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B.F. Goodrich Loses VCM Cancer-Link Case

A Federal district court in Camden, N.J. has ordered B.F. Goodrich Company to pay almost $400,000 in compensatory damages to a New Jersey woman whose husband's death was linked to emissions of vinyl chloride gas from Goodrich's Pedricktown, N.J., polyvinyl chloride plant.

Mrs. Grace M. Grasso charged that Goodrich failed to perform tests on emissions of vinyl chloride gas from its PVC plant, which opened in 1970 less than two miles from Mrs. Grasso's home.

Mrs. Grasso's husband, John C. Grasso, died of liver cancer in January, 1977, at the age of forty-nine. Mrs. Grasso was awarded $391,291 in compensatory damages, including over $37,000 to cover medical expenses incurred during her husband's six-month illness and $285,000 to cover his future estimated wages.

"We firmly believe that exposure to vinyl chloride at the low level found at Pedricktown could not have caused Mr. Grasso's angiosarcoma," Goodrich said in a prepared statement. The company says its belief is based on laboratory studies and medical evidence. "All angiosarcoma cases attributed to vinyl chloride exposure," the company adds, "have been in workers who have experienced high concentrations of vinyl chloride in the workplace over long periods of time. The Pedricktown facility began operations only in 1970 and has not emitted high levels of vinyl chloride. In fact, no one either inside or outside any Goodrich facility is being exposed to such conditions," Goodrich says.

A Goodrich spokeswoman in its Akron, Ohio, headquarters says Mrs. Grasso's case is the first of its kind brought in connection with the company's Pedricktown plant. Goodrich is reviewing the court's decision and is considering an appeal, the spokeswoman says.

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2nd plant reports brain tumor deaths

By BILL INMAN
Post Reporter

A federal health investigation into the brain cancer deaths of 10 chemical workers at Union Carbide's Texas City plant has turned up five additional brain cancer deaths at Monsanto's nearby chemical facility.

Both plants once produced the cancer-causing agent vinyl chloride. The substance has been linked by scientists to the brain tumor glioblastoma multiforme.

"We're trying to cooperate and coordinate our efforts fully with the government," said Monsanto spokesman John Spano from the company's St. Louis headquarters.

"We're concerned, as others are, about the incidence of this form of cancer. We want to stress, however, that the glioblastoma form has not been determined in these last five cases."

The federal investigation stemmed from a Union Carbide worker's complaint received Nov. 27 by the Occupational Safety and Health Administration.

A scientific team including OSHA and National Institute for Occupational Safety and Health specialists soon found at least 10 Union Carbide workers had died of brain cancer between 1962 and 1978.

Six of the 10 victims had glioblastoma multiforme listed as cause of death on their death certificates. And another two of the group were thought to have that same form of cancer. An 11th Union Carbide worker, still living, also has been diagnosed as having the glioblastoma tumor.

Monsanto began sifting health records and death certificates of some 1,300 workers after it learned of the Union Carbide study, Spano said. OSHA officially approached the plant Feb. 14 and conducted chemical exposure checks.

"It's far too early to make any kind of judgment," said Dr. Joseph Wagner, monitoring the OSHA investigation from Washington.

"At this stage of the game, we're concentrating on Union Carbide, where we feel we have a good sampling."

George Pettigrew, regional NIOSH director, said the records of current and former Union Carbide workers — some 10,000 — are being reconstructed for an epidemiological study.

The time-consuming study will include researching demographic disease patterns and records of plants that produce vinyl chloride. Study results are expected to be months away.

Complicating the record-gathering process, said Pettigrew, is the latency

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Another chemical plant finds brain tumor deaths

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period involved. "It appears that maybe 20 years or so after vinyl chloride exposure, the cancer shows itself. That's something like a time bomb, and it makes our job a lot more difficult."

Two of the five brain cancer deaths at Monsanto have already been earmarked by company researchers for detailed glioblastoma tests, said Spano.

"Nothing has been confirmed thus far," he said.

Monsanto purchased the plant in the mid-40s from the federal government. Vinyl chloride monomers were used in production from 1953 to 1968. Unlike the Union Carbide plant, Monsanto no longer processes the material.

No Monsanto employee complaints have been filed with federal agencies concerning vinyl chloride, said Joe Clark, head of personnel at the Texas City plant.

He said the company has notified workers through staff meetings of the potential hazard.

Area OSHA director R. Davis Layne said no citations have been issued against Union Carbide or Monsanto in the past six months for chemical exposure above legal levels.

He said there are "too many complicating factors at this point" to make any definitive connection between the chemical and the Texas City deaths.

The Houston Post/Tues., March 6, 1979/

Lel v. Health

VINYL CHLORIDE AND BIRTH DEFECTS

In the late summer of 1974, a researcher in Ohio reported that vinyl chloride gas might be contributing to a higher than normal incidence of birth defects among children born in communities where such gas is produced or where it is used in the manufacture of polyvinyl chloride resin. In early 1976, an excess of stillbirths and miscarriages among the wives of heavily exposed vinyl chloride workers also was reported. Much misinformation and misunderstanding has resulted from these two reports. The purpose of this paper is to put forth the facts and to set the record straight.

This paper documents three key points:

- Research conducted in Ohio purporting to show a relationship between vinyl chloride emissions and an excess of birth defects has been roundly criticized by experts in the field and has been refuted by a series of studies conducted by the Federal Center for Disease Control.
- According to experts from Harvard University and the University of Texas, the single study alleging an excess of stillbirths and miscarriages among the wives of heavily exposed vinyl chloride workers is "inadequate," "misleading" and essentially "worthless."
- Two separate animal studies found that even at extremely high levels of exposure, vinyl chloride did not produce mutagenic or teratogenic effects in the test animals even though it has been found to be capable of producing a mutagenic reaction in salmonella bacteria.

Background

In January 1974 three cases of angiosarcoma, an extremely rare type of liver cancer, were discovered among long-term workers exposed to high concentrations of vinyl chloride monomer (VCM), the gaseous industrial chemical used to produce polyvinyl chloride (PVC) resin. Ultimately, over a period of 16 years, 23 deaths were confirmed in four U.S. plants, and approximately 48 in other countries. The workers' jobs principally involved cleaning residue of PVC resin from the polymerization reactors in which it was produced from VCM.

As a result of these findings, the U.S. Occupational Safety and Health Administration in 1974 announced standards to drastically reduce worker exposure to vinyl chloride. In 1976 the Environmental Protection Agency issued regulations limiting emissions of VCM into the atmosphere around vinyl chloride and PVC resin plants. The Food and Drug Administration currently is considering regulations on the use of PVC food and beverage packaging materials.

Because of these regulations and through industry efforts, VCM exposures in the workplace have been reduced a hundred-fold or more in the past four years. Emissions into the atmosphere have been decreased by over 90 percent. Similarly, new and better PVC packaging materials have been developed to eliminate the possible migration of residual vinyl chloride from the PVC into finished food and beverage products.

Additional Research Conducted

As a consequence of the angiosarcoma discovery, a wide range of scientific research projects have been undertaken or expanded in the past few years to investigate further the possible health effects of vinyl chloride exposure. Among other findings of this research, VCM was shown to be capable of producing a mutagenic reaction in salmonella bacteria; and an increase in chromosomal breakage was found in a small number of heavily exposed PVC polymerization workers although, in another study, no chromosomal changes were seen in workers exposed at lower levels. Because of these findings, concern was raised that VCM might also cause malformations or birth defects in humans.

Study of Ohio VCM Plant Towns Undertaken

To investigate this supposition, Dr. Peter F. Infante, then of the Ohio Department of Health, examined the birth records of children born between 1970 and 1973 in three towns in northern Ohio -- Painesville, Avon Lake and Ashtabula -- that contained vinyl chloride polymerization plants.

In a preliminary report released in August 1974 and in a paper subsequently published in 1976, Dr. Infante reported that the rate of birth defects, based on hospital records, in each of the three Ohio towns was significantly higher than the average for both the state of Ohio and for the balance of the three counties in which the towns were located.

Dr. Infante further reported a major excess in birth defects of the central nervous system (CNS), which he considered to be "the greatest cause for concern," and also in adult deaths from CNS cancer.

