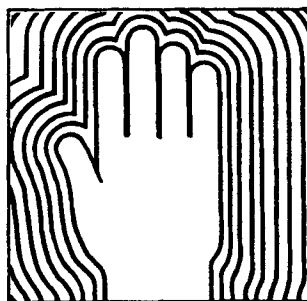


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Evidence

By George Black

An overview of OSHA's

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A newly convicted killer—the vinyl chloride molecule.

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number of cases stands at 16 in this country and 26 world-wide—extraordinarily high figures when one considers that just over 100 cases of angiosarcoma of the liver had previously been reported in medical literature. All the quoted figures may be too low, in fact, since angiosarcoma is so rare that it may often go undiagnosed. Four of the first 10 U.S. cases among vinyl chloride workers were discovered only upon re-examining slides of pathologic tissue taken during autopsies. Beyond sheer numbers, though, the deaths have raised disturbing questions about a whole modern life style that depends so heavily on products derived from synthetic chemicals.

Because of its versatility and relative cheapness, polyvinyl chloride, or PVC, is used in about 55 percent of plastic products. Chances are you ride to work on a vinyl seat, walk across vinyl-tiled floors on shoe soles of PVC, eat sandwiches wrapped in PVC film from a vinyl tablecloth, and relax to the sounds of PVC records. The week-old infant in his mother's arms is likely to suck on a vinyl pacifier. In its early days, during World War II, vinyl chloride gas (VC) was even used for a brief time as an anesthetic during surgery.

Are these finished PVC products dangerous? Aerosol propellants using VC gas—mainly hair sprays and pesticides—have been banned by various government agencies, but so far no one has discovered harmful effects from unreacted VC gas leaching out of finished PVC products. Researchers from the Food and Drug Administration, the Environmental Protection Agency, the National Cancer Institute, and the Consumer Product Safety Commission are following the problem closely, however, and the National Institute for Occupational Safety and Health (NIOSH) is conducting an experiment in which PVC pellets are placed in closed chambers and monitored for escaping VC. In an interview with CBS News, Ralph Harding, president of the Society of the Plastics Industry, remarked about these products: "Nothing in these days is totally certain without a great deal of detailed study and there hasn't been time for that, but I know in our case, we're going right ahead and using all these products with no concern, no fear, in the case of our own family."

After a year now of intensive study by individual companies, OSHA and NIOSH, and union-financed researchers, the problems of controlling VC exposures in the workplace

are far more clear-cut. There are three basic steps in the production of finished vinyl products. At the first stage VC, or the "monomer," is produced through a closed process, usually involving a reaction between ethylene and chlorine. VC monomer is then shipped as a liquified compressed gas to the plants that manufacture PVC resin. There, batches of VC are "polymerized" by mixing with catalysts in giant vats or reactors. After drying, the resulting PVC resins are "compounded"—a process in which stabilizers, lubricants, and plasticizers are added. Before being bagged for shipment to fabricating plants, the resins may be converted to PVC pellets. The final step—the fabrication end of the industry—covers a huge range of processes in which the PVC is turned into finished products. In the United States, there are 15 monomer plants employing 940 workers, 36 PVC plants with 5,600 workers, and about 7,500 fabrication plants with approximately 350,000 employees.

At each stage of the process, there are certain trouble spots where VC is likely to escape into the air. Both monomer and polymerization plants face the problem of controlling random leaks that occur from pump seals, compressors, valves, gaskets, and storage tanks within the vast closed systems. Both must also deal with reducing emissions that occur in quality control sampling. During loading or unloading of the VC monomer for shipment between plants, tank car loaders may be exposed to as much as 200 parts per million (ppm) of VC in air.

When the commercial process for manufacturing PVC plastics was first introduced in the late 1930's, the prime worry was keeping concentrations of the volatile VC gas low enough to avoid explosions and fires. As a result, production facilities are usually spread out over plant sites of several acres. VC in the air, then, is not confined to a small area, but low levels often can be found over the entire plant. Most monomer plants, which are usually open-air facilities, have lower concentrations than polymerization plants.

The highest exposures in the polymerization plants are experienced by the workers who climb down into the reactors to chip out PVC residue, in some plants with a hammer and chisel. VC concentrations as high as 1,600 ppm have been reported in the reactors in the past, and exposure levels can still reach 500 ppm for reactor cleaners. Fourteen of the 16 U.S. deaths have occurred among men who at one time or another

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These two old-style processes, which allowed VC to escape into the air, are phased out in VC n...omer plants. Below, VC mist is vented to the air as a way of gauging the amount of VC in the tank car. Below right, a worker draws a sample from the closed system for lab analysis.



cleaned reactors. This figure may be somewhat misleading, however, since, at the Louisville plant at least, this job is the usual starting place for new hires.

Fabricating plants are most concerned about the small amounts of VC left in PVC resins. During shipment or storage it can leach out through the bags or into the box if packaged in bulk. The fabricating operations with the most potential for exposure involve heating the resin, as in extruding PVC around an electrical wire, a case where any unreacted VC may be driven off into the air.

In the year since the B. F. Goodrich revelation, much more evidence linking VC with angiosarcoma of the liver has come to light. In 1958 and 1959 Dow research scientists reported that, when inhaled, VC concentrations as low as 100 ppm could cause liver problems in rats and rabbits. Based on these results, Dow set a limit of 50 ppm as a time-weighted average (TWA) for its own plants.

In 1962, however, the American Conference of Governmental Industrial Hygienists, relying on different research results, set a TWA of 500 ppm, which aimed primarily at preventing nauseous effects in workers. When OSHA came into existence in 1971, this 500 ppm limit was adopted as the OSHA standard. It remained in effect until April 5, 1974, when OSHA's emergency temporary standard cut the limit to 50 ppm.

