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PVC AND HEALTH

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A BACKGROUND STATEMENT

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PVC AND HEALTH -- A BACKGROUND STATEMENT

Since mid-1974 the polyvinyl chloride industry has been the subject of widespread misunderstanding concerning its product and issues of occupational and public health. Much of the misunderstanding has arisen because of a lack of public knowledge of the nature of the product, PVC; of the research that has been done concerning PVC and health; and of the industry's role in, first, raising and, then, taking action on the issue. The purpose of this paper is to set forth the facts and get the record straight.

The paper documents six key points.

1. PVC became the second most widely-used plastic product in the United States because of its versatility and reasonable cost. Although the public is most familiar with its consumer uses, PVC is virtually indispensable in many industrial applications, with 43 percent of it being used by the building and construction industry.
2. As a result of the industry's efforts, the residual vinyl chloride monomer (VCM) content has been reduced to "non-detectable" levels in packaging products made from food-grade PVC resins. Therefore, there is no reasonable possibility of VCM migration into foods, drugs, cosmetics or other products contained in such packages.

3. When the possibility of a cancer connection first became apparent, the industry acted responsibly by informing the government and the public. It has conducted or supported most of the research on PVC and health.
4. Even before the federal Occupational Safety and Health Administration issued standards for worker exposure to VCM, the industry took the initiative to develop technology for substantially reducing employee exposure to VCM. It accomplished much more than it had felt was technologically possible when the standards were first proposed. In less than 24 months, plant exposure levels, and emissions into the environment, have been reduced a hundredfold or more.
5. When the Food and Drug Administration's concern over the presence of VCM in distilled alcoholic beverages was made known, the industry supplied research data to the agency and stepped up its research program, even before the discovery of any link between VCM and cancer.
6. The federal government's Center for Disease Control, after an extensive study, reported that the evidence to date did "not establish any association between (birth defect) cases and vinyl chloride exposure." The Center's study included analysis of the findings of Dr. Peter Infante, formerly of the Ohio Department of Health, which had been interpreted by the press as establishing a link between PVC production facilities and an increased occurrence of birth defects. A recent study identifying an apparent statistical excess of miscarriages and still births among

the wives of workers heavily exposed to VCM requires additional investigation before any conclusions can legitimately be drawn.

Polyvinyl Chloride and its Versatile Products

Polyvinyl chloride products have been part of the industrial and consumer scene for 30 years. PVC has grown to be the second most widely used plastic in America. U.S. consumption in 1975 of PVC and its copolymers was approximately 3.7 billion pounds, compared with 22.7 billion pounds for all plastics.

Polyvinyl chloride is an exceptionally useful, versatile product. It is tough and inert; it is resistant to fire, water and chemicals; it is an electrical insulator; it can be made rigid or flexible, thick or paper-thin; opaque or transparent. And its cost is reasonable.

Because it can do so many things economically, PVC was quickly put to use in an array of industrial and consumer products that range across the entire spectrum of the U.S. economy. PVC has long been familiar to the consumer in such everyday items as floor tiles, curtains, shoes, phonograph records, automobile upholstery, umbrellas and raincoats, luggage and sporting goods. It helps keep the household -- and business and industrial firms -- running through its use in telephone equipment, electrical insulation, house siding, pipe and tubing and many other applications where it can meet specific requirements economically.

For some fundamental uses PVC is virtually indispensable. To cite three examples: PVC has displaced virtually every other type of material for wire and cable insulation on the basis of its performance, cost and durability. In the medical field, such PVC products as blood bags and surgical-medical tubing have saved literally thousands of lives. The belting industry has stated that there is no known

substitute for conveyor belting made from PVC -- which would affect industries that range from coal mining to grain and processed-food handling.

The unique properties of PVC make it particularly useful as a packaging material. About 300 million pounds of PVC are used each year in the United States in the packaging of food. As a result it has become an important element in the national food distribution system. Bottles, tubes, blister packs, meat packaging, can liners, plastic films, and jar and bottle cap liners are among its many applications.

