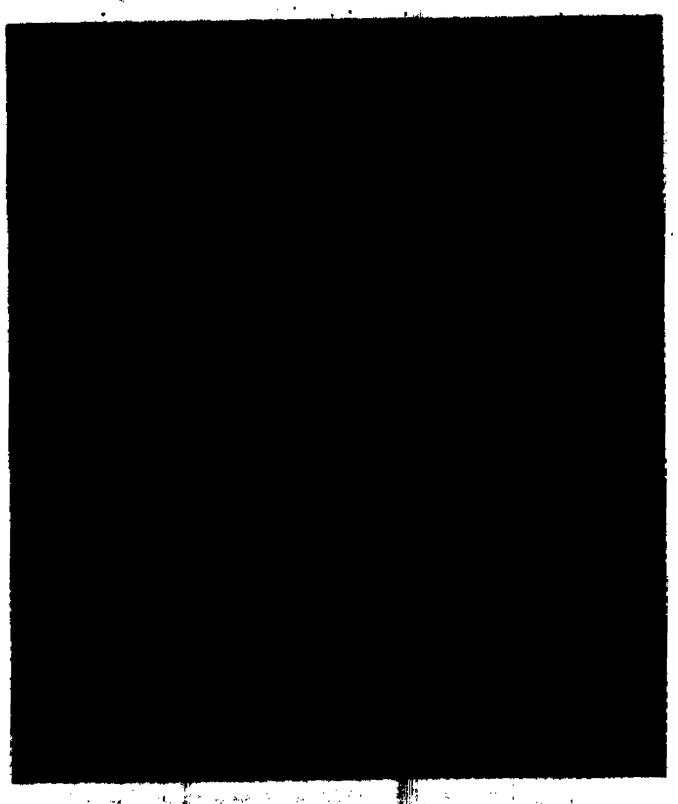


PVC: what's happened since VCM?

Changes in the manufacturing procedure for VCM and PVC as well as the government action that spurred them have failed to dampen the demand for this plastic. But more importantly this may have set the future pattern for resins.

The vinyl chloride monomer (VCM) occupational health hazard has been brought under control to such an extent that workplace problems no longer exist. Initially this problem created a rapid change in the method of manufacturing polyvinyl chloride. However, the full impact will not be evident for another year or two when the industry comes into full compliance with the recently issued EPA emission regulation.

Engineering miracles were required almost overnight in order to meet the severe safety problem that almost shut down the PVC industry. As a result PVC with extremely low levels of residual vinyl chloride monomer (RVCM) is now produced which can be processed and used with safety. Interestingly though, PVC has been used safely for food packaging, building products, potable water transmission, medical applications, and in other markets for many years, so that it might be said that the cure had no short range implications.

Most processors that purchase large quantities of PVC, such as the auto, appliance, electrical, and building industries, require resin that has no more than 5 parts per million (ppm) of residual RVCM, so that they will not be required to have "regulated" processing areas.

Technology currently used results in PVC that contains less than 10 ppm of RVCM while some companies are producing PVC with as little as 1 ppm or less. Practice indicates that resin with 10 ppm or less of RVCM will result in processing emissions below the 0.5 ppm OSHA "action level". This fact relieves the processors of monitoring and health check requirements.

Health menace discovered

In 1964 it was discovered that a bone problem developed in the hands of men who cleaned the reaction polymerizing vessels. The industry then initiated studies to determine what long term effect VCM might have on worker's health. The "hand problem" was eliminated through better working practices including the development of hydraulic reactor cleaners.

It had been known that high levels of VCM could have intoxicating and even anesthetic effects. This led to research that eventually provided the scientific basis for the various government regulations of VCM.

On January 23, 1974, B.F. Goodrich voluntarily reported to NIOSH (National Institute for Occupational Safety & Health) and Kentucky state authorities three cases of angiosarcoma of the liver, a rare cancer, that had fatally affected employees working in their Louisville PVC polymerizing plant.

