

An Overview of the Vinyl Chloride Hazard in Canada

Introduction

While acknowledging a direct relationship between industrial operations and progress in achieving an improved standard of living, the Science Council has become concerned about costs that are hidden or ignored. The Council shares the growing public concern over involuntary exposure to insidious hazards both within and outside the workplace. It must be possible to reduce the risks associated with industrial activity while stimulating needed industrial growth and innovative activity.

The Science Council has an ongoing interest in the role of science and the scientist in policy formulation. The effectiveness of communication between scientists and policy formulators must be improved. As well, growing controversy over the risks of exposure to such things as cyclamates, lead, radiation, mercury, asbestos, points to a need for more communication with the public. What is known, needs to be clearly expressed and analyzed. What is not known or what needs to be known, must also be clearly stated.

In the course of its study on Policies and Poisons, the Council will examine six hazards, lead, radiation, asbestos, mercury, oxides of nitrogen, and monomer vinyl chloride, from medical, technical, legal and regulatory perspectives. Seminars on each hazard were held, where the participants were asked to identify the major issues surrounding each hazard. Overviews are being written, compared and analyzed before the release of a Science Council Report.

The Council felt that the six cases selected represented a broad enough spectrum of hazards to enable it to make general observations and recommendations on how Canada is coping with man-made hazards of an insidious and long-term nature. In particular, vinyl chloride monomer was chosen because it is a typical example of the relatively new synthetic organic chemicals that are continuously being introduced into the environment and the market place. There is no agreement on exactly how many new chemicals are being introduced annually. Figures in the literature range from several hundred to one hundred thousand. For example, it has been calculated that there are about 2.5 million chemicals now in the biosphere. Since World War II a very large number of new chemicals have been introduced, but very few have been completely tested for adverse effects. Only 3000 have been tested for carcinogenesis and 1000 of these have, in fact, been found to be carcinogenic.

There are differences between vinyl chloride and the other hazards selected.

- 1) All the others are industrial waste by-products. The vinyl chloride monomer to which people are exposed is wasted, but it is not a by-product. It is an essential building block in the fabrication of polyvinyl chloride

resin. The extent of its waste is a measure of the inefficiency of the industrial process.

- 2) It appears that dangerous exposure to vinyl chloride monomer is mainly a workplace phenomenon. There is no evidence, as yet, to indicate that people are being exposed to dangerous levels outside the workplace or in consumer products. The other hazards in the study are not solely occupational.
- 3) Actions taken to reduce the risk associated with exposure to vinyl chloride monomer, from the time it was first publicly recognized as a fatal risk (1973), have been forthright and rapid. Indeed, the cooperative attack on the problem by industry, labour and governments have led some to label the vinyl chloride experience a "success story," since they feel that worker exposure has been reduced to the extent that it is no longer a risk. If indeed the vinyl chloride episode has been successful, then there are lessons to be learnt and conclusions to be drawn from this experience that cannot, as yet, be extracted from the other hazards under study, where varying degrees of controversy still exist.

The Vinyl Chloride Problem

The Properties of Vinyl Chloride Monomer

Vinyl chloride monomer (VCM) is a synthetic organic compound that is quite small and simple in structure. It has a chemical formula of $\text{CH}_2 = \text{CH Cl}$ and a molecular weight of 62.5. Vinyl chloride monomer is technically classified as a chlorinated hydrocarbon.*

VCM is a colourless gas under normal conditions of temperature and pressure, but is usually stored and transported as a liquid under its own vapour pressure. VCM was used as a propellant in pressurized spray containers in the United States until it was banned.

Vinyl chloride monomer has a pleasant odour and is practically insoluble in water, but is soluble in alcohol, ether, carbon tetrachloride and fats. This suggests that VCM retained in container material can be extracted from or will migrate to substances in the container. Investigative work into the mechanism and rate of transfer is taking place. VCM, in the vapour phase, is 2.15 times heavier than air. This has implications for the dispersion of vinyl chloride monomer in the workplace and in the environment.

Vinyl chloride monomer is explosive within limits of 4-22% by volume in air. Its flash point temperature is -78°C and it can auto-ignite at 472°C . VCM is photo-degradable and will break down into simpler harmless substances when exposed to sunlight. In a 2-day period of exposure a concentration of VCM will diminish by one-half.