As with every other organic material, PVC burns when in the presence of high heat or fire. A principal combustion by-product of burning PVC is hydrogen chloride, an irritant gas which when mixed with water becomes hydrochloric acid. In contrast to odorless carbon monoxide, the "burning leaves" smell of hydrogen chloride warns of its presence immediately.

Fire and heat do not cause the depolymerization of PVC back into vinyl chloride gas.

Vinyl Chloride Monomer -- The Raw Material

The sole source of PVC is vinyl chloride monomer, a gaseous industrial chemical derived from petroleum or natural gas and chlorine. It is the raw material from which polyvinyl chloride resin is made by a process called polymerization. The process for PVC manufacture in large vessels or reactors was discovered in Germany in the 1930s and similar processes have been used to make PVC resin in the United States ever since production began here.

About 1,500 U.S. workers are engaged in producing VCM and 5,000 are involved in polymerization. In addition, an estimated 700,000 men and women have jobs involving the manufacture of products from PVC. They work for transporters, processors and fabricators who mold, extrude or form PVC resin into finished plastic products. And more than 2.2 million jobs in user industries depend on PVC, according to a 1974 study by the consulting firm of Arthur D. Little, Inc.

Like many other raw materials used to produce useful, safe end products, VCM had been known for years to have some worker related health effects. It was known by the medical profession to be an anesthetic; it also presented flammability and explosion risk potential. However, controls were devised for these problems. In 1962, a safety standard of 500 parts per million was adopted for worker exposure. The standard was adopted by the American Conference of Governmental Industrial Hygienists (ACGIH) after careful study of all available medical data on the subject. ACGIH is a professional governmental organization devoted to technical and administrative aspects of worker health protection. One of its principal functions is the promotion of standards and techniques in industrial health. Thus the standard was not an arbitrary one, but was set after professional evaluation of the situation. This same level was accepted in 1971 by the newly created Occupational Safety and Health Administration (OSHA).

A Health Problem Emerges*

Information on possible medical effects of VCM was scanty and incomplete

* For a chronological listing of important events in the VCM health situation, see Appendix I.

during the 1950's and '60's. Virtually all medical research on vinyl chloride was sponsored by the PVC industry. (The first inkling of a potential problem was a 1949 study of 73 workers in a Russian plastics fabricating plant. The study indicated evidence of hepatitis, but concluded that this was due to exposure to a polychloro-biphenyl plasticizer (PCB) used in the factory, and not to VCM.) The industry in the United States sponsored animal experiments from the mid '50's onward. Its efforts in searching out and calling public attention to medical effects of VCM are a matter of record:

- o In 1966, a reversible disease of the bones of the fingers (acroosteolysis) was discovered among some heavily exposed PVC reactor cleaners. Prompt and appropriate industrial hygiene efforts by the industry quickly eliminated this problem.
- o In 1970, Dr. P.L. Viola of the Regina Elean Institute for Cancer Research in Rome, Italy, and a medical director of Solvay & Cie., a leading European PVC producer, reported producing cancers in test animals at high exposure levels (10,000 to 30,000 ppm). The news media did not report these findings and the U.S. federal government, organized labor and the independent scientific community saw no need to take action. But four European PVC producers immediately began planning additional sophisticated animal inhalation research projects under the direction of Dr. Cesare Maltoni of the Istituto di Oncologia and Centro Tumori in Bologna, Italy. Two European companies undertook epidemiological studies of workers who had been exposed to VCM

at high and sustained levels. A condition of the research was that the results, whatever they might show, would be made public upon completion of the research in 1975.