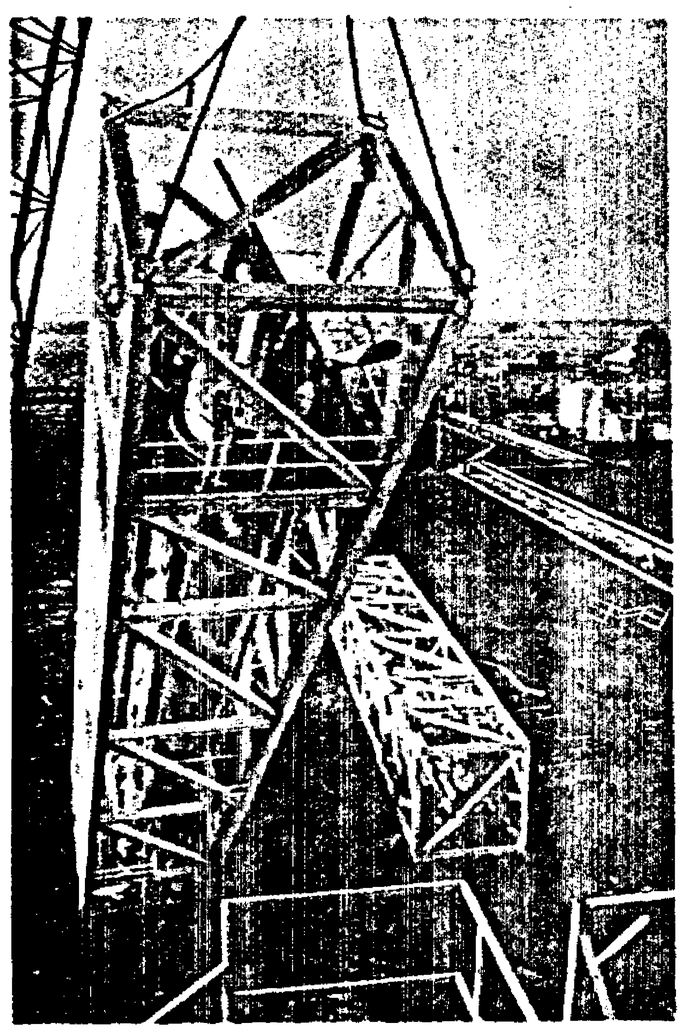
This resulted in an extensive search by the industry through old medical records for other cases which might have gone unnoticed. Ultimately it was determined that 48 deaths due to angiosarcoma had occured between 1961 and 1976, including 18 in the U.S. All the deceased had been exposed to high levels of VCM for long periods of time and death followed exposure by an average of 20 years. It was estimated that exposure had probably been over 250 ppm daily for at least several years. Most had been reactor cleaners, where the highest VCM concentration existed.

Resin producers took immediate steps to reduce worker exposure to VCM and began to develop new technology.

OSHA action

At the time of the B.F.G. announcement the Occupational Safety & Health Administration standard for VCM had been 500 ppm maximum exposure. This standard was based on 1971 recommendations by the ACGIH (American Conference of Governmental & Industrial Hygienists).

April 5, 1974 OSHA set an emergency temporary standard of less than 50 ppm. On May 10 they issued a proposal for a "no detectable" exposure. Even though progress had been made in VCM containment, the industry did not believe that this level could be attained. On October 1, 1974 OSHA adopted an exposure standard of 1 ppm on a time-weighted average for eight hours, with 5 ppm ceiling for 15 minutes.



New continuous stripping column to remove VCM from PVC developed by B.F. Goodrich is being installed. Because these units are fast and efficient, they provide a lower "residence time" and heat history for the resin compared to batch stripping.