These reports attracted wide press attention and speculation, even though Dr. Infante, in his Academy of Sciences paper, had warned:

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

While the press totally ignored this statement, a careful analysis of the data contained in the report lends credence to the reservations expressed in the paper's conclusion. In addition, serious questions as to the quality of the research and the value of the findings of the study have been raised by two eminent scientists -- Dr. Brian MacMahon, chairman of the department of epidemiology, Harvard University Graduate School of Public Health, and Dr. Thomas D. Downs, professor of biometry, University of Texas Health Science Center. The two scientists were engaged by The Society of the Plastics Industry to conduct independent critical reviews of all known literature relating to vinyl chloride and birth defects.

For comparison purposes, the Infante study examined the birth defects rates in nine communities without PVC facilities, but which were located in the same general geographical area as the three plant towns. Two of them were found to have birth defects rates higher than any of the communities with PVC facilities.

Not only was this discrepancy unexplained, but the report also combined cases of CNS malformations from one of these two communities -- North Ridgeville -- with those from the three plant towns in developing the basic statistics. This unusual procedure was explained in the report by stating that North Ridgeville was "proximate" to one of the plant towns. In reality, the two are nearly 10 miles apart -- approximately twice the distance that the Environmental Protection Agency has determined, through extensive air monitoring, as the maximum that vinyl chloride gas can travel through the air before decomposing into other, non-toxic, materials.

The inclusion of North Ridgeville data in the Infante study is both misleading and inappropriate. Dr. MacMahon, in his critique of the study, called the addition "completely unjustified." Dr. Downs said "in our judgment the inclusion...is reprehensible."

In addition, if one examines the data from the four towns separately, rather than in combination, the fact emerges that while one of the plant towns -- Painesville -- did have over half of the observed CNS birth defects, the non-VCM town had 25 percent of the total. Another of the plant towns -- Avon Lake -- which has had a VCM facility in its midst for the longest period of time of all three communities, had no CNS defects at all.

Nearly the same situation applied in the case of CNS cancers among adults. The report, once again, added cases from North Ridgeville to the three plant towns. When examined separately, only Painesville and North Ridgeville, which has no VCM facility, showed an excess of adult CNS cancer deaths. The other two VCM plant towns showed no excess.

When the hard data from the three VCM plant towns and North Ridgeville are examined individually, more unexplained differences than similarities in CNS malformation and adult cancer rates emerge. The procedure of "combining" data from three widely separate communities -- Painesville is located about 30 miles to the west of Ashtabula and Avon Lake lies another 50 miles west of Painesville -- plus a town without a VCM facility, effectively obscured these significant differences.

The sources Infante used for information on birth defects are routine reports of birth. Dr. MacMahon points out in his critique that birth certificates are "a notoriously poor source of information on congenital malformations." He states that the rate for the state of Ohio as a whole suggests that only about half the medically significant malformations are being reported.

Equally as important as the manner in which the data was compiled and presented is the fact that no attempt was made to determine whether any of the mothers involved (or their husbands) had ever been exposed to vinyl chloride, either by working in one of the VCM plants or by living in close proximity to them. Nor were any measurements made to determine if there was any vinyl chloride at all in the ambient air in these communities. Furthermore, interviews were not conducted of any of the subjects to determine, for example, if there was a history of birth defects in the family or if the mothers might have been exposed during pregnancy to some other toxic substance. Also, no attempt was made to compare the current birth defects rate with those existing before the VCM facilities were constructed.

Dr. MacMahon in his critique states that while Infante focuses attention on the central nervous system defects because of their unusual severity, 13 of the 17 categories examined are in excess and several such as oral clefts and club foot are in substantial excess. Since known teratogenic agents in humans and experimental animals produce specific malformations, it is unlikely that any agent would produce the variety of malformations found in excess in these cities, Dr. MacMahon says. A more likely explanation, he states, is some artifact, such as reporting differentials, that would apply to all categories of malformation.

Dr. MacMahon cites numerous shortcomings in the Infante research and sums up his critique by stating: "I am fairly well convinced that the finding results from a combination of chance, reporting differentials and epidemiologic gerrymandering." Dr. Downs, also highly critical of the research procedures, concluded his review with the comment: "It does not seem possible to salvage anything from this study."

Birth Defects Questions Studied by CDC

Because of the questions raised by Dr. Infante's Ohio study and the publicity that his results were receiving, the Center for Disease Control (CDC) of the U.S. Department of Health, Education and Welfare undertook an investigation of the possible relationship between vinyl chloride exposure and birth defects in humans.

The results of this investigation were published in the July 19, 1975, issue of Morbidity and Mortality, an official CDC weekly publication. In the first section of the two-part study, a comparison of birth defect rates in hospitals in two widely separated cities with VCM installations -- one in Pottstown, Pennsylvania, the other in Painesville, Ohio (which was included in Dr. Infante's study) -- showed no rate increase in the Pennsylvania community as compared with the state average. The CDC investigation did find an increase in CNS malformations in Painesville, similar to that reported 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 1970-1974. For each malformation case, two normal births were investigated as "controls" for comparison purposes. The results of this research, which covered a number of factors not included in Dr. Infante's study, can be summarized as follows:

- None of the interviewed parents of the children with CNS birth defects ever worked at either of the two VCM polymerization plants in Painesville (one set of parents could not be located, but records show they did not work at the plant at the time of their infant's birth).
- In the "control" group, two of the fathers of "normal" children were working at one of the VCM plants at the time of their infants' births.

- Neither of the parents in either group lived within two miles of either of the two plants.
- A statistical analysis of the actual distances between the two VCM plants and both residences and workplaces of the parents of "cases" and "controls" showed no difference between either group.

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 (capable of causing malformations), the evidence to date did "not establish any association between (birth defect) cases and vinyl chloride exposure."

The results and conclusions of the CDC investigation were also published for professional scrutiny in the November 29, 1975, issue of The Lancet, a prestigious British medical journal.

Dr. MacMahon concluded that it is not the presence of the two PVC plants that is responsible for the high malformation rate in Painesville. The most likely explanation, he said, seems to be "random fluctuation."

Second CDC Investigation Undertaken

Despite the publishing of the CDC research, some individuals continued to refer to Dr. Infante's study as the definitive, and indeed the only, investigation into the possibility of vinyl chloride induced birth defects. Dr. Infante, in defense of his own work, argued that there were several methodological errors in the CDC study that could account for its negative findings.

In order to settle the question once and for all, CDC decided to undertake a second, even more definitive investigation. The methodology for the study was modified to take into account Dr. Infante's objections. Charleston, West Virginia, where a vinyl chloride plant had been located since 1938, was selected as the study site. The investigation began in February 1976 and the results submitted in report form to the Director of CDC by the Cancer and Birth Defects Division of the Center's Bureau of Epidemiology on July 26, 1976.

Study Finds "No Relationship"

As in the earlier study in Painesville, Ohio, researchers contacted the parents of all children born with CNS defects in Kanawha County (Charleston and suburbs) from 1970 to 1974. A "control" group, consisting of the parents of "normal" children born in the same hospital immediately before or after a child with a CNS defect, were also interviewed. Air pollution, prevailing wind and other data were also collected.

The results of this investigation can be summarized as follows:

- Except for 1974 (the last year included in the study), rates of CNS birth defects in Kanawha County were higher than total U.S. rates.
- Five "case" parents out of 41 (those with children born with CNS defects) and no "control" parents reported a family history of CNS defects.

- Two "case" fathers and two "control" fathers were employed in the VCM plant at the time their children were conceived. Three additional "control" fathers had worked in the plant on a contract basis for a short time and therefore also had possible exposures.
- No mothers in either group had ever worked at the plant.
- Using sophisticated analytical techniques, no significant differences were found between the two groups as to their places of residence in relation to the plant at the time of their infants' conception.

The study noted, however, that of the nine "case" parents and ten "controls" who lived within three miles of the plant, most of the "case" parents tended to live east of the plant, while most of the "control" group lived south of the plant.

Because of this curious case "cluster," CDC said it "gave particular attention to the possibility that the cluster may have been caused by increased VCM emissions." While winds in the Charleston area are highly variable, the West Virginia Air Pollution Control Commission reported that suspended particulate matter, a good indicator of wind direction, was heavier in the southwest, thus "suggesting a prevailing wind from the northeast," i.e., away from the "cluster" and the plant.

