# VINYL CHLORIDE: RISKS AND BENEFITS

The use of chemicals in our society is so common that we tend to take their benefits for granted. Chemicals play an essential role in modern agriculture, industry and public health. Today's style of living depends on chemicals and would be inconceivable without them.



But as our ability to make and use chemicals grows, so does our concern for their possible undesirable effects. When we learn of possible harmful effects of a chemical which is performing very useful functions, we are faced with several alternatives. Should we ban it altogether? Should we carefully restrict its use? Should we continue to use it without restrictions since only "possible" harmful effects have been suggested? To help us select the best course of action, we should examine both the risks and benefits involved. With this information, we are in a better position to make a rational decision rather than one based on intuition.

This background paper discusses risks and benefits for one chemical --vinyl chloride--and documents the following four key points:

- Vinyl chloride monomer, the raw material used to make polyvinyl chloride plastics, offers many benefits which make it virtually indispensable in our society.

- Industry workers are working in a safe environment. Based on a wide variety of epidemiological human health studies, the current Occupational Safety and Health Administration (OSHA) vinyl chloride standard provides a wide margin of protection for the industry's workers.

- Current standards limiting emissions ensure that public health in communities surrounding VCM plants is being adequately protected. There is no evidence of an excess number of cases of angiosarcoma of the liver (a rare form of cancer) in communities surrounding vinyl chloride plants and no evidence that public health will b materially improved by a further tightening of the Environmental Protection Agency (EPA) standards limiting vinyl chloride emissions.

- One of the most outstanding applications for PVC is in food packaging. There is no reasonable likelihood of vinyl chloride monomer getting into the diet from polyvinyl chloride packaging materials. Even if this monomer did migrate from the package into the food, there is no scientific evidence showing that residual vinyl chloride monomer at the levels found in PVC food packaging products is carcinogenic.

The Vinyl Chloride Industry

Polyvinyl chloride (PVC) is produced from vinyl chloride monomer (VCM), a gaseous industrial chemical, by a process called polymerization. Important for making industrial and consumer products for over 35 years, PVC has grown to be the second most widely used plastic in America. Production in 1978 by 21 U.S. manufacturing companies was 5.7 billion pounds, an 8 percent increase over the 5.3 billion pounds produced in 1977.

Because of its versatility, PVC has important applications in building and construction, the motor vehicle industry, apparel and home furnishings, phonograph records, plastic pipe and communications equipment as well as in miscellaneous products from bottles to meat wrappings and from credit cards to medical tubing.

About 1,500 U.S. workers are engaged in producing vinyl chloride monomer and 5,000 are involved in polymerization of the gas into PVC. In addition, an estimated 700,000 men and women have jobs involving the manufacture of products from PVC. They work for the transporters, processors and fabricators who mold, extrude or otherwise form PVC resin into finished plastic products.

One way to measure the impact of the vinyl chloride industry on our economy is to look at what would happen if companies in the PVC resin industry were forced to shut down production. When the Occupational Safety and Health Administration in 1974 announced that it proposed to replace the vinyl chloride monomer Emergency Temporary Standard of 50 parts per million (50 ppm) with a permanent "non-detectable" tolerance level, the companies in the PVC resin industry stated they would be unable to meet the newly proposed standard. The research firm Arthur D. Little, Inc. was then commissioned by The Society of the Plastics Industry, Inc. (SPI) to identify and estimate the loss in employment and domestic production that would be generated by such an event.

The conclusions reached in the Arthur D. Little analysis were that "an immediate shutdown of all PVC resin plants and the subsequent unavailability of PVC resin could result in a loss of between 1.7 and 2.2 million jobs in consuming and related industries and a loss of domestic production value of $65-90 billion annually."

When OSHA changed its proposal from "non-detectable" to exposures that would not exceed 1 ppm average for an eight-hour period, the standard became technologically feasible, although still extremely difficult and costly to achieve.

In brief, vinyl chloride monomer and its polymer, PVC, have become virtually indispensable in our society today, a clear indication of the many benefits this versatile chemical has brought to American life.

Vinyl Chloride and Health

While the social and economic benefits of vinyl chloride are one side of the coin, on the other side are the possible harmful health effects from high dosage exposure to the chemical. In recent years, concern has been expressed by the manufacturing companies, their employees, the government, scientists, environmentalists and the media about the safe manufacture and use of vinyl chloride. This concern has been in three general areas.