Special thanks are due to J. Arnold, Esso Chemicals, and M. J. Phillips, University of Toronto, who provided technical and medical information. Please note that the manuscript was completed in January 1977.

*It has been argued that since vinyl chloride monomer is of the same chemical family as chloroform, formaldehyde, carbon tetrachloride, etc., which are all known to be toxic to the liver, vinyl chloride monomer should have been suspected of having similar effects on the liver and appropriate tests should have been done.

Under certain conditions of temperature and pressure and in the presence of catalytic agents, molecules of vinyl chloride monomer can polymerize into very large molecules by continuously adding to themselves. Substances with this capability are called monomers while the end products of the process are polymers. The polymer of vinyl chloride monomer is polyvinyl chloride, a substance easily converted into plastic sheets, films, or more solid material. This capability of polymerization renders VCM industrially useful.

Industrial Background

Polyvinyl chloride (PVC) was the first fully synthetic plastic. It was first produced in Germany during the 1930s and in 1974, world-wide production exceeded 18 billion pounds. It has many uses:

- in rubber-like form (electrical wire insulation and sleeving),
- in film form (garments, curtains, auto upholstery),
- as rigid shapes (floor tiles, house siding, phonograph records),
- as piping (for gas, oil, water pipelines),
- as extruded rigid shapes (window frames, household appliances),
- in foam or expanded form (cushions, fishing floats),
- in latex (impregnated paper, fabric and leather),
- as a copolymer (in food wrap).

Most vinyl chloride monomer plants built in the last five years have been based on "balanced" oxychlorination technology — a continuous process using ethylene as the only hydrocarbon feed. In "unbalanced" operations the by-product HCl is not utilized. In some operations both ethylene and acetylene are utilized as feed. The system is closed with a substantial portion of it exposed to the outside atmosphere so that leaked VCM is readily dispersed and worker exposure minimized.

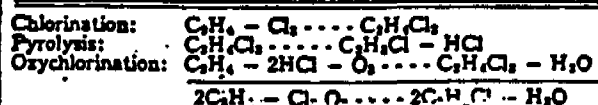
There are three major steps in processing:

- Direct chlorination — Ethylene and chlorine are reacted to produce ethylene dichloride (EDC). The reaction takes place at 70-100°F in a circulating stream of EDC and in the presence of soluble FeCl_3 catalyst.

Pyrolysis — EDC is purified by distillation and thermally cracked to produce VCM and by-product HCl. Conversion is limited to 50-60% per pass to minimize by-product and coke formation.

- Oxychlorination — Ethylene, HCl, and an oxygen source (usually air) are reacted to produce EDC. This reaction takes place in the vapour phase at 390-500°F in the presence of $\text{CuCl/CuCl}_2\text{-KCl}$ catalyst on alumina. EDC is recovered from the reactor effluent, neutralized, washed, and then combined with the EDC produced in direct chlorination for purification. HCl conversion is essentially complete; an excess of ethylene is usually employed. The reaction is highly exothermic and close temperature control is required to maintain selectivity and prevent catalyst volatilization. The oxychlorination process is not in use in Canada.

The reaction steps can be represented as follows:



Overall conversion efficiencies to VCM of 93-96% on ethylene and 91-92% on chlorine are reported.

Unlike vinyl chloride manufacture, polymerization of the monomer to polyvinyl chloride resin (PVC) in Canada is a batch process, i.e., the monomer and other additives are charged and reacted in a pressure vessel and then removed for drying and purification at termination of the reaction. The pressure vessel is opened and cleaned and the entire cycle is repeated.

Several polymerization processes and polyvinyl chloride resin types are commercially available throughout the world. However, only two basic types are produced in Canada — emulsion and suspension (which accounts for about 95 percent of the polyvinyl chloride resin manufactured in Canada). In each basic resin type a number of resin grades are available, each tailored to specific end-use applications.

The vinyl chloride (possibly with a comonomer) in a water medium, with surfactants or emulsifiers and initiator is polymerized at a specified temperature to produce a resin of a particular molecular weight for a given final application. The reaction is exothermic and good temperature control is essential.

The diverse uses of PVC suggest a wide assortment of processing operations from blending, milling, calendering, coating, extrusion, pelletizing, to moulding. The processing equipment also differs widely but for the most part, the basic principles are the same.