Furthermore, if the case "cluster" was the result of VCM plant emissions, CDC theorized that "one would also expect an approximate correlation between a decrease in atmospheric VCM levels and a fall in CNS defect rates." According to the report, no such correlation was found.

The report concluded: "The investigation did not reveal an association between the case clustering within three miles of the plant and exposure to VCM or other chemicals."

In its summary of the entire study, CDC concluded that "no relationship between infants with malformations and parents' exposure to vinyl chloride could be established."

The CDC's conclusion was strongly supported by Dr. Downs. After a comprehensive review of the data in the CDC study, he said: "Our conclusion, therefore, is that the available scientific evidence does not indicate any association between vinyl chloride and community birth defects."

No Link in Canadians' VCM Study

In October, 1977, Dr. Gilles P. Theriault, Chairman of the Department of Social and Preventative Medicine at Laval University in Quebec, reported at the annual meeting of the American Public Health Association on a preliminary study comparing birth defect rates in two widely separated industrial communities in Quebec. One community -- Shawinigan -- contained a polyvinyl chloride production (PVC) facility. The other community -- Drummondville -- did not have such a plant. The two industrial communities of approximately equal population are more than 50 miles apart.

In his report, Dr. Theriault noted an apparently higher rate of birth defects in Shawinigan, the city with the PVC plant. He pointed out, however, that while the industry in Drummondville is primarily textile, in Shawinigan there is "an aluminum refinery plant, a carbide plant, a chemical factory and a pulp and paper mill."

Referring to the presence of other atmospheric pollutants in the environment of Shawinigan, Dr. Theriault said, "The present study does not permit linking the observed phenomenon to a particular pollutant, be it vinyl chloride or any other teratogenical agent."

To arrive at his conclusion that a higher overall rate of birth defects existed in Shawinigan, Dr. Theriault combined all types of birth defects. But as Dr. MacMahon has pointed out in a review of a variety of birth defect studies, "the known teratogenic agents in humans and experimental animals have considerable specificity in the malformations they produce." Therefore, Dr. MacMahon concluded it would be "unlikely" that any one pollutant would be responsible for the full range of birth defects reported in studies similar to Dr. Theriault's. A more likely explanation is that some artifact is responsible -- such as reporting differentials -- that would apply to all categories of malformations, he said.

Dr. Downs, who also undertook an independent review of birth defect research, also stated that the pattern of birth defects in the Theriault study is consistent with known incidences of the various malformations. If a single teratogen were involved, he concluded, one type of birth defect would most likely be greatly increased, rather than the slight increase observed for most of the deformities on the list.

Even Dr. Theriault found the increase in birth defects in the same order of magnitude in several organ systems "puzzling." The explanation, he said, could be that the chemical (vinyl chloride) in the Shawinigan environment produces by itself or in combination with other air pollutants a broad spectrum of developmental effects.

Or, he said, the apparent influence between Shawinigan and Drummondville can result from an artifact such as ignoring defects diagnosed after hospital discharge, different diagnosis or different reporting criteria used in the seven hospitals contacted.

Dr. Theriault appears to be in agreement with other scientists who have raised serious questions on the significance of the data obtained in this most recent study. In the conclusion of his report, he acknowledges that "further studies are needed to assert that vinyl chloride causes birth defects in the community living near a polymerization plant."

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 the April 3, 1976 issue of The Lancet. The study by Dr. Infante et al., was conducted at a single PVC resin plant in Pennsylvania. It purported to show that the wives of workers exposed to heavy concentrations of VCM had a statistically significant increase in the number of stillbirths and miscarriages compared to 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. Second, 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 stillbirth 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.

Both Dr. MacMahon and Dr. Downs, after separate reviews of the study, were highly critical of the analytical methods used. Dr. Downs said that the "misleading conclusions" drawn by the authors were brought about through the "selection and use of their control group." Dr. MacMahon called the data "worthless," the analysis "naive" and the test "inadequate and misleading." "In short," he said, "this paper is strewn with evidence of carelessness and incompetence and deserves, in my opinion, no consideration whatsoever in weighing the

question of whether there is or is not a genetic risk associated with exposure to VCM."

Animal Studies Show No Teratogenic Effects From VCM

In 1977, J.A. John, et al., conducted animal studies on rats, mice and rabbits to determine the effects on fetal development when the subjects inhaled vinyl chloride. Groups of mice were exposed to 50 ppm and rats and rabbits were subjected to 2,500 ppm of vinyl chloride. In the summary of their report, which was published in Toxicology and Applied Pharmacology, the authors said, "While maternal toxicity was observed, vinyl chloride alone did not cause significant embryonal or fetal toxicity and was not teratogenic in any of the species at the concentrations tested."

Two years earlier in 1975, I. Purchase, et al., carried out an animal study in England on the chromosomal effects from inhalation of vinyl chloride. Fifteen male mice were exposed to VCM levels of 30,000, 3,000 and 1,000 ppm of vinyl chloride for six hours a day for five consecutive days. Examinations were carried out after each male was mated with a female. In their report, which was published in the August 1975 The Lancet, the authors said: "There was no significant increase in the number of early deaths per implantation compared with the control group exposed to air alone, indicating that VCM does not produce dominant lethal mutations in mice at these exceptional high levels. It appears, therefore, that the mutagenic effects of vinyl chloride, expressed as chromosomal aberrations in lymphocytes, do not occur in the germ cells...The potential danger of mutagenic effects on the fetus via the sperm does not, therefore,

seem to exist." Unfortunately, the details of this animal study have not been published. This same report did suggest that increased chromosomal changes could be seen in highly exposed workmen.

Conclusion

Since 1974, a number of studies have been undertaken to determine the potential mutagenic or teratogenic hazard of vinyl chloride exposure. Extensive experiments conducted by the U.S. Center for Disease Control have failed to discover any relationship between birth defects in children and their parents' exposure to vinyl chloride. This research refutes an earlier, less definitive study conducted in three towns in Ohio, and a more recent one conducted in Canada. Animal studies have likewise failed to find a link between VCM exposure and either mutagenic or teratogenic effects.

One study undertaken at a single plant in Pennsylvania, which reported that the wives of workers exposed to heavy concentrations of vinyl chloride had a greater number of stillbirths and miscarriages than the wives of workers exposed to little or no VCM, has raised numerous questions by experts about the methodology and conclusions drawn from this study.

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VINYL CHLORIDE MIGRATION AND FOOD PACKAGING

In early 1973, a national distiller reported to the Treasury Department's Bureau of Alcohol, Tobacco and Firearms (BATF) the presence of vinyl chloride in distilled alcoholic beverages packed in experimental polyvinyl chloride (PVC) bottles. As a result of the report, BATF banned the further use of experimental PVC bottles with alcoholic beverages and the Treasury Department withdrew its provisional approval for the use of PVC bottles for distilled alcoholic beverages. The Food and Drug Administration (FDA), which has responsibility for "alcoholic foods" under the Food, Drug and Cosmetic Act, proposed a regulation banning the use of PVC from all alcoholic foods and began to study the question of vinyl migration from food packaging containing vinyl chloride. All of this occurred prior to a discovery in 1974 which associated vinyl chloride monomer (VCM) with cancer in humans.

Since the initial report of vinyl migration and following the establishment of the cancer link, an environmental group has petitioned the FDA to ban completely all PVC food packaging materials. The FDA has proposed a regulation that would withdraw its "prior sanctions" from rigid and semi-rigid PVC packaging products and has banned the use of another chemical product, acrylonitrile (AN), to fabricate beverage containers. During the last five years, newer, more sensitive equipment has been developed to measure vinyl chloride migration and PVC manufacturing processes have

been dramatically improved which permit the production of packaging materials containing only minute amounts of residual vinyl chloride monomer (RVCM).

In other areas, a number of legal actions have been taken by various groups which sometimes have tended to cloud rather than clarify the issue. In addition, the results of several complex scientific studies have not been clearly understood. The result has been confusion and apprehension in the public's mind concerning the use of packaging materials made of PVC. The purpose of this paper is to present the facts regarding vinyl chloride migration from food packaging and to place the issue in its proper perspective.

