

BIO-MEDICAL RESEARCH
DOCUMENT DESCRIPTION FORM

63 68 69 76

77 78

Duplicate in all cards: →

year as-1961-

File number
[Right justify
[Numeric only]

Sub-Index
Code

Author(s), as Last Name FS (No Punctuation) and
coden for journal as JAMA preceded by one blank space

1	20	21	40	41	60	61	62
						11	
						12	
						13	

Title of Report; end with space-hyphen-hyphen-space. Follow with Index Terms,
separated from each other with comma-space. Avoid other punctuation;
do not abbreviate.

1	2	61	62
		21	
		22	
		23	
		24	

PROPOSED FOR APPROVEMENT TO THE NATIONAL
EXHIBITION STANDARDS FOR VITAL RECORDS
BIO-MEDICAL LETTER NO. 12, 1978

Source (Journal, Vol., Number, Pages, Date)

1	2	61	62
		31	
		32	

Brief Summary

1	2	10	61	62
			61	
			62	
			63	
			64	

SUMMARY:

R&S 113429

100-1175802

U.S. ENVIRONMENTAL PROTECTION AGENCY
PROPOSED AMENDMENTS TO THE
NATIONAL EMISSION STANDARD
FOR VINYL CHLORIDE

COMMENTS BY THE
HEALTH COMMITTEE
POLYVINYL CHLORIDE SAFETY GROUP
THE SOCIETY OF THE PLASTICS INDUSTRY, INC.

On October 21, 1976, the Environmental Protection Agency ("EPA") promulgated the existing National Emission Standard for Vinyl Chloride (the "Vinyl Chloride Standard" or the "Standard").^{1/} Less than eight months later, on June 2, 1977, EPA proposed amendments to the existing Standard.^{2/}

The Society of the Plastics Industry, Inc. ("SPI") already has commented on the circumstances surrounding EPA's proposal of the amendments and on many aspects of the proposed amendments themselves. These comments will focus on the health-related issues raised by the proposed amendments. Our comments are divided into four parts: (I) introductory and general comments on the existing Standard and on the proposed amendments; (II) comments previously submitted to EPA that are applicable to the

^{1/} 41 Fed. Reg. 46560-73 (1976).

^{2/} 42 Fed. Reg. 28154-59 (1977).

proposed amendments; (III) comments discussing additional information and issues that have been raised; and (IV) conclusions.

I. Introduction.

We know of no information, old or new, that would justify lowering the existing Standard, as EPA has proposed. The existing Standard was based on EPA's very conservative interpretation of all available health-related data and information. As a result, SPI believes the existing Standard provides at the very least an ample margin of safety to protect the public health. The statute requires no more -- it does not require absolutely no public health risk.

The existing Standard was the culmination of 32 months of intensive effort by EPA and by all interested parties to evaluate the health hazards associated with vinyl chloride exposure and to develop regulations that provide the requisite protection of the public health. SPI already has noted the events that led to its promulgation. (Transcript of July 19 meeting, pp. 9-11.) Those events included EPA's publication of the Scientific and Technical Assessment Report on Vinyl Chloride and Polyvinyl Chloride, (the "STAR Document") and the Quantitative Risk Assessment for Community Exposure to Vinyl Chloride (the "Risk Assessment Document"), a public hearing on the proposed standard, and the submission of numerous written comments.

The events that preceded the existing Standard are in sharp contrast to those that preceded the proposed amend-

R&S 113431

ments. To our knowledge, the proposed amendments were not preceded by a new or supplemental STAR document or risk assessment document, or by the development of other analytical or evidentiary material. Nor are we aware that EPA intends to update its STAR or risk assessment documents.

EPA's Federal Register notice cited as a basis for the proposed amendments only the "Standard Support and Environmental Impact Statement: Emission Standard for Vinyl Chloride" (the "Standard Support Document"), and three journal articles dealing with control technology.^{3/} The Standard Support Document, published in October, 1975, referred to the STAR Document that had been published in June, 1975. The Risk Assessment Document was published in December, 1975. All of this information was published well before the existing Standard was promulgated.