Meanwhile, in 1970 Dr. P. L. Viola, a physician for the European chemical firm Solvay, undertook a series of animal experiments to investigate acroosteolysis—a condition involving softened finger tip bones that had become common among PVC workers, especially reactor cleaners. Quite by chance, Dr. Viola discovered that rats inhaling extremely high doses of VC — 30,000 ppm — developed cancerous tumors. Because of impure VC in Viola's tests, Dr. Cesare Maltoni, acting at the request of European chemical companies, began exposing test animals to lower concentrations. Preliminary reports of Maltoni's work showed that levels as low as 250 ppm were inducing various tumors, including angiosarcomas, in rats. When this news filtered back to the American plastics industry, the Manufacturing Chemists Association in early 1973 contracted for animal studies with Industrial Bio-Test Laboratories and for an epidemiologic study of VC workers with Tabershaw-Cooper Associates. The first results of the Bio-Test experiments came through in April 1974 after Dr. John Creech, Goodrich's plant physician in Louisville, had independently discovered the first angiosarcoma deaths among workers. The results showed that some mice exposed to 50 ppm, as well as rats and hamsters at higher levels, developed angiosarcomas of the liver. In June of last year Maltoni confirmed the Bio-Test results with evidence that VC induced angiosarcomas in both rats and mice at 50 ppm and in hamsters at higher concentrations.

The animal evidence by itself raises problems of interpretation in setting safe exposure levels for humans. Maltoni clearly identified a dose-response effect. That is, the more VC his test animals breathed the more likely they were to get cancer. But no results from ongoing experiments at levels below 50 ppm are currently available. However, Dr. Marvin Schneiderman of the National Cancer Institute has predicted that, based on Maltoni's data, tumors will occur below 50 ppm if enough animals are exposed long enough.

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Secondly, many in the plastics industry question the whole concept of extrapolating effects on animals to similar effects in man. While it is true that different species of test animals frequently respond to a chemical in different ways, in 1970 the Surgeon General's Ad Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens stated that "the finding of cancer in two or more animal species may be extrapolated to indicate a carcinogenic hazard to humans." This principle recently withstood a challenge in court when the U.S. Court of Appeals for the Third Circuit substantially upheld OSHA's standard on ethyleneimine—a carcinogen that had been proved to cause cancer in rats and mice.

"We'll probably never have a more clear-cut set of animal data than with vinyl chloride," says Dr. Donald V. Lassiter, special assistant for occupational health in OSHA. "It is very unusual to find the same tumor in the same organ—in this case, angiosarcoma of the liver—in both animals and humans exposed to the same chemical."

The discoveries of excess cancer in populations of VC workers certainly add weight to the animal evidence. The major epidemiologic studies and their results so far include:

- **Tabershaw-Cooper Associates**—8,384 VC and PVC workers were studied. Researchers Dr. Irving Tabershaw and Dr. William Gaffey found that, in addition to angiosarcoma of the liver, there were more cancerous tumors than expected in other parts of the body, including the respiratory system and the brain. They also found that the total number of people dying in the study population was only 75 percent of what would be expected for the general population. The results are limited by the number of workers in the study who have had only short term exposures to VC.

- **Harvard School of Public Health**—Dr. John Peters and Dr. Richard Monson studied the deaths of 161 workers at two B. F. Goodrich plants in Kentucky. They found that deaths from lung cancer and suicide occurred almost twice as often as expected, from brain cancer four times as often, and from angiosarcoma of the liver 10 times as often. The death rate in the study increased greatly after 1965.

- **Mt. Sinai School of Medicine**—Under the direction of Dr. Irving Selikoff, medical examinations were given to currently employed workers at Goodyear's Niagara Falls PVC plant, and a mortality study of 255 em-



ployees and former employees with long-term exposures (over 10 years) was undertaken. Among the workers examined, the researchers found significant numbers of lung and liver abnormalities. It was also discovered that three of the group of 255 workers had died of angiosarcoma of the liver. The rate of death from cancers of all types was considerably higher than expected in this group, and the overall mortality rate was slightly higher than expected.

- **NIOSH**—Along with the Center for Disease Control in Atlanta, NIOSH is conducting a national search for all angiosarcoma deaths since 1965 and an epidemiologic survey of 11 polymerization and fabricating plants. Though the survey is not completed yet, study director Dr. Joseph Wagoner says that so far excess deaths from cancers of the respiratory system, blood-forming tissues, and brain—as well as the liver—have been uncovered. The total number of deaths in these 11 plants is also more than could be expected.