Typically, the resin is blended with a number of additives and processing aids depending on the end product, kneaded under heat and pressure into a molten or plastic state, and then formed into the desired or final form.¹

More than 90 percent of the vinyl chloride produced in Canada in 1973 was used in the manufacture of PVC. The remainder was used in the production of 1,1,1 trichloroethane.²

Production quantities and values of VCM are not available in Canada because of the secrecy requirements of the Statistics Act. Under this Act, production and export figures are not published because there are less than four companies involved.

The sole producer of vinyl chloride monomer in Canada is Dow Chemical of Canada Limited in Sarnia, Ontario, with a reported capacity of 200 million pounds per year. This is about 5% of U.S. production and about 1.25% of world production. Until late 1975 vinyl chloride monomer was also produced by Gulf Oil Canada Limited in Varennes, Quebec. Since termination of the Quebec plant, the balance of monomer required to satisfy the Canadian market has been imported from the United States. Dow Chemical of Canada Limited has announced plans to expand their vinyl chloride monomer manufacturing facility by 1978 with a 700-million-pound per year plant in Fort Saskatchewan, Alberta.

There are nine major monomer producers in the U.S. with 14 plants and a total capacity approaching 7 billion pounds per year.

Table 1 shows polyvinyl chloride resin manufacture in Canada. A third producer, Monsanto Canada Limited, with a reported annual capacity of 40 million pounds, terminated polyvinyl chloride production at their Lasalle, Quebec plant toward the end of 1975.

TABLE 1
CANADIAN PVC RESIN PRODUCTION

Producer	Plant Location	Plant Capacity - Million Lbs.	Projected PVC Production Figures for 1979
Esso Chemical Canada.....	Sarnia, Ontario	80	250
B.F. Goodrich Canada Ltd.....	Niagara Falls, Ont.	72	270
B.F. Goodrich Canada Ltd.....	Shawinigan, Quebec	80	80
Diamond Shamrock.....		—	200

Sources: Arnold, 1976, p. 4.

Note: For comparative purposes, polyvinyl chloride resin capacity in the United States is reported at 6.5 billion annual pounds with approximately 40 plants. World-wide, resin production on an annual basis in 1974 was reported at 18.4 billion pounds.

TABLE 2
PRODUCTION OF PVC RESIN

Year	PVC Resin Quantity (lbs)	% Increase Production from Previous Year	Total Amount of Synthetic Resins Quantity (lbs)	% PCV Synthetics
1974.....	251,805,215	10.2	948,990,800	27
1973.....	247,968,819	11.4	1,043,616,000	24
1972.....	217,402,888	10.0	921,694,000	24
1971.....	171,871,471	10.7	733,200,000	23
1970.....	160,360,209	10.0	657,931,000	24
1969.....	145,343,743		555,855,000	26
AVERAGE.....		10.5		24.7

Note: 1975 figures not available. They are confidential to meet secrecy requirements of the Statistics Act.

Sources: Statistics Canada, *Specified Chemicals*, Information Canada, Ottawa, December, 1972, cat. no. 46-002, p.2.

TABLE 3
INTERPROVINCIAL AND FOREIGN SHIPMENTS OF PVC, 1969

Destination of Shipments	Dollar Value \$'000	% of Total Shipments	Estimated % of Total Production
Quebec.....	7,094	35.9	
Ontario.....	10,707	54.3	
Exports.....	1,558	7.9	0.03
Survey Totals.....	19,736	98.1	0.4

Note: Origins of shipments are confidential to meet secrecy requirements of Statistics Act.

Sources: Statistics Canada, *Interprovincial and Foreign Shipments of Selected Chemical Products 1969*, cat. no. 31-517, June 1971, p. 1.

Polyvinyl chloride production capacity in Canada will be increased in 1979. B. F. Goodrich Canada Limited announced expansion plans for their existing Niagara Falls plant and Diamond Shamrock has announced plans to erect a new plant in Fort Saskatchewan.⁹

The Shawinigan plant of B. F. Goodrich was built in 1942 and is the largest producer of polyvinyl chloride resin from vinyl chloride monomer gas. The plant had previously been owned by several other companies which were almost totally U.S. owned. This is also the case with other large chemical products companies in Canada.