This paper documents four key points:

- There is no reasonable likelihood today of vinyl chloride monomer (VCM) getting into the diet from PVC food packaging materials.
- Today's virtually momomer-free PVC resins were developed through an intensive effort by the plastics industry which reduced the residual vinyl chloride monomer in rigid and semi-rigid products from 500 parts per million (500ppm) to as low as 2 parts per billion (2ppb).
- There is no scientific evidence to date showing that vinyl chloride monomer in the levels found in PVC food products is carcinogenic.
- In recent months the Food and Drug Administration (FDA) appears to be reassessing its previously expressed position regarding proposed regulations for the use of PVC in food packaging materials.

Background

Early in 1973, Schenley Distillers, Inc. reported to the U.S. Treasury Department's Bureau of Alcohol, Tobacco and Firearms (BATF) that it had found evidence of the presence of residual vinyl chloride monomer (RVCM) in distilled alcoholic beverages, such as vodka and gin, which it was packaging in experimental bottles made of polyvinyl chloride (PVC). The company said levels up to 20 parts per million (20ppm) had been found in vodka and 25 parts per million (25ppm) in gin.

Regulation of the safety and purity of alcoholic beverages is normally handled by BATF. Legally, through its administration of the Food, Drug and Cosmetic Act, the Food and Drug Administration (FDA) also has applicability to "alcoholic foods." In May, 1973, the BATF banned the further use of experimental PVC plastic bottles for distilled alcoholic beverages and the Treasury Department withdrew its provisional approval for the use of PVC bottles for the same use. The FDA meanwhile published a proposed regulation which would ban the use of polyvinyl chloride from all alcoholic foods but would reaffirm the "prior sanctions" for all other uses. In addition the FDA began to study the question of vinyl migration from food packaging.

The Society of the Plastics Industry, Inc. (SPI) subsequently supplied data to the FDA which indicated that small amounts of vinyl chloride could migrate to non-alcoholic foods from older formula PVC bottles then in production. But because the 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 for a carcinogen.

The actions by federal agencies to ban the use of PVC bottles for distilled alcoholic beverages and the data supplied by the SPI indicating that small amounts of VCM could migrate to non-alcoholic foods from older formula PVC bottles, preceded an important public announcement by a large chemical company in January 1974. The B.F. Goodrich Company announced that it suspected that VCM was implicated in the death of three workers at the company's Louisville, Kentucky, polymerization plant. This was the first association of VCM with cancer in humans.

FDA and the Food, Drug and Cosmetic Act

A 1958 amendment to the Food, Drug and Cosmetic Act requires that any new food additive must undergo strict testing to establish its safety. Not only are direct additions to the food covered by the amendment but also unintentional trace additions that might come from materials used in packaging food. These are 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."

The 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 Bans Only PVC Rigid and Semi-Rigid Products

In July 1975, the Health Research Group, one of the Ralph Nader affiliated groups, petitioned the FDA to ban completely all PVC food packaging.

That September, the FDA responded by:

1. Withdrawing its "prior sanctions" for all rigid and semi-rigid PVC products.
2. Proposing a ban on the use of rigid and semi-rigid PVC products, including bottles, blister packs, boxes and pipe, except water pipe.
3. Permitting the continued use of water pipe under an interim food additive regulation until further proof of "no migration" is obtained.

The FDA further stated that it had reason to believe there was no migration from plasticized PVC film, can and cap liners, coatings, gaskets of flexible tubing and, therefore, proposed to affirm the previous sanctions for their continued use.

Data Shows No Risk To Public

In mid-December 1975, the SPI submitted its comments on the proposed FDA regulation. The detailed submission consisted of 125 pages of comment and 700 pages of data to show that manufacturing processes for PVC had been dramatically improved and that there was no risk to the public from the use of PVC food packaging materials because:

- All new PVC packages contain essentially no detectable vinyl chloride monomer when tested using the FDA test method.
- Any vinyl chloride that might have entered food packaged in old packages would probably have evaporated rapidly before ingestion could have occurred.

The SPI pointed out that the probability of vinyl chloride monomer getting into the diet from packaging materials was, therefore, virtually nil. However, the SPI urged the FDA to adopt a substitute ruling which would require that rigorous test methods be used to assure no reasonable expectation of VCM migration.

On the same date that the SPI submitted its data, the U.S. Council on Wage and Price Stability asked the FDA to withdraw its proposed PVC regulations on the grounds the actions may be "unnecessary or may be more restrictive than is required to prevent ingestion of vinyl chloride."

Not Carcinogenic Except at High Levels

In the middle 1970's, Dr. Cesare Maltoni of the Institute of Oncology and Tumor Centre of Bologna, Italy, reported that he had induced tumors in rats by ingestion of vinyl chloride. However, his experiments were conducted by gavage (introduction of materials into the stomach by a tube) and at extremely high dosages. By comparison, the SPI's 1975 proposal to the FDA would prevent human ingestion of VCM even at levels 1,000,000 or more times lower than those used by Dr. Maltoni.

Studies in the mid 1970's by Dow Chemical Company on how the body handles inhaled VCM tended to confirm the results of earlier reports, including those of Dr. Maltoni, that only at high dose levels does VCM overwhelm the body's natural mechanism for eliminating many unwanted materials from the system.

Industry Reports VCM Reductions to FDA

In January 1977, representatives of companies producing PVC met with FDA officials to present and discuss information on the industry's capabilities for minimizing residual vinyl monomer content of rigid and semi-rigid PVC bottles and sheet materials. Many of the industry scientists reported that at levels of apparent extracted "vinyl chloride" below 10 parts per billion (10ppb), great difficulty was experienced in confirming that the tests really were showing vinyl chloride rather than some other "interferences" extracted from the PVC package.

One of the companies at the FDA meeting reported that since January 1975, all of its PVC food grade bottle compound was produced to a controlled specification of less than one part per million (1.0ppm) vinyl chloride monomer. The company said these levels represented a 500-fold reduction from the levels in 1973.

At that January meeting, the FDA requested additional raw data from the SPI to justify the industry's claims regarding residual monomer levels of the materials then being produced. The FDA also requested further details on the analytical procedures being used by the industry. The industry agreed to supply the information.

Data Shows Great Reduction in VCM Level

In April 1977, the SPI submitted the data requested by the FDA's Bureau of Foods at the January meeting. The data showed the PVC industry had reduced the residual vinyl chloride monomer in rigid and semi-rigid products from levels of approximately 500 parts per million (500ppm) to levels well below five one hundredths parts per million (.05ppm). Also, as requested by the FDA, the SPI provided a detailed rationale explaining why no vinyl chloride can reasonably be expected to migrate from such rigid and semi-rigid PVC food-contact products.

VCM Level "Vanishingly Small"

In early 1977, Ethyl Corporation submitted to FDA a report of an experiment which determined that "VCM can be reduced in container walls to a point where VCM cannot be detected in container contents" and thus might be described as "vanishingly small." The Ethyl Corporation experiments established that at a level of eight one hundreths part per million (0.08ppm) or 80 parts per billion (80ppb) no migration occurred in its bottles. "Thus no VCM could reasonably be expected to become a component of the bottle contents under intended conditions of use."

Later in the year, FDA raised technical objections to the Ethyl data and would not agree that there is no migration from PVC containers with a finite level of VCM. The Ethyl Corporation agreed to supply the additional supporting data requested by the FDA.

SPI Asks for Amendment of "Food Additive" Definition

The end of March 1977, SPI filed a petition with the FDA to amend the regulatory definition of "food additive." The SPI petition proposed that a substance which poses no special toxicological problems and which cannot be detected migrating to food with an analytical procedure sensitive to 50 parts per billion (50ppb) would, by definition, not be considered to be a food additive. As of the end of June 1978, the FDA had not yet ruled on the SPI petition.

Acrylonitrile Enters the Picture

In August 1977, an FDA Administrative Law Judge ruled against the use of acrylonitrile (AN) to fabricate beverage containers. That fall, in a letter to the Ethyl Corporation, FDA Commissioner Donald Kennedy said the final rule on the use of polyvinyl chloride food packaging materials "will necessarily reflect many of the judgments and conclusions of the law reached in the related final decision on the status of acrylonitrile."

