA officials we have spoken to indicate it was never FEA's intent to restrict EPA's ability to impose health protective emission requirements on industry. The reporting form used to determine industry's progress toward the targets even separates changes in energy consumption due to government requirements so firms will not bear any onus for excess energy consumption required for compliance.^{15/} Even more important is the fact that FEA guidelines apply to an entire industry. SPI attempts to apply these to a single process within only a segment of that industry. This misses the point of the targets, which is to give industry the choice of how to achieve increased efficiencies. A minor increase in energy use from one process simply does not justify discarding the standard. SPI's comments also present unsupported figures indicating the energy required for control of the oxychlorination process is greater than EPA originally estimated. Yet, in the preamble to the proposed amendments, EPA states that the adoption of a recycling and oxygen feed system eliminates the supplemental feed problem. This is because

the effluent gas stream would be more concentrated using the technology to be installed in new plants, requiring less energy to reduce emissions.

V. Degree of Emission Reductions

EDF believes the degree of emission reductions resulting from the proposed amendments is significant enough to justify their promulgation. But the actual extent of reduced emissions which result from the proposed amendments is less important than the fact that they represent progress toward EPA's goal of zero emissions -- the only level adequately protective of human health.

SPI maintains inconsistent positions in its prepared statement for the July 19 hearing on the quantity of emissions reduced. On one hand, it is recognized that even with the existing standard, EDC purification and VCM formation plants will have emissions of 2.5 lb/hr excluding any emissions from the oxychlorination process or fugitive emissions. By lowering allowable emissions from 10 to 5 ppm, a 1.25 lb/hr reduction would result. Yet SPI then goes on to say any reduction under the proposed amendments would come solely from improved controls on the oxychlorination process. This ignores the 1.25 lb/hr reduction attributable to other parts of the process. SPI also suggests that there only be a 10 ppm limit on the oxychlorination process. The 0.9 lb/hr reduction from 10 to 5 ppm limit, which this would preclude, is not insignificant. Also considering

the substantial reduction required to reach 10 ppm, it does not seem unduly difficult, especially at the design stage, to adapt the technology to a lower limit.

Industry has expressed a great deal of concern over the offset policy as a means of reducing community exposure to vinyl chloride. In its July 19 comments, SPI chose to focus attention on the impact of the policy on annual ambient levels from vinyl chloride plants at distances of five miles.

(Despite repeated requests, EDF has not received a copy of the dispersion study conducted by Dames and Moore. That study conspicuously does not consider the effect of a single plant expansion which probably causes a greater increase in ambient levels than certain combinations of plants.) Scientific analysis of the process of cancer indicates that even carcinogens at low doses, with levels in parts per billion, may pose a health risk^{16/} and thus constitute a legitimate concern of EPA. It should be recognized that by examining annual levels, instead of shorter time periods, and distances of five miles, instead of closer to the plant, a "best case," from industry's point of view, is described. Figures in the Standard Support Statement demonstrate for those same five mile levels, substantially higher levels will be found at shorter distances with a tremendous difference between short-term and annual ambient levels even for plants complying with the existing standard. These figures demonstrate the value of reducing existing emissions,

as done by the proposed amendments, and the need for an offset policy to prevent the increase, especially of short-term levels, caused by expansion of an existing plant or construction of a new plant. EPA's ambient level estimates, based on dispersion modeling for a large polyvinyl chloride suspension/
dispersion plant are: ^{17/}

<u>Time</u>	<u>Concentration</u>
5-minute average maxima	12 ppm
24-hour average maxima	0.68 ppm
annual average maxima	90 ppb

Other modeling done by EPA at greater distances to determine the maximum ambient levels produced by a cluster of four ethylene dichloride - vinyl chloride and polyvinyl chloride plants complying with the existing standard produced the following figures: ^{18/}

<u>Time</u>	<u>Concentration</u>
5-minute average maxima	3.1 ppm
24-hour average maxima	0.59 ppm
annual average maxima	99 ppb

These figures strikingly demonstrate that for the annual ambient levels in the parts per billion range cited by SPI, short-term levels in the parts per million range could occur. In fact, for plants complying with the existing standard it is possible that ambient air concentrations will exceed the maximum allowable occupational exposure established by the Occupational Safety and Health Administration (OSHA) of a 5 ppm ceiling averaged over a fifteen minute period. ^{19/}

There is reason to believe carcinogens pose a threat to human health at slightly higher exposure levels over a relatively brief period of time. This is significant because control of point sources, whose emissions are to be reduced by one-half under the proposed amendments, has, according to EPA,^{20/} a disproportionately large impact on reducing short-term ambient levels. The tables above demonstrate the likelihood of high short-term ambient levels even when annual ambient levels are much lower. Hence, if short-term exposure to a carcinogen poses a risk, the significance in terms of protecting health of any reductions under the proposed amendments is greater than some numbers might indicate.

That a greater threat may exist from short-term exposure to somewhat higher ambient levels of vinyl chloride is consistent with current theories of chemical carcinogenesis.

One theory proposes that cancer is induced in a single cell.^{21/} This so-called "one-hit" model implies that the total dosage and not the length of exposure determines whether cancer will be induced. Thus a single exposure to vinyl chloride could conceivably cause cancer in the population surrounding vinyl chloride plants. Another theory, known as the multi-hit or multistage model, suggests that a single cell must undergo a series of changes before it can generate a tumor.^{22/} This theory also suggests that exposure to slightly higher concentrations, even of short duration, may pose a threat. The work

of Crump, et al.^{23/} ties this all together by showing that most models of carcinogenesis will have a linear dose-response relation at low doses, assuming there are already carcinogens present which act in conjunction with the specific carcinogen under study. By combining these theories, an interesting conclusion is reached: short-term exposure to a chemical carcinogen at slightly higher levels than are normally present presents a potentially significant risk of cancer. As the Standard Support Document points out, this is just the type of exposure which will be most affected by the proposed amendments.