The industry filed a petition for judicial review of the standards. In January 1975, the court of appeals upheld the OSHA standards, by contending that OSHA is not restricted to setting standards that are feasible with known technology. Because of the judicial proceedings, the implementation date for the standards was delayed until April 1, 1975.

Meeting the new standards

The industry's opposition to the "non-detectable" standard had been based on the then current technical impossibility of achieving this standard and on the impracticality of using air-line respirators.

In the final regulation OSHA changed from "non-detectable" to a level of 1 ppm continuous to 5 time averaged peak ppm that brought the standard into the realm of technological feasibility, although still difficult and costly to achieve. The introduction of a time weighted peak gave the industry a practical flexibility that was not available under the standard that had been proposed.

By permitting the use of gas mask rather than air line respirators at levels below 25 ppm, OSHA eliminated a major compliance difficulty with the standards. Meeting the OSHA requirements has resulted in technological progress far beyond expectation,

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

EPA and emissions

The Environmental Protection Agency (EPA) established a vinyl chloride task force in February 1974 and on May 31, 1974, requested emission data from manufacturers under provisions of the Clean Air Act. On June 11, 1974 they 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 with the cooperation of the PVC industry to reduce VCM emissions by 75 to 90 percent of 1974 levels, even though only a few measurements above 1 ppm were recorded.

On December 24, 1975, EPA published the limitations on air emissions of vinyl chloride. The regulations require substantially reduced VCM emissions from PVC processing plants, which due to the sharply reduced RVCM in the resin is less of a problem than in the past.

The science versus the politics of safety

Few headlines are so alarming, perplexing and personal in their implications as those concerning safety. When discussing safety, part of the problem concerns defining its meaning. An excellent dissertation on this subject by W.W. Lowrance of Harvard University provides some logic:

Safety is not measured. Risks are measured. Only when those risks are weighted on the balance of social values can safety be judged: a thing is safe if its *risks* are judged to be acceptable.

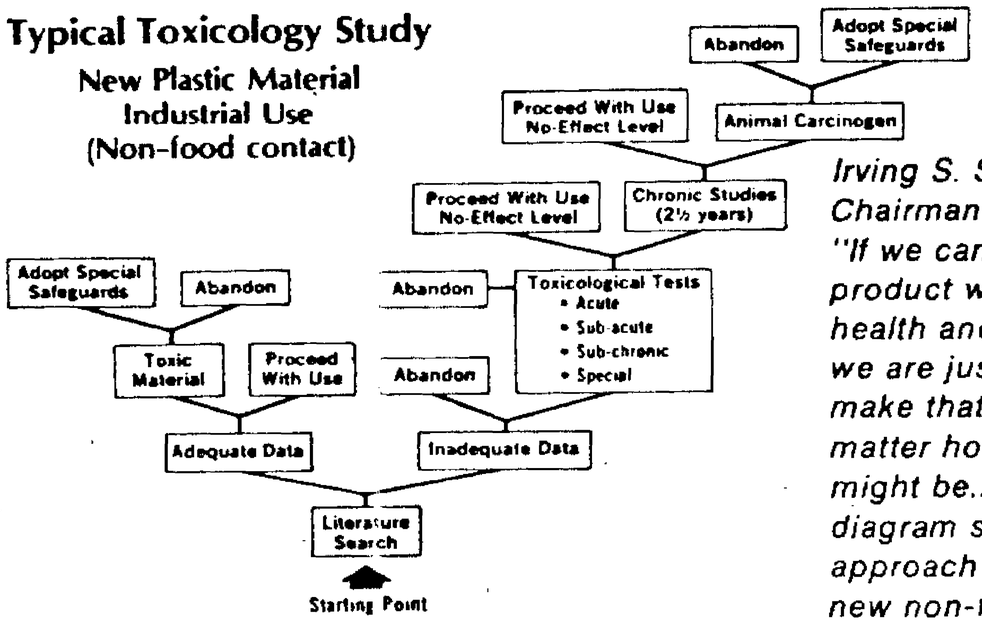
- Measuring the probability and severity of harm is an empirical, scientific activity.
- Judging the acceptability of risks is a normative, political activity.
- Realizing that no pursuit can be absolutely free of risk is a matter of irrefutable fact.

