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1525 18th Street, NW, Washington, D.C. 20036 • 202/833-1484

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

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

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Executive Summary of Industry
Position on Implications of Proposed
Vinyl Chloride Amendments

- I. EPA's achieving its overall environmental goals depends in substantial part on gaining industry confidence in the Agency's fairness, openness and consistency.

A. Industry supports the Agency's stated goals:

1. EPA's Deputy Administrator, in her remarks to the Chamber of Commerce of the United States on May 3, 1977, pledged that EPA would embrace "the following simple procedures":

"First, we will sincerely take a long, hard look at every potential regulatory move and ask ourselves whether it is really needed. Second, if we conclude that it is, we will do our best to write it in clear and concise English. Third, we will see to it that public participation and involvement take place from the very start of the regulatory development process. No surprises. Fourth, we will consider economic and social impacts. Fifth, we will favor economic approaches whenever these would seem to work as well or better than regulatory approaches."

- B. Industry is seriously concerned that the Agency as a whole may not be applying these established goals.

- II. The entire chemical industry is aware of EPA's proposals for further regulating vinyl chloride. The industry is concerned with the implications of EPA's actions.

A. The regulatory process - background:

1. After 32 months of consideration and extensive public participation, EPA promulgated a standard. Industry pledged to do its best to meet it.
2. After a court challenge was filed, EPA failed to support its own action. Industry was excluded from the settlement negotiations in which a private group suggested particular amendments for EPA to propose. EPA agreed to propose amendments because it thought a court would overturn its actions.

"It was a very difficult evaluation, but the Agency, our office and the people in the office of Air and Waste Management, decided the risks of losing this case were serious enough that we had to consider means of avoiding such a loss. If we had lost the case and it had been determined the industry, for example, had to meet a zero emission goal and a zero emission standard, or that there should be no emissions visible or otherwise, the industry would be faced with the horrible problem but there would also be a domino effect covering the asbestos standard and any other standard the Agency would propose under this area." (EPA Staff attorney, Transcript of September 8, 1977 meeting)

3. The industry believes the existing Standard is totally defensible, and objected to the settlement. The proposed amendments were not well thought out and not adequately explained; the circumstances had not changed and no new health data exists on which to base the amendments. EPA agreed to formally propose them before discussing them with the industry. These proposals do not represent the informed and considered judgment of the Agency.
 4. Industry is very concerned with the entire process that led to the proposals, and the absence of procedural and substantive due process.
- B. The proposed amendments to the Vinyl Chloride Standard contain two major new policy aspects that are far-reaching.
1. Zero emission goal - EPA has caused uncertainty by proposing this goal.
 - a. "In order to insure that the standard continues to approach the only level of emissions which is known to be absolutely protective of health, namely zero emissions, EPA is proposing amendments...." (Preamble to proposed amendments, 42 Fed. Reg. 28154 (1977)).
 - b. EPA already stated it would continue to review the existing standard and lower it if necessary.
 - c. Industry is not opposed to periodic review and to changes shown to be necessary. Industry supports rational risk assessments and realistic approaches. Industry objects to unnecessary controls and to automatic, arbitrary and unrealistic goals.
 - d. In developing the existing Standard, EPA considered the health risks of vinyl chloride exposure. EPA expressly rejected a zero emission level. Our question is whether EPA is now proposing to abandon its policy of risk analysis and adopt automatic zero emission goals without examining actual health risks.

- e. Abandoning risk analysis in favor of zero emission goals would not properly utilize society's resources.
 - f. The Clean Air Act does not require a zero emission level or a zero emission goal.
 - (1) The Clean Air Amendments of 1970 rejected the approach embodied in the Senate Bill that would have required EPA to prohibit emissions of hazardous air pollutants unless industry could demonstrate a safe level.
 - (2) Congress was aware of and did not object to EPA's approach in the existing Standard.
 - g. EPA should not state a goal unless it intends to reach it.
 - (1) The only way to achieve a zero emission level is to shut down the entire industry. EPA has recognized Congress did not intend this result.
 - (2) Stating an unrealistic goal misleads the public.
 - h. Vinyl chloride is a health hazard at very high levels of exposure. Studies have been made, but there is no evidence that exposure to low levels of vinyl chloride is hazardous to man. The existing Standard will result in minute ambient vinyl chloride concentrations. EPA and independent studies indicate 1 ppb or less. There is no evidence that exposure to such infinitesimal concentrations has resulted in any adverse health effect.
 - i. The zero emission goal implies zero risk, but we do not live in a riskless society. Meaningful comparisons must be made of the risk involved.
2. Offset requirements
- a. "EPA believes that a policy of no net increase in emissions due to new construction is justified because of the hazardous nature of vinyl chloride. However, EPA recognizes the potential difficulties in implementing such a policy and interested persons are urged to submit comments and factual information relating to this policy." (Preamble to proposed amendments, 42 Fed. Reg. 28156 (1977)).
 - b. The effects of the offset requirements were not adequately considered.
 - (1) This offset requirement is different from EPA's overall offset policy. It would require vinyl chloride emissions to be offset only with vinyl chloride emissions. A company could only obtain

offset credits from its own plant or by bargaining with its competitors.

- (2) After the existing Standard is fully implemented, vinyl chloride emissions will be so small that little offset credit will be available. The offset requirement would create an impediment to growth.
- (3) The offset requirements raise serious competitive and antitrust questions.
 - (a) Could such a policy create market dominance?
 - (b) Could it create competitive inequities?
 - (c) What would be the extra costs of offset and who would bear them?
- (4) One company has cited the following anti-competitive effects:
 - (a) "Many of the [vinyl chloride] monomer producers use much or all of their production internally, with the result that the merchant business is divided between seven companies, of which three account for 86% of the total. Inability to build new plants within the logical market area will put a premium on potential offsets (whether or not they are actually realized) and allow expansion of existing large plants, while preventing the expansions or redesigning of small, older plants."
 - (b) "Older [polyvinyl chloride] plants will become obsolete and noncompetitive earlier than normal, and companies which cannot provide the capital necessary for economically-sized new plants will be forced out of the business, again resulting in concentration of an industry where the top six producers are estimated to have 56% of the market when ongoing expansions are complete."
- (5) The offset requirements would hinder expansion of existing plants and increase the number of plant locations. Energy usage and costs would increase.

III. Recommendations

A. The concepts reflected in the proposed vinyl chloride amendments affect the entire chemical industry. The Administrator should turn his personal attention to these issues.

1. The chemical industry is concerned with EPA's actions.
2. The action memorandum by which the Administrator proposed the amendments stated "Since we have already agreed to propose these amendments, there are no major decision issues." The Assistant Administrator for Enforcement stated that "circulation of this package for concurrence at this point appears to be only a pro forma exercise," and that the settlement motion was signed by counsel and filed "without formal review and concurrence at the Assistant Administrator level."
3. The Administrator should decide the case personally.
4. The industry needs to know whether EPA is seriously considering changing its regulatory approach with respect to these types of chemicals - adopting zero emission goals instead of utilizing rational risk assessments, and adopting offset requirements for specific chemicals.
5. The Administrator should meet with the executives of the vinyl chloride industry. That industry is concerned that the Administrator does not understand its views. The issues deserve the Administrator's personal attention.