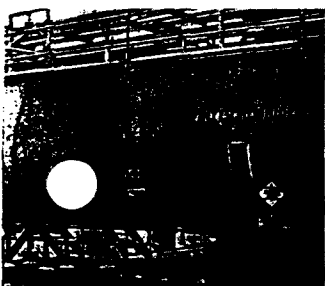
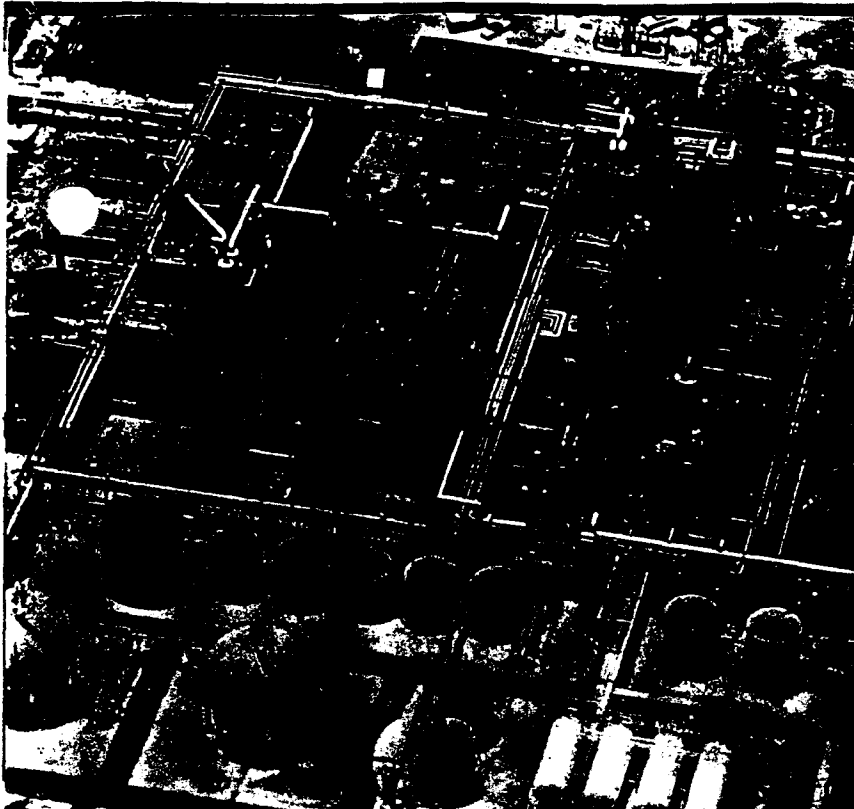
- **University of Louisville**—In a program just getting underway, B. F. Goodrich has contracted with the university's medical

VC workers at Dow's Midland, Michigan, plant are given a series of medical tests by a team from Mt. Sinai School of Medicine in New York. Because angiosarcoma of the liver is so rare, good medical surveillance is crucial to detect new cases.

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Aerial view of a Texas plant where VC monomer is manufactured. The highest exposures in this type of plant usually occur during tank car loading.

school to establish a better examination procedure for early detection of angiosarcoma, start a registry of angiosarcomas of the liver in the Louisville plant and eventually for the entire industry, and begin a basic research program into VC effects.

These studies basically agree that:

- Deaths from angiosarcoma of the liver occur far more frequently among VC workers than would be expected.
- There also appears to be an excess of cancers in other parts of the body.
- The incidence of cancer rises sharply after 15 years from onset of exposure.

To set a safe level of exposure for VC, based on these facts, is no simple task. The chief problem is that no one has an accurate record of how much VC the dead workers were exposed to. It is generally agreed that VC levels in the 1940's were extremely high—perhaps reaching several thousand ppm in operations such as reactor cleaning—and that exposure levels have been gradually lowered since then. Since companies did not monitor extensively for VC until recently, exposure estimates are based largely on individual workers' memories of smelling VC in the air. (The odor threshold apparently varies between 400 and 2,000 ppm for different people.) The casual attitude toward VC levels in those days can be seen in one veteran worker's comment: "When there was enough of the stuff so that you could smell it, we just thought it was a cheap drunk."

For reasons mentioned earlier, Dow did monitor fairly closely and did strive to keep exposure levels low long before the rest of the industry. At the hearings on OSHA's proposed standard, Dow was able to present evidence that 335 employees exposed for seven years at levels under 200 ppm had not developed angiosarcoma of the liver. Unfortunately, however, this group excluded many workers with the longest exposures (over 20 years).

Another puzzling fact is that, so far, angiosarcoma of the liver has been found in only three of the eight U.S. polymerization plants that have been operating for more than 20 years. Industry spokesmen have implied that there may have been high exposures or some strange chemical mix peculiar to the three plants. However, since comprehensive studies with good followup rates for all polymerization plants haven't been completed, it is not possible to conclude that angiosarcoma won't show up in any of the other plants. Industry-wide, about three-quarters of all the employees who have gone more than 20 years since onset of exposure (the group at greatest risk) haven't been traced yet.

The missing piece at the very center of the puzzle is that cancer researchers are not entirely sure how the basic cancer-causing mechanism works. "Many people who work in cancer research would say that any level of carcinogenic exposure, even the smallest amount, is not safe," says Dr. William Lloyd, head of NIOSH's Office of Health Surveillance and Biometrics. "We now believe that cancer may not result from the cumulative build-up of a substance over a period of time but that it may be activated by a single instance of exposure." The Surgeon General's Ad Hoc Committee on Carcinogens also concluded that a "safe" exposure level for any carcinogen cannot be determined.

In proposing a permanent standard for VC, OSHA relied, then, on a combination of animal and human data, considerations of economic and technological feasibility, and NIOSH's recommendation that any employee exposed to VC should wear a respirator. OSHA's proposed VC standard, issued on May 10, 1974, set a limit of "no detectable level," which was defined in measurement terms as 1 ppm.

At hearings on the proposed standard, representatives for plastics companies pointed out that it was simply impossible to reduce VC levels low enough to meet the stan-

dard, painting a grim picture of the economic disruptions that would occur if the standard went into effect. Speaking for many in the industry, B. F. Goodrich said that it would be forced to close its plants. According to a study by a consulting firm hired by the Society of the Plastics Industry (SPI), 2.2 million workers could be thrown out of work and as much as \$90 billion in production lost each year in plastics and related industries if all VC production were to stop. A study by OSHA's own consulting firm, which relied on data from the plastics companies, confirmed that at present, the technology to eliminate all leaks in monomer and polymerization plants does not exist. The SPI recommended a phased reduction schedule of VC levels, starting with a 25 ppm TWA and 40 ppm ceiling to go into effect in 1974 and culminating in a TWA of 10 ppm and a ceiling of 25 ppm in two years.