Because there are degrees of risk, there are consequently degrees of safety. Science contributes to the public-political decision but it does not represent the complete basis for the decision. It provides probabilities and consequences of events, not their value to people.

Safety is relative to and can change with time and can therefore be judged differently at different times. Knowledge of risks evolves from experience and has personal and social standards of acceptability; these also change. So that steering a course to industrial and consumer safety requires the proper blend of science and politics.

Government officials have been notoriously reluctant to give vocal support to the use of "risk benefit analysis" in making any public health decision. This makes the recent comments of outgoing FDA administrator Alexander Schmidt all that more significant.

"We build highways, we build bridges, we build buildings, knowing full well what the statistical probability of people being killed is in doing those things. So it is not reasonable to believe the use of chemicals in our society can be totally without risk."



Irving S. Shapiro, Board Chairman of DuPont, states, "If we cannot make a product without adverse health and safety effects, we are just not going to make that product, no matter how profitable it might be..." This block diagram shows the DuPont approach used in developing new non-food contact plastics.

carcinogen, government biostatisticians calculated that from 1964 to 1974 there should have been 10 excess deaths from angiosarcoma among people living within five miles of VCM and PVC resin plants in the U.S. The survey showed, in fact there were no excess deaths from angiosarcoma among this group. This led to the conclusion that "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".

EPA action

On October 21, 1976 the new EPA emissions standard was issued to eliminate the possibility of future problems. It affects about 60 PVC, VCM and ethylene dichloride plants. The order states that any VCM emissions from equipment preceding and including the stripper is limited to 10 ppm, this includes stripping process water.

Compliance or request for a waiver must be registered with EPA in 90 days. The granting of waivers by EPA to a maximum of 2 years require detailed time schedules showing engineering and equipment improvements taken to meet the standards. It will be difficult to meet the 90 day period. Lack of technology as well as unavailability of equipment indicate that some operations could take up to 2 years to comply.

The new controls are estimated by the government to cost the industry $200 million for equipment plus as much as $70 million/yr in operating costs.

The FDA and monomer migration

PVC packaging being supplied to end product manufacturers in 1976 contains little or no measurable residual monomer. There is therefore no liklihood of VCM getting into the diet from PVC food packaging materials. These virtually monomer-free PVC resins were developed more than three years ago, when the issue of RVCM migration from packaging into the contained substance first came to light. This was prior to the discovery of any link between VCM and cancer in humans.

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

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 and FDA took under study the question of vinyl migration from food packaging.

SPI subsequently supplied data to FDA which indicated that small amounts of vinyl chloride could migrate to non-alcoholic foods from the "old formula" (i.e. high RVCM) PVC bottles then in production. But because the FDA 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 exists no such thing as a "safe dosage" of a carciaogen.

