



EQUITABLE
ENVIRONMENTAL
HEALTH
INC.

Mr. Milton Freifeld

January 11, 1977

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I will be happy to discuss this with you by phone if you have any questions or require additional information. We greatly appreciate the opportunity to serve MCA and sincerely hope we will have additional opportunities in the future.

Sincerely,

Richard L. Davis

RLD/jpm

Enclosure

MANUFACTURING CHEMISTS ASSOCIATION

By _____
Milton Freifeld

SCC
2-1456

RECEIVED SEP 18 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)

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 BFA - EDF claims that the proposed vinyl chloride regulations constitute a less stringent standard than it could have insisted upon from the court in the litigation which it instituted. Actually EDF could not have pressed the court to change the original regulations to set an immediate zero emission limitation. The court is only empowered to decide whether EPA's regulations were arbitrary and capricious. At best from EDF's standpoint EPA could have decided that the first rulemaking was arbitrary and not in accordance with §112 of the Clean Air Act. Such a ruling would have voided the regulation, and EPA could then, if it chose, have begun another public rulemaking proceeding in which it would presumably be an impartial arbiter of comments from all concerned. As it stands, however, the proposed standard is the result of coercion by one party with a particular point of view and acquiescence by the EPA (It seems significant to note that EPA has never allowed such an unseemly settlement where industry has in the first instance filed a court challenge to a regulation promulgated by EPA.). In effect the proposed regulation in this instance has been dictated by a private party, and this is contrary to the Clean Air Act which has delegated impartial rulemaking authority exclusively to EPA.

EWS - The key seems to rest on whether or not sinogens do have or do not have a threshold effect. If they do not have, then EDF's position sooner or later will prevail re "zero emissions" goal. If they do have, the threshold must be determined and regulations promulgated to limit emissions below such ambient level.

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 BFA - 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.

While EDF's claim that industry will have the opportunity to challenge in court any final rulemaking which may result from the proposal in question is true, because of the way §112 is drafted anyone opposing the proposed rule bears a heavy burden of showing with particularity in the rulemaking proceedings why the proposed regulation is improper. In short it is anomalous that EDF, a single public interest group, has not only avoided this burden in its litigation of the original regulations through a settlement agreement with EPA, but also it has been able to shift this burden to those parties opposing the new regulations which it has dictated to EPA.

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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

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2-1460
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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 HLK - Basis? Not so. 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 HLK - Which? Must be specific. 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. HLK -

This paragraph states that data indicating a safe level of vinyl chloride has not been developed. To date, the literature supports this statement. A "no effect" level for vinyl chloride has not been demonstrated in laboratory animals. Current epidemiological studies of workers exposed to low levels of vinyl chloride lack a sufficient latency period and a sufficiently large number of workers.

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 HLK - Evidence? In fact, all did.

Request for negative data dose-effect curve is indicative. Also epidemiology hasn't found any

CDK - (Comments on entire page) The discussion of epidemiology of workers exposed to low levels of vinyl chloride focuses on only 4 individuals, two of whom may not have been exposed to the compound. Toxicity of low incidence (such as carcinogenicity linked to low levels of chemical exposure) emerges only after wide and prolonged use in a very large number of subjects. In the 4 cases cited, the angiosarcomas were confirmed but not the cause of the malignancy. Other causative factors might be involved and should be considered and evaluated.

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 HLK - Not confirmed.

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 ppt, significantly lower than levels to which other polyvinyl chloride workers were exposed.

HLK - Not confirmed.

There have also been two confirmed cases of angiosarcoma HLK - Not so.

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 HLK - Speculation. 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 HLK - Speculation* 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. He may only be seeing the beginning of a cancer - Bullshit. HLK. epidemic.

*The hunt of Antio cases has been so thorough in 1975, that every case recorded on a death certificate has gone to CDC.

There is also evidence which indicates angiosarcoma is HLK - What kind?
not the only health risk associated with vinyl chloride.

Angiosarcoma served as a "marker disease," its rarity allow-
ing 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,

CDK - Reference 4 should be checked for accuracy and interpretation.
review of the report by Infante was written by Dr. McMahon ~~and~~
and is attached.

Dr. Peter Infante, currently with NIOSH, has observed an increase .. HLK - His papers have been discredited by CDC. Infante is an income

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. P. deSerres of
NIHES, 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/}

HLK - What? Some important test data was made public just as EPA was ... HLK - Not so - This paper shown to have been speculative.

promulgating the original standard and may not have been fully .. HLK - Let EPA so state
considered. Other data not available at the time the regulations HLK - What?