At the opposite extreme stood Peter Bommarito, president of the United Rubber Workers who spoke for the entire AFL-CIO when he said, "This country survived for nearly 200 years without PVC, and we can survive in the future without it. If PVC cannot be made and used safely, then the proposed standard must be replaced by an orderly procedure to phase out vinyl chloride production and find substitutes for its products. . . ."

The lines were drawn. Faced with a decision that, in Bommarito's words "would test the wisdom of a saint," OSHA gave prime consideration to workers' health but, at the same time, promulgated a standard it believes will allow the plastics industry to continue to operate.

In essence, OSHA's permanent standard on vinyl chloride, published in the *Federal Register* of October 4, 1974, requires that employers limit VC exposures to 1 ppm as a TWA and 5 ppm as a ceiling. If feasible engineering controls and work practices will not reduce levels to 1 ppm, they must be used to reduce exposures to the "lowest practicable level" and employers must make respirators available to employees. For the first year—until January 1, 1976—each worker may decide whether he wants to wear a respirator as long as the levels he faces are not over 25 ppm. There are no deadlines for reaching the 1 ppm level through engineering controls since the technology is so uncertain, but employers must draw up plans for reducing levels and make them available to OSHA.



One key provision of the standard outlines what parts of the many-sided PVC industry are covered. The standard applies to the "manufacture, reaction, packaging, storage, handling, or use of VC and PVC" but not to the handling or use of finished PVC products. PVC is not considered a "finished product" until it passes all stages of production where mass melting occurs. The standard, for instance, covers such fabricating operations as injection molding, extrusion, banbury mixing, and calendering but does not include thermoforming or blister packaging.

During the hearings the SPI recommended that fabrication plants be exempted from the standard because VC exposures have been very low in these plants. However, some exposures in fabrication facilities do exceed 1 ppm. In a survey of seven fabricating plants, NIOSH found an average TWA of about 2 ppm.

In addition, there have been reports in Connecticut of two angiosarcoma deaths in fabricating plants. One case involved a worker who ran a wire coating machine that extruded PVC, and the other involved an accountant who had occasionally entered a building where PVC was made into calendered film. Neither tumor entirely fits the pattern of angiosarcomas in other VC workers, but these deaths raise a very provocative question. Because fabrication workers are the ones most likely to have had long-term, low-level exposures to VC in the past, evi-

About 350,000 workers use PVC resins to fabricate finished plastic products. Most experts believe fabricating plants should have little difficulty in meeting OSHA's standard of one part per million VC in the air.

Vinyl Chloride Abroad

Though much of the early research on vc was done in Europe, foreign countries have generally looked to the U.S. for leadership in controlling vc exposures. Some current exposure limits in the rest of the world are:

Canada (Ontario)	10 ppm TWA, 25 ppm ceiling
England	50 ppm ceiling, 25 ppm TWA
France	no official regulation
Holland	50 ppm ceiling
Italy	50 ppm ceiling
Japan	committee recommendation expected by end of 1974
Norway	temporary ban on PVC production
Sweden	1 ppm TWA adopted on Oct. 14, 1974
West Germany	50 ppm ceiling with proviso that exposures be kept as low as possible

dence from these plants is crucial in establishing a "safe" or minimal risk level of exposure.

To meet the problem of covering the great variety of fabricating operations, then, the concept of an "action level" has been written into the standard. If a fabricating plant finds that vc exposure levels are below 0.5 ppm on initial monitoring, then that plant is effectively exempted from most of the rest of the standard. These employers need not monitor again unless they have some reason to suspect that exposures have gone up or changes have been made in the production process. (Plants where exposures are above 1 ppm must monitor at least monthly.) Most fabricators believe their plants should have little difficulty getting down below the action level with minor improvements in ventilation.

Under the requirements for monitoring methods, OSHA has left the employer considerable leeway by writing a "performance" standard which requires only that the method used be accurate within certain limits. The reasoning behind this is that vc monitoring methods are undergoing rapid technological improvement. At the Society of Plastics Engineers' recent conference on

vc, 27 different manufacturers of vc monitors displayed their wares, including such equipment as infrared analyzers, continuous monitors using a paper tape, and portable gas chromatographs. The method chosen may make use of either personnel sampling—measurements in each worker's breathing zone—or area sampling.

Perhaps the simplest and cheapest method is the carbon tube used by NIOSH and by OSHA inspectors. As an air sample is drawn through the tube, the carbon absorbs the vc. The chief disadvantages of this technique are that the carbon must later be analyzed in a lab for vc content (NIOSH will do this) and that the sampling time of two hours makes short peaks of exposure hard to detect. A detailed account of how to use this method can be obtained by writing to NIOSH, Office of Technical Publications, 1014 Broadway, Cincinnati, Ohio 45202. Ask for a copy of P&CAM No. 178—"Vinyl Chloride in Air: Physical and Chemical Analysis Branch Analytical Method."

Other provisions of the standard include:

- **Regulated areas**—In parts of a plant where vc levels exceed 1 ppm, a regulated area with access limited to "authorized persons" must be established and daily rosters of the people who enter it maintained. Since the standard aims at protecting people, only those areas where workers are actually present are covered.

- **Training**—Employees must be informed of the cancer risk associated with vc, instructed in the proper uses of respirators, and made aware of work practices that could release dangerous amounts of vc into the air.

- **Medical surveillance**—Annual medical exams, including blood tests, must be given free of charge to all employees exposed to levels above 1 ppm, regardless of whether or not they wear respirators. For employees with over 10 years exposure, the exams must be given every six months. At the request of the examining physician, alternative medical tests may be substituted for OSHA's recommended procedures.