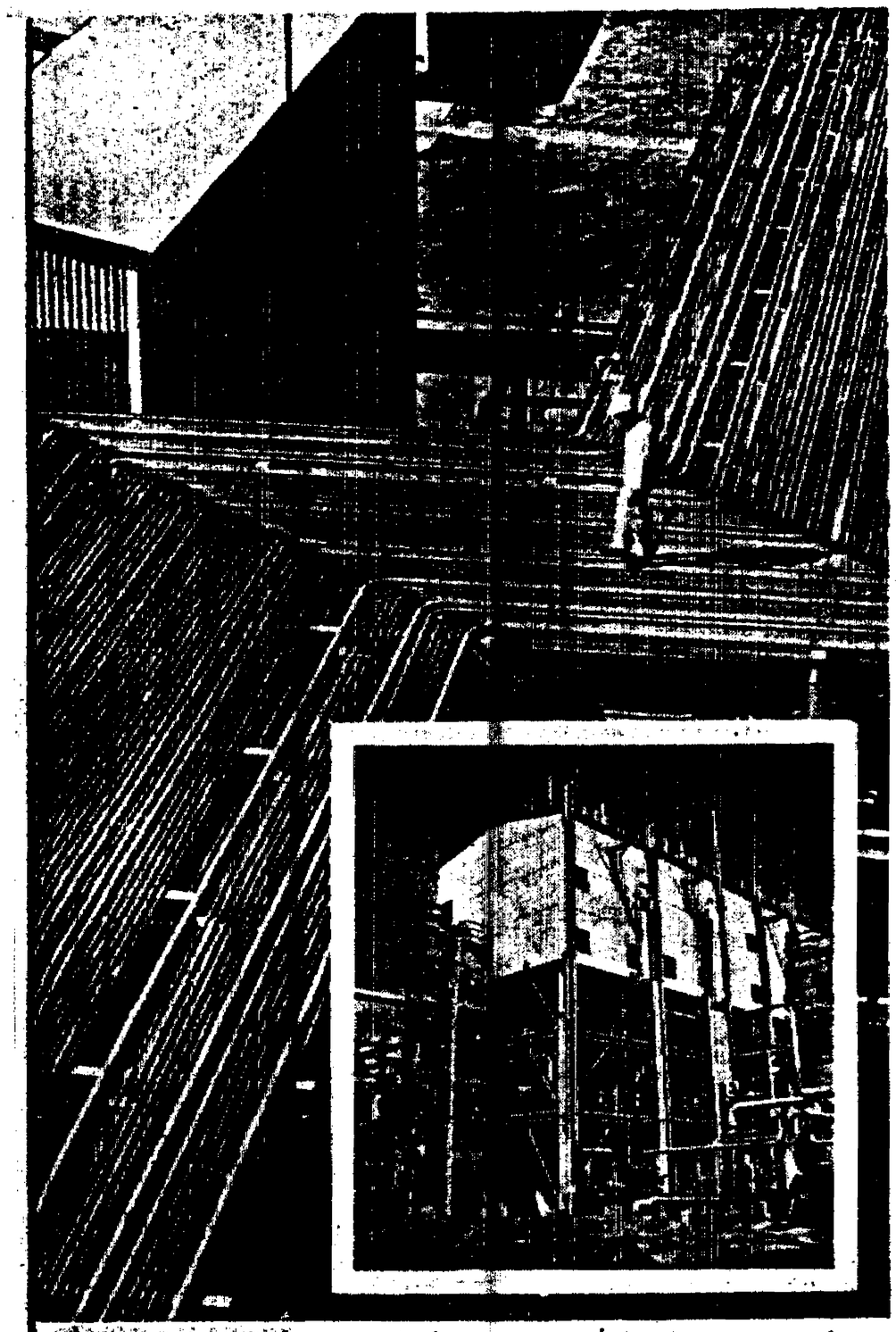
On July 1, 1975, the Health Research Group, a Ralph Nader affiliate petitioned FDA to ban completely all PVC food packaging materials. FDA responded on September 3 with a