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..HLK - Source?

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

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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/}

CDK - The data generated by Dr. Maltoni and Dr. Kaloyanova are cited as memos, not published reports. As such these data represent preliminary results from incomplete studies. Appropriate consideration and meaningful evaluation of these observations await completion of the experimental work and publication of final reports. Preliminary results of experiments do not constitute scientific evidence.

HLK - Not competent.

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,

HLK - Just the opposite - A dose effect relation is seen.

reductions would have to be achieved so that there would be no net increase in total vinyl chloride emissions. This offset policy is necessary because, as EPA requires, the back-ground documents, ^{10/} an emission standard for vinyl chloride released cannot prevent the total amount of vinyl chloride released from a particular facility from increasing. If there should be expansion or a new plant built, there would be one million people live within five miles of existing plants and would not be adequately protected if no thought was given to overall levels of exposure. A clustering of local sources on the same site could triple or even quadruple the concentration of vinyl chloride produced by just one plant. Another approach 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 reasonable policy within a given radius. EDF, however, felt this position and did not pursue it, though it has been legally supported.

It should be emphasized that this approach is not new. EPA has already developed a similar approach for regulating new construction in areas which have not attained the primary air quality standards. In both cases, the objective is the same: no increase in the levels of

EWS - By avoiding being specific, EDF manages to create an impression that growth or expansion could or might create an unhealthy situation.

EWS - This is inconsistent with EDF's zero-risk to health position. Offset permits continuation of something less than zero emissions which EDF contend it necessary to protect health.

EWS - It is new having been in effect for less than a year. Its results are not yet known.

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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. EOP feels the major difference, that this policy involves a single, confirmed human carcinogen, offers more support than EWS - Implies a no threshold effect. even non-complying air quality regions for pollutants which are not necessarily carcinogenic.

As a first step in implementing this trade-off approach, EWS - (Comment on entire paragraph) If a new facility is the same size as the existing one and yet emissions from the old plus new cannot exceed the old, is this not ultimately going to lead to zero emissions?

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 EWS - Are fugitive emissions consistent from one time to another? I doubt it.

Two methods of calculating credit would be available EWS - (Comment on entire paragraph) Great reliance on the "graphite" approach.

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 EWS - Has this been established? 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 negative 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.

EWS - Only the first innovator is rewarded. All similar sources must thereafter use by regulation. By definition, such reductions cannot be used for "offset" purposes.

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.

EWS - May not be a viable option.

Unfortunately, EPA 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.

EWS - It might also be said that EDF adopts a negative attitude toward economics, technology and medical data.

EWS - Does EDF have a stake in research firms? Who does the research is unimportant.

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 no 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. Those 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.^{11/} 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 JAM - The EDF has apparently not read or does not understand the guidelines issued by the FEA [see FR 29642 (1977)] attached. The efficiency goals are set not only on a general industry basis (chemical) but also by subclass. In the SPI testimony the target for the entire chemical industry was cited. If we look in more detail, we find that the target for SOC 2869 (the class which includes VCM) is 15.9% after allowing 1.5% for environmental and other government regulatory actions. It is obvious that the EDF could single out any specific process and claim that its increased energy consumption can be counterbalanced by some other process with even greater improvements. The improvements envisioned by increased energy consumption must justify the increases in energy requirements and it is the position of SPI that they do not.

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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 JAM - The EDF also has not understood the comments relative to the increase in energy requirements to meet a 5 ppm emission limit for the oxychlorination reactor. The SPI testimony (also that of Shell's) stated that the operation of an oxygen-recycle technology system requires a 7% increase in energy over that of the EPA's typical air feed oxychlorination plant. This matter was discussed with EPA at the June meeting in Durham (which is part of the public record). The EPA stated at that time that they had not realized this and would investigate the matter further. In fact, the EPA has discussed this further with Shell (and perhaps others) on at least two occasions. These telephone discussions are also part of the public record. The SPI testimony was simply pointing out that, in the support document for the original standard, the EPA rejected the use of incineration to control the oxychlorination vent because it required an increase of 6% in energy consumption. Since oxygen-recycle technology requires an even greater amount of energy, we fail to see the rational for the proposal. The EPA is simply incorrect in its preamble statement that the oxygen-recycle technology does not require additional energy.

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

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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

JAM - Again EDF has failed to review the data as presented by EPA. EPA has claimed, in its proposed regulation, that there will be an emission reduction of VCM from new typical size oxychlorination plants of 11.6 lb/hr. Using the data presented by EPA in its Support Document, it can be seen that this reduction will come solely from the proposed new standard from oxychlorination vents.