On September 17, the FDA issued a final order banning the use of AN for beverage bottles. A month later, as the first step in appealing the FDA's acrylonitrile (AN) beverage container decision, the SPI filed a "Petition for Review" in the United States Court of Appeals in Washington. Similar petitions and amicus curae briefs were submitted by several companies.

New FDA Sensitive Analytical Procedure

At a meeting with scientific staff members of the FDA's Bureau of Foods in September 1977, industry representatives learned

for the first time that the FDA had developed a new improved analytical procedure for determining RVCM in packaging materials sensitive to the low parts per billion range. The industry further learned that the procedure had been used to reassess the RVCM content of flexible PVC packaging materials and that levels in the low parts per billion range were found.

In January 1978, in a letter to FDA Commissioner Donald Kennedy, Tenneco Chemical Company said that it had learned that FDA scientists had developed new techniques for determining RVCM in food-contact materials which were sensitive to detections of one to two parts per billion (1-2ppb). As these new techniques may have been applied to Tenneco rigid and semi-rigid products, the company said, it wanted the opportunity to submit additional data to that which it had submitted to FDA in 1975. At that time the technique developed by the FDA had a lower level of detection of 350 parts per billion (350ppb). Furthermore, Tenneco said its own analytical chemists evaluated the new FDA techniques and their evaluation was that there were significant problems with the new FDA techniques that make them unsatisfactory for determining RVCM in PVC film. Tenneco also urged that a further final comment period be offered prior to adoption of the final order on vinyl chloride polymers in contact with food.

In response to the Tenneco letter, William F. Randolph, FDA Acting Associate Commissioner for Compliance, said the FDA was "aware that the circumstances have changed significantly since our proposal (PVC regulations) was issued on September 2, 1975" and that the public will be given an additional opportunity to submit data and comments. "The precise nature and timing of 'that opportunity' have not yet been decided," he said.

Residual VCM Reduced To Two Parts Per Billion

In mid-February 1978, Ethyl Corporation presented preliminary data to FDA technical personnel which showed that residual vinyl chloride monomer (RVCM) can be stripped from PVC to a level of approximately two parts per billion (2ppb) and said that this "may well be the lowest level to which RVCM can be reduced." FDA scientists agreed that if these data are confirmed and supplemented by studies with bottles, the diffusion model for predicting migration (used for AN) would not be applicable to these low levels of RVCM. Thus, the principles of the AN beverage container decision would not be relevant to PVC containers.

Maltoni Data Fails To Show AN Carcinogenic

A major criticism of risk extrapolations for both acrylonitrile and vinyl chloride was that they were based on the results of incomplete feeding data in one case and on inhalation data in the other. In the early spring of 1978, Prof. Maltoni reported that he had now completed his ingestion studies of acrylonitrile and vinyl chloride. The final report on the acrylonitrile study on rats failed to show whether or not AN is carcinogenic. The report concludes that under experimental conditions at a level of 5 mg/kg administered to the rats three times per week, AN exhibited a "borderline oncogenic effect." However, the researchers reported "at present, our data do not make definitive evaluations possible," and they proposed further investigations.

While Prof. Maltoni's ingestion and inhalation studies of the effects of vinyl chloride on rats has been completed, his final report has not yet been released. It is expected shortly. Some

indication of his findings may be reflected in a talk he gave two years ago.

In March 1976 at a Colloquium held in Paris, Prof. Maltoni presented a comprehensive review of his work to that date on vinyl chloride carcinogenicity. A monograph of the papers and discussions at the Colloquium has just become available.

From his gavage (stomach tube) animal feeding experiments, Prof. Maltoni drew the following conclusions:

1. At 50 mg/kg and 16.65 mg/kg VCM produces angiosarcomas of the liver and nephroblastomas (abnormal growth in kidneys). These two tumors are the most characteristic produced by the VC monomer.
2. At 3.3 mg/kg the two angiosarcomas which were observed were not located in the liver (one appeared in the lung, the other near the kidneys).
3. There is a clear relationship between dose of monomer and tumor response with a sharp drop-off between 16.65 mg/kg and 3.33 mg/kg.

Prof. Maltoni further stated that in his experiments the 3.33 mg/kg dosage appeared to have a "border line" carcinogenic effect. He also reported that in another experiment in which animals were treated with 1 mg/kg, 0.3 mg/kg and 0.03 mg/kg, no tumors had been observed after 57 weeks into the test.

At the Occupational Safety and Health Administration's May 1978 public hearings on the establishment of a generic occupational cancer policy, Dr. David P. Rall, director of the National Institute of Environmental Health Sciences, testified that humans appeared to be 500 times less sensitive to vinyl chloride than the most sensitive laboratory animals when doses are compared on the basis of lifetime intake in miligrams per kilograms body weight (mg/kg).

Different "Risk Assessment" Methods Used

In the early Spring of 1978, the FDA made available an assessment of the risk of liver cancer from aflatoxin contamination of corn and peanut products. A careful study of the report showed that the FDA had drastically departed from the methodology the industry had used for vinyl chloride and acrylonitrile risk assessments. In the case of VC and AN the risk extrapolation was handled very conservatively using the Mantel-Bryan "worst case" statistical interpretation in a manner to yield a 99 percent confidence factor for the result. No such conservative treatment of the toxicological data was applied for aflatoxin before performing the Mantel-Bryan extrapolation.

Using the more conservative procedure as a model and all available data on VC and AN, a staff scientist at Keller and Heckman, legal counsel to SPI, recently calculated the risk from cancer associated with these two residual monomers in food packaging. Although his calculations should be considered only illustrative and not conclusive because he lacked complete data, his findings do give a rough indication of the risks involved.

Cancer Risk: One In One Hundred Million

When the scientist applied the Mantel-Bryan "worst case" assumptions to vinyl chloride he calculated that if a man's entire diet was contained in PVC packaging a safe total dietary exposure to man would be 5.2-10.4 parts per billion (ppb). Since it is assumed that PVC could not package more than 10 percent of the diet, an actual migration level of ten times the safe exposure level could be set as a "tolerance." This tolerance

(not more than 52-104ppb migrating to food) assures that the risk of cancer would be far less than one in one hundred million. Therefore, a finding of "non-detectable" with an analytical method sensitive to two parts per billion (2ppb) should assure virtually absolute safety.

In a similar calculation for AN, assuming that 5 mg/kg administered three times a week is a "no effect level," and that no more than 50 percent of the carbonated beverage consumption were packaged in AN copolymer containers, the scientist calculated a tolerance of 31 parts per billion (31ppb) would be virtually absolute safety. Therefore, the present analytical sensitivity of 10 parts per billion (10ppb) is sufficient to reduce any risk from AN to below any meaningful level.

Conclusion

Much has happened since the controversy over the migration of residual vinyl chloride monomer (RVCM) from food packaging arose in 1973. Newer, more sensitive equipment and more advanced techniques have been developed which permit the measurement of RVCM migration in parts per billion instead of parts per million.

In the last few years PVC manufacturing processes have been dramatically improved. One company reported that it had stripped RVCM to as low as two parts per billion (2ppb) which, it said, may be the lowest level to which RVCM can be reduced. Another company reported it had reduced the VCM levels in its general purpose bottle-compound by 500 fold in three years and was continuing to improve its technology for further reductions.

Several studies have shown that vinyl chloride is not carcinogenic except at high levels and PVC packaging being supplied to end product manufacturers in the last few years contain little or no measurable residual monomer. There is, therefore, no reasonable likelihood of VCM getting into the diet from present PVC food packaging materials and no scientific evidence that VC monomer can be found at any level in food products now packaged in PVC.

July 1978

For Additional Information Contact:

The Society of the Plastics Industry, Inc.
355 Lexington Avenue, New York, NY 10017.
(212) 573-9400

REPRODUCTION STUDIES WITH VINYL CHLORIDE

Reproductive studies conducted in 1975-76 by Dow Chemical showed that vinyl chloride, 500-2500 ppm, had no effect on implantation, resorption, or skeletal/organ development in mice, rats, or rabbits.

conoco

Interoffice Communication

To Distribution

From J. J. Hall

Date January 29, 1980

Subject

Attached is a very rough draft of what I thought I might cover at our meeting with representatives of the neighborhood association in Oklahoma City on February 14.