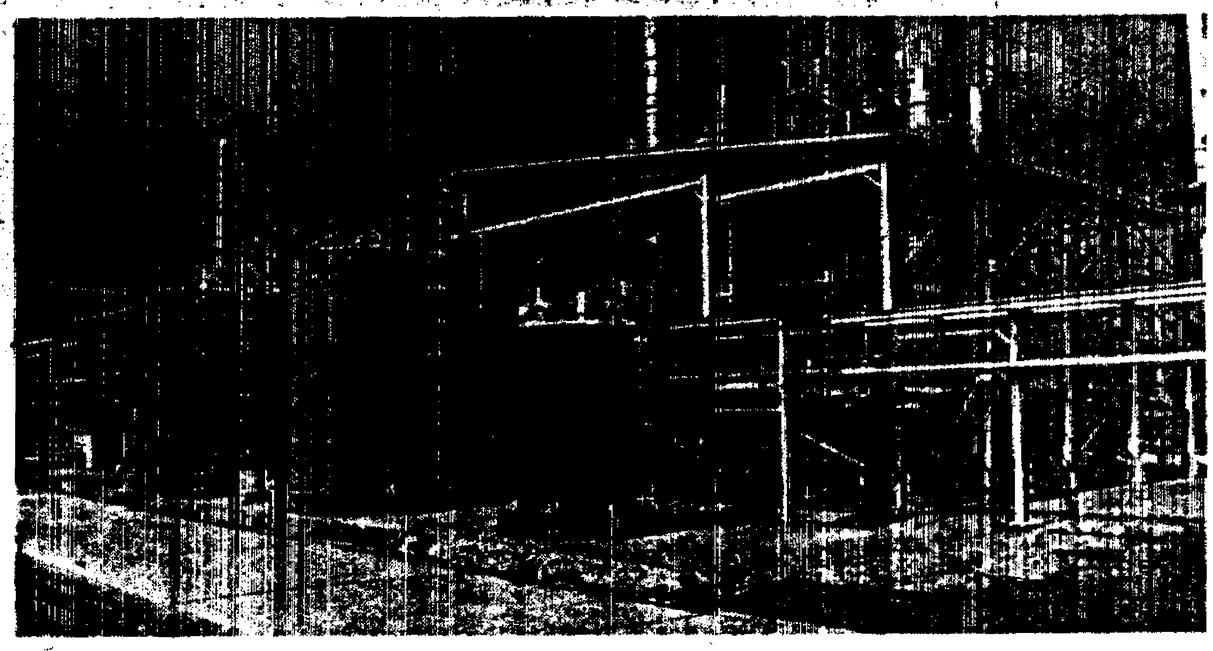
A healthy industry

Due to the versatility and capability of the PVC industry in solving its VCM problems, its future looks stronger now than in the past. There are now 21 PVC and 11 VCM (including Diamond Shamrock to be on stream in a year) producers. A mild VCM shortage could occur at the end of 1977 but new facilities coming on stream in 1978 will make it a short one.

Strong demand for PVC is leading to plant expansions. Air Products at 200 MM lb/year will add 120 MM lb next year; Conoco is adding 165 MM lb capacity by 1978 to give them a total of 560 MM lb. Diamond Shamrock has a 570 MM lb. capacity in PVC, but the big story is their entry into VCM with 1-billion lb/yr capacity coming on stream in 1978. Firestone will add 200 MM lb PVC in 1978 to give them 600 MM lb/yr. Goodyear at 250 MM lb will add 50 MM lb more next year; Stauffer at 350 MM lb will add 80 MM lb more next year; Robintech at 250 MM lb adds 50 MM lb next year and 200 MM lb in 1979; Shintech currently at 220 MM lb will add 110 MM lb next year. Tenneco will have 700 MM lbs by 1978 when 190 MM lb are added. Union Carbide, with its 400 MM lbs/yr is also making changes.

Add in 500 MM lb for Borden, 200 MM lb for Certain-Teed, 180 MM lb for Ethyl, 180 MM lb for General Tire, 220 MM lb for Georgia-Pacific, 1100 MM lb for Goodrich, 180 MM lb for Hooker, 120 MM lb for Pantasote, 150 MM lb for Rico. So PVC total for now is about 6.4 billion lb/yr and will add 1.26 B lb in 1978 and another 0.6 B lb for 1979.





Here is the first PVC plant designed to meet OSHA regulations without masks. This Georgia-Pacific plant, completely automated and computerized, started operating in February 1975. It includes safety devices such as these three refrigerated tanks to be used only in emergency if any reactor cooling problems develop.