- Occupational health -- the effect on workers in vinyl chloride monomer plants and PVC polymerization plants.

- Community health -- the effect on residents in areas surrounding vinyl chloride monomer manufacturing and polymerization plants.

- General public health -- the effect through possible ingestion of foodstuffs packaged in bottles or various types of wrappings made of PVC.

The Occupational Health Question

In January 1974 three cases of angiosarcoma of the liver, an extremely rare type of cancer, were discovered among workers exposed over a period of many years to high concentrations of vinyl chloride monomer. Ultimately, extensive research has shown that over the past 16 years there have been a total of 23 deaths from angiosarcoma in six U.S. plants and approximately 48 in other countries. As a result of these findings, OSHA in late 1974 announced regulations to drastically reduce worker exposure to vinyl chloride.

The new limitations set exposures so as not to exceed one part of vinyl chloride per million parts of air (1 ppm) averaged over an eight-hour day. To put these infinitesimal figures into perspective, one part per million in distance is approximately the same as one inch in 16 miles; in time, one minute in two years; and in weight, one ounce in 32 tons.

The new regulations greatly reduced occupational exposure to vinyl chloride. From 1951 to 1974 the recommended maximum average for worker exposure was 500 ppm. In 1974, OSHA issued an Emergency Temporary Standard reducing the exposure to 50 ppm where it remained until the 1 ppm standard took effect in April 1975.

When angiosarcoma of the liver was found in PVC workers in 1974, a number of steps were soon taken reducing occupational exposure and an extensive series of tests on animals was started. Retrospective studies were made of liver angiosarcomas contracted by vinyl chloride workers. In addition, comparison studies were made of causes of death between vinyl chloride workers and the general population.



A quantitative risk assessment for community exposure to vinyl chloride was made for the Environmental Protection Agency. Professor Richard C. Wilson of the Harvard University Department of Physics, in reviewing the analysis, stated that the EPA report was based primarily on early animal studies and, when compared with later epidemiological data, was "more pessimistic than need be."

Two recent industry studies administered by the Chemical Manufacturers Association (formerly the Manufacturing Chemists Association) examined the effects on rats of exposure to vinyl chloride. The results of the effects on rodents were then extrapolated to humans with appropriate adjustment for metabolic factors. Based on the studies it was predicted that there would be one to two angiosarcomas if 100 million workers were exposed to 1 ppm of vinyl chloride (the current standard) daily for 35 years. Since there are no more than 6,500 VCM and PVC polymerization workers in this country, the real lifetime risk is almost zero. To put this into further perspective, the

Statistical Abstract of the U.S. and Mortality Tables show the lifetime accident risk for railroad workers is 12 in every 100,000, and for commercial airline pilots is six in every 100,000.

In citing risk levels, it is sometimes overlooked that a risk level is not constant. For example, a risk level of one in one million means that the actual risk could vary anywhere from zero up to one in one million as the upper limit.

Numerous studies have been undertaken in the past five years to identify a "safe level" for occupational exposure to vinyl chloride. The results of these studies show that the current OSHA standard of 1 ppm provides an ample margin of protection to the health of industry employees.



The Community Health Question

In February 1974, following the discovery of worker deaths from angiosarcoma, the Environmental Protection Agency began studies to determine if any health hazard existed for people living in the vicinity of vinyl chloride monomer or PVC resin plants.

After nearly three years of investigation, on October 21, 1976, the EPA promulgated regulations to reduce vinyl chloride

emissions (and, consequently, community exposure) by approximately 95 percent. EPA had estimated the five-mile radius annual average of vinyl chloride to be 17 parts per billion (17 ppb) in 1974. Its new regulations were intended to reduce these exposure levels to less than one part per billion when the industry reached full compliance in 1978.

The two model EPA calculations, which estimated that the average vinyl chloride exposure for the 4.6 million people living within five miles of VCM and PVC resin plants was 17 parts per billion (17 ppb), were later revised to estimate exposure levels of less than 10 parts per billion (10 ppb).

In the rule-making process, SPI and various companies in the industry submitted medical, technical and legal data to EPA. Included was a report to SPI by the environmental consulting firm of Dames and Moore which established that the original EPA estimate of 17 ppb of vinyl chloride as a yearly average exposure within five miles of vinyl chloride installations was far too high. The actual average exposure levels today are in the range of 0.2 ppb, according to the Dames and Moore study.