- **Signs and labelling**—Warning signs in regulated areas and labels on PVC containers must include the words "cancer-suspect agent."

- **Recordkeeping**—Monitoring and medical records must be maintained for at least 30 years, and these results must be made available to employees and their representatives. This is the first time section 8(c)(3) of the Act, the "employee rights" provision, has actually been written into a standard,

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and similar provisions are likely to appear in all future health standards.

It goes without saying that the plastics companies are not happy with the standard OSHA finally promulgated. "OSHA may believe that it has adopted a compromise position between organized labor on the one hand and industry on the other," says Ralph Harding of the SPI, "but the result is a standard that does not take into account in a practical way the known medical and technological facts. As we read the OSHA Act and the legislative intent expressed prior to passage, the law was never intended to eliminate the worker's job in order to make it safe nor was it intended to make the worker's eight-hour day the equivalent of a shift on the rack [a reference to the respirator requirement]."

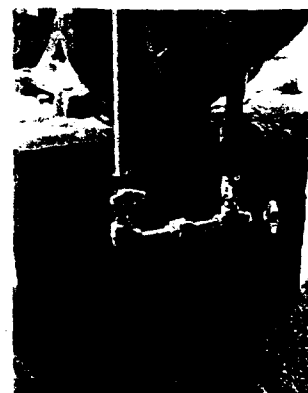
Representatives of the workers involved are much more hopeful about the standard. "We didn't get everything we wanted, and the standard has some serious failings," says Sheldon Samuels, director of health, safety, and environmental affairs for the Industrial Union Department (IUD) within the AFL-CIO, "but many of the goals the IUD has been pushing for since the beginning of OSHA were written into this standard—things like keeping medical records for a long term and holding an industry not to its worst plants but to its best plants in setting up feasibility requirements. The voluntary respirator provision bothers us, we feel that continuous monitoring should be required for the ceiling level, and we think OSHA made a mistake in deleting the proposed requirement to keep food facilities separate. Overall, though, labor feels that the Office of Standards has done its best job to date." To individual members of the unions involved, the IUD is sending out 25,000 copies of a special bulletin explaining why respirators should be worn.

At press time, the plastics companies were engaged in complicated legal maneuvering over the OSHA standard. Several companies and the SPI had filed suits against the standard in appeals courts. All the cases are likely to be consolidated into a single suit to be heard before the U.S. Second Circuit Court of Appeals in New York. The court scheduled a hearing for the third week of December 1974. In the end the court may uphold the standard, or it may remand all or part of the standard to OSHA for reconsideration. The AFL-CIO has entered into the case as a party on the side of the OSHA standard. In a separate action the SPI has peti-

tioned OSHA to stay the standard until enough respirators are available to implement it or until the court of appeals makes its ruling. If OSHA denies the petition, the SPI may go to court seeking a temporary stay of the standard.

If the standard is upheld, will companies be forced out of business? At this time, few within the plastics industry are willing to make predictions about that subject. A typical view is that of Richard Fleming, vice-president of Air Products and Chemicals (one of the companies challenging the standard in court): "There are tremendous pressures on the industry to cause it to try to operate rather than to shut down immediately—the job security of perhaps hundreds of thousands of employees and the billions of dollars invested in plants. For these reasons, most VC-PVC operations may be expected to make every effort to comply. I cannot project what will come of these efforts or how long they will be continued. This will surely vary with the individual firm. It is abundantly clear that, if any producer can comply, the costs for VC and PVC under this regulation will go up dramatically and production volumes will decline sharply."

Below, a cut-off pipe returns VC to the closed manufacturing system when a pump must be repaired. Below left, a safety inspector takes a "grab-bag" air sample to be analyzed for VC.



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Meanwhile, most companies seem to be going ahead with plans to reduce VC levels and order respirators. In its third quarter report for 1974, B.F. Goodrich announced that 2 million would be spent in the next three or four years to cut exposures in its six monomer or polymerization plants, modernize facilities, and increase production. B.F. Goodrich is also continuing construction of a new Louisville PVC plant with vastly improved technology to be completed in 1975.

"There is no big technological breakthrough just around the corner that is going to cut exposures overnight," says Dr. Paul Lobo, director of the organics and polymers division for Tenneco. "Right now we have 1 ppm of VC in the plant offices, and we're not even sure where it's coming from. Most of the improvements are going to be step-by-step, trial-and-error things that take time."

Considerable progress has been made since the emergency temporary standard went into effect on April 5 last year. At the hearings last summer, John Nelson, a Goodrich vice-president, testified that VC levels in the Louisville plant had been cut from the 35-40 ppm range to 12-14 ppm at that time. At another company's PVC facility, an indoor plant with small reactors, levels had been cut to as low as 11 ppm last summer and, according to union sources, are now in the 3-5 ppm range.

Much of the activity in polymerization plants focuses on ways of reducing exposures when reactors are cleaned. Part of the problem is that the smaller the reactor, the more often it must be cleaned and the more potential for exposure. In some older plants reactors can hold 1,100 gallons, while in newer plants reactors with 20,000 to 35,000 gallon capacities have been built. B.F. Goodrich uses a high-pressure water spray system built into the reactors, making it necessary to open them up less often. Tenneco has licensed a new PVC process, which, in theory, should allow no film deposits on reactor walls. Consequently, it is hoped reactors will not need to be opened on a routine basis in the Tenneco plant now being built in Pasadena, Texas.