EPA has cited no new information on the health effects of vinyl chloride exposure, much less any information, on which the proposed amendments could be justified. EPA should have obtained new information and updated its analyses before publishing the proposed amendments. Certainly, it should not promulgate any amendments before it does so and provides interested parties an opportunity to comment.

At the July 19, 1977 meeting on the proposed amendments, the Environmental Defense Fund, Inc. ("EDF") made allegations regarding certain claimed health risks associated with exposure to low concentrations of vinyl chloride.^{4/} Some of these

^{3/} 42 Fed. Reg. 28157 (1977).

^{4/} Transcript, pp. 55-57.

R&S 113433

allegations also were raised before the existing Standard was adopted, but were shown to be incorrect. EDF also purported to be aware of "quite new information" relating to vinyl chloride exposure. EDF did not identify this information, nor did it provide supporting material for this claim. EDF's spokesman stated that EDF had discussed the alleged information with employees of the National Institute for Occupational Safety and Health and that they would "provide this information as soon as possible."^{5/} To our knowledge, that alleged information has not yet been identified nor submitted to EPA. Accordingly, SPI has not yet had the opportunity to review and comment on it.

These comments necessarily must focus on presently available information. Because EPA has not cited any new health information or provided any new evaluations of the health risks of vinyl chloride exposure, and because EDF has not yet made available any new information to support its allegations, SPI's ability to comment on the proposed amendments in a thorough and informed manner has been restricted. SPI therefore reserves the right to modify the comments herein and to submit additional comments on the health and other aspects of the proposed amendments. EPA has agreed to receive and consider additional comments, even if submitted after the published date for submitting comments.^{6/}

^{5/} Transcript, p. 57.

^{6/} Transcript of September 8, 1977 meeting, p. 70.

II. Comments Previously Submitted to EPA.

Before the existing Standard was promulgated, SPI analyzed the STAR Document and the Risk Assessment Document and submitted written comments critiquing the documents as they relate to public health matters, discussing specific objections, and listing certain questions. Once again, SPI would like to call the Agency's attention to those comments. SPI does not believe the Agency has yet given them adequate consideration and weight. Because they are applicable to the proposed amendments, they are attached hereto as Appendix I.

In addition to the comments previously submitted, we would like to call the Agency's attention to other information supporting SPI's conclusion that the proposed amendments to the already stringent requirements of the existing Standard are unnecessary.

III. Additional Comments.

A. Epidemiology.

1. Occupational exposure in the manufacture of vinyl chloride monomer and polyvinyl chloride.

Published epidemiological evidence indicates that the adverse health effects alleged to result from exposure to vinyl chloride have been observed only in groups of workers with the greatest levels of exposure. Studies on populations of workers with exposure to low concentrations of vinyl chloride, however, have shown the absence of such health effects. These

R&S 113434

studies present a consistent pattern of epidemiological evidence that deserves considerable weight.

A study published in 1974 by Tabershaw and Gaffey^{7/} of 8384 workers that had been exposed to vinyl chloride found no angiosarcomas of the liver in the lower exposure group

A study published in 1975 by Ott, Langner and Holder^{8/} of 594 workers observed no angiosarcomas of the liver. The Tabershaw and the Ott studies reported no significant excess of tumors in the lower exposure groups.

A recently published study by Fox and Collier^{9/} included 7717 workers who had been exposed to vinyl chloride in the manufacture of polyvinyl chloride in Great Britain. Four cases of liver cancer were found, only two of which were angiosarcoma. The cases of angiosarcoma "were associated with exposures to very high concentrations of [vinyl chloride monomer]." With respect to whether vinyl chloride exposure causes cancers other than those of the liver, the study found "no evidence to support this suggestion."

7/ I. Tabershaw and W. Gaffey, Mortality Study of Workers in the Manufacture of Vinyl Chloride and Its Polymers, 16 Journal of Occupational Medicine, pp. 509-18, (1974).