Please give me any comments you may have, but I'd specifically like your thoughts on the following:

1) Is this too much detail or not enough? "Short & simply" (5 vs. 9 pages)

2) Should we address the question of mutagenicity/teratogenicity?

Please respond as soon as possible, but I need your input at least by Friday, February 1.

J. J. Hall

JJH:ajo

Distribution:

R. E. Lehmkuhl
Norm Frost
Al Amsden
John Friend
Bill Broddle

DRAFT #1 1/28/80

IN 1974 THE B.F. GOODRICH COMPANY ANNOUNCED THAT THE PLANT PHYSICIAN AT ITS LOUISVILLE, KY PVC PLANT HAD IDENTIFIED THREE CASES OF LIVER CANCER AMONG LONG-TERM PLANT EMPLOYEES. THE COMPANY SAID IT SUSPECTED THAT VINYL CHLORIDE MONOMER (VCM) MIGHT BE IMPLICATED IN THE THREE DEATHS.

THIS ANNOUNCEMENT BY BFG TRIGGERED ONE OF THE MOST INTENSIVE INVESTIGATIONS IN THE HISTORY OF OCCUPATIONAL HEALTH. IT BECAME THE TOPIC OF HUNDREDS OF MAGAZINE AND NEWSPAPER ARTICLES, TELEVISION SPECIALS, AND SPECIAL MEDICAL CONFERENCES. VCM HAS BECOME ONE OF THE MOST STUDIED CHEMICALS FROM A TOXICOLOGY STANDPOINT.

I WANT TO DISCUSS WITH YOU SOME CONCEPTS OF TOXICOLOGY IN GENERAL, AND THEN MOVE INTO SPECIFICS REGARDING VINYL CHLORIDE AND POLYVINYL CHLORIDE. FINALLY, I'D LIKE TO ANSWER ANY QUESTIONS YOU MIGHT HAVE.

I OFTEN GET ASKED QUESTIONS LIKE "WILL THIS STUFF HURT YOU" AND I ALWAYS FEEL UNCOMFORTABLE BECAUSE I KNOW THE PERSON ASKING THE QUESTION IS LOOKING FOR A STRAIGHT ANSWER: YES OR NO. BUT THAT'S A QUESTION WITHOUT A DIRECT ANSWER. YOU CAN SAY NO, IF ..., OR YOU CAN SAY YES, BUT ..., AND SPEND THE NEXT 20 MINUTES QUALIFYING YOUR ANSWER. BUT THERE ARE GOOD REASONS FOR SOUNDING EVASIVE WHEN YOU TRY TO ANSWER SUCH A QUESTION. SO ... BEFORE WE START TALKING SPECIFICALLY ABOUT VCM & PVC I'D LIKE TO GIVE YOU A SHORT COURSE IN TOXICOLOGY SO THAT YOU'LL UNDERSTAND WHY ANSWERS MUST BE COMPLEX.

TOXICOLOGY

TOXICOLOGY BEGAN, AS YOU MIGHT SUSPECT, AS THE STUDY OF POISONS. AS A MATTER OF FACT, THE ROOT WORD TOXON - REFERS TO BOWS & ARROWS.

TOXIKON - POISON ARROW

TOXOLOGY - STUDY OF BOWS & ARROWS

ONE OF THE EARLIEST PRACTITIONERS OF TOXICOLOGY (IN THE 16TH CENTURY) WAS THEOPHRASTUS BOMBASTUS VON HOHENHEIM (ALIAS PARACELSUS). HE IS REMEMBERED (BY SOME, AT LEAST) FOR HIS RECOGNITION THAT ... "ALL SUBSTANCES ARE POISONS. THERE IS NONE WHICH IS NOT A POISON. THE RIGHT DOSE DIFFERENTIATES A POISON AND A REMEDY."

ANOTHER WAY OF STATING THAT, AS EXPLAINED BY PROFESSOR EMIL MRAK SPEAKING BEFORE THE U.S. CONGRESS CONCERNING THE SAFETY OF PESTICIDE CHEMICALS: " THERE ARE NO HARMLESS SUBSTANCES; THERE ARE ONLY HARMLESS WAYS OF USING SUBSTANCES". ALL OF THIS LEADS US TO A BASIC PREMISE OF TOXICOLOGY, THE CONCEPT OF THRESHOLD.

ALL CHEMICALS PRODUCE A RESPONSE (E.G. TOXICITY, IRRITATION, SENSITIZATION, NARCOSIS) AT SOME LEVEL. BUT, A LEVEL EXISTS FOR ALL SUBSTANCES FOR WHICH NO RESPONSE MAY BE EXPECTED.

EXAMPLE: STORY ON WATER

WHAT I M WORKING TOWARD HERE IS THE CONCEPT OF DOSE - PROBABLY THE LEAST UNDERSTOOD CONCEPT IN TOXICOLOGY BY THOSE NOT TRAINED IN THE FIELD.

DOSE IS THE AMOUNT OF MATERIAL REQUIRED TO PRODUCE THE DESIRED AFFECT.

WHEN YOUR DR. TELLS YOU TO TAKE TWO ASPIRIN & GO TO BED, HE HAS A REASON. IF HE TOLD YOU TO CRUMBLE ONE ASPIRIN & TAKE JUST A PINCH OF THE POWDER, IT WOULDN'T CURE YOUR HEADACHE. IF HE TOLD YOU TO TAKE THREE BOTTLES OF ASPIRIN, IT MIGHT HAVE DRASTIC EFFECTS.

SO IT MAKES SENSE THAT AS YOU INCREASE THE DOSE YOU INCREASE THE RESPONSE ...

THIS ALL LEADS US TO THE DOSE/RESPONSE CURVE.

NOTE: Toxicology is not an exact science; calculations have variability: $LD_{50} \pm 50\%$

(DRAW EXAMPLE ON BOARD)

DISCUSS EXAMPLE

LD 50

LD 10

CAN BE USED FOR OTHER RESPONSES

ROUTE OF EXPOSURE

INHALATION/DERMAL/ORAL

DIFFERENT EFFECTS --H_2O LEAD CHROMATE

ACUTE VS CHRONIC EFFECTS

BEST WAY TO DESCRIBE: EXAMPLE OF ALCOHOL

ACUTE EFFECTS: DRUNKEN STUPOR
BLURRED VISION
GIDDEYNESS
EUPHORIA
HEADACHE
UPSET STOMACH
NAUSEA
LACK OF BALANCE
CNS DEPESSANT

CHRONIC EFFECTS: LIVER
INCREASED AGING
ADDICTION

TOXICITY ≠ HAZARD

TOXICITY INHERENT PROPERTY OF THE COMPOUND LD 50, CATALOG OF ADVERSE EFFECTS

HAZARD LIKELIHOOD OF EXPOSURE IS CONSIDERED (EXAMPLE: BLOCK OF LEAD, N_2)

LIKE MANY SUBSTANCES, VCM HAS BEEN KNOWN FOR YEARS TO HAVE SOME TOXIC PROPERITIES. BUT PRIOR TO 1974 IT WAS CONSIDERED TO BE A RATHER INNOCUOUS CHEMICAL. IT WAS KNOWN AT EXTREMELY HIGH CONCENTRATIONS TO BE AN ANESTHETIC, IN FACT IT WAS ACTUALLY USED AS AN ANESTHETIC FOR A WHILE.

THE FIRST INKLING OF A POTENTIAL CHRONIC PROBLEM WAS A 1949 STUDY OF WORKERS IN A RUSSIAN PLANT. HEPATITUS WAS SEEN. BUT IT WAS CONCLUDED THAT A PCB PLASTICIZER WAS PROBABLY THE CULPRIT.

another chemical

IN 1961 A STUDY BY THE DOW CHEMICAL COMPANY ON LABORATORY ANIMALS SHOWED SLIGHT LIVER DAMAGE AT 100 PPM BUT A SIMILAR STUDY AT YALE FOUND NO CAUSE FOR CONCERN.

FROM 1951 TO 1970 THERE WAS A RECOMMENDED STANDARD DEVELOPED BY A PANEL OF EXPERTS OF 500 PPM FOR WORKER EXPOSURE. WHEN THE OSHACT WAS PASSED IN 1970 THIS CONSENSUS STANDARD WAS ADOPTED AND MADE INTO LAW. (STOP AND DISCUSS PARTS PER MILLION.)