At its three monomer plants in Texas, Dow has instituted a series of procedures that were keeping exposure levels below 10 ppm at the time of the hearings last summer. When loading tank cars, for instance, the hose is completely emptied into the car by purging it with nitrogen before disconnect-

ing. Magnetic loading gauges are also being put into service so that the loader doesn't have to vent VC into the air to check the level in the car. Lab workers removing VC samples from the system use a closed loop sampling method that prevents any VC from escaping, and all unused samples are returned to the system. When any part of the system needs to be opened up for maintenance work, it is first purged with inert gases.

Almost everyone in the industry agrees that the ultimate answer to getting VC levels in fabrication plants even lower is to reduce the amount of unreacted VC monomer in PVC resins. All PVC producers are making efforts along these lines, though the tricky chemical balancing process involved means that production has dropped slightly and the PVC produced is not as high-quality. Still, the outlook in this area is encouraging. Tenneco, as one example, is aiming at 50 ppm of VC in PVC resins, and the company's plant in Burlington, New Jersey, has reduced these levels to 20 ppm and lower. Before 1974, the amount of unreacted VC usually ranged between 300 and 500 ppm in the resins.

In the end, the tragic paradox of setting a standard to protect VC workers is this: Proof that low-level VC exposure is dangerous—at least the kind of proof that industry is demanding—will come only in the form of more dead workers in the future. Obviously, though, since VC workers cannot be treated like experimental animals, we must rely on the "best available evidence" at present to minimize risks for these workers.

"I would feel safe at 25 ppm," says Richard Fleming of Air Products, "and I wouldn't be saying that if I felt that we would be killing a lot of people. I have no incontrovertible evidence, but you have to remember that nothing in life is totally without risk. You can't eliminate risk and still live, so you have to balance the risk factor against practicalities."

"I have to rely on other people to let me know if my health is in danger," says Sanford Beck, president of the Oil, Chemical, and Atomic Workers' local at Air Products' Calvert City, Kentucky, plant. "I know nothing about the medical terms. I don't want to see the plants shut down and people out of work, but I don't want to see them dying at an early age either. If man can go to the moon, surely we can control vinyl chloride."

Mr. Clack is assistant editor of JOB SAFETY & HEALTH.

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Vinyl Chloride

The Canary in the Coal Mine



Two leading scientists discuss the implications of the vinyl chloride health hazard.

Shortly after OSHA's permanent standard on vinyl chloride came out, *Job Safety and Health* talked with two researchers deeply involved in the investigation of angiosarcoma among these workers. Dr. Irving Selikoff, director of the Environmental Sciences Laboratory at the Mt. Sinai School of Medicine, first became well known for his research into diseases related to asbestos. He is also the editor of the *Journal of Environmental Research*, president of the Society for Occupational and Environmental Health, and a past president of the New York Academy of Sciences. Dr. Joseph Wagoner, director of the Division of Field Studies and Clinical Investigations of the National Institute for Occupational Safety and Health (NIOSH), is heading up NIOSH's epidemiologic study of workers in the vinyl chloride industry.

Q. Both you and NIOSH, Dr. Selikoff, have recommended a "no exposure" level for vinyl chloride. Are the limits set in OSHA's standard—1 part per million (ppm) as a time-weighted average and 5 ppm as a ceiling—adequate to protect workers?

Dr. Selikoff: I interpret the 1 ppm limit as being a no exposure level. It is unlikely that any company would instruct its engineers to plan a system with a small leak. They would design production processes with a zero level in mind, recognizing—as I think OSHA has recognized—that in human affairs some slight mistakes will occur.

Dr. Wagoner: There is no compromise in the standard as far as the 1 ppm average or 5 ppm ceiling goes. I think these are entirely consistent with what NIOSH has recommended. There is really no acceptable level of exposure since science is unable to define what a "safe" level for a carcinogen is. But we recognize that we have to take into account the sensitivity of our measuring instruments. From that point of view, then, I have no problems with the 1 ppm level.

Q. Do you see any problems developing from the part of the standard that says vinyl chloride levels

must be reduced to the "lowest practicable levels" through engineering controls and that respirators will be made available if these levels are above 1 ppm?

Dr. Selikoff: I think implementing the standard will have to be worked out on a plant-by-plant basis. In the large polymerization facilities the design for reaching 1 ppm levels is already available as functioning units. In at least two polymerization plants, I have seen on-line equipment that was giving 1 or 2 ppm some months ago. I have great confidence in the engineering skills of our petrochemical industry, and I believe that the 1 ppm requirement will be met relatively soon.

It is true that there may be some processes in which attaining this level will be difficult. But I am sure there will be no compromise on the part of OSHA with the essential principle—that no workers be exposed to cancer-producing chemicals.

Dr. Wagoner: I think there are certain problems with the standard. I sat on the Advisory Committee for Asbestos when one of the world's leading experts on respirators described them as pure instruments of torture. We have to recognize that respirators are no substitute for good engineering control. A respirator can be totally effective, but if it's not used, it is worthless. And I think the standard's reliance on voluntary usage of respirators for that first year opens the way to major problems. [Between January 1, 1975, and January 1, 1976, wearing a respirator is at the individual worker's discretion if vinyl chloride levels are below 25 ppm.] Many plants are not organized, and this provision seems to leave enforcement activity up to the worker. If we accept the concept that there is no known safe level for a carcinogen, then it seems rather inconsistent to say that we will make using a respirator voluntary.

During our own investigations on vinyl chloride, we refused to put any NIOSH investigators into any plant until we had adequate respirators for them to wear. On this basis we feel strongly that it should be mandatory for the worker to have the benefits of those respirators, too.

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Q. Why are the media paying so much attention to vinyl chloride when other toxic substances have had equally disastrous effects on larger groups of workers?