- o In the United States, the Manufacturing Chemists Association in 1973 commissioned a study of all causes of death in vinyl chloride workers, to be done by Tabershaw-Cooper Associates of Berkeley, Cal. The preliminary results, announced in May 1974, showed that vinyl chloride workers, in the aggregate, experienced an overall mortality less than that of a comparable group of U. S. males. In workers with the highest exposure, there was an excess of deaths from liver cancer (primarily angiosarcoma), and from cancers of the respiratory system and brain, as well as from lymphosarcoma. These excesses were not statistically significant.
- o Early in 1973 a technical delegation from the U.S. PVC industry visited Dr. Cesare Maltoni in Italy, to review the progress of his research. Dr. Maltoni, whose work was supported by the European industry, had detected a variety of tumors in test animals at concentrations as low as 250 ppm. The American industry then requested a meeting with the National Institute of Occupational Safety and Health to call the Maltoni results to the attention of the U.S. government. The meeting was held in July 1973 and included discussions of various kinds of cancers that Dr. Maltoni had found.

- o In February 1973, the industry contracted with the Industrial Bio-Test Laboratories, Inc., of Northbrook, Illinois, for lifetime chronic inhalation studies using test animals. An interim report released in April 1974 indicated that exposure to vinyl chloride produces tumors in mice at levels as low as 50 ppm.
- o In April 1973, Dr. Maltoni revealed some of his preliminary results in a public meeting in Italy. Members of the U.S. government were present at the meeting.
- o In January 1974, a doctor at the B. F. Goodrich Company identified three cases of angiosarcoma, a rare type of liver cancer, among PVC reactor cleaners. The company announced publicly that it suspected VCM of being implicated in the deaths of these three workers at its Louisville, Kentucky plant.

The public announcement by B. F. Goodrich attracted wide attention in the press and immediately brought a variety of government agencies into the picture.

In the publicity that followed, the vinyl chloride industry was roundly criticized, including speculation that the industry had previous knowledge of the hazards of VCM but purposely withheld this information from government officials, its employees and the public.

The record does not support such charges. As noted previously, the industry has sponsored the majority of the medical research on VCM conducted to date (and essentially all of it conducted before 1974). Also, it was a member of the industry who made the first tenuous connection between VCM exposure and angiosarcoma in humans. This information was announced promptly to the public.

In fact, were it not for the actions taken by the VCM-PVC industry from 1970 onward, we might still know next to nothing about the health effects of VCM inhalation.

Action by the U. S. Government

Following the B. F. Goodrich announcement, five federal regulatory agencies immediately began investigations into the nature and scope of the hazard. They were:

1. The National Institute of Occupational Safety and Health (NIOSH), which conducts research and makes recommendations to the Department of Labor on occupational health standards.
2. The Occupational Safety and Health Administration (OSHA), a division of the Department of Labor which promulgates and enforces occupational health standards.
3. The Environmental Protection Agency (EPA), which sought to determine if VCM plant emissions into the atmosphere were a health hazard.
4. The Food and Drug Administration (FDA), which sought to determine if residual VCM was migrating from PVC food packaging materials into foods and beverages.
5. The Consumer Product Safety Commission (CPSC), which, along with EPA and FDA, had authority to control the use of VCM as a propellant in some aerosol sprays.

The Food and Drug Administration, the Environmental Protection Agency and the Consumer Product Safety Commission -- under their various authorities -- subsequently issued orders banning or recalling, or both, hair sprays, cosmetics, pesticides and other household aerosol products containing VCM as the propellant. The VCM-PVC industry in no way opposed these actions.

Occupational Health

When the link between VCM and cancer in humans made by B. F. Goodrich Company doctors was confirmed by their examination of the records of employees of a polymerization plant, they promptly notified officials of the National Institute of Occupational Safety and Health, as well as state medical officers, that it appeared that three long-term workers had died of a rare form of cancer, angiosarcoma of the liver.

This report was made to NIOSH and announced publicly on January 22, 1974. A week later it was discovered that another former employee of the same plant was found to have died of the same disease. This resulted in an extensive search by the industry through old medical records for other cases. Ultimately, 18 deaths, involving workers who had been exposed to high levels of VCM for many years, were confirmed in four U.S. plants, and 20 in other countries. These deaths occurred over a period of 15 years. The workers' jobs principally involved cleaning residue of PVC resin from the reactors in which it was produced. Their work thus resulted in high exposure to VCM over a period of many years.