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

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

2. Other Types of Exposure.

The existing Standard is based on EPA's calculations that average ambient exposure within five miles of vinyl chloride plants before installation of controls to meet the existing Standard was about 17 parts per billion ("ppb").^{10/} SPI already has criticized EPA's approach in this regard. The most fundamental objection is that EPA's model does not square with actual monitoring observations which demonstrate that ambient concentrations are far less than EPA's predictions.

In any event, EPA estimated that the ambient annual average vinyl chloride concentrations remaining after implementation of the existing Standard would be only 5% of the unregulated levels,^{11/} or less than 1 ppb. The diffusion modeling study prepared by Dames and Moore, and submitted to EPA by SPI on August 9, 1977, confirmed EPA's estimate that implementation of the existing Standard would result in roughly a 95% reduction in ambient vinyl chloride concentrations. That study indicated the mean annual average vinyl chloride concentration within five miles of EPA's typical vinyl chloride plant in compliance with the existing Standard would be "on the order of 0.15-0.25 ppb."

There is no epidemiological evidence that exposure to these minute ambient concentrations poses any risk to public health. Suggestions or allegations to the contrary at EPA's July 19 meeting^{12/} simply are incorrect.

^{10/} See Appendix I, pp. 8-11.

^{11/} 41 Fed. Reg. 46560 (1976).

^{12/} Transcript, p. 55-56.

R&S 113437

The claim^{13/} that an electrical insulation worker and an accountant employed in a PVC plant were "confirmed" by the National Cancer Institute as liver angiosarcoma cases is false. These cases have been discussed before, and the claim has been discredited. As a result, the National Institute for Occupational Safety and Health ("NIOSH") has agreed that "[t]able II [of non-polyvinyl chloride polymerization workers thought to have some vinyl chloride exposure] will not be presented in the Current Intelligence Report we intend to submit to [the Journal of Occupational Medicine]." ^{14/}

Another claim by EDF at the July 19 meeting was that:

"Now, there is evidence that vinyl chloride workers, not necessarily exposed to the high levels involved in cleaning out reactor vessels are developing lung cancer.

And this morning we had hoped to have with us Dr. Peter [Infante] and Dr. Joseph [Wagoner] to discuss this particular data. It is quite new information and unfortunately both of them are here in Washington today but are attending meetings on another carcinogen. Before the ^{15/} Occupational Safety and Health Administration.

We have discussed this briefly, however, with Dr. [Infante] and Dr. [Wagoner] and they will provide this information as soon as possible."

EDF has not yet provided the "quite new information" it referred to, and we are not aware of any such information.

^{13/} Transcript, p. 55.

^{14/} NIOSH (R. Kaminski) letter to Dr. T. R. Torkelson, dated September 1, 1977.

^{15/} Transcript, p. 56-57.

In an effort to obtain the alleged information, SPI requested under the Freedom of Information Act any such new NIOSH records relating to vinyl chloride and any possibility of lung cancer.^{16/} The response from Dr. John F. Finklea, the Director of NIOSH, did not include any such new data or information.^{17/} The reports by Tabershaw and Gaffey, by Ott, Langner and Holder, and by Fox and Collier on industrial populations consistently show no relationship of lung cancer to low vinyl chloride exposure.

At the July 19 meeting, EDF also referred to the interim results of ongoing studies by Professor Cesare Maltoni, and claimed EPA did not have "sufficient opportunity to evaluate Maltoni's revised studies prior to the promulgation of the final standard. . ."^{18/} EDF stated the interim results:

"suggest that mammary carcinomas can be induced in laboratory animals at levels of one part per million or less."^{19/}

The final results of the experiments are not yet available. In reporting the interim results, however, Dr. Maltoni stated:

"In the experiments BT9 and 15 we have observed a rather large number of mammary tumours in treated and also in control groups (including carcinomas, carcinosarcomas and fibroadenomas).

^{16/} SPI associate counsel's letter dated July 19, 1977.

^{17/} NIOSH (J. Finklea) letter dated August 23, 1977.

^{18/} Transcript, p. 59.

^{19/} Transcript, p. 55.