While the risk of angiosarcoma to the community resident by this exposure to VCM is very low, its meaning can only be grasped by a comparison with other risks. For example, the theoretical risk of cancer from exposure to VCM is less than

that of annually smoking 1/15 of a cigarette, drinking 1/3 ounce of wine or 1-1/2 cans of diet soda or eating 1/2 tablespoon of peanut butter.

In brief, all existing medical and technical data indicate that the EPA standards, originally promulgated in October 1976, provide an ample margin of protection to community health in the neighborhoods around vinyl chloride monomer and PVC resin plants.

The Vinyl Chloride Migration Question

The vinyl chloride migration issue arose in 1973, when a manufacturer of distilled alcoholic beverages reported to the U.S. Treasury Department's Bureau of Alcohol, Tobacco and Firearms (BATF) the presence of vinyl chloride in gin and vodka packaged in experimental PVC bottles. As a result of the report, the BATF allowed the experimental bottle permit to expire and permanent authority was not granted for the further use of the bottles for alcoholic beverages. The Food and Drug Administration (FDA), which is responsible for "alcoholic foods," then proposed a regulation banning the use of PVC for packaging all alcoholic foods but reaffirming its

"prior sanctions" for all other uses. In addition, FDA intensified its study of the question of vinyl chloride migration from food packaging.

In July 1975, the Health Research Group, a Ralph Nader affiliate, petitioned the FDA to ban all PVC food packaging materials completely. The FDA responded by proposing a ban on all rigid and semi-rigid PVC products. In doing so, however, the FDA stated that it had reason to believe there was "no migration" from plasticized PVC film, can and cap liners, coatings, gaskets or flexible tubing and would reaffirm its "prior sanctions" for their continued use.

Through intensive effort by the plastics industry, the residual VCM in rigid and semi-rigid products has been reduced from as much as 500 ppm to as low as 2 ppb. Furthermore, at these levels, recent data indicate that the remaining 2 ppb vinyl chloride monomer is so tightly bound in the polymer matrix that migration is impossible. Therefore, a finding of "non-detectable" with an analytical method sensitive to two parts per billion (2 ppb) should assure virtually absolute safety.

Although it has been suggested that general public exposure may occur through ingestion of residual vinyl chloride monomer which may have migrated from PVC food containers to the food or drink, the data cited above indicate this does not happen today.

In short, there is no scientific evidence showing that vinyl chloride monomer at the levels potentially found in PVC food packaging today poses any risk. FDA currently is reassessing its previously expressed position regarding proposed regulations for the use of PVC in food packaging.



Comparing Risk and Benefit

The importance of having some type of risk/benefit calculation was clearly stated in 1976 in a report by the Federation of American Scientists as follows:

> "There is needed some simple measure of cost and benefit that would make widely different risk situations comparable so as to attempt to maintain, in different areas, roughly similar standards for spending government and industrial funds to save lives. Without such a standard, as economists will sense immediately, cancer-avoiding expenditures cannot be spent efficiently. And, in addition, the public will have the greatest difficulty distinguishing minimal risks from large ones."

In his risk/benefit analysis of vinyl chloride, Prof. Wilson asks two questions: (1) "Is the risk worthwhile to society or to the individual worker?" (2) "At what costs can we reduce the risk further and is this worthwhile?"

As we have seen, the lifetime risk of contracting liver cancer from occupational exposure to vinyl chloride is about one in 100 million. The risk for a community resident living near a vinyl chloride plant is one possible cancer case per century

and is even less than that for the potential ingestion of vinyl chloride monomer from PVC food packaging materials. To reduce the hazards of vinyl chloride to current levels, the industry has spent close to $1 billion. To reduce the present infinitesimal risks by an additional factor would cost between three and four times as much as already spent. This could not be justified for the minute, if not theoretical, benefits that would be gained.

To Sum Up

All existing medical and technical studies for vinyl chloride indicate that the present OSHA and EPA standards provide an ample margin for safety for workers and for people living in the vicinity of vinyl chloride monomer and PVC resin plants. Studies also show there is no reasonable likelihood of vinyl chloride monomer getting into the diet from PVC food packaging.

In brief, when risk and benefit are compared for vinyl chloride, the data clearly show that occupational, community and public risks from inhalation and ingestion are very small compared to the many benefits that vinyl chloride and polyvinyl chloride provide to our society today.

###

August 1979

For Additional Information Contact:
The Society of the Plastics Industry, Inc.
355 Lexington Avenue, New York, N.Y. 10017
Phone: (212) 573-9400