Tenneco's large-reactor PVC plant at Pasadena, Tex., with its computer controls on every part of the process, is capable of producing PVC variations previously made only in small reactor batches. These conduits carry the electrical wiring between the reactor plant and the computer building.

proposed regulation that would (a) permit the continued use of flexible plasticized PVC film for wrapping meats and other food products, (b) withdraw the prior sanction on the use of rigid PVC bottles and thick semi-rigid wrap such as blister packs, and (c) permit continued use of PVC water pipe until further proof of "no migration" is obtained.

The proposed regulation further stated that if the PVC RVCM content is improved, the FDA would review any new data. SPI submitted an 800 page report December 19, 1975 which shows 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 all new PVC packages now available contain essentially no detectable RVCM using the FDA test method, so there is no reasonable possibility of migration, SPI, in its comments urged the FDA to adopt a substitute ruling which requires that rigorous test methods be used to assure no reasonable expectation of RVCM migration. Even with the older resins it is not likely that VCM entered the diet as a result of PVC packaging because it would probably have evaporated before ingestion could actions may be "unnecessary or may be more restrictive than is required to prevent the ingestion of vinyl chloride".

Now that PVC can be processed to such a low RVCM concentration and no migration occurs, FDA could be interested in reviewing the data. Final decision is still pending but it is unlikely to occur until after the new administration takes office. However, fear of adverse consumer reaction has stunted PVC growth in the rigid and semi-rigid markets packaging, while other packaging applications have actually increased.

Other actions

On June 23, 1975 NIOSH published a notice in the Federal Register (40 Fed. Reg. 26390 et seq.) requesting information on certain chemicals. NIOSH identified in this bulky report a long list of chemicals reportedly producing or suspected of carcinogenic response in animals. Among those listed are many of interest to the plastic industry: PE, acrylic, PS, PTFE, PUR, PVAL, PVC, nylon, etc. The nature of the publication is such that it calls on industry for further study to substantiate or disprove the referenced findings. The publication has however,

Industry is cleaning house

The plastics industry recognizes its responsibilities in protecting employee and consumer health. The best manufacturing practice is to have the least possible exposure to any chemical. The SPI with other chemical industry groups has worked diligently with the Congress to develop a workable and effective Toxic Substances Control Act. The tempo of industrial toxicity testing has increased many fold. Toxicology studies are both more numerous and more sophisticated than they were only a few years ago.

When the industry-supported organization CIIT (Chemical Industry Institute of Toxicology) was formed April 29, 1975 it listed objectives pertinent to all of the chemical industries including the plastics industry. They include the need for better information, faster communication, and improved methodology in the testing. CIIT members companies include all the plastic producers.

Toxicology studies

Most of the toxicology data on plastics and chemicals has been developed by industry organizations.

The SPI Toxicology Strategy Committee is looking into the long range

action to research data missing in older studies.

Who does what?

Although no master plan has been formally adopted, several industry associations appear to have staked out certain areas for action. SPI is concerned with the manufacturing and fabricating of plastics and any danger these activities pose to its employees and the consumers. However, toxicity emphasis is on the monomers because there is little danger that polymerized plastics, due to thei· high molecular weight might be toxic. Any toxicity would come from residual monomers as was the case with PVC.

MCA is primarily concerned with basic chemicals and what occurs during the production of monomers before they are polymerized. They worked on the VCM problem and now are also deeply involved in styrene, acrylonitrile, and other monomers. CIIT plans to study basic chemicals of all types this includes the chemical precursors of monomers.

For example, CIIT starts off with ethylene and toluene, MCA takes the next step of studying VCM and styrene monomers and SPI is concerned with PVC and PS polymers. This includes residual monomer as well as breakdown into monomers due to faulty processing.