OSHA's New Standards

After fact-finding hearings, OSHA promulgated an emergency temporary standard which lowered the maximum VCM limits from 500 parts per million (ppm) to 50 ppm. This decision was based primarily on preliminary reports from the Maltoni study that rats did not develop angiosarcoma at 50 ppm. On May 10, 1974, after Industrial Bio-Test reported that mice developed angiosarcoma at 50 ppm, the agency proposed a permanent worker safety standard which would reduce worker exposure to the "no detectable level."

Public hearings were then held by OSHA. The industry's position was essentially that the OSHA standard was unrealistic in three basic ways:

- o It did not take into account in a practical way the known medical and technological facts. OSHA relied heavily on animal studies in proposing its standard, even though more relevant human mortality data are available.
- o Its requirements were far in excess of what is felt to be realistically required to protect employee health.
- o Attaining the standard was not considered to be feasible employing the then existing technology.

The industry therefore recommended the adoption of a higher numerical standard than was finally proposed, with phased reductions over a number of years.

During the hearings, evidence was presented which clearly showed that the employee deaths from angiosarcoma were a result of conditions existing a decade or more ago, when exposure levels were many times greater than they are today. Data developed by the Dow Chemical Company showed no excess mortality from any

cause among long-term workmen exposed to levels below 200 ppm.

In October 1974 the agency announced a permanent standard for VCM which called for reducing exposure levels to 1 ppm averaged over an eight-hour day, with peak exposure levels not to exceed 5 ppm as measured over any 15-minute period. This standard was originally scheduled to go into effect January 1, 1975.

The standard further said that, during the first year, employers were to provide respirators for employees exposed to between 1 and 25 ppm, but that it was up to the employee whether he wanted to wear it or not. At exposure above 25 ppm, wearing of respirators was mandatory. After January 1, 1976, wearing of respirators would be mandatory for all workers whenever levels exceed the 1 ppm and 5 ppm ceilings.

The new rules applied not only to VCM and PVC resin plants but also to processors and fabricators including firms engaged in "transportation, storage, handling or use" of VCM and PVC resin, unless exposures were found to be below the so-called "action level" of 0.5 ppm.

The industry filed a petition for judicial review of the standards.

In January 1975, the court of appeals upheld the OSHA standards. It declared that OSHA is not restricted to setting standards that are feasible with known technology, but that it is permissible to set standards that may be achievable at some undetermined time in the future with technology as yet undeveloped.

Because of the judicial proceedings, the implementation date for the standards was delayed until April 1, 1975.

Meeting the New Standards

Nevertheless, industry members proceeded immediately to accelerate their efforts to reduce exposure levels. The industry's opposition to the "non-detectable" standard had been based principally on the virtual technical impossibility of achieving this standard and on the impracticality of using bulky air-line respirators that would be uncomfortable and would inhibit workers from moving around the job.

The regulations finally promulgated by OSHA were considerably different from those that were originally proposed. OSHA's change from "non-detectable" to a level of 1 ppm to 5 ppm brought the standard into the realm of technological feasibility, although still extremely difficult and costly to achieve. Since some fluctuation is apt to occur in even the best-controlled plants, the introduction of a peak gave the industry flexibility that was not available under the no-peak, no-detectable level, proposed standard. It introduced a new dimension into the solution of the design and development problems.

In addition, by permitting the use of "gas mask" type respirators at levels below 25 ppm, OSHA eliminated a major compliance difficulty with the standards.

The industry's all-out effort to meet the OSHA requirement has resulted in technological progress that PVC producers themselves did not feel was possible a year ago. The industry-wide cost will approach \$300 million and the achievements have to date far surpassed the expectations of industry executives and technical people alike.

For example, one producer announced in December 1975 that, using a variety of new technological developments, it had reduced the average level of vinyl chloride in the air of its plants to a range of from 1 to 3 ppm with employee

exposure much lower than that. The total cost of its efforts will be about \$42 million.