In our breed of Sprague-Dawley rats spontaneous incidence of mammary tumours show fluctuation from stock to stock of animals: as a matter of fact such a high incidence of mammary tumours was not detected in earlier experiments on VC. The same phenomenon was also observed in other uncorrelated experimentations." 20/

EPA's then Assistant Administrator for Air and Waste Management stated that the Agency did consider Dr. Maltoni's interim report before promulgating the existing Standard.

"Informal discussions with ORD indicated that, due to the relatively large numbers of malignant mammary tumors in the control animals with no vinyl chloride exposure, definite conclusions concerning the significance of the tumors at the lower concentrations cannot be reached at this time. Also, based on informal discussions with ORD, we concluded that the new data did not provide reasons for altering the approach we had adopted for regulating vinyl chloride, but instead supported that approach." 21/ (emphasis supplied.)

In any event, an analysis of epidemiological data of women employees with vinyl chloride exposure in PVC fabricating plants, showed no excess risk of death from breast cancer. 22/

At the July 19 meeting, EDF mentioned the so-called "neighborhood cases", two angiosarcoma cases to which it previously has referred. EDF claimed these cases "signify the risk associated with living near a vinyl chloride plant." 23/

20/ C. Maltoni, report to the Members of the European Cooperative Group for the Experimental Bio-Assays on Vinyl Chloride Carcinogenicity, undated.

21/ EPA (R. Strelow) memorandum, Recent Health Findings on Vinyl Chloride, dated December 15, 1976.

22/ Organizational Resource Counselors, Inc., Report on a Case Control Study Covering White Female Employees of PVC Fabricators (May, 1977). (Appendix III.)

23/ Transcript, p. 55.

R&S 113439

This claim has been demonstrated to be incorrect. EPA's Risk Assessment Document concluded on the basis of EPA's epidemiological evidence that "[T]his survey has produced no evidence that living around vinyl chloride plants is a risk factor in the occurrence of liver angiosarcoma."^{24/} Subsequently, in the public hearing on EPA's proposal that ultimately became the existing Standard, EDF mentioned these same so-called "neighborhood cases." Dr. William Marcus from EPA's Office of Toxic Substances summarized the Agency's conclusions.

"I would like to say that EPA investigated very carefully those cases, and we consulted with our expert doctor, Hans Popper of Mount Sinai, and it was his expert opinion that these people did have angiosarcoma that was of a different type than that caused by vinyl chloride monomer, and I must say, to date we do not have any evidence that angiosarcoma has been produced by vinyl chloride monomer in the general population."^{25/} (emphasis added)

In all probability, these cases were part of the background incidence of angiosarcoma that is unrelated to vinyl chloride.

In February, 1976, for example, the Center for Disease Control reported the occurrence of four angiosarcomas in Wisconsin residents in a 2 1/2 year period and a total of 10 angiosarcomas since 1964, roughly twice as large as expected.^{26/} These residents did not live near vinyl chloride facilities and the cases presumably reflect the background incidence of angiosarcoma.

^{24/} See Appendix I, pp. 12-14.

^{25/} Transcript, Public Hearing on Vinyl Chloride, February 3, 1976, p. 42.

^{26/} Center for Disease Control, 25 Morbidity and Mortality No. 8, for week ending February 28, 1976 (released March 5, 1976). (Appendix IV.)

R&S 113441

Although a latency period range exists for angiosarcoma, in some areas vinyl chloride plants have been in operation for long periods of time, more than long enough to have covered a sufficient latency period. SPI pointed out in its comments to the existing Standard that vinyl chloride monomer and polyvinyl chloride plants have been in operation in Niagara Falls for 30 years, and that seven polyvinyl chloride plants have operated more than 25 years.^{27/} Thus, extensive production occurred well over 20-25 years ago. In spite of this, no adverse health effects from exposure to low vinyl chloride concentrations have been demonstrated.