Testing facilities

Chemical testing facilities in U.S. and world wide are being strained to the limit with the massive workload, not only from plastics and chemicals but also metals, papers and food. Fortunately a number of fully qualified facilities are operated by U.S. chemical companies, such as Dow Chemical and DuPont. Monsanto is now completing a large complex.

NIOSH reports that 47 toxicology labs (industrial and private) currently function in the U.S. CIIT plans to establish their own laboratory. In the mean time, like most government agencies (National Cancer Institute, NIOSH, etc.) work is contracted to private labs. FDA is also in the process of building a large lab. University lab's are active but need sponsorship to finance the very expensive chronic or life time animal studies, usually several years in duration.

NIOSH estimates a shortage of 50,000 professionals exist in the area of occupational and product safety. They add that there are only 850 professional toxicologists and the American College of Veterinary Pathology lists only 300 pathologist members.

Ability to pay

In light of great public, political and media interest in the subject of carcinogens, the problem of limited resources is very real. The testing needed to provide the basis for competent judgements about the hazards of materials used is extensive and a large amount of money is required.

To determine the carcinogenic effects from long term, low-level exposure requires that each testing program take at least 2 to 4 years and millions of dollars to complete. In a short time the total bill could add up to billions.

In all probability the life-line to financially supporting the toxicology tests will be through industry associations.

Death of PVC

Somewhat like Mark Twain, the reports of the death of PVC have been greatly exaggerated. Cost has gone up, but not significantly. And despite all the damaging publicity its growth is healthy, possibly maintaining 12% annual growth for the next 3-4 years.

The usual cost increases of energy raw materials, etc. have affected PVC, but no more than for other resins, metal, paper, and other materials. Safety costs per pound should only involve parts of a penny, in fact, in the short run production costs could be lowered due to the changes in manufacturing technology.

In the meantime yearly production capacity for VCM and PVC has been considerably increased. A VCM shortage could occur late 1977 to early 1978 before almost another 2 1/2 billion lbs comes on stream, at which time we'll have a 7 billion lb capacity in U.S.

Total impact

Even though the chemical industry has been producing and handling large amounts of many toxic chemicals with comparative safety for years, the case history of VCM has put the "fear of God" in the hearts of the plastic/chemical industry. The U.S. plastics industry vitally understands health-related hazards and is determined to do everything in its power to be sure that it does not sustain another surprise like VCM. *D.V. Rosato*

EXAMPLE OF BLATANTLY IRRESPONSIBLE WRITING! BOO

Industry pipe standard

Potable PVC water pipe and fittings do not pose a health risk based on extensive research conducted by the industry since 1974. The amount of time, cost, and scientific expertise dedicated to the program is impressive. But also impressive is PVC pipe consumption, which could grow to 1.3 billion lb this year and to 2 1/2 billion lb in 1980.

When water passes through any pipe (steel, coated steel, cement-asbestos, plastics, etc.) there is a possibility of some leaching out or material extraction from the pipe wall. So when the VCM problem developed, pipe and resin producers initiated studies to obtain data for possible future regulations.

In the September 1975 FDA proposals, data were requested on PVC pipe although no regulation on its use was proposed. Considerable data were supplied in the SPI 800-page December 1975 report to the FDA.

In February 1976 a joint PPI (Plastics Institute of SPI) and Uni-Bell Plastic Pipe Association groups was set up to look into the VCM extraction question and to establish a standard for self-regulation.

This group made its findings available to NSF (National Sanitation Foundation) which has been checking and certifying all potable water pipe under their Standard 14. NSF approves pipe based on raw materials, formulation, and pipe performance.

After reviewing the situation, NSF in August 1976 developed its test and evaluation approach to change its standard by February 1, 1977. If adopted, in its present form, it will put a limit of 10 ppm VCM in PVC pipe. With this limit, there is no detectable extraction. NSF will use a test method developed by the PPI committee on VCM that is accurate to 2 ppb (parts per billion). This test should allay the fears of those who felt that we might experience another liquor bottle fiasco.