Dr. Selikoff: There are a number of reasons for this. Through bitter experience in these past 10 years, we have all become thoroughly aware of the long incubation periods associated with occupational cancers. This has been true of cancers caused by asbestos, arsenic, benzidine, beta-Naphthylamine, and so on. The petrochemical industry, which grew enormously during and following World War II, has created many new products that have become essential to our industry and community. If there was to be a cancer hazard associated with these new products, it would first be seen in the early 1970's. Vinyl chloride, then, is the first evidence that some of these chemicals that have been introduced can be carcinogenic. Vinyl chloride may be unique—and we all hope it is—or it may be one of a series of new cancer-causing agents that are going to become apparent. In this sense, vinyl chloride is similar to the canaries we used to send into the coal mines to see whether there was too much methane.

You have to remember, too, that we are only beginning to see the effects of vinyl chloride itself. Very few workers were employed in the vinyl chloride polymerization industry back in the late 1940's and early 1950's. Yet the cases of angiosarcoma now showing up are derived from that small group. The average duration of the cases now being seen is 20.5 years from onset of exposure. Since most vinyl chloride workers began employment in the 1950's and sixties, liver cancer that will occur in this much larger group will not appear until the 1980's and nineties.

There also seems to be evidence of increased numbers of neoplasms [tumors] other than angiosarcoma, such as cancer of the lung, pharynx, brain, and the system that forms blood cells. If this is confirmed, then we are dealing with a broader cancer problem than we were first aware of.

The last point I would make is that we do not know the level of vinyl chloride exposure associated with angiosarcoma. It may be low—1, 2, 3, or 4 ppm—or it may be that only 10 ppm or higher will give a significant number of cancers. If it's low, then we are in trouble because the fabricating part of the industry—where vinyl chloride is made into finished products and exposures are generally lower—employs many more workers. Estimates vary from 350,000 to 1,500,000.

Dr. Wagoner: I think there are three other points we must recognize in regarding vinyl chloride as a test case. Once again, within a very short period of time, we've seen that data from animal studies, as in the case of bis-Chloromethyl ether, predicted what we would see in humans. We produced angiosarcoma of



the liver and other tumors in animals with vinyl chloride, and now we are seeing these in humans. This reconfirms the importance of pretesting chemical agents on animals.

Secondly, vinyl chloride is the classic example of the idea that the occupational environment cannot be considered in a vacuum. Over and over again we are seeing occupational health problems extended out into the general population. The workplace is the best predictor of environmental causes of cancer.

Finally, vinyl chloride raises a problem that has been completely overlooked in the past. As far as I know, there have been only one or two studies in the entire history of occupational medicine on the potential mutagenic, or chromosome-altering, properties of an agent.

Q. What is the evidence for the mutagenic effects of vinyl chloride?

Dr. Selikoff: There are few data so far, and I believe that they should be interpreted with caution at this time. We have found in very limited studies that significant chromosome abnormalities are more often present among vinyl chloride workers than among control subjects. Laboratory studies in Sweden and in the United States have also demonstrated the mutagenic potential of vinyl chloride in bacterial test systems. We feel, however, that broad conclusions are not warranted at this time though, obviously, because of the potential importance of the subject, additional studies should be rapidly undertaken.



Left, Dr. Selikoff.
Above, Mt. Sinai.

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Dr. W. foreign govern of angi a case in an o we four premise lower t interval demic where we're facilitie

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Left, Dr. Joseph Wagoner of NIOSH.
Above, Dr. Irving Selikoff of the
Mt. Sinai School of Medicine.

Q. *There are at least two pieces of evidence linking liver problems with work in fabricating plants—six German tile workers who are showing signs of liver disease and the two Connecticut workers who died of angiosarcoma. Has any other evidence from fabricating plants appeared yet?*

Dr. Wagoner: Data have become available from the foreign literature. NIOSH put out a call to all foreign governments and scientists to alert us to any cases of angiosarcoma, and, indeed, in Scotland we found a case in an individual who used polyvinyl chloride in an oil cloth factory. It is very similar to the case we found in Connecticut. If we accept the very basic premise that as you lower the exposure level, you lower the incidence of the tumor and lengthen the interval in which the disease is latent, then the epidemic of angiosarcoma in fabricating plants is somewhere off in the future. So it doesn't surprise me that we're not seeing as many cases in fabrication facilities.

Dr. Selikoff: I would be worried, in fact, if we were seeing many at this time. Full judgment on this matter, however, will have to await further experience.

Q. *Is there such a thing as "vinyl chloride liver disease"—in other words, a precursor of angiosarcoma?*

Dr. Selikoff: Yes. This has been well demonstrated by Dr. Hans Popper and Dr. Louis B. Thomas. There is characteristic liver disease associated with vinyl chloride that appears both before the advent of angiosarcoma and, in some cases, seems to exist in its own right without angiosarcoma. The appearance of the liver is quite characteristic, and there are a number of other distinct liver changes that go along with the condition. Last year this liver condition was also described among people taking arsenic for treatment of psoriasis. It has appeared as well among vineyard sprayers in Germany who use arsenic. A capable pathologist will be able to recognize what we can now term vinyl chloride liver disease.

Q. *Why does angiosarcoma seem to show up in some vinyl chloride manufacturing or polymerization plants and not in others? Why aren't the cases distributed several to each plant?*

Dr. Wagoner: I have a theory on this. The theory is that we have found them whenever we have looked hard enough.

Dr. Selikoff: I think that's probably the best theory. I would add that we would not expect to find angiosarcoma in plants that first went into operation in the last 10 or 15 years. The experience of these facilities will have to be evaluated 5, 10, or 15 years from now. Support for Dr. Wagoner's judgment is also evident in the fact that angiosarcomas have appeared in so many different plants, indicating that they are unlikely to be something unique to the process or materials in one or two plants.