3. Conclusion.

The absence of evidence suggesting vinyl chloride related angiosarcomas at low exposure levels is significant. Available epidemiological evidence indicates an absence of angiosarcoma or other health effects in workers exposed to low concentrations of vinyl chloride. In comparison to those low levels of worker exposure, the ambient vinyl chloride concentrations around a vinyl chloride plant are almost non-existent. There is no credible evidence that exposure to such infinitesimal concentrations has resulted in angiosarcoma or other adverse health effect in the general population.

^{27/} Appendix I, Risk Assessment Document, pp. 7, 10.

B. Risk Assessment.

SPI's previous comments discussed the methodology and assumptions used in EPA's Risk Assessment Document on which the existing Standard was based. We questioned the validity of the diffusion modeling calculations. We also questioned EPA's acceptance of the linear dose-response model, pointing out that the authors of EPA's Risk Assessment Document acknowledged that biological responses generally are better represented by a log-probit model. In promulgating the existing Standard, EPA recognized that its calculations were not based on estimates of then-current emission data and that use of the log-probit model instead of the linear model would lower the predictions by one tenth to one one hundredth.

Even using EPA's linear basis, however, the calculated risk is so small that it is difficult to comprehend without comparing it to other risks existing in everyday life. Such a meaningful risk comparison has been prepared by Professor Richard Wilson and already submitted to EPA.^{28/} Professor Wilson has compared the yearly risk associated with various events with the average yearly risk of living within five miles of a polyvinyl chloride plant, calculated as 5×10^{-8} , a number he suggests "uses EPA numbers in EPA calculations and is probably pessimistic." For example, that risk of living within five miles of a polyvinyl chloride plant for one year is equivalent to the risk of contracting cancer from eating 1/2 of a tablespoon of peanut butter,

^{28/} Attachment to Comments by Air Products and Chemicals, Inc. dated August 18, 1977.

or to the risk of contracting cancer from increased cosmic radiation during a three-day visit to Denver, Colorado, or to the hazards from smoking 1/15 of a cigarette.

Professor Wilson also makes another important point. Even the calculated risk of living near a vinyl chloride plant is so small that steps to eliminate that theoretical risk could give rise to greater public risks.

In commenting on the originally proposed vinyl chloride standard, SPI also questioned the exclusion of available evidence that a threshold level of effects may exist for vinyl chloride exposure. The Federal Register preamble to EPA's original proposed standard carefully avoided the conclusion that vinyl chloride is a non-threshold pollutant. Rather, EPA carefully distinguished between the terms "non-threshold pollutant" and "apparent non-threshold pollutant." EPA defined these terms as follows:

"The term 'non-threshold pollutant' refers to a substance which creates a risk of adverse health effects at all ambient levels (other than zero). An 'apparent non-threshold pollutant' is, quite simply, a substance which, on the basis of available information appears to be a non-threshold pollutant." ^{29/}

EPA stated the opinion that vinyl chloride is an apparent non-threshold pollutant.

Occasionally, in proceedings on the proposed amendments to the existing Standard, some of the EPA staff have referred to vinyl chloride as a "non-threshold pollutant" rather than an

^{29/}40 Fed. Reg. 59534 (1975).

"apparent non-threshold pollutant."^{30/} It is not clear whether these references were incorrect and inadvertent or whether they reflect a change in EPA's position. If EPA has changed its position, that has not been clearly announced or explained, and no information has been provided to support such a change. Certainly the absence of a threshold has not been demonstrated. The distinction between the two terms is important and we urge the Agency to reconfirm that it does not consider vinyl chloride to be a "non-threshold pollutant."

On the basis of available information, SPI suggests that as a practical matter vinyl chloride is an "apparent threshold pollutant", rather than an "apparent non-threshold pollutant" as EPA originally concluded. The epidemiological evidence, discussed above, is wholly consistent with the existence of a practical threshold in man for low vinyl chloride exposures. SPI's previous comments pointed out that even the "no-threshold" concept is not universally accepted by scientists, and referred to papers of various scientists that a threshold may exist.^{31/} Additional materials discussed below also support the existence of a practical threshold in man.