Central to the company's approach is a continuous stripping process which gives new efficiencies in removal of VCM and PVC resin. Newly polymerized resin is fed to the top of the stripping column while steam is fed to the bottom. The rising steam strips off VCM which is then collected for reprocessing.

Other PVC producers have been equally innovative and successful in developing technology to reduce exposure to levels not felt possible in 1974.

It should be emphasized that the hazards related to vinyl chloride in the manufacture of polyvinyl chloride involve the direct inhalation of unreacted vinyl chloride monomer gas by workers. There has never been any positive evidence to indicate hazards to employees who handle or transport products fabricated from PVC resin.

The Plant Community -- EPA and Emissions

The Environmental Protection Agency (EPA) established a vinyl chloride task force in February 1974. On May 31, 1974, EPA requested emission control data from manufacturers under provisions of the Clean Air Act and on June 11, 1974 the agency announced that preliminary monitoring test results showed "no scientific evidence to indicate that these emissions pose an imminent hazard to people living near these plants..."

EPA said nonetheless it would propose regulations to reduce VCM emissions by 75 to 90 percent of 1974 levels, even though only a few measurements above 1 ppm were recorded. The industry has been working steadily -- and openly -- on the development of these standards with EPA ever since.

On December 16, 1975, EPA Administrator Russell Train announced the proposed limitations on air emissions of vinyl chloride. These regulations were published in the December 24 issue of the Federal Register. The regulations will require the industry to reduce emissions of vinyl chloride from vinyl chloride and polyvinyl chloride plants substantially. However, the industry had already been working to reduce vinyl chloride in the work area to meet the OSHA standard on VCM, and had anticipated the necessity of minimum emissions from the plant to the surrounding community.

A public hearing on the proposed standards was held February 3, 1976, in Washington, D.C. At the hearing, the industry pledged to "do its best" to meet the standards, and urged EPA to provide leadership in establishing a joint research program involving labor and management, citizens groups and government, to find definitive answers to continued questions about the health effects of vinyl chloride in the atmosphere.

Additional comments regarding the technical aspects of the standards were submitted by the industry to EPA following the hearing.

The producers of VCM and PVC do not believe there is any current risk, nor has there been any prior risk, to the health of people who live near vinyl chloride gas and PVC resin plants.

This position is supported by a government survey of all angiosarcoma deaths in the United States between 1964 and 1974. Working on the questionable theory that there is no safe level for exposure to a carcinogen, government biostatisticians calculated that during this time period there should have been 10 excess deaths from angiosarcoma among those people living within five miles of

VCM and PVC resin plants in the U.S. The survey showed, however, that there were no excess deaths from angiosarcoma among those people.

The government report concluded: "This survey has produced no evidence that living around vinyl chloride plants is a risk factor in the occurrence of liver angiosarcoma."

In addition, at the EPA public hearing, Dr. William Marcus of EPA's office of toxic substances, stated that there is no evidence "that angiosarcoma has been produced by vinyl chloride monomer in the general population."

The focus of the health risk associated with the production and use of VCM has been on workers inside the plant. EPA's decision to seek strict emission controls on VCM is viewed by the industry as primarily a precautionary step in the best interests of the public.

The industry as a matter of principle is dedicated to assuring that the public health will never be threatened by the manufacture of vinyl chloride monomer or PVC resin.

Birth Defects -- No Relationship Established

Concern that VCM might prove to be capable of causing malformations or birth defects was raised because of isolated findings showing that VCM was capable of producing a mutagenic reaction in salmonella bacteria. Also, an increase in chromosomal breakage was found in a small number of heavily exposed PVC polymerization workers.

In August 1974, Dr. Peter F. Infante, formerly of the Ohio Department of Health, reported that birth records in three towns in eastern Ohio -- Painesville, Avon Lake and

Ashtabula -- that contained PVC installations indicated a rate of birth defects in each town significantly higher than the average for the state of Ohio and also for the balance of the three counties in which the towns were located. He further reported a major excess in birth defects of the central nervous system (CNS) and also in adult deaths from central nervous system cancer. In the paper reporting his findings, Dr. Infante had warned:

"These preliminary findings do not link polyvinyl chloride production facilities with the increased occurrence of congenital malformations and central nervous system tumors in adults but indicate the need for further study of possible contributing factors."