EWS - Again EDF assumes no threshold.

JAM - On the other hand, EPA has also proposed that the allowable emissions from other sources in a VCM plant be reduced by 50%. Again, from the Support Document, the data shows that this is a meaningless proposal because the EPA has stated that there are no (zero) emissions from these other sources. What SPI attempted to point out is that the EPA's table showing "zero" from these other sources is not precisely correct and that the emissions may be about 2.5 lbs/hr. With the proposed 50% reduction, a maximum of 1.25 lbs/hr might be realized and that this figure is insignificant.

JAM - Nowhere in the SPI testimony was it suggested that a 10 ppm limit be adopted for oxychlorination vents. SPI simply pointed out that the EPA has published data in its original support document showing the impact of a 10 ppm limit. The EDF's statement that 0.9 lb/hr reduction is "not insignificant" demonstrates that they have little understanding of how to measure impact.

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 Names and Monre. 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 HLK at low doses, with levels in parts per billion, may pose a HLK health risk ^{15/} 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 modelling for a large polyvinyl chloride suspension/ dispersion plant are:

Time	Concentration
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:

Time	Concentration
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.

that the proposed standard would have less than a 0.1 ppb effect on the average annual concentration within the five mile radius. The EPA has failed to evaluate this impact.

EWS - Models are notoriously inaccurate. Any modelling data should be checked against actual measurements.

JAM - The data given in Table 6-3, 6-4, 6-5, and 6-6 of the "Support Document" (which is that used by EDF) shows the maximum at one given point VCM concentration for the various types of VCM or PVC plants and has nothing to do with the average exposure of persons living within five miles of a plant.

The proper data to use (if one wishes to use EPA data) is that contained in the "Quantitative Risk Assessment" document (December 1975). This report shows for uncontrolled plants that persons living as close as 1300 feet from a typical PVC plant, the annual average exposure level is about 300 parts per billion (ppb). Those living five miles from this plant have an average annual exposure of 4 ppb, with an overall average for all persons living within five miles of 17 ppb. For plants controlled to the existing standard, the average annual exposure of all persons living within five miles of a plant is about 2 ppb. These exposure levels are so far from the OSHA allowables that the EDF testimony should be dismissed for its lack of candor.

Furthermore, the EDF has missed the point of the SPI testimony which was to challenge the validity of the results of the EPA's calculations in the "Risk Assessment" document. The Dames and Moore study shows that the annual average VCM concentration within five miles of a controlled typical PVC suspension or dispersion plant was less than 0.25 ppb rather than the 2 ppb cited by EPA. Also, the SPI testimony offered data (again in Dames and Moore report) that the proposed standard would have less than a 0.1 ppb effect on the average annual concentration within the five mile radius. The EPA has failed to evaluate this impact.

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

EWS - What is the source of this allegation?

JAM - The EDF raises the question regarding the effect of short term exposure to higher levels of VCM. I will leave comment on this to the medical group. What the EDF has done, however, is mix "apples and oranges" by citing data from the "Support Document" in an attempt to rebut the SPI testimony concerning the average exposure of persons living within five miles of VCM-PVC plants.

HLK - Only a theory, and not a good one at that. Some carcinogens at one concentration are essential for life, at a second - ax:

CDK - References 21-25 should be checked for accuracy and interpretation. The first sentence of the first paragraph on this page (18) should be referenced. The discussion of theories of chemical carcinogenesis is selective, incomplete and cursory. Again, references 21-23 should be checked in order to determine accuracy and appropriate interpretation.

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 HLK - Not so. 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 CDK - The first sentence of this paragraph should be referenced. that the risk of actually developing cancer following only a brief exposure is very real. In the case of asbestos, workers HLK - Not VCM. 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.

CDK - The discussion on this page argues for an investigation of chemical interaction, potentiation and enzyme induction (all needed) but does not argue for long-term inhalation tests of low levels of vinyl chloride as might be expected from the first sentence.

HLK - Also tobacco.

HLK - Not VCM.

HLK - Very Speculative.

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.

EWS - Is it safe to make such an assumption. Can EDF speak authoritatively for EPA and other activist groups?

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.

EWS - This seems inconsistent with the above assumption.

EWS - Is the public an authority on health and control matters to say nothing about technology and economics.

EWS - Had EDF adequately demonstrated this technology? Or is it just a gleam in Houston Research's eye.

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.

EKS - ~~zero emissions~~
~~whole plant~~

is unattainable in practice ~~because of~~

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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