IN 1966 A REVERSIBLE DISEASE OF THE BONES OF THE FINGERS CALLED ACROOSETEOLYSIS WAS DISCOVERED AMONG SOME HEAVILY EXPOSED REACTOR CLEANERS.

THIS DISCOVERY TRIGGERED RESEARCH PROJECTS IN BOTH THE UNITED STATES AND EUROPE IN AN ATTEMPT TO DISCOVER THE EXACT CAUSE OF THE DISEASE.

A LEADING EUROPEAN PVC PRODUCER, REPORTED AT THE 10TH INTERNATIONAL CANCER CONGRESS IN HOUSTON IN MAY 1970 THAT HE HAD BEEN ABLE TO PRODUCE CANCERS (BUT NOT ANGIOSARCOMA) IN TEST ANIMALS AT EXTREMELY HIGH LEVELS (10,000 TO 30,000 PPM) OF VCM EXPOSURE. DR. VIOLA'S FINDINGS WERE SUBSEQUENTLY PUBLISHED IN THE JOURNAL OF CANCER RESEARCH IN 1971.

THE PVC INDUSTRY BEGAN PLANS FOR MORE EXTENSIVE ANIMAL STUDIES AT LEVELS OF EXPOSURE MORE LIKELY TO BE ENCOUNTERED IN ACTUAL PLANT SITUATIONS. EPIDEMIOLOGICAL STUDIES OF PLANT WORKERS WERE ALSO PLANNED.

AN ANIMAL INHALATION STUDY WAS CONDUCTED UNDER THE DIRECTION OF DR. CESARE MALTONI OF ITALY.

IN THE UNITED STATES THE CHEMICALS MANUFACTURERS ASSOCIATION IN JUNE 1973 ANNOUNCED THAT 17 PVC PRODUCERS HAD AGREED TO SPONSOR A STUDY OF ALL CAUSES OF DEATHS IN VINYL CHLORIDE WORKERS. IN FEBRUARY 1973 THE INDUSTRY ALSO CONTRACTED FOR LIFETIME CHRONIC INHALATION STUDIES USING TEST ANIMALS.

SOME PRELIMINARY RESULTS OF DR. MALTONI'S STUDY BECAME AVAILABLE IN EARLY 1973. DR. MALTONI HAD DETECTED A VARIETY OF TUMORS IN TEST ANIMALS AT CONCENTRATIONS AS LOW AS 250 PPM.

THEN ... IN JANUARY 1974, B.F. GOODRICH NOTIFIED GOVERNMENT OFFICIALS REGARDING THE THREE ANGIOSARCOMA DEATHS.

AFTER A SPECIAL "FACT-FINDING" HEARING HELD IN FEBRUARY 1974, OSHA PROMULGATED AN EMERGENCY TEMPORARY STANDARD WHICH LOWERED THE MAXIMUM VCM WORKPLACE EXPOSURE FROM 500 PPM TO 50 PPM.

ON MAY 10, THEREFORE, OSHA PROPOSED A PERMANENT WORKER STANDARD WHICH WOULD REDCUE IN-PLANT EXPOSURE TO THE "NO DETECTABLE LEVEL" AND REQUIRE COMPLETE IMPERVIOUS SUITS AND SELF-CONTAINED BREATHING EQUIPMENT.

PUBLIC HEARINGS, UP TILL THEN THE LARGEST EVER HELD BY OSHA, BEGAN IN WASHINGTON ON JUNE 25.

AT THIS HEARING, OSHA HEARD EVIDENCE PRESENTED BY REPRESENTATIVES OF LABOR, GOVERNMENT, PUBLIC INTEREST GROUPS, SCIENTISTS AND ENGINEERS. AFTER WEIGHING ALL THE EVIDENCE, OSHA PUBLISHED A PERMANENT STANDARD OF 1 PPM AVERAGE ALLOWABLE WORKER EXPOSURE WHICH WENT INTO EFFECT ON APRIL 1, 1975. INDUSTRY WIDE COST OF COMPLIANCE RAN BETWEEN $300 AND $400 MILLION IN CAPITAL EXPENDATURES PLUS YEARLY OPERATING EXPENSES. THE CONOCO PVC PLANT IN OKC HAS SPENT APPROXIMATELY TO REACH COMPLIANCE WITH THIS STANDARD.

EPA INVESTIGATIONS

AT THE SAME TIME THE OSHA STANDARDS WERE BEING HAMMERED OUT, THE ENVIRONMENTAL PROTECTION AGENCY (EPA) BEGAN INVESTIGATIONS INTO WHETHER VCM CONSTITUTED A HAZARD TO THE HEALTH OF PERSONS LIVING IN THE VICINITY OF PVC PLANTS.

AN EPA TASK FORCE, ESTABLISHED IN FEBRUARY 1974, DETERMINED THAT THERE WAS "NO SCIENTIFIC EVIDENCE TO INDICATE THAT THESE EMISSIONS POSE AN IMMINENT HAZARD TO PEOPLE LIVING NEAR THESE PLANTS ..."

NONETHELESS, THE EPA SAID IT WOULD PROPOSE REGULATIONS TO REDUCE VCM EMISSIONS DRASTICALLY FROM 1974 LEVELS.

EPA'S INVESTIGATIONS INTO VINYL CHLORIDE RESULTED IN THE PUBLICATION OF FOUR MAJOR DOCUMENTS ON THE SUBJECT: (1) A 67-PAGE PRELIMINARY ASSESSMENT OF THE ENVIRONMENTAL PROBLEMS ASSOCIATED WITH VINYL CHLORIDE -- SEPTEMBER 1974, (2) A SCIENTIFIC AND TECHNICAL ASSESSMENT REPORT ON VINYL CHLORIDE AND POLYVINYL CHLORIDE -- JUNE 1975, (3) A QUANTITATIVE RISK ASSESSMENT FOR COMMUNITY EXPOSURE TO VINYL CHLORIDE -- DECEMBER 1975, AND (4) AN EXTENSIVE TWO VOLUME STANDARD SUPPORT AND ENVIRONMENTAL IMPACT STATEMENT -- SEPTEMBER 1976.

THE AGENCY ALSO OFFERED INTERESTED PARTIES THE OPPORTUNITY TO MEET WITH EPA OFFICIALS TO DISCUSS PROPOSED METHODS OF CONTROLLING VCM EMISSIONS.

AFTER 22 MONTHS OF EXTENSIVE STUDY AND DISCUSSIONS, THE AGENCY OFFICIALLY PROPOSED ON DECEMBER 16, 1975, A STANDARD REGULATING EMISSIONS OF VINYL CHLORIDE INTO THE AMBIENT AIR. A PUBLIC HEARING WAS HELD IN FEBRUARY 1976. THE OFFICIAL RECORD OF THE AGENCY'S INVESTIGATION OF VINYL CHLORIDE LISTED 699 DOCUMENTS TOTALING SOME 9,000 PAGES.

IN OCTOBER 1976, AFTER MORE THAN TWO AND A HALF YEARS OF INTENSIVE INVESTIGATION EPA PROMULGATED NATIONAL EMISSION STANDARDS FOR VINYL CHLORIDE GAS AND PVC RESIN PLANTS.

THE EPA STANDARDS REDUCED EMISSIONS BY APPROXIMATELY 95 PERCENT FROM 1974 LEVELS. THE STANDARDS WOULD THEORETICALLY REDUCE THESE EXPOSURE LEVELS FROM APPROXIMATELY 17 PPB (STOP AND DISCUSS PARTS PER BILLION) TO LESS THAN ONE PPB AS A YEARLY AVERAGE. BASED ON EPA'S OWN CALCULATIONS, THIS COULD RESULT AT A MAXIMUM IN APPROXIMATELY ONE CASE OF ANGIOSARCOMA EVERY TWO YEARS AMONG THE FIVE MILLION PEOPLE LIVING IN THE VICINITY OF THESE PLANTS. CONSIDEREING THAT MORE THAN 80,000 OF THESE PEOPLE COULD BE EXPECTED TO DIE FROM OTHER CAUSES DURING THAT SAME TWO-YEAR PERIOD, THE THEORETICAL ONE ANGIOSARCOMA CASE WAS CONSIDERED AN ACCEPTABLE RISK BY EPA.