The press widely reported Dr. Infante's findings, but totally ignored his warnings that he had reservations about the significance of his data.

Faults in Infante Study

There are, in fact, serious unexplained discrepancies, unwarranted assumptions and other information gaps in his material.

For example, Dr. Infante also examined birth defect rates in nine communities without PVC facilities but located in the same general area as the three plant towns. Two of these nine were found to have birth defect rates higher than any of the communities with PVC facilities. He then went on to lump cases of central nervous system malformations from one of these two communities together with those from the three plant towns, even though this community was nearly 10 miles away from the nearest plant town.

This lumping of data from various communities is a most unorthodox procedure for a scientific investigation. When the data for each town is examined separately, they show two highly interesting phenomena:

- o One plant town did have over half of the observed CNS birth defects, but the non-PVC town had 25 percent of the total.
- o Another plant town, which has had a PVC facility for the longest period of time of all three communities, had no central nervous system defects at all.

Similar discrepancies occurred in the case of central nervous system cancers among adults because of Dr. Infante's lumping of data from PVC plant towns as much as 80 miles apart plus data from a town without a PVC facility.

Several other serious defects in the study cast additional doubt on its medical and scientific validity:

1. No attempt was made to determine whether any of the women involved had ever been exposed to VCM.
2. No measurement was made to determine if there was any VCM at all in the ambient air in these communities.
3. Dr. Infante did not interview any of the subjects.
4. He did not obtain the occupational histories of the mothers or fathers of the children registered as having birth defects.
5. He made no attempt to compare current birth defect rates with those existing before the PVC facilities were constructed.

Government Center for Disease Control Investigates

Because the Infante Study attracted wide publicity, the Center for Disease Control (CDC) of the U.S. Department of Health, Education and Welfare decided to investigate the possible relationship between vinyl chloride exposure and birth defects in humans.

CDC made a two-part study. The first part compared birth defect rates in hospitals in two widely separated cities with PVC installations -- one in Pennsylvania, the other in Painesville, Ohio (which was also investigated by Dr. Infante).

The second part of the CDC study involved a thorough investigation of the 15 cases of CNS malformation recorded at the Painesville Hospital from 1970-74. For each malformation case, two normal births were investigated as "controls" for comparison purposes.

The CDC concluded, on the basis of its own investigations and a thorough analysis of the existing research data, that while the possibility could not be ruled out that VCM might be teratogenic, the evidence to date did "not establish any association between (birth defect) cases and vinyl chloride exposure."

The results and conclusions of this research were also reported in the November 29, 1975 issue of Lancet, a prestigious British medical journal.

While the evidence compiled to date does not indicate a relationship between VCM exposure and an excess in birth defects, the industry nonetheless favors further objective and thorough scientific investigations in this area of mutual industry and public concern.

In this regard, the CDC is conducting an investigation into CNS birth defects in Charleston, West Virginia, where a PVC resin plant has been located

since 1938. According to press reports of the study, 53 children with CNS defects who were born between 1970 and 1973 have been identified.

As with the earlier CDC study in Painesville, researchers will attempt to contact the parents of each child to learn where they worked and how far they lived from the PVC plant, especially during early pregnancy. The findings in this parent group will be compared to those among a "control" group of individuals who had normal children.

Vinyl Chloride and Fetal Deaths

In early February 1976, Ralph Nader's Health Research Group released to the press the text of a study scheduled to be printed in a future issue of Lancet. The study, by Dr. Infante et. al., was conducted at a single PVC resin plant in Pennsylvania. It showed that the wives of workers exposed to heavy concentrations of VCM had a statistically significant greater number of still births and miscarriages than the wives of workers exposed to little or no VCM.

While the research results certainly merit further investigation, there are a number of factors in the study that have raised some doubts concerning the sweeping conclusions that have been reached from the research.