SPI offers as part of its comments, a paper presented on May 23, 1977 at the American Industrial Health Conference by John A. Zapp, Jr., Ph.D., a toxicologist. (Appendix V.) We urge

^{30/} E.g., Transcript of July 19, 1977, meeting, pp. 4,5.

^{31/} Appendix I, pp. 4-5.

the Agency to consider and take into account Dr. Zapp's opinion that no-effect levels exist for carcinogens, and the evidence and logical reasons supporting his opinion. In particular, we hope the Agency will fully recognize the simple fact pointed out by Dr. Zapp that every organism, including man, has a finite life span, and thus a practical threshold. As he noted, that view is supported by the World Health Organization Scientific Group.

In any event, even assuming for purposes of discussion the absence of a threshold level of effects, a recent study not yet published suggests that the risk of angiosarcoma to humans from low vinyl chloride concentrations is less than the risk of spontaneous occurrence.^{32/} That study, by Gehring, Watanabe and Park, was submitted to EPA by the Dow Chemical Company.^{33/} The paper suggests a plausible explanation for the absence of adverse health effects in workers or general populations exposed only to low concentrations of vinyl chloride, an absence fully supported by available epidemiological data.

III. Non-Carcinogenic Effects.

In previous comments, SPI discussed the possibility that vinyl chloride may be a mutagen and/or a teratogen. In order to assess this area better, SPI sought an independent evaluation and interpretation of the available information. SPI's Health Committee requested Dr. Brian MacMahon, Professor and Chairman of the Department of Epidemiology of Harvard University's School of Public Health, to perform such a review.

^{32/} P. Gehring, P. Watanabe, and C. Park, Resolution of Dose-Response Toxicity Data for Chemicals Requiring Metabolic Activation Example -- Vinyl Chloride (July 12, 1977).

^{33/} Dow Chemical U.S.A. (V. K. Rowe) letter to EPA (D. Goodwin) dated July 28, 1977.

A copy of Dr. MacMahon's report^{34/} is attached as Appendix VI, and offered as a comment on the proposed amendments. Dr. MacMahon expresses concern regarding the potential mutogenic and potential teratogenic aspects of vinyl chloride, but he concluded:

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

One recently published article, by Picciano, Flake, Gay and Kilian^{35/} was not available for inclusion in Dr. MacMahon's review. That article reported on new cytogenetic studies on 209 vinyl chloride production workers who had up to 28 years of exposure. Chromatid aberrations, chromosome aberrations and the proportion of abnormal cells were analyzed. No significant differences were observed between the group of workers exposed to vinyl chloride and a control group.

IV. Conclusions.

SPI's previous comments noted that industry had sponsored studies of the health effects of vinyl chloride, outlined potential areas for additional research, and indicated that

^{34/} Brian MacMahon, M.D., Vinyl Chloride and Human Reproduction (August 11, 1977), together with a copy of Dr. MacMahon's curriculum vitae.

^{35/} D. Picciano, R. Flake, P. Gay and D. Killian, Vinyl Chloride Cytogenetics, 19 Journal of Occupational Medicine, pp. 527-30 (August, 1977).

the industry expected to continue its efforts. SPI recommended, however, that cooperative research efforts be undertaken and "that the government should take the lead in calling together interested parties with a view toward establishing a consensus on what areas should be studied, who can best conduct the necessary studies, and the protocols which should be followed."

The industry has continued its research efforts. The results are reflected in our comments. Unfortunately, the government has failed to implement our recommendation that it take the lead in providing a forum for discussing and coordinating further research.

SPI's previous comments concluded:

"The most reasonable conclusion which can be drawn from the Risk Assessment Document and the other documents issued as part of the proposed Standard is that vinyl chloride poses no health risk for the general public because of the small concentrations which exist in the ambient air."

Since that time, the conclusion has become even more valid.

In October, 1976, EPA promulgated the existing Vinyl Chloride Standard. The industry is complying with that Standard, and controls are being implemented. The existing Standard already provides an ample margin of safety to protect public health. We know of no information that would indicate a need to lower the existing Standard. Accordingly, the proposed amendments should be withdrawn.

September 25, 1977

R&S 113447