Scientific evidence for other carcinogens demonstrates that the risk of actually developing cancer following only a brief exposure is very real. In the case of asbestos, workers who were exposed for only one month showed substantially increased rates of lung cancer.^{24/} Persons living outside asbestos plants, with low level exposures for only seven years or less, developed mesothelioma, an extremely rare cancer associated with asbestos exposure.^{25/} The risks of short-term and low dose exposure to a carcinogen are not just theoretical, and constitute a substantial basis for regulation, especially since §112 requires protection be given with an ample margin of safety from just these types of threats to health.

Exposure to even small doses of vinyl chloride must be viewed in context. First, individual responses to carcinogens vary and there may be people who will be susceptible to carcinogens at low levels. Hence, even a slight reduction in vinyl chloride levels could reduce the incidence of cancer. Also, EPA cannot ignore the fact that people are subjected to many other chemical exposures, such as to polychlorinated biphenyls (PCBs). Half of the U.S. population is believed to have accumulated 1-3 ppm of PCBs in their fatty tissues. These compounds are similar to DDT and other chlorinated pesticides. Their metabolism activates specific liver enzyme systems, enabling the liver to more readily metabolize such chemicals as vinyl chloride. The presence of PCBs and certain pesticide residues in our bodies may render us more susceptible to cancer from a given dose of vinyl chloride than otherwise would be predicted. There may be other additive effects of carcinogens which again would make low dose exposure, or higher dose exposures over a short-term, more dangerous than they would initially seem. ^{26/}

VII. Availability of Interim Emission Limits

EDF recognizes that some plants may experience particular difficulties in meeting the standards under the proposed amendments. EPA has also recognized this and has included a relief valve. A particular plant which, despite a full effort, is unable to comply may request an interim emission limit lower

than that required by the proposed amendments. Plants are given one and one-half years to determine how they will comply. This is a reasonable amount of time to develop projections as to whether compliance will be possible, before installation of equipment begins. EDF believes specific criteria would not be appropriate for granting interim limits because the Administrator will be considering problems applicable to a specific plant. We assume plant operators will have no difficulty obtaining such interim limits if, even with their best efforts, compliance will be impossible.

Issuing an interim limit will have an important impact on the surrounding community. It is therefore extremely important that at least a public meeting be held to enable interested citizens and groups to present their position and challenge, where appropriate, industry's basis for an interim limit. Of course, confidential and proprietary information need not be revealed. EPA has an ample record of protecting such information. There is no reason not to have the non-confidential information subject to public discussion. Contrary to SPI's belief, there are many responsible citizens, environmental and civic groups, which could contribute to such a process and possibly even aid industry by suggesting alternative processes and procedures, just as EDF has done with respect to suggesting the ozone-UV process as an alternative control technology.

EDF has been extremely disappointed with the stance industry has taken in trying to reduce the levels of vinyl chloride, a human carcinogen, released into the environment. The flexibility of the interim emission standard in these proposed amendments points out the real purpose of the amendments -- to have industry, with tremendous technological expertise at its disposal, try harder. Only with their expertise and cooperation can EPA's goal of zero emissions ever be achieved.

VIII. Conclusions

EDF supports the proposed amendments to the National Emission Standard for vinyl chloride. As we have pointed out, the initially mandated reductions simply do not go far enough toward compliance with the law. These proposed amendments represent an important first step towards achieving EPA's goal of zero emissions and may have a significant effect in protecting public health by reducing short-term exposure to higher doses which the current standard allows. The proposed amendments will also result in a substantial reduction in emissions from new sources which must comply with the reduced emission levels before operation is permitted. Finally, and perhaps most important, the offset policy should encourage the development of technology which will ultimately permit a substantial reduction in fugitive emissions from existing sources, as well as preventing residents of areas surrounding

vinyl chloride plants from being exposed to levels of vinyl chloride two or three times those of just a single controlled plant in their area.

As we stressed at the July 19 hearing, these proposed amendments represent a compromise. Industry will be able to comply without the necessity of developing new technology. The public health will receive a greater degree of protection, closer to that envisaged by the Clean Air Act. EDF supports the promulgation of these amendments.

Footnotes

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6. B.I. Castleman, Statement to the U.S. Environmental Protection Agency on the Proposed National Emission Standard for Vinyl Chloride, Feb. 3, 1976, at pp. 6-7.
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8. Memo from Ms. Verne Lesho, Sec'y to Dr. M.N. Johnson, B.F. Goodrich, Akron, Ohio to Dr. Peter Infante, NIOSH (Nov. 11, 1976).
9. Memo from Dr. Edward J. Fairchild, II, Associate Institute Director, Cincinnati Operations, NIOSH to Chief, Technical Evaluation and Review Branch, Office of Extramural Coordination and Special Projects, Re: Update Information on Vinyl Chloride (Jan. 3, 1977).
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20. Standard Support and Environmental Impact Statement, supra note 10, at 6-20, 6-21.
21. N. Arley and N. Iverson, On the Mechanism of Experimental Carcinogenesis, 31 ACTA PATHOL. MICROBIAL. SCAND. 164-171 (1952).
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