LET ME DIGRESS FOR A MOMENT AND DISCUSS THAT TERM "ACCEPTABLE RISK". IT'S IMPORTANT THAT WE UNDERSTAND THAT THERE IS NO SUCH THING AS ZERO RISK. ALL HUMAN ACTIVITIES FROM GETTING OUT OF BED, TO TAKING A SHOWER, TO DRIVING A CAR INVOLVE SOME AMOUNT OF RISK. EVEN NOT GETTING OUT OF BED INVOLVES RISK!

SO WHETHER WE DO IT CONSCIOUSLY OR NOT, WE ARE CONSTANTLY CHOSING TO PARTAKE IN ACTIVITIES BECAUSE WE JUDGE THE RISKS TO BE ACCEPTABLE. LET ME GIVE YOU SOME EXAMPLES OF SOME EVERYDAY RISKS THAT HAVE BEEN QUANTIFIED:

INDIVIDUAL RISK OF FATALITY

MOTOR VEHICLE	300 CHANCES/MILLION
FALLS	90 CHANCES/MILLION
FIRE	40 CHANCES/MILLION
AIR TRAVEL	9 CHANCES/MILLION
LIGHTNING	½ CHANCE /MILLION
ALL CANCER	3000 CHANCES/MILLION
VINYL CHLORIDE	1/10 CHANCE /MILLION
70 VS 55 MPH	50 CHANCES/MILLION

Remember: Toxicology is not an exact science & is only as good as the assumptions

IF WE CAN ASSIGN MATHEMATICAL VALUES TO RISK, IT FOLLOWS THAT WE CAN COMPARE RISKS WHICH ARE ROUGHLY EQUIVALENT. GETTING BACK TO THE SUBJECT AT HAND, PROFESSOR RICHARD WILSON OF HARVARD UNIVERSITY HAS CALCULATED THAT THE RISK OF LIVING WITHIN FIVE MILES OF A PVC PLANT FOR ONE YEAR IS EQUIVALENT TO THE RISK OF CONTRACTING CANCER FROM EATING 1/2 TABLESPOON OF PEANUT BUTTER, OR TO THE RISK OF CONTRACTING CANCER FROM THE INCREASED COSMIC RADIATION DURING A THREE-DAY VISIT TO DENVER, COLORADO, OR TO THE HAZARD FROM SMOKING 1/15TH OF A CIGARETTE.

GETTING BACK ON TRACK ... IN NOVEMBER 1976

THE ENVIRONMENTAL DEFENSE FUND FILED SUIT IN THE COURT OF APPEALS IN WASHINGTON CHALLENGING THE EFFECTIVENESS OF THE STANDARD.

THE EDF AND EPA NEGOTIATED IN PRIVATE MEETINGS FROM WHICH THE INDUSTRY WAS EXCLUDED. ALTHOUGH AN EVENTUAL RULING BY THE COURT THAT INDUSTRY REPRESENTATIVES HAD A LEGITIMATE RIGHT TO INTERVENE IN THE CASE.

THE RESULT OF THOSE SECRET NEGOTIATIONS WAS A FORMAL AGREEMENT ON MARCH 24, 1977, BETWEEN EPA AND EDF TO PROPOSE AMENDMENTS TO THE EXISTING VINYL CHLORIDE STANDARD WHICH HAD BEEN PROMULGATED ONLY FIVE MONTHS PREVIOUSLY. THE PROPOSED AMENDMENTS WERE PUBLISHED IN THE FEDERAL REGISTER ON JUNE 2, 1977.

THE AGENCY HAD RECEIVED OR OBTAINED NO NEW MEDICAL OR TECHNICAL INFORMATION THAT WOULD JUSTIFY ANY CHANGES IN THE STANDARD.

USING METEOROLOGICAL READINGS PLUS SOPHISTICATED COMPUTER PROGRAMS, IT WAS ESTABLISHED THAT THE ORIGINAL EPA ESTIMATE OF 17 PPB OF VINYL CHLORIDE AS A YEARLY AVERAGE EXPOSURE WITHIN FIVE MILES (NEAR) OF UNCONTROLLED VINYL CHLORIDE INSTALLATIONS WAS FAR TOO HIGH.

INSTEAD IT WAS DETERMINED THAT MEAN VINYL CHLORIDE CONCENTRATIONS ON THE ORDER OF 2.5-4.5 PPB FOR EACH UNREGULATED PLANT ARE REDUCED TO CONCENTRATIONS ON THE ORDER OF 0.15-0.25 PPB WHEN IN COMPLIANCE WITH EXISTING STANDARDS.

SEVERAL EXPERTS HAVE VOICED OPINIONS REGARDING ACCEPTABLE AMBIENT CONCENTRATIONS OF VINYL CHLORIDE. DR. CARLO TUMBURRO, DIRECTOR OF A VC RESEARCH PROGRAM AT THE UNIVERSITY OF LOUISVILLE MEDICAL SCHOOL, DR. CHARLES SHAW, CHIEF OF THE MEDICAL GENETICS SECTION OF MD ANDERSON AND DR. MITCHELL ZAVON, PROFESSOR OF INDUSTRIAL MEDICINE AT THE UNIVERSITY OF CINCINNATI HAVE ALL STATED THAT CONCENTRATIONS OF VC ON THE ORDER OF 10 PPB SHOULD BE SAFE FOR HUMAN EXPOSURE.

ONE LAST POINT: I MENTIONED THAT THE EPA ESTIMATED THAT AN AMBIENT LEVEL COMPLIANCE WITH ITS STANDARD COULD RESULT AT A MAXIMUM OF ONE CASE

OF LIVER CANCER EVERY TWO YEARS IN AN EXPOSED POPULATION OF 5 MILLION. ANGIOSARCOMA IS CONSIDERED A VERY RARE FORM OF CANCER. THE NATIONAL AVERAGE IS ONE CASE PER 78,000 DEATHS. OUT OF A POPULATION OF 5 MILLION YOU WOULD EXPECT 80,000 DEATHS FROM ALL CAUSES IN TWO YEARS SO AN INCIDENCE OF 1 CASE OF ANGIOSARCOMA EVERY 2 YEARS IS NO MORE THAN WOULD BE EXPECTED TO OCCUR NATURALLY.

cc John French 9-30-80 fire Health

J. J. Hall - chemicals

RECEIVED
SEP 25 1980

20A /The Houston Post/Sun., Sept. 21, 1980 ★★

Evacuees return home as probers seek cause of plant blast

FITCHBURG, Mass. (AP) — About 2,000 people returned home Saturday while investigators puzzled over the cause of a chemical plant explosion that sent a cloud of poisonous chloride gas into the air.

Two plant workers were seriously hurt and 16 people were treated for smoke inhalation in the Friday night blast, which damaged several mixing chambers and a smokestack at the Great American Chemical Corp. plant.

City officials ordered an evacuation of nearby areas. About a half mile of the area's major highway, Massachusetts 12, was closed Saturday and local traffic on the Boston & Maine railroad was rerouted.

"Everybody was allowed to return to their homes at about 1 a.m., although some chose not to until things settled down more," police Lt. Edward Gallant said Saturday.

Firefighters continued to pour water on one of the mixing chambers Saturday to keep it cool until the remaining vinyl chloride and polyvinyl chloride gas could be removed, fire department officials said. The fire marshal, meanwhile, was expected to spend several days trying to pinpoint the cause of the blast.

The plant, about one mile from downtown Fitchburg and 45 miles northwest of Boston, combines gases and water to make plastic pellets, used in the manufacture of toys and other products.

The injured employees were working in the plant's processing center when the mixing chambers apparently overheated and exploded, knocking down one of the concrete walls of the building, authorities said. It was not immediately clear how many of the factory's 15 mixing chambers were involved.

The injured men were admitted to a local hospital with burns and cuts.

Deputy Fire Chief James Keane said automatic sensing devices at the plant detected leaking gas shortly after 7 p.m. Friday. He and other firefighters responded and saw a "thick, heavy, white dense cloud lying near the ground" when they arrived at the plant.

Jim,

This got much wider play than I would have expected, probably because VCM was involved. This company has in the past (and maybe still) been a VCM customer of ours. The incident may have the attention of your OKC neighbors.

D

9/22

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