For example, the number of families participating in the study -- only 62 in the "exposed" group -- is quite small. Secondly, the wives themselves were not interviewed by the researchers, nor were their ages at the time of conception obtained. All data in the study was based solely on the "recall" of the husbands. Similarly, hospital or other medical records were not checked, nor was any attempt made to contact the wives' doctors for their possibly valuable input.

Even more importantly, there is no indication in the report that any attempt was made to correlate fetal death rates with either length or degree of exposure. This is especially vital in light of the fact that the husbands in the "exposed" group who were 30 years of age and older (and who presumably had the greatest accumulated exposure), did not report an excess of fetal deaths when compared to those 30 and older in the "control" group.

In addition, when women with chronic still birth and miscarriage problems were eliminated from the study (standard procedure in research of this type), the difference in fetal death rates between the "exposed" and "control" groups was not reported as statistically significant by the authors.

Finally, even if subsequent research should confirm these tentative conclusions on vinyl chloride and fetal deaths, it should be remembered that, since the research was conducted, VCM exposure levels throughout the industry have been reduced a hundredfold or more. Even if a problem did exist, it has already been eliminated.

Vinyl Chloride and Packaging -- FDA Enters the Picture

PVC packaging being supplied to end product manufacturers in 1976 contain little or no measurable residual monomer. There is therefore no reasonable likelihood of VCM getting into the diet from PVC food packaging materials.

These virtually monomer-free PVC resins were developed through an intensive effort by the industry. This effort began more than two years ago, when the issue of vinyl chloride migration from packaging material into the contained substance first came to light prior to the discovery of any link between VCM and cancer in humans.

Schenley Distillers, Inc., reported to the Treasury Department's Bureau of Alcohol, Tobacco and Firearms the presence of vinyl chloride in distilled alcoholic beverages, such as vodka and gin, packed in experimental PVC bottles. Levels up to 20 ppm in vodka and 25 ppm in gin were reported by the distiller. Regulation of the safety and purity of alcoholic beverages is normally handled by BATF although legally the Food, Drug and Cosmetic Act, administered by FDA, also has applicability to "alcoholic foods."

BATF then banned the further use of the experimental PVC bottles with alcoholic beverages. As a result, the U.S. Department of the Treasury withdrew its provisional approval for the use of PVC plastic bottles for distilled alcoholic beverages. FDA, meanwhile, took the question of vinyl migration from food packaging under study.

The Society of the Plastics Industry, Inc., subsequently supplied data to FDA which indicated that small amounts of vinyl chloride could migrate to non-alcoholic foods from the older formula PVC bottles then in production. But because FDA's expected proposal on food additive use of PVC was nearly two years in coming, pressure on the FDA from consumer groups and Congressmen began to build. These groups contended that zero migration could be the only "safe" level because there is no safe dosage.

On July 1, 1975, the Health Research Group, a Ralph Nader affiliate, petitioned FDA to ban completely all PVC food packaging materials. FDA responded on September 3 with a proposed regulation that would (a) permit the continued use of plasticized PVC "film" for wrapping meats and other food products, (b) withdraw

the prior sanction on the use of rigid PVC bottles and "thick" wrap such as blister packs, and (c) permit continued use of PVC water pipe until further proof of "no migration" is obtained.

Food, Drug and Cosmetic Act

Food additives are regulated under the Federal Food, Drug and Cosmetic Act. A 1958 amendment to this act requires that any new food additive must undergo strict testing to establish its safety. The amendment covers not only direct additions to the food itself, but also unintentional trace additions that might take place from materials used in packaging food, known as "indirect additives."

However, under the provisions of the Act, a substance is excluded from the definition of "food additive" if it may not reasonably be expected to become a food component or if its use was sanctioned by FDA prior to September 6, 1958. Several products polymerized from vinyl chloride were approved prior to that date and as a result PVC resins were considered to have "prior sanction."