Q. *Are there any optimistic developments that have come out of the whole vinyl chloride problem?*

Dr. Selikoff: I can make two pleasant observations about this unhappy situation. One is that a number of industry groups have made valuable contributions to the developing studies on vinyl chloride. I would particularly comment upon the research results of the Dow scientists. We at Mt. Sinai, in our own studies, have had the cooperation of the Goodyear Company and the Union Carbide Company. Industry's cooperative stance in general has been noteworthy. Secondly, the maturity of many labor unions was evident in the rapid response they made. The cooperation of the Textile Workers of America; the Oil, Chemical, and Atomic Workers; the International Association of Machinists; the United Steelworkers; the International Chemical Workers; the United Rubber Workers; the Industrial Union Department of the AFL-CIO; and others has enabled scientists to obtain information much more quickly than might otherwise have been the case.

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Historical Hazards



Things have changed a lot where vinyl chloride is concerned since this picture was taken in early 1974. Here, a safety inspector in a polyvinyl chloride plant uses a portable organic vapor analyzer to "sniff" for vinyl chloride leaks near a reactor.

Under OSHA's emergency temporary standard (in effect between April 5 and December 31, 1974), he was not required to wear a respirator since vinyl chloride levels were apparently under 50 ppm. The meter appears to be registering about 30 ppm of vinyl chloride in the air. According to the permanent vinyl chloride standard now in effect, however, he must wear an air-supplied respirator.

For a summary of the rapid vinyl chloride developments, see the article beginning on page 4.

ustry sources have cited, as a kind of opti-
note, data from an epidemiologic study un-
n by Tabershaw-Cooper Associates for the
actur. Chemists Association. The overall
ity rate for the workers in that study was less
ould be expected for the general population.
vinyl chloride problem, then, less serious than
lly thought?

Wagoner: I think there are fallacies in that line
oning. The Tabershaw-Cooper study includes
ody who has as little as one year's experience
l chloride plants, and they studied these peo-
en during the first year after they were ex-
Now, there is no such thing as instantaneous
. Biologically it is nonsense to expect to see a
stic effect resulting in death within one year.
udy includes a disproportionate number of in-
als who have had an insufficient latent period
ch the cancer could become manifest. Nat-
they are seeing a deficit in the total number
ths.

have looked at their data, and we also see a
ant deficit of cirrhosis of the liver in this pop-
l. I have talked to the medical directors of the
nies involved, and they tell me that they have
aggressive screening programs for alcoholism.
olism is highly associated with cirrhosis of the
In this way, then, and in many other ways the
ytes studied are more healthy than the general
ation it was used as a control group. That
includes people who are in hospitals with
and people who work in other industries with
risk of cancer. I think that if the workers
d are looked at again in 10 years, the study
isions will be the exact opposite of what they
w.

Selikoff: In general, we like to evaluate the expe-
of a group when it is "at risk." Because large
ers of workers who are not currently at risk
cluded in this study, we can't use it to evaluate
will happen to people who are at risk. I'm
ent that as further data accumulate and more
rs are traced—a large number, after all, were
aced in this study—appropriate conclusions will
awn. Both Dr. Tabershaw and Dr. Gaffey
[thors of the study] are competent and knowl-
ble people, but it seems inevitable that indi-
ls who are not thoroughly familiar with the
ications that go along with scientific data will
te the findings in ways in which they were not
t to be evaluated.

Dr. Selikoff: you have testified about toxic effects
yl chloride that were known as early as 1938.
didn't people pay more attention to this evi-
e at that time? In other words, how do we pre-
future vinyl chloride disasters?

Dr. Selikoff: The evidence was indirect and limited,
but more important, our concepts were undevel-
oped. By that I mean that when a substance is
known to be biologically active in one organ system,
we must at least admit the possibility that it may be
active in other ways as well and look for such
activity. It has been known for at least 25 years
that vinyl chloride could have toxic effects on the
liver. Today, with such information, we would feel
that other biological effects, primarily cancer, would
have to be taken into consideration. All substances
now known to have some organ toxicity should be
looked at as soon as possible with regard to their
possible carcinogenic effect. This can be done
through animal studies or through a combination of
animal studies, epidemiologic studies, and clinical
studies.

If an agent is carcinogenic, it's obviously impor-
tant to know this as soon as possible. However, I
think negative data would be equally valuable. We
can't go running off in all directions at one time. It
is important for us to know that some things are safe
and that we can devote our very limited resources to
those of which we are most suspicious.

Dr. Wagoner: The Toxic Substance Control Act,
which has been passed by both houses of Congress
and is now held up in a House-Senate conference
committee, addresses the very basic issues involved
here. Must we continue to suppose that industrial
chemicals are safe until proved otherwise and then
go out after the fact to see the devastating effects?
Or, is it more rational to pretest agents before they
are introduced into the workplace?

Q. The director of environmental health for a large
chemical company once made this argument to me:
Relatively few workers are exposed to the hazardous
effects of vinyl chloride, but many lives are saved
in other industries because of polyvinyl chloride
products like hospital equipment. How do you re-
spond to that view?

Dr. Wagoner: I think we can have our polyvinyl
chloride products and a safe environment for the
worker at the same time. I don't think these are
mutually exclusive possibilities, and I don't think we
should have polyvinyl chloride products if it means
that as many as one extra person will die.

Dr. Selikoff: The very fact that there are relatively
few workers involved would suggest that the feasi-
bility for control is greater. We really have no op-
tions in the matter. Congress passed the Occupational
Safety and Health Act to make sure that no worker
should suffer ill health or risk his life as a result of
occupational exposure.

*Dr. Selikoff and Dr. Wagoner were interviewed by George
Clack.*