

Tab VC-EPA

R.W. Lyndie
9/19/74

**PRELIMINARY ASSESSMENT
OF THE ENVIRONMENTAL PROBLEMS
ASSOCIATED WITH
VINYL CHLORIDE AND
POLYVINYL CHLORIDE**



**Report on the Activities and
Findings of the Vinyl Chloride Task Force**



**ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C.
SEPTEMBER 1974**

GENC 013310

PRELIMINARY ASSESSMENT OF THE ENVIRONMENTAL PROBLEMS

ASSOCIATED WITH

VINYL CHLORIDE AND POLYVINYL CHLORIDE

A Report on the Activities & Findings of the

Vinyl Chloride Task Force

Compiled by the Office of Toxic Substances
Environmental Protection Agency
Washington, DC
September 1974

With Contributions from the Following Task Force Members

OFFICE OF WATER AND HAZARDOUS MATERIALS

Mr. Glenn E. Schweitzer, Office of Toxic Substances (Chairman)
Dr. Nancy Beach, Office of Toxic Substances (Coordinator)
Mr. John B. Ritch, Office of Pesticide Programs
Mr. David Becker, Office of Water Quality Planning & Standards
Dr. Richard Rhoden, Office of Water Quality Planning & Standards
Mr. William T. Musser, Office of Water Program Operations
Mr. Benjamin H. Pringle, Office of Water Program Operations

OFFICE OF AIR AND WASTE MANAGEMENT

Mr. Mike H. Jones, Office of Air Quality Planning & Standards
Mr. Alessi D. Otte, Office of Solid Waste Management

OFFICE OF ENFORCEMENT AND GENERAL COUNSEL

Dr. William M. Reid, Office of Technical Analysis

OFFICE OF PLANNING AND MANAGEMENT

Dr. Joel Jacknow, Office of Planning and Evaluation

OFFICE OF RESEARCH AND DEVELOPMENT

Dr. Lawrence A. Plumlee, Office of Program Integration
Dr. Henry F. Enos, Office of Monitoring Systems
Dr. Robert McGaughey, Office of Environmental Sciences
Dr. Andrew J. McErlean, Office of Environmental Sciences
Mr. Paul E. des Rosiers, Office of Environmental Engineering
Dr. Dale A. Denny, NERC-Research Triangle Park
Mr. Frank P. Scaringelli, NERC-Research Triangle Park

STAFF OFFICES

Mr. George Marienthal, Office of Regional Liaison
Ms. Leslye Arsht, Office of Public Affairs
Mr. Pope A. Lawrence, Office of Federal Activities
Mr. Bryan F. LaPlante, Office of Legislation

REGIONAL OFFICES

Mr. George J. Moein, Region IV, Atlanta, Georgia
Dr. Oscar Ramirez, Jr., Region V, Dallas, Texas

GENC 013311

PREFACE

This Report summarizes the activities and findings of the Task Force established by the Administrator on February 14, 1974, to assess the character and extent of the problems associated with the production, distribution, use, and disposal of vinyl chloride and polyvinyl chloride. The discussion and conclusions presented in the Report should be considered preliminary since the Task Force has only scratched the surface of a complicated subject and analyses within the Agency are continuing. The Report is not a statement of Agency policy even though many of the recommendations are already being implemented.

During the lifetime of the Task Force the Agency took several regulatory steps concerning vinyl chloride. These were directed to banning pesticidal sprays containing vinyl chloride as a propellant and requesting information from industry pursuant to Section 114 of the Clean Air Act concerning vinyl chloride air emissions and related control technologies. Since these activities have been or are being documented in detail in other reports, they are mentioned only briefly in this Report.

Similarly, in recent months the Occupational Safety and Health Administration, the Food and Drug Administration, and the Consumer Product Safety Commission took a series of regulatory actions directed to vinyl chloride. While recognizing many of the problems facing other Government agencies and the implications for EPA of their regulatory steps, the Report dwells primarily on those activities of direct responsibility to EPA, and problems such as worker exposure to chemicals, use of polyvinyl chloride in food packaging, and consumer products containing vinyl chloride have not been a major concern.

The Report is organized into an Executive Summary, three Sections, and Appendices. The first Section discusses the nature and magnitude of the problems associated with vinyl chloride and polyvinyl chloride activities. The second Section discusses previous and planned activities within the Federal Government of particular significance and the role of industry. The Report concludes with a Section setting forth the specific recommendations of the Task Force. The Appendices present a considerable body of original data developed by the Task Force with the assistance of a large number of EPA specialists.

GENC 013312

TABLE OF CONTENTS

	Page
PREFACE	i
EXECUTIVE SUMMARY	1
Background	1
EPA Concerns	2
Further Steps	3
CHARACTER AND SCOPE OF PROBLEMS BEYOND THE WORKPLACE	4
Emergence of the VC Problem	4
Exposure to VC of Special Importance to EPA	5
Pesticidal Sprays	
Discharges from VC/PVC Plants: Materials Balance and Monitoring Data	
Transportation Accidents	
Unreacted Monomer Entrapped in PVC Products	
Health Effects of Vinyl Chloride	8
Persistence of VC	10
Ecological Effects of VC	10
Other Chemicals of Concern in PVC Activities	11
Size and Character of the PVC Industry	12
Lessons Learned from VC/PVC Experiences Relevant to Other Chemical Problems	13
INTERESTS AND ACTIVITIES OF GOVERNMENT AGENCIES AND INDUSTRY	16
EPA Regulatory Authorities	16
Pesticide Registration	
Air Pollution	
Water Pollution	
Solid Waste Disposal	

GENC 013313

	Page
Ocean Dumping	
Drinking Water	
Proposed Toxic Substances Control Act	
Supporting Research Activities	
Regulatory Interests of Other Agencies	19
Aerosol Sprays	
Worker Protection	
Unreacted VC Monomer in PVC Products	
Transportation Handling	
Related Research Activities	
Role of Industry	22
Reducing Discharges of VC and Other Toxic Chemicals	
Medical Surveillance	
Fenceline Monitoring for Chemical Discharges	
Toxicological Testing of VC	
Testing for Persistence and Environmental Fate and Effects of VC and PVC	
Testing for Levels of Unreacted Monomer in PVC Resins and PVC Products	
RECOMMENDATIONS	26
Regulatory and Directly Supportive Actions by EPA	26
Steps by Industry	29
APPENDICES	
APPENDIX I - SELECTED ECONOMIC CONSIDERATIONS	
APPENDIX II - PRODUCERS OF VC AND PVC	
APPENDIX III - THE MATERIALS BALANCE AT VC AND PVC FACILITIES	
APPENDIX IV - INTERIM METHOD FOR SAMPLING AND ANALYSIS OF VC IN WASTE WATER EFFLUENTS AND AIR EMISSIONS	
APPENDIX V - SUMMARY OF REGIONAL ACTIVITIES	

APPENDIX VI- PERSISTENCE OF VINYL CHLORIDE

APPENDIX VII- HEALTH EFFECTS OF VINYL CHLORIDE

APPENDIX VIII- DISPOSAL OF PRODUCTS CONTAINING POLYVINYL
CHLORIDE

APPENDIX IX - ACTIVITIES OF TASK FORCE

GENC 013315

EXECUTIVE SUMMARY

Background

EPA's recent concern over vinyl chloride (VC) and polyvinyl chloride (PVC) was triggered by reports in January 1974 of (a) deaths of four PVC workers believed to be attributable to exposure to VC, and (b) an estimated material loss of VC and PVC of six percent during the PVC polymerization process. The investigations of the Task Force confirm that in the United States substantial amounts of VC -- probably exceeding 200 million pounds annually -- and large quantities of PVC -- probably exceeding 50 million pounds -- are being discharged into the environment during the PVC production process. Meanwhile, additional epidemiological and toxicological evidence supports the linkage between worker deaths and VC exposure.

The VC/PVC industry has experienced rapid growth at home and abroad in recent years with PVC products currently permeating our entire economy. This multi-billion dollar industry involves not only several dozen large manufacturers of VC and PVC resin but also thousands of fabricators producing a variety of products based on PVC and probably employing more than 300,000 workers. There are readily available substitutes for PVC in some of these products; more expensive substitutes for others; and no substitutes for still others. A principal constraint on near-term production increases has been availability of ethylene, a petroleum derivative. A new constraint is the uncertainty over Governmental regulatory actions affecting VC/PVC activities.