FDA is authorized to re-evaluate the safety of any substance used in food-contact articles at any time. Use of a prior-sanctioned substance may be prohibited or limited when FDA determines that such use may be injurious to health.

FDA, in its September 3 proposal, seeks to remove prior sanctions from rigid and semi-rigid PVC products, including bottles, blister packs, boxes and pipe, except for water pipe, and fruit coatings.

The agency has stated that it has reason to believe there is no migration from plasticized PVC film, can and cap liners, coatings, gaskets or flexible tubing, and, therefore, proposes to permit their continued use.

No Risk to the Public

SPI submitted its comments on the proposed FDA regulation on December 19, 1975, accompanied by more than 700 pages of data to show that manufacturing processes for PVC have been dramatically improved and that there is no risk to the public from the use of PVC in food packaging materials because :

- 1) All new PVC packages now available contain essentially no detectable vinyl chloride monomer using the FDA test method, so there is no reasonable possibility of migration. SPI, in its comments, urged the Food and Drug Administration to adopt a substitute ruling which requires that rigorous test methods be used to assure no reasonable expectation of VCM migration.
- 2) Even in the past it is not likely that vinyl chloride entered the diet as a result of PVC packaging. Any vinyl chloride that might have entered food packaged in old packages would probably have evaporated rapidly before ingestion could have occurred.

The probability of vinyl chloride monomer getting into the diet from packaging material is thus virtually nil.

It should also be noted that the U.S. Council on Wage and Price Stability asked the FDA on December 19 to withdraw its proposed PVC rules on grounds the actions may be "unnecessary or may be more restrictive than is required to prevent the ingestion of vinyl chloride."

Not Carcinogenic Except at High Levels

As an added element of safety, studies being conducted by The Dow Chemical Company of how the body handles inhaled VCM tend to confirm a report made during the OSHA hearings, that only at high does VCM overwhelm the body's natural mechanism for eliminating many unwanted materials from the system.

Following his earlier inhalation experiments, Dr. Maltoni in 1975 reported inducing tumors in rats by ingestion of vinyl chloride. However, these experiments were conducted by gavage and at extremely high dosages. In comparison, the industry's proposal to FDA would prevent human ingestion of VCM even at levels 1,000,000 or more times lower than those used by Maltoni.

An extensive French study of PVC packaging of liquids by the Groupe D'Etude Pour Le Conditionnement Moderne concluded, after reviewing all the evidence, that:

"Far from being a threat to the health of consumers, PVC, thanks to its impermeability to oxygen, its mechanical qualities and potential usages by the consumer as well as its advantageous price in usage, represents considerable progress for the consumer and the national community."

Moreover, although vinyl monomer may be a carcinogen, PVC is not itself toxic in the same way that toxic chlorine gas is not harmful when combined with sodium to form sodium chloride (table salt). PVC is not volatile, it is inert, and has been shown in testing to be harmless when it is ingested.

Conclusion

The fundamental, underlying fact that needs to be stressed in public discussions of the health implications of VCM is that the only fully established hazards related to vinyl chloride and the manufacture of polyvinyl chloride involve the direct inhalation of unreacted vinyl chloride monomer gas by industry workers.

There is no health hazard in the handling or use of end products made from polyvinyl chloride because the vinyl chloride content of these products is either non-existent or infinitesimally small.

The fact that prolonged inhalation of VCM at very high levels does create a health hazard was brought to the attention of the government and the public by the VCM-PVC industry itself in 1974. Virtually all research on the VCM health issue prior to that time was done by the industry.

The industry reacted swiftly to all aspects of actual or potential health problems relating to the worker, the community and the consumer. As described in this paper, the industry believes its accomplishments in the short time period since 1974 have been impressive.

Plant exposure levels and emissions into the environment have been drastically lowered. New and better packaging resins have been developed. Technological breakthroughs that appeared impossible have been achieved, although at great cost to the industry and, eventually, to the nation.

The VCM-PVC industry intends to continue its efforts to supply to the consumer a safe, economical product that performs literally hundreds of useful functions in the national economy.

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