Polyvinyl chloride resin production accounts for 25 per cent of all synthetic resins produced in Canada (Table 2). Considering that these resins are then fabricated into thousands of end-products, polyvinyl chloride contributes substantially to the Canadian economy. It is also a rapidly growing industry which is increasing production by 10.5 per cent each year.

Although the Statistics Canada survey of Interprovincial and Foreign Shipments is for only 1 year, it indicates the proportion of PVC resins being shipped as exports. Since 1969, the number of products has decreased in Quebec and presumably the proportion of PVC resins shipped to Ontario has decreased. Using the estimated value of production for 1969 and the value of exports of PVC resins, exports are less than 0.03 per cent of PVC production in Canada. (Table 3).

Table 4 shows the approximate number of workers employed in Canada in the overall vinyl industry. Workers in this instance refers to men and women engaged in process and fabrication operations, maintenance, technical, and supervisory roles.⁴

The number of workers in the U.S. employed in the vinyl industry (VCM and PVC manufacture and fabrication) is approximately 600,000⁵

The production of vinyl chloride monomer and polyvinyl chloride does not contribute substantially to Canadian employment (550 people directly employed and 1425 office workers). Employment in the fabrication of PVC end-products is difficult to estimate because of the variety of products and the number of small companies utilizing it. The Plastic Industry Council estimates that there are 50,000 workers in related plastic fabrication plants in Canada generating an annual income of about \$500,000,000.

Canada's production satisfies about 70 per cent of its own demand for PVC resins. The amount of PVC resins exported is significant in a supply-demand profile. The fact that we import 30 per cent of the PVC resins required indicates room for continued growth within Canada. (Table

Canada imports PVC resins, films and sheets annually from several countries. The U.S. supplies an average of 80.8 per cent of the resins and 72.5 per cent of the films and sheets. Other major suppliers are West Germany, Japan, Sweden, Italy, France and Spain (about 20 per cent of the imports). In 1975, total PVC imports valued \$33,-\$18,000. This is 0.1 per cent of Canada's total imports from all sectors or 0.6 per cent of all imports of inedible fabricated materials.

"The 400-million-lb/year polyvinyl chloride plant planned by Diamond Shamrock, a subsidiary of Diamond Shamrock Canada Ltd. and Alberta Gas Trunk Line Co. Ltd., will cost about \$50 million. First stage of the project, capable of turning out 220 million-lb/year of polyvinyl chloride, should be onstream in first-quarter 1979. The partners will set up a joint venture to operate the plant, slated to be built near Fort Saskatchewan, Alta. The Unit is expected to attract polyvinyl chloride fabricating in-

dustries to the area, including polyvinyl chloride pipe and wire and cable insulation. Feedstocks for the new operation will be purchased from Dow Chemical Canada, which will be producing vinyl chloride monomer from ethylene to be made by Alberta Gas Ethylene at Red Deer, Alta. Building of a 1.2-billion-lb ethylene unit will start soon."

Polyvinyl chloride production is likely to continue to grow by 10.5 per cent each year. The establishment of a new plant in Alberta will increase this annual growth substantially. By 1979 the production of PVC resins will be about 360 per cent greater than in 1974 if the rate of increase in production and demand remains the same for the next five years as it has for the last 5 years and if the Alberta plant produces its estimated 220-million lb capacity of PVC. This is an increase which cannot be ignored. It will have a large impact on the Canadian economy since this increase in production should cause a multiplier effect in the fabrication sector.

TABLE 4
CHARACTERISTICS OF COMPANIES PRODUCING VCM AND PVC

Companies Involved	Location	% Foreign Ownership	Controlling Country	Employment†	
				Plant	Office
<i>Vinyl Chloride Monomer</i>					
Dow Chemical.....	Sarnia, Ont.	100.00	U.S.	90	250
Gulf Oil (until 1972).....	Varennes, Que.	71.10	U.S.	210	—
<i>Polyvinyl Chloride</i>					
B. F. Goodrich Chemical.....	Shawinigan, Que.	100.00	U.S.	160	47
Imperial Oil (Exxon).....	Niagara Falls	82	—	82	29
Monsanto (until 1975).....	Sarnia, Ont.	80.20	U.S.	100	1,100
Gulf Oil (until 1972).....	Ville Lasalle	99.40	U.S.	410	—
	Varennes, Que.	71.10	—	200	—
TOTAL EMPLOYMENT.....				550	1,426

Source: Statistics Canada, *Inter-corporate Ownership 1972*, Information Canada, November 1974, cat. no. 61-513; Scott's, *Quebec Industrial Directory 1973-74*, 6th edition, Penstock Publications Limited; Scott's, *Industrial Directory of Ontario Manufacturers*, 10th edition, Penstock Publications Ltd., June 1976.

TABLE 5
CONSUMPTION OF POLYVINYL CHLORIDE RESINS IN CANADA

Year	Quantity Produced (lb)	Percentage of Total Consumption Produced in Canada	Quantity Imported (lb)	Percentage of Total Consumption Imported	Total Consumption (lb)
1974.....	251,805,215	63.6	115,176,900	31.4	366,982,000
1973.....	247,968,819	72.5	93,933,000	27.5	341,902,000
1972.....	217,402,888	67.8	103,305,800	32.2	320,709,000
1971.....	171,871,471	69.9	73,892,600	30.1	245,764,000
1970.....	160,360,209	74.9	53,870,700	25.1	214,231,000
AVERAGE.....		70.7		29.3	

Source: Statistics Canada, *Specified Chemicals*, 1972 through 1975, cat. no. 46-002.

Medical Problems Associated with Exposure to Vinyl Chloride Monomer

Vinyl chloride came to world attention as a health hazard in December 1973 when three instances of a rare form of liver cancer, angiosarcoma, were reported in workers from the B. F. Goodrich plant in Louisville, Kentucky. These cases attracted attention because of the rarity of this particular type of cancer. If carcinoma of the lung or colon had developed in these workers, the connection between vinyl chloride and cancer would probably still be unrecognized.

In addition to the carcinogenic effects of vinyl chloride, there are other toxicological effects. Most of the information available comes either from studies of industrial workers or from animal experiments. Emphasis must be placed on the human studies, but for a proper perspective and understanding of the problem, we must include and study data from experimental animal work.

When large scale production of polyvinyl chloride started in the late 1930s, vinyl chloride was considered one of the safest industrial chemicals. Aside from two reports of acute vinyl chloride intoxication, without serious consequences, there were no indications of an occupational health hazard with this chlorinated hydrocarbon. In 1949 Tribukh *et al* reported hepatitis without jaundice, hypotension, anemia, chronic gastritis, skin and respiratory lesions in 73 workers in a Soviet plastics factory. The findings were attributed to plasticizers.¹ Suci, in Romania, remarked with reference to this as late as 1963, that transient toxic inflammation of the liver must have been concerned. These observations made in the Soviet Union and Romania remained unnoticed in the West because the data were inaccessible. As late as 1968, Schottek, in a lecture held in Leipzig, concluded that liver and kidney damage was caused by chronic exposure to vinyl chloride.

In the meantime, injury to the health of cleaners of polymerization reactors was reported in the West in the mid-sixties. Opinion on the innocuousness of vinyl chloride gas changed. Injuries to health manifested themselves in many different ways, i.e., as bandlike bone effects on the terminal ossicles of the fingers (acroosteolysis), as blood flow disturbances in the hands, and as "pins-and-needles" and abnormal sensitivity to cold (Raynaud's syndrome). In addition, plate-like hardening of the connective tissue, mainly of the forearms (scleroderma) was detected. The findings were published in 1966 and interpreted as manifestations of occupationally-induced disease.² Despite these reports it was the general conclusion that the processing of polyvinyl chloride was not a serious health hazard. Many standard textbooks, even up to 1972, emphasized the harmlessness of processing PVC.³ This was probably due to the results of animal studies that had taken place prior to 1970.

Toxicological studies of vinyl chloride monomer date back to 1930 when Patty observed the acute toxicity of massive dosages of vinyl chloride in guinea pigs. When exposed to 5-7% and to 2.5% vinyl chloride, these animals lived 1 hour and 8 hours respectively; however, no alterations were noted after a 1-hour exposure to 1.5% nor to 1-hour exposure to 0.5% vinyl chloride. A number of studies since have dealt with acute poisoning by massive exposure to high dosages of