VC has induced angiosarcoma of the liver in rats and mice exposed to concentrations of 50 ppm at intervals simulating occupational exposure, and this same rare and fatal tumor has been identified in at least 15 former workers in U.S. PVC facilities. Cancers at other sites, non-malignant liver disease, and a unique occupational disease -- acroosteolysis -- have also been attributed to VC exposure. There is no direct evidence that VC contributes to adverse health effects at the lower levels of exposure encountered outside the workplace; however, two recently reported cases of angiosarcoma of the liver in non-workers who had lived near PVC fabrication plants suggest the possibility of such a correlation. At the same time there has been little effort to search for adverse effects at these lower levels. Since carcinogens are generally considered not to have a "no effects" threshold level, there should be concern with possible risks to health at even the lowest levels of exposure to VC which are encountered in the ambient air, and possibly in water.

Preliminary monitoring results at seven industrial complexes involving 10 PVC resin and 2 VC plants indicate that the levels of VC in the ambient air near the plants fluctuate sharply, apparently due to the periodic opening of reactor kettles in the PVC plants, accidental plant discharges, variations in the production process, and meteorological conditions. While almost all of the samples collected contained detectable levels of VC, more than 90 percent of the instantaneous observations and 97 percent of the 24-hour samples showed amounts less than 1 ppm. At

several of the chemical complexes, a number of individual air samples showed more than 1 ppm. At one PVC plant a high of 33 ppm was obtained at one site; however, repeated sampling indicated that this level was an unusually high excursion with the average at this site less than 1 ppm. Most of the air sampling was done within one-half mile of the property lines of the plants. In one case a level of 3.4 ppm was recorded at a distance of three miles from the plant, but the average of several readings at this site was approximately 0.5 ppm.

Water effluents were also monitored, and levels varied considerably depending on the in-plant handling of wastes and treatment of wastewater. The highest level for wastewater leaving the plant site was 20 ppm. More typically, levels of 2 to 3 ppm were found. Not unexpectedly, the levels of VC entrapped in sludge and other solid wastes from the reactor kettles ranged from 100 ppm to, in one case, 3,000 ppm.

EPA Concerns

The principal near-term issues facing the Agency include (a) an assessment of the risks associated with exposure to VC, with such an assessment hampered by inadequate data concerning health effects at the levels likely to be encountered in the environment and only very preliminary monitoring results, (b) the costs to industry to reduce the levels of VC entering the environment, keeping in mind that much of the cost will be passed on to society as a whole, and (c) regulatory and related steps which will contribute to reducing the risks at an appropriate cost. Two closely related areas of interest are (a) the amount of Agency resources to be directed to VC/PVC in the months and years ahead, and (b) lessons that have been learned in addressing VC/PVC that can save time and resources in addressing other chemicals.

VC air emissions from PVC polymerization plants -- and to a lesser extent from VC plants and possibly PVC fabrication plants -- are the most immediate concern to the Agency. The earlier problems related to the use of VC as a propellant in pesticidal sprays have been largely resolved with the banning of such sprays. Other current concerns related to VC include the Agency's capability to provide sound advice in the event of transportation accidents involving the release of VC; the fate and effects, if any, of VC trapped in water effluents, and particularly VC that might thereby appear in drinking water; and the migration of unreacted VC from PVC products into drinking water or into the ambient air.

There are of course a host of other chemicals involved in VC/PVC activities that should be of concern. Impurities in the VC, PVC as inhaled or ingested particulate, additives introduced to alter the properties of PVC, copolymers used in conjunction with PVC, and chlorinated hydrocarbon wastes from VC production all need further investigation. The by-products associated with PVC incineration and the leaching of additives, and particularly plasticizers and toxic metals, from PVC products which come into contact with the aquatic environment need additional study.

Further Steps

Development of an air emission standard for VC is currently under-way, with additional monitoring activities being planned in the immediate future to improve the basis for the standard. While additional epidemiological and toxicological data are slowly becoming available, it is unlikely that there will be a good technical basis within the next few months or perhaps even within several years for establishing an appropriate ambient level to protect public health. Therefore, a performance standard may be far easier to develop and implement than a standard based upon achieving a specific air quality level. Initial estimates indicate that available control technology when installed can reduce VC emissions by about 75 percent from PVC resin plants and 90 percent from VC plants with a concomitant increase in the cost of PVC of about four percent. Currently available information indicates that such reductions should result in ambient air levels which present no established risk to health or welfare. Meanwhile, close liaison with the Department of Labor is important to insure that the regulatory approach to protect the worker is compatible with EPA regulatory activities. ✓

The Agency should monitor for VC in drinking water supplies. Monitoring is also needed in the ambient air -- indoors and outdoors -- distant from chemical complexes to determine whether concentrations of PVC products release quantities of unreacted VC that should be of concern. Further refinement of monitoring methodologies is needed in support of these efforts. The limited toxicological and epidemiological studies that are planned should be fully supported.

The Agency should continue its leadership role in bringing together other Agencies to exchange views on regulatory actions, supporting activities, and research projects related to VC and PVC. Industry should be strongly encouraged to accelerate its efforts to reduce VC discharges and its very limited research, testing, and monitoring activities to clarify further the problems associated with VC and PVC.

Finally, we have been alerted in a rather dramatic fashion to the need for greater attention to an important segment of our industrial base which will surely continue to expand in the years ahead. Many of the considerations and uncertainties that have punctuated the VC/PVC deliberations undoubtedly characterize a far broader swath of concerns over high volume industrial chemicals in general, and plastics in particular. Hopefully, we can extrapolate from current experiences with VC and PVC in identifying problems with other potentially important commercial chemicals early in their embryonic stage and thus minimize health and environmental hazards and also the economic dislocations attendant to corrective actions. In this regard the Agency should continue its efforts to seek early enactment of the Toxic Substances Control Act which can provide a much needed broader basis for addressing these types of problems. ✓

CHARACTER AND SCOPE OF PROBLEMS BEYOND THE WORKPLACE

Emergence of the VC Problem

On January 22, 1974, the B. F. Goodrich Company, the largest U. S. producer of PVC resin, notified the National Institute of Occupational Safety and Health (NIOSH) that four workers from its PVC polymerization plant in Louisville, Kentucky, apparently had died from a rare cancer, angiosarcoma of the liver. All four workers had been closely associated for many years with the production of PVC resins. The rarity of the tumor and the clustering of deaths at a single plant raised suspicions that an occupational disease related to VC* exposure had been found. Since that time, 10 additional cases of this tumor, which developed in U.S. PVC polymerization workers since 1961, have been confirmed. This tumor has also been reported in seven workers at European polymerization plants, one worker at a U.S. PVC fabrication plant, two workers at European fabrication plants, one worker at a European VC plant, and two residents in the general population near U.S. fabrication plants.

Concurrently, toxicological data from animal studies became available which further strengthened the suspicion of VC as the etiological agent in the formation of the liver cancer. A broad spectrum of cancers was reported by Professor Cesare Maltoni of Italy in different animal species at various exposure levels. His inhalation studies of rats exposed to 50 ppm at repeated intervals approximating occupational exposures have produced angiosarcomas of the liver and abdomen as well as tumors of the kidney and skin. In mice exposed to VC the same tumors have been observed, with the addition of lung tumors. Animal studies sponsored by U. S. industry have confirmed Maltoni's observations at 50 ppm. Recent epidemiological studies also suggest the possibility of multiple cancers attributable to VC exposure.

Meanwhile, statements by industry and Government officials indicated that the material loss to the environment during the PVC polymerization process may be about six percent, with more than 75 percent of the losses being VC air emissions. Also, it soon came to light that VC was being used as a propellant in pesticidal sprays, and the EPA Regional Offices were becoming more aware of railroad accidents involving VC tank cars.

Until this series of events the Agency had not been particularly concerned with VC as an urgent problem. PVC plants had been on the list of industries to be examined as candidates for new source performance standards to limit air emissions. Also, limited studies of PVC disposal were underway, and VC and PVC resin manufacturing activities have been addressed in the Effluent Guidelines promulgated under the Federal Water Pollution Control Act. However, only since January have VC/PVC activities been elevated to the level of priority Agency attention.

** Vinyl chloride (CH_2CHCl) is a colorless, faintly sweet smelling gas at room temperature. As a gas it is readily flammable and explosive but is usually handled industrially as a liquid under pressure. Polyvinyl chloride resin is a fine powder which is produced by polymerizing vinyl chloride. The resin is the base ingredient for a wide variety of plastics.*

Exposure to VC of Special Importance to EPA

Pesticidal Sprays

Spurred by the active interest of a consumer protection organization, the Health Research Group, one of the earliest EPA concerns this year was the use of VC as a propellant in a large number of pesticidal sprays. After the searching of EPA pesticide registration files more than 50 different sprays containing VC -- including a large number used indoors -- were identified. It has been estimated that in addition to the cans in the possession of consumers, up to 100,000 cans were in the channels of trade.

Preliminary tests at EPA research facilities showed that a 30 second release of an aerosol containing VC could result in a concentration as high as 400 ppm in the air. Related tests showed that in closed rooms VC will persist for many hours, and even when diluted by ventilation, will probably result in some VC exposure within the household for at least several hours. (See Appendix VI).

Discharges from VC/PVC Plants: Materials Balance and Monitoring Data

Industrial reports and analytical studies (see Appendix III) confirm that generally the material loss during the PVC polymerization process ranges from 4.5 to 7.5 percent. During recent months industry has taken a variety of steps to reduce the losses, and these losses may be now declining. The losses will vary with the type of process, the age of the plant, the level of technology that is employed, and manufacturing practices. However there is no doubt that in the United States substantial amounts of VC -- probably exceeding 200 million pounds annually -- and large quantities of PVC -- probably exceeding 50 million pounds -- are being discharged into the environment during the PVC polymerization process. Most of the VC escapes directly into the atmosphere, with lesser amounts dissolved in water effluent streams and entrapped in sludge and solid wastes. PVC losses occur as particulate in air emissions, suspended solids in water effluents, and components of solid wastes.

A principal area of VC leakage is associated with the operation of the polymerization kettles, including losses when they are opened or when they are recharged or sampled. Other losses occur during the transfer of VC from tank cars to storage, during the PVC drying process, and from leaks at a variety of valves, flanges, and pump seals throughout the process. Polymer losses are similarly distributed among a variety of activities including dust collector losses, disposal of oversize particles, and sampling losses. In this regard two aspects are particularly significant: there are a variety of PVC processes with differing problems and control possibilities, and in every case the number of potential leakage points is very large.

Losses at VC plants occur during the loading process, as the result of venting of gases, from leaks in pumps, and at other points. These losses are considerably less than one percent but still may be environmentally significant. As in the case of PVC polymerization activities, current industrial efforts should reduce these losses. No mass balance data are available concerning losses at PVC compounding and fabrication plants. However, the only source of VC at these facilities is the unreacted monomer in the PVC resin which suggests that environmental discharges are less than at the VC and PVC polymerization plants.

To obtain more direct evidence on VC discharges from VC/PVC activities, ambient air, waste water effluents, and solid wastes from seven chemical complexes were monitored during May. The 2 VC and 10 PVC production facilities located at these seven complexes are listed in the table below:

Vinyl Chloride and Polyvinyl Chloride Manufacturing Complexes
Monitored by EPA Regional Offices

Louisville, Ky.	PVC Plant	The B. F. Goodrich Co. B. F. Goodrich Chemical Co.
Leominster, Mass.	PVC Plant	Borden, Inc. Borden Chemical Division
Plaquemine, La.	PVC Plant	The Goodyear Tire & Rubber Co. Chemical Division
Long Beach, Calif.	VC Plant	Dow Chemical, U.S.A.
	PVC Plant	The B. F. Goodrich Co. B. F. Goodrich Chemical Co.
	PVC Plant	American Chemical Corporation
Painesville, Ohio	VC Plant	American Chemical Corporation
	PVC Plant	Uniroyal, Inc. Uniroyal Chemical Division
	PVC Plant	Robintech, Inc.
Delaware City, Del.	PVC Plant	Stauffer Chemical Co. Plastics Division
	PVC Plant	Diamond Shamrock Corporation
	PVC Plant	Diamond Shamrock Chem. Co.
Flemington, N. J.	PVC Plant	Tenneco, Inc. Tenneco Chemicals, Inc.

The preliminary monitoring results indicate that the levels of VC in the ambient air near plants fluctuate sharply, apparently due to the periodic opening of polyvinyl chloride reactor kettles, accidental plant discharges, variations in the production process, and meteorological conditions. A summary of the monitoring results at each complex can be found in Appendix V. The monitoring method developed for this activity, and subsequently refined, is presented in Appendix IV. Since the samples were limited in number, time, and duration, additional monitoring is in order to obtain a more definitive assessment of VC discharges.

Most of the air sampling was done up to three miles beyond the property lines of the plants although in two regions the EPA sampling teams were able to conduct part of the study within the plant property. Almost all air samples contained detectable levels of VC. However, more than 90 percent of the instantaneous samples and 97 percent of the 24-hour samples showed less than 1 ppm. In one case a level of 3.4 ppm was recorded at a distance of three miles from the plant. The average of several readings at this site was about 0.5 ppm. A high value of 33 ppm was observed around one complex at a distance of 0.3 miles from the fence-line although the average at this site was less than 1 ppm.

The levels of VC in water effluents varied considerably depending on the in-plant handling of wastes and treatment of wastewater. The highest level for wastewater leaving the plant site was 20 ppm. More typically, levels of 2 to 3 ppm were found. Not unexpectedly, the levels of VC entrapped in sludge and other solid wastes from the reactor kettles ranged from 100 ppm to 3,000 ppm.

Transportation Accidents

* It is estimated that more than two-thirds of the produced VC is transported from the production site to another location, frequently located hundreds of miles away. More than 95 percent of the shipments travel by rail tank car, with a small amount being shipped by water. During the past three years there have been 16 reported rail accidents involving VC tank cars. The immediate concern has been prevention of fire and explosion and only recently has attention been directed to the long-term effects, if any, that might be associated with a one-time massive exposure to VC. 1/ ✓

Unreacted Monomer Entrapped in PVC Products

Industry has reported to EPA that PVC resin contains in very unusual cases as high as 8,000 ppm of unreacted VC monomer although the levels are usually between 50 and 1,000 ppm. Presumably these levels are substantially reduced as the resin is processed further, with much lower levels (e.g. 5 to 20 ppm) present in finished products containing PVC.

Nevertheless, the eventual fate of the unreacted monomer in PVC products is of concern. Conceivably, it could be contributing to a general environmental background level of VC, and detectable levels of VC may be present where there is a heavy concentration of products containing PVC, and particularly new products.

In view of EPA's responsibilities concerning drinking water, a problem of special significance is the possible migration of unreacted monomer into the water from PVC pipe or liners used in drinking water systems. At present little is known about such migration.

Health Effects of Vinyl Chloride

There is no direct evidence about the health effects on man of VC at the levels of exposure that have been or are likely to be encountered outside the workplace; however, the two recently reported non-occupational cases of angiosarcoma of the liver in neighborhoods near PVC fabrication plants suggest the possibility that there may be a correlation between the incidence of angiosarcoma and low levels of exposure. There are also recent reports of angiosarcoma among workers at fabrication and VC plants who presumably were exposed to relatively low levels of VC. At the same time epidemiological and toxicological studies have clearly linked VC to angiosarcoma of the liver and other adverse effects at the higher levels of exposure that have been encountered in the workplace. Given the previous lack of effort to search for effects at low doses, it seems prudent to assume that there probably is not a no-effects threshold for VC, and there should be concern about the possible health effects at any level of exposure.

Extrapolation of effects from animals to man, from intermittent to sustained or peak exposures, and from high to low dose levels is fraught with uncertainty. Nevertheless, such extrapolations can be useful in helping set the basis for the necessarily subjective judgements that must be made as to health risks. With regard to the toxicological data, studies are currently underway at the National Cancer Institute and within EPA using statistical methods to extrapolate from the effects at 50 ppm to likely effects at 1 ppm and lower. Such statistical techniques must be viewed with caution but can be helpful in providing a sense of perspective in assessing risk. The relative sensitivities of rats, mice, and men to VC are not known, nor is there good information on the relative sensitivities within a human population. Another difficulty is interjected in attempting to deal with the extrapolation from worker exposure (i.e. 40 hours per week) to neighborhood exposure (i.e. up to 168 hours per week), even assuming that time weighted averages are the determinant in ambient air rather than peak levels.

The risks, if any, associated with ingestion of VC, via drinking water, food, or other routes are totally unknown. It is prudent to assume that ingestion is no less worrisome than inhalation although the likelihood of sustained ingestion at even low levels seems remote.

Summarized below are some of the most important known health effects of VC. A more detailed presentation of health data is set forth in Appendix VII, recognizing that additional information is continuously becoming available. Ongoing Agency studies are taking this information into account.

Anesthetic Effects of Acute Exposures: These effects have occurred in PVC workers exposed to high concentrations of VC as the result of accidents or inadequately ventilated reactor vessels. A dizziness, nausea,

and loss of consciousness occur which are reversible upon exposure to fresh air. Human volunteers have reacted in a similar way to high levels of VC inhaled for brief periods. These subjects reported feeling dizzy or inebriated, experienced loss of certain reflexes, and encountered feelings of impending unconsciousness. The effects were proportional to concentrations and duration of exposure.

Acroosteolysis: A small proportion (from 1 to 3 percent) of workers involved in manual cleaning of PVC reactor vessels have experienced a combination of symptoms known as acroosteolysis. This is characterized by a soreness and thickening of the skin at the fingertips, a gradual dissolution of bone calcium at fingertips and toes, skin sores, and frequently heightened sensitivity of the hands to cold (blanching of the skin and pain). These symptoms were first described in 1967, and apparently occur only after several years of high levels of exposure.

Liver Function Abnormalities: Changes in blood chemistry attributed to alterations in liver function have been observed in PVC workers whose 8-hour exposures to VC averaged 300 ppm. At levels below 300 ppm, the noted functional changes were minimal, suggesting a dose-response relationship with respect to liver function. There has been no overt liver disease noted. From Europe, there are reports that liver damage was found in Russian workers, and disease of the liver, skin, and other organs has been discovered in workers in Rumania and France. Other chemicals are invariably present in the occupational setting, and may have interfered with the effect often attributed to VC alone.

Liver Angiosarcoma: A fourth effect related to occupational exposure is angiosarcoma of the liver, a rare form of liver cancer which is a progressive and invariably fatal disease. It has recently been reported in 15 workers in PVC facilities in the United States. The exposure time of these workers in the factory setting has ranged from 11 to 30 years. Many of these workers were engaged in cleaning polymerization reactor vessels in an area where exposure levels were the highest.

The etiological role of VC in the induction of liver angiosarcoma is not certain because of possible confounding factors. The occupational exposure of the workers to other chemicals precludes identifying this substance as the sole cause for cancer. However, taking into account the effect of VC on animals in the absence of other chemicals, the implication of VC as the possible etiological agent is very strong, and unless another carcinogenic agent is identified, VC must clearly remain the prime suspect.

The reported cases of angiosarcoma of the liver have in the past been extraordinarily rare. For example, in the Third National Cancer Survey (1969-1971), a population of 21 million persons residing in nine geographic areas was sampled for incidence and type of cancer. In this period, only eight cases of liver angiosarcoma had been newly diagnosed among that ten percent of the U.S. population.

Controlled Exposures of Animals to VC: On laboratory mammals VC concentrations of 5 to 20 percent have narcotic effects which are not unlike the human anesthetic effects noted above. The acroosteolysis syndrome has never been produced in animals, although disturbances in peripheral blood circulation, abnormal cartilage formation in the toes, and abnormal skin lesions have occurred in rats. Liver enlargement in rats has been seen with inhalation exposure as low as 100 ppm for 6 months, but little is known about frank liver disease caused by VC exposure.

Among the several animal inhalation experiments employing repeated exposures of over six months duration, two have disclosed liver angiosarcoma at 50 ppm and higher in mice and rats. It remains to be determined whether the liver angiosarcoma observed in animals are precisely the same as those reported for occupationally exposed workers and for non-workers. Nevertheless, the similarities observed between the animals and man strongly suggest that the animal carcinogenic reaction is like that reported for PVC workers.

Persistence of VC

As discussed in Appendix VI, very preliminary investigations at EPA laboratories suggest that in the ambient air near the emission source VC can be considered as a stable pollutant whereas VC rather quickly escapes from agitated or aerated water.

The available results indicate a rate of reaction of about 8 to 10 percent per hour for VC in air. The direct and indirect reaction products identified include ozone, nitrogen dioxide, carbon monoxide, formaldehyde, formic acid, and formylchloride. High eye irritation levels found with human exposure levels are consistent with these products. Although VC would disappear significantly over longer travel distances, the conversions anticipated within a few miles downwind of VC emission sources indicate that VC can be considered a stable pollutant near emission sources. The usual meteorological dispersion equations for gases could be applied to approximate concentrations. Because of strong inversions at night during the fall and winter period, buildup of VC near emission sources might be of particular concern during such periods.

Ecological Effects of VC

As indicated above, preliminary studies concerning the volatility of VC from aqueous solutions as well as analyses of hydrolysis and photolysis suggest that the impact of VC in the aquatic environment may not be significant. However, if there is a continued input of VC into water, it is possible that a steady state concentration of VC could be reached. Bioaccumulation and/or biotransformation might then become of considerable concern.

Potential terrestrial ecosystem effects, as well as transport pathways from source to plant or animal receptors, of VC are unknown. However, the suspected volatility of VC may result in a large dilution factor which might reduce the toxicological or bioaccumulation hazard to an insignificant level.

Given the lack of past attention to the ecological effects of VC, some inferences drawn from the behavior of other low molecular weight chlorinated hydrocarbons may be helpful in anticipating the fate and effects of VC. In particular, 1, 1, 2 trichloroethane and 1, 2 dichloroethane comprise a portion of the waste products -- often referred to as tars -- from the production of VC and are of concern in themselves as well as possibly suggesting VC behavioral patterns. Other potentially hazardous compounds, such as hexachlorobenzene and hexachlorobutadiene, are also found in these tars. Therefore, tars are discussed below.

Other Chemicals of Concern in PVC Activities

Immediately following the January report of worker deaths related to VC exposure, questions arose as to whether other chemicals, such as vinylidene chloride, might also contribute to angiosarcoma either independently or in conjunction with VC. Little work has been done to date to clarify this concern. Also, the toxicity of PVC particulate has become a significant interest. There have been some inhalation toxicology studies conducted on PVC. However, there are no readily available data to indicate whether any substantial risk is involved at the levels of exposure that might be encountered via inhalation or ingestion of PVC outside the workplace. 2/

As pointed out in Appendix VIII, a large number of chemicals are used in PVC products as antioxidants, antistatics, colorants, fillers, plasticizers, and stabilizers, and many of them can reach man through a variety of routes. The health effects of some of these chemicals are reasonably well known; the effects of others have yet to be explored. Several of them are particularly good candidates for further investigation, e.g. cadmium, barium. However, the Task Force has not attempted to assess in any detail the known health risks nor sort out the priorities for further investigation.

A special concern of the Task Force has been disposal of products containing PVC and disposal of the by-products of PVC/VC plants. As discussed in Appendix VIII incineration of PVC produces HCl and possibly metallic vapors. As the volume of PVC and other plastic products entering municipal waste systems continues to grow, the possibility of problems resulting from incineration and land disposal -- particularly leachates -- will increase. In addition, toxic leachates from PVC used in the lining of fish tanks are known to have caused damage to aquatic organisms. 3/

The adverse effect of the tars from VC plants on aquatic organisms has been of special concern since they are known to affect at least some marine species at concentrations of 2.5 ppm. Worms and barnacles are also affected at levels below 5 ppm. Bioaccumulation of the tars appears possible through the food chain, and these materials also adhere to particles in water. However, relatively short biological half lives and rapid excretion rates may prevent serious accumulation of the tars. 4/

GENC 013326

Size and Character of the PVC Industry

During 1973 VC production in the United States was at the 5.35 billion pound level with PVC and its copolymers at the 4.56 billion pound level. The industry has been operating for about forty years, and over the past five years has shown an annually compounded growth rate of 14 percent -- a rate of growth that is expected to taper off only moderately in the next few years. A few of the most significant characteristics of the industry are summarized below with additional details presented in Appendices I and II. 5/

PVC has become a very important polymer as evidenced by the broad dependence of nearly every branch of industrial and commercial activity upon products and components fabricated from this plastic. Markets include the apparel, building, construction, electrical, home packaging, recreation, and transportation industries. The wholesale value of the annual output of fabricated products is at least several billion dollars.

The synthesis of VC is conducted in fifteen U. S. plants, and thirty-seven plants are engaged in polymerization with almost all of these plants currently operating at or near capacity. Five new PVC resin plants are under construction and together with expansions at five others will yield an additional annual capacity of 1.378 billion pounds. Additional plants are involved in manufacturing copolymers using VC. Approximately 7500 plants are engaged in fabricating products from PVC. It is estimated that 1000 to 1500 workers are employed in monomer synthesis, an additional 5000 are engaged in PVC polymerization operations, and approximately 350,000 are associated with the 7500 PVC fabrication plants.

More than 97% of the monomer is used for the manufacture of homopolymer and copolymer resins, with the remainder utilized primarily for (a) the production of methyl chloroform, (b) additives in specialty coatings, and (c) until recently, aerosol propellants. Over 90% of the VC produced in the United States is manufactured by ethylene-based processes; the remaining 10% is synthesized by the acetylene-based process. In both processes VC is made by a continuous rather than a batch process.

PVC resins are manufactured by four polymerization processes: suspension - 79% of total; emulsion - 13%; bulk - 6%; and solution - 2%. These are all batch processes.

The number of PVC fabrication plants is at least several thousand but no complete compilation by company, location, and capacity is known to exist. For example, the B. F. Goodrich Company alone supplies finished resins and compounds to about 2200 U. S. customer plants. Some of the more important products are set forth in Appendix II.

Appendix I discusses the opportunities for PVC substitutes at comparable and at higher price. In many cases there are substitutes; in some cases there are no substitutes. At the present time worldwide shortages of ethylene and the uncertainty of regulatory actions concerning VC are creating more intensive searches for alternatives to PVC resins in a variety of applications.

Lessons Learned from VC/PVC Experiences Relevant to Other Chemical Problems

Except for continuing concern over spills and accidents, Government and industry have been rather complacent with regard to the potential environmental threat from the high volume industrial chemicals (e.g. the top fifty in terms of production levels). This complacency is in large measure attributable to the relative absence of visible and uncontrolled dangers from exposure to the chemicals during their long histories. In addition, since each of these chemicals is manufactured by a number of companies, firms may lack incentive to invest individual company resources to clarify the safety aspects of their usage. Clearly, the experience with VC -- the twenty-second leading chemical in terms of production -- underscores the problems that can result from such complacency. Despite the continuing commercial importance of these high volume chemicals, it cannot be assumed that adequate research, testing, and related safety measures will be taken by industry, and vigorous governmental leadership in this area seems essential.

The Agency's experience in addressing VC discharges from PVC plants has highlighted the need for three key types of information for decision-making and the difficulty of such decisions in the absence of adequate information:

- The levels of exposure to populations beyond the fenceline, with monitoring data being the key ingredient in estimating such levels.
- The health and environmental effects of the levels of exposure that are encountered, drawing on available epidemiological, toxicological, and ecological data from all sources.
- The feasibility -- in terms of technology, cost, and time -- of introducing controls to reduce discharges.

In all of these areas, concerted short-range efforts enhanced significantly the existing data base and provided critical inputs into the decision-making process.

Reliable techniques for sampling and analysis of VC were not available and had to be developed in a short period of time. Similarly, monitoring personnel gained their experience during the actual operations. While each chemical problem that arises will undoubtedly have unique characteristics, EPA should be able to improve its anticipatory monitoring capability by such steps as limited stockpiling of equipment (e.g. Tedlar bags), clarification of organizational and funding responsibilities, and development of immediately available contractor support services.

In the pesticides area, the use of VC in aerosol propellants has emphasized the need for greater attention to the many inert ingredients in pesticides. With regard to water pollution and to drinking water contamination, EPA must extend its emphasis beyond the traditional concerns with gross pollution effects and with toxic metals and pesticide contaminants to include a wide range of other organic chemicals. Similarly, in the area of air pollution, VC has awakened the entire environmental community to the broad problem of uncontrolled and unmonitored chemical discharges reaching neighborhoods adjacent to chemical complexes. Also, the potential problems associated with the incineration and burial of PVC products may be common to a variety of plastics.

Even at this late date all the commercial products using VC have probably not been identified by EPA and other Government agencies, pointing out the need for a better means of acquiring information concerning the uses of toxic chemicals. Finally, the problem of unreacted monomer in PVC products has opened a broad vista of possible new concerns associated with contaminants in polymers in general.

REFERENCES

The material presented in this Section is based largely on original investigations and analyses conducted within the Agency. Most of these activities are elaborated in the Appendices which also cite many of the relevant scientific publications. However, the Appendices do not cover the entire range of the activities of the Task Force, and a few additional references concerning this Section are set forth below.

1. Estimates based inter alia on informal communications with the Department of Transportation and Manufacturing Chemists Association.
2. A small sampling of the available literature on the effects of PVC inhalation follows:

Cylwik, B., "Histological and Histochemical Changes of the Liver in Experimental Polyvinyl Chloride Pneumoconiosis," *Rocz. Akad. Med. im. J. Marchlewskiego w Białymstoku* 17: 93-111, 1972. (Translation).

Popow, J., "Influence of Polyvinyl Chloride (PVC) Dust on the Respiratory System in the Rat," *Roczniki Akademii Med. im. Juliana Marchlewskiego w Białymstoku* 24: 5-48, 1969 (Translation).

Szende B. et al, "Pneumoconiosis Developing after Inhalation of Polyvinyl Chloride," *Orv. Hetil.* 112: 85-6, January 10, 1971.

Wooley, W. D., "Toxic Products from Plastics Materials in Fires," *Plastics & Polymers* 41 (No. 156), 280-286, December 1973.

3. Bernhard, M. and A. Zattera, "The Importance of Avoiding Chemical Contamination for Successful Cultivation of Marine Organisms," 1970. *Helgolander Wiss. Meeresunters.* 20:655-675. Also, informal communications with Bureau of Sport Fish and Wildlife, Department of Interior.
4. Jernelev, A., R. Rosenberg, and S. Jensen, "Biological Effects and Physical Properties in the Marine Environment of Aliphatic Chlorinated By-products from Vinyl Chloride Production," *Water Research* 6: 1181-1191.
5. See also:

Frey, H. E., "Polyvinyl Chloride Resins," *Chemical Economics Handbook*, Stanford Research Institute, September 1973.

Modern Plastics, May 1974, pp. 44-46.

INTERESTS AND ACTIVITIES OF GOVERNMENT AGENCIES AND INDUSTRY

EPA Regulatory Authorities

Pesticide Registration

On April 26, 1974, the Agency determined that the potential risk associated with continued use of VC in pesticidal sprays was unjustified, given the acceptable substitutes which were available. Therefore, on that date Notice was given of the emergency suspension, and intent to cancel the registrations, of all spray products containing VC for use in the home, food handling establishments, hospitals, or other enclosed areas. At the same time EPA requested that all existent stocks of such products be recalled by the manufacturers (39 FR 14753).^{*} In addition, EPA will no longer register pesticides containing VC for indoor or outdoor uses, and all existing registrations have now been withdrawn or amended to substitute another propellant.

At present a few implementing details of this determination remain. Perhaps the most important action is to insure prompt removal of the cans containing VC from commercial channels and environmentally sound disposal of these products, i.e. proper land disposal. EPA Regional Offices have been actively pursuing this problem and should complete their efforts within several months.

Air Pollution

The results of the initial monitoring efforts clearly document the fact that neighborhoods adjacent to PVC resin manufacturing complexes are being exposed to some level of VC air emissions. At present there is no scientific evidence to indicate that these emissions pose an imminent hazard to people living near these plants. However, because of the severe health effects associated with occupational exposure to VC and the lack of data regarding the levels at which effects begin to occur, prudence dictates that steps should be promptly taken to reduce the emissions to the lowest practical level. Indeed, EPA, together with state and local air pollution authorities, has an immediate responsibility to insure that these levels are reduced.

PA
min

The key questions revolve around (a) the levels of VC concentration that should be achieved outside the plant area, and (b) the regulatory approach that is most appropriate, e.g. ambient air standard, performance standard for new sources, or emission standard for hazardous air pollutants. Several factors bear on such determinations in addition to the uncertainties inherent in the health risks involved, namely: the effect of regulations which are to be promulgated in early October by the Department of Labor on VC levels in the workplace; the technical feasibility, costs, and timing of control technologies and other approaches to reducing emissions; and compliance schedules for the industry as a whole and for individual plants.

^{*}The FR citations identify the Volume and Page of the appropriate Federal Register announcement.

Depending on the air emission level and/or the level of technology to be achieved, the costs of compliance could have several effects: The price of PVC could increase, thus opening the way for substitutes in some products. Some of the older plants might find it more attractive economically to close or to replace the old technology with new. New plants presumably would emphasize even more than at present larger reactors with fewer requirements for entry and other innovations to reducing leakage rates.

On May 31, EPA requested the manufacturers of VC and PVC resin to provide detailed technical and economic information concerning steps that have been and could be taken to reduce VC emissions. The information was sought under Section 114 of the Clean Air Act.

The Task Force believes that a standard based upon achieving a specific air quality level will be very difficult to develop using currently available data. On the other hand a performance or emission standard, which is designed to drive down the emissions as low as practical, and in the longer run drive technology toward more environmentally acceptable approaches, would seem consistent with the desirability of reducing risks from carcinogens to the minimum possible level.

Present preliminary estimates are that emissions can be reduced by 75 percent in PVC plants and 90 percent in VC plants. Such reductions can be achieved by employing best available control technology which includes a variety of control measures that could be in place from within several months to two years after promulgation of regulations. Each plant would likely use different combinations of such measures to achieve the necessary reductions. Currently available information indicates that such reductions should result in ambient air levels which present no established risk to health or welfare. The cumulative costs of the control technology are estimated to increase the cost of PVC resin by about four percent.

An expanded monitoring program to gain additional data at selected plants to assist in setting an air standard is needed. Twenty-four hour integrated samples taken during a period of several days or longer at a number of sites around representative complexes are desirable. To the extent possible in-plant activities should be correlated with external readings. Since no previous monitoring was done at fabrication or copolymer plants, they should also be included.

Water Pollution

In view of its low solubility and volatility from water, VC is not currently a candidate for the hazardous substances list under Section 311 (spills) of the Federal Water Pollution Control Act. Similarly, VC in water has not been shown to present a threat to aquatic life, and therefore there is no basis at present to develop water quality criteria under Section 304(a) or to consider designating VC as a toxic effluent. At the same time, in view of the monitoring data indicating discharges up to a level of 20 ppm of VC from at least two PVC resin plants, further investigations of its effect, if any, on the aquatic environment seem in order.

The Effluent Guidelines for the Plastics Industry promulgated by EPA cover only PVC polymerization activities and not compounding or fabrication activities. However, some of the potentially most troublesome water effluent problems relate to the toxic materials used in the compounding process.

Also, as previously mentioned, the possibility of toxic additives in PVC products leaching into the aquatic environment is of concern. Further clarification of these problems is needed prior to considering regulatory action.

Solid Waste Disposal

Problems associated with disposal of PVC products through incineration and burial are discussed in detail in Appendix VIII. The emission of HCl is the only clearly identified incineration problem at present although there are many uncertainties concerning the fate of PVC additives during the incineration process. There are well accepted environmentally sound landfill techniques that should adequately contain PVC products. At the same time there are sufficient uncertainties -- particularly with regard to additives -- in both of these areas to warrant more detailed investigations in the months ahead. There is no evidence at present that PVC will revert to VC during incineration or as the result of biological or chemical activity during environmental exposure.

Disposal of the solid and semi-solid wastes from VC/PVC plants poses many problems encountered with hazardous wastes in general. One particular concern is the disposal of tars -- a concern that was heightened last year when a large number of cattle were contaminated due to poor handling and disposal practices involving hexachlorobenzene wastes.^{1/} Another problem is the possible exposure of personnel at landfills to sludges containing up to 3000 ppm of entrapped VC which might be escaping. Given the widespread concern at the local level over VC/PVC activities, EPA guidance on handling such hazardous wastes would be welcomed. In the longer term the steps called for in the proposed Hazardous Waste Management Act might be particularly appropriate.

Ocean Dumping

The October 1973 criteria for evaluating ocean dumping permit applications prohibit dumping of organohalogen compounds, except for narrowly defined trace amounts, and compounds which may combine with other substances to form organohalogens in the marine environment. These criteria cover the principal earlier concerns over ocean disposal of the by-products of VC/PVC manufacturing activities which were triggered by reports of fish kills in the North Sea from disposal of tars and of the buildup of organohalogen compounds near Puerto Rico. Unfortunately, earlier ocean disposal practices for tars in the Caribbean also have had adverse effects on marine life.^{2/}

GENC 013333

Drinking Water

Currently there are no data on VC concentrations in community water supplies, primarily because no one has ever looked for VC. Conceivably, it could be present in drinking water. Possible sources are PVC polymerization plants just upstream from water intakes and from PVC products used in the distribution system such as PVC pipe and storage tank liners.

Monitoring a few selected water supplies should provide a basis for assessing VC concentrations that may be found in water supplies from both industrial pollution and product contamination. Adequate sampling and analytical procedures will of course be required to insure the soundness of the results. The results should be used to determine the need for additional sampling and possible research requirements.

Proposed Toxic Substances Control Act

An important authority which is currently missing is the Toxic Substances Control Act. The requirements for reporting of industrial production data envisaged in the Act would enhance knowledge of the types and extent of different uses of VC. The testing provision would be the basis to obtain much needed data -- and particularly data on toxicity and persistence -- for assessing the risks associated with low concentration levels of VC, including those levels that are likely to persist beyond the workplace. The proposed regulatory provisions would provide a mechanism for addressing those products using VC not now subject to regulation under other laws. Also, if considered appropriate, steps might be taken to limit the amount of unreacted VC in certain PVC products which could eventually migrate out of these products to pose an unnecessary risk.

Supporting Research Activities

As a component of the national effort to clarify the health risks associated with VC, the Agency plans to support a toxicological effort at the University of Cincinnati. These studies are designed to determine the effects of VC on the developing fetus, to determine changes of VC toxicity caused by nutritional imbalance and interactions with other common chemicals, and to develop cell culture techniques for rapid screening of the oncogenic potential of VC and related compounds. Also, epidemiological studies of neighborhoods near PVC activities are scheduled to complement related efforts of other Government agencies.

Regulatory Interests of Other Agencies

Aerosol Sprays

Early this year evidence indicated that some supplies of hair sprays containing VC were still on the market, and the Food and Drug Administration (FDA) requested that all known manufacturers recall these

supplies. In early April, three manufacturers initiated recalls for hair spray and other drug and cosmetic aerosol products. On April 22, FDA published a notice of proposed amendments to the Federal Food, Drug and Cosmetic Act concerning the use of VC as an ingredient, including propellant, of (a) aerosol drug products, and (b) cosmetic aerosol products (39 FR 14215). At the same time, but in a separate notice, FDA requested a list of all marketed drug products containing VC as an ingredient or packaged in containers of or lined with PVC (39 FR 14238). On August 26, FDA published regulations which (a) banned the use of VC in cosmetic aerosol products, and (b) required a new drug application as a condition for marketing drug aerosol products when VC is used as an ingredient (39 FR 30830).

The Consumer Product Safety Commission has undertaken two steps. An information gathering process was initiated in May to determine the specific aerosol products containing VC which are being or have been used (39 FR 16511). The Commission has identified more than 25 aerosol products containing VC and is currently continuing its analyses. On August 21, the Commission promulgated a regulation, effective from October 7, banning as hazardous substances "self-pressurized products intended or suitable for household use that contain VCM as an ingredient or in the propellant" (39 FR 30114).

Worker Protection

The Occupational Safety and Health Administration (OSHA) of the Department of Labor, responsible for worker safety, determined that VC levels exceeding 50 ppm in the workplace present a hazard and on April 5 set an emergency temporary standard at that level (39 FR 12342). To initiate the process for setting a permanent standard, on May 10, OSHA proposed lowering the standard to the level of detection, defined at 1 ppm plus or minus 0.5 ppm (39 FR 16896). Public hearings to gather information for a permanent standard and to assist OSHA in making a final judgement as to the adverse effects of VC and the appropriate levels of exposure to workers were held in June and July. The final standard is to be set by October 5, 1974.

Much of the information being developed by OSHA is of direct relevance to EPA concerns, and particularly concerns over an air standard. Even more importantly the regulatory action taken by OSHA within the next several months can have a profound effect on the need for and character of action by EPA. If OSHA uses health data as the basis for its standard, it is important that the interpretation of the data not be inconsistent among agencies. Also, OSHA should be encouraged to recommend control techniques which will not simply vent VC to the environment external to the workplace.

Unreacted VC Monomer in PVC Products

Early last year reports were received of possible migration of VC to distilled spirits and wines packaged in PVC bottles under an experimental program authorized by the Department of Treasury. Subsequent investigations by FDA confirmed that residual VC had migrated from the PVC

into various distilled spirits and wines. Since there were no available toxicological studies supporting a safe level of VC in food, FDA published a proposal which in essence would preclude the use of PVC resin in contact with alcoholic food (39 FR 12931). At the same time, the Department of Treasury withdrew the approval of the experimental use of PVC bottles to contain distilled spirits. Since there was no indication, at that time, that VC migration occurred from PVC in contact with non-alcoholic foods, FDA proposed a regulation which identified criteria for safe use under the prior sanction (38 FR 12931). Recently, however, FDA has received data confirming VC migration from PVC packaging into a variety of foods and currently is considering limitations on the use of PVC in food packaging.

The Consumer Product Safety Commission has not taken a position on unreacted monomer in consumer products.

Transportation Handling

The problems associated with VC have heightened the concern of the Department of Transportation (DOT) as to whether any changes in its regulations are warranted since some commercially important chemicals have been identified as carcinogens. A major question is whether a single exposure to these chemicals can cause cancer. At present, DOT is considering the desirability of changes in labeling requirements and/or packaging requirements for carcinogens but has not yet reached a conclusion.

In July 1974, DOT published (a) proposals to amend the bulk dangerous cargoes regulations for the carriage of VC (39 FR 26752), and (b) a requirement for protective head shields on uninsulated tank cars carrying liquefied flammable compressed gases such as VC (39 FR 27572). In a related action in August, DOT proposed amending the requirements for handling freight cars carrying hazardous materials to include those placards as "Dangerous" (39 FR 29197).

Related Research Activities

The Center for Disease Control (CDC) and the National Institute of Occupational Safety and Health (NIOSH) are maintaining a nationwide surveillance network of all cases of angiosarcoma of the liver which have been reported since 1965. For each case identified, the health history of the individual will be reviewed and analyzed to determine if there was any connection with VC or PVC plants. CDC/NIOSH are also conducting studies to determine if other cancers and other mortality causes are associated with exposure to VC. In these studies, pathological information will be obtained from hospitals. A CDC survey among meat wrappers in Houston, Texas, should determine if chemicals produced upon combustion of PVC film may be implicated in "meat wrappers asthma."

CDC/NIOSH are conducting a comprehensive epidemiological survey of workers from 11 polymerization and fabricating plants. Employee medical records are being subjected to intense screening to determine the scope and magnitude of VC effects. Hospital data obtained in this study are being sent to the angiosarcoma network. NIOSH is also planning studies to determine the levels of exposure at fabricating plants and to determine if cosmeticians exposed to VC from aerosol hair sprays have had any cases of liver angiosarcoma.

The Consumer Product Safety Commission plans to support rodent experiments to determine the effects over a lifetime of single dose and/or intermittent exposures of VC at several dose levels. Reproductive, mutagenic, and teratogenic effects may be considered.

The National Institute of Environmental Health Sciences (NIEHS) has taken an active role in bringing together interested Government agencies, industry, and the academic community to begin to assess the public health implications of a broad range of chemicals used in the plastics industry. An initial meeting in Pinehurst, North Carolina, from July 29 to 31 was designed to set the stage for a continuing effort to sort out research priorities within Government and industry, as well as to highlight the types of considerations that should surround regulatory actions in this field.

The National Cancer Institute is providing pathology services (human and experimental animal) and in collaboration with the Armed Forces Institute of Pathology is establishing a case registry for VC associated diseases.

The National Bureau of Standards (NBS) is conducting research on the development of calibration methods for EPA. This includes preparation of standard VC air mixtures in the ppm range and of charcoal sampling tubes with known VC loadings. NBS is also doing research to develop more sensitive techniques for the detection of VC in the atmosphere.

Role of Industry

During the past several months industry has cooperated extensively with the Task Force and with individual Agency offices in the assessment of problems associated with VC/PVC activities. Summarized below are some of the areas of greatest concern involving major industrial commitments.

Reducing Discharges of VC and Other Toxic Chemicals

There is no doubt that industry has taken and can continue to take a variety of immediate steps at relatively little cost to reduce the VC losses at VC and PVC polymerization facilities. During the past few months many plants have already started to tighten maintenance and operating procedures; other plants are installing improved pumps, seals,

and disconnect devices; while still other plants are introducing more significant process changes. One company is reportedly spending \$3 million to tighten the processes at a single PVC facility; another company reports that it has 100 engineers working to introduce modifications that will dramatically cut VC losses at several plants.

In the longer run significantly different approaches to the polymerization process may be in order. Clearly, the opening of the reactor kettles is a major source of discharges, and a continuous rather than batch process should be considered as an example of a design change to reduce VC losses. In the batch process the trend toward larger kettles will probably accelerate. At the same time some companies may elect to mark time with regard to major modifications or significant new departures until the initial OSHA and EPA regulatory approaches become clearer.

A number of other toxic chemicals are also associated with VC/PVC activities. As previously mentioned the disposal of tars and the discharges of toxic metals at PVC compounding plants are of particular concern. A number of the troublesome chemicals may be better known to industry than Government, and industry should not delay in taking corrective actions even though these chemicals have not yet been designated for control by the Government.

Medical Surveillance

Clearly, VC concerns have triggered extensive medical surveillance programs of VC and PVC workers throughout the industry. These programs should become routine to cover a far broader swath of chemicals at VC/PVC and other chemical complexes. Published analyses of the results of such programs would be very valuable to EPA and other agencies.

In addition, industry has a responsibility to support medical surveillance programs for residents in neighborhoods adjacent to VC/PVC complexes and other types of plants releasing chemicals into these neighborhoods. The character of such surveillance will obviously depend on the type of chemicals involved and the arrangements that can be worked out by industry with local health authorities. ✓

Fenceline Monitoring for Chemical Discharges

Traditionally, the chemical industry has conducted very little fenceline monitoring not required by Federal, state, or local agencies to determine the chemical discharges leaving plant property. During the past several months, however, monitoring for VC has become a concern, and hopefully this concern will rapidly spread to other chemicals. Clearly, a plant manager should know the chemical mix of the air emissions ✓

drifting over the plant fence into nearby neighborhoods. Similarly, he should be fully aware of the chemical cross section of his liquid and solid waste streams. Thus, a far more intensive physical monitoring effort on the part of industry is needed -- monitoring not only for gross pollution (e.g., biological oxygen demand, chemical oxygen demand, total suspended solids) but for individual chemicals as well, including VC and related chlorinated hydrocarbons.

Toxicological Testing of VC

Until the recent revelations concerning the relationship of VC to angiosarcoma of the liver, the efforts of U.S. industry to clarify the chronic toxicity of VC were nearly negligible, despite the commercial importance of VC. The industrial studies of the early sixties and the recent Manufacturing Chemists Association (MCA) toxicological study on behalf of a number of companies have not been adequate, in terms of direction, scope, or quality. Even the additional toxicological studies which have been proposed by MCA calling for animal exposures down to 1 ppm of VC may not be sufficient if the objective is to understand in some detail the biological effects from the types of dose levels likely to be found in the workplace and beyond. This proposed effort, while important, is but a small step toward a very complicated problem. Also, a number of experts have expressed concern over the design and statistical significance of the studies as currently planned.

Testing for Persistence and Environmental Fate and Effects of VC and PVC

A related area is industry's responsibility to clarify the environmental fate and effects of the chemicals it manufactures, and in this case the behavior of VC in water and air (including degradation products) and the fate and effects of products containing PVC in soil and water. This is a new area which has not attracted sufficient attention from industry but which is of crucial importance in assessing environmental impacts of chemical activities. Governmental leadership will probably be essential in helping to point the way as to the types of tests and analyses that are the most appropriate.

Testing for Levels of Unreacted Monomer in PVC Resins and PVC Products

In view of the likelihood that FDA will limit the levels of unreacted VC allowed in PVC food packaging, industry has recently accelerated efforts to analyze the levels of VC that are present in PVC resin used for food packaging and in the packaging itself. This relatively inexpensive procedure should be extended to other types of products as well. It is particularly important that the manufacturers of resin, who in general are well equipped to carry out the necessary sampling and analysis, advise their customers (i.e., the fabricators) of the quality of the resin in terms of unreacted monomer in addition to the usual quality criteria. The fabricators in turn have a responsibility to be aware of the levels of unreacted monomer that persist in the products that eventually reach the marketplace.

REFERENCES

The technical information presented in this Section is based principally on informal communications with the concerned EPA offices, other Federal agencies, and industrial representatives. Two relevant publications not cited in the Appendices are identified below:

1. Environmental Contamination from Hexachlorobenzene, Office of Toxic Substances, Environmental Protection Agency, July 20, 1973.
2. Aubert, M., "Effect on the Marine Environment of the Combustion at Sea of Some Industrial Waste", Center of Biological Studies and Research and of Oceanographic Medicine (C.E.R.B.O.M.), Nice, France, January 1974.

RECOMMENDATIONS

This Section sets forth the recommendations of the Task Force concerning steps that should be taken by the Agency and steps that the Agency should encourage industry to take in the near term to (a) help clarify and reduce the risks associated with VC/PVC activities, and (b) take full advantage of our experiences with these chemicals in addressing other chemicals.

Regulatory and Directly Supportive Actions by EPA

Recommendation #1:

An air standard for VC should be established as soon as practical under the Clean Air Act for VC and PVC polymerization plants and, if warranted by further investigations, for PVC fabrication plants. The Agency should determine the ambient levels that are likely to be achieved and, to the extent possible, the health risks associated with such levels

Recommendation #2:

Additional ambient air monitoring should be carried out to support regulatory action under the Clean Air Act. These efforts should include sampling at a number of carefully selected sites around a few VC, PVC polymerization, and PVC fabrication plants. The monitoring measurements made at these facilities should be correlated with specific in-plant activities such as reactor venting.

Recommendation #3:

More detailed material balance studies should be conducted, in cooperation with industry, at a few VC and PVC polymerization plants. Specific VC leakage points should be more clearly identified, and attempts should be made to correlate the magnitude and timing of the estimated losses with the levels of VC detected in a monitoring program.

Recommendation #4:

A program should be initiated to determine whether and to what extent background levels of VC are present in the ambient air -- indoors, and outdoors--due to the presence of PVC products.

Recommendation #5:

A limited VC monitoring program should be undertaken of drinking water supplies which might be contaminated from VC discharges from nearby PVC plants. Prior to undertaking the program, sampling and analysis procedures should be carefully reviewed and refined as necessary.

Recommendation #6:

A study should be conducted to determine the amount of VC migrating out of PVC products used in water distribution systems--such as PVC pipe or storage tank liners. Prior to undertaking the program sampling and analysis procedures should be carefully reviewed and refined as necessary.

Recommendation #7:

To insure comparability of results between laboratories EPA should further develop its interim method into a standardized method for monitoring levels of VC. Concurrently, the Agency should also investigate the feasibility of developing continuous air monitoring devices.

Recommendation #8:

Monitoring and bench-scale studies should be conducted around industrial storage and disposal sites and municipal disposal sites to determine the types and quantities of toxic substances leached or discharged out of (a) semi-solid and solid wastes generated by VC/PVC facilities, or (b) PVC products discarded by consumers. If these studies indicate that there could be a health or environmental hazard, guidelines should be developed to control the storage and disposal of these wastes.

Recommendation #9:

The responsible Office should continue to support currently planned VC toxicological studies.

Recommendation #10:

The responsible Office should continue to support currently planned VC epidemiological studies.

Recommendation #11:

Industry More intensive studies should be conducted on the behavior of VC in the atmosphere and in the aquatic environment, and particularly on its degradation products and related chemical reactions. These studies should be supported by both industry and Government.

Recommendation #12:

Industry The industries covered by the Effluent Guidelines for the Plastics Industry promulgated under the Federal Water Pollution Control Act should be expanded beyond the production of resins to include the compounding and directly associated activities that result in discharges into the water of toxic metals and other chemicals of particular concern.

Recommendation #13:

Enforcement efforts, including spot checks of manufacturers, distributors, and retail outlets, should continue to be pursued vigorously to insure that pesticidal sprays containing VC as a propellant are removed from the channels of trade as rapidly as possible.

Recommendation #14:

Regional, State, and local authorities should be kept fully informed of Agency efforts under the Clean Air Act and other authorities. As the Federal approach becomes clearer, they should be encouraged to undertake supportive actions as appropriate.

Recommendation #15:

The Agency should build on the experience gained in responding to the problems associated with VC in strengthening its organizational, manpower, and contractor resources to anticipate and respond to similar situations involving other chemicals. Readily available information on the handling of VC should be made available to the Regional Offices to assist them in responding to rail or barge accidents resulting in the release of VC.

Recommendation #16:

Laboratory procedures for safe handling of VC should be developed and distributed to all EPA laboratories. Consideration should be promptly given to how such procedures can most effectively be developed for a number of carcinogens that are likely to be of concern to the Agency.

Recommendation #17:

Should the Toxic Substances Control Act be enacted, prompt consideration should be given to the need for and feasibility of (a) requirements for industrial testing of the toxicity of VC at low ambient levels and the persistence of VC in different media, and (b) limitations on the levels of unreacted VC monomer in selected PVC products.

Recommendation #18:

The Agency should continue its leadership role in bringing together the interested Federal agencies to exchange views on regulatory actions, supporting activities, and research projects directed to problems associated with VC and PVC. In addition, an appropriate interagency mechanism should be developed to address a broader spectrum of potential problems associated with the plastics industry.

Recommendation #19:

Industry EPA should exercise leadership in stimulating Governmental and industrial efforts to analyze in depth the other high volume chemicals (e.g., top 50 in terms of pounds of production) to identify those which deserve additional testing or controls to clarify or reduce potential environmental problems.

Steps by Industry

Recommendation #20:

Industry All possible steps to tighten up operating and maintenance procedures to reduce VC and PVC losses at VC, PVC polymerization, and PVC fabrication facilities should be taken promptly without waiting for further Governmental regulatory actions. R&D efforts should be expanded to develop new approaches to reduce losses during polymerization, such as continuous flow systems.

Recommendation #21:

Industry Each VC and PVC resin facility, and indeed chemical complexes in general, should have up-to-date information on the character and extent of the chemical pollutants that are leaving the plant property as air, water, or solid waste discharges or degradation products. A systematic monitoring program operated by industry at the fence line and beyond will in many cases be essential to ascertain the nature of the pollutants reaching nearby neighborhoods.

Recommendation #22:

Industry The levels of unreacted VC monomer in all grades of PVC resin should be routinely ascertained and purchasers of the resin should be advised accordingly. Also, analyses of the rates of release of VC monomer from PVC products should be expanded.

Recommendation #23:

Industry The Manufacturing Chemists Association should, in consultation with interested Government agencies, carefully reevaluate its planned VC toxicological experiments at low doses to insure that the design is (a) statistically reliable, and (b) relevant to the ambient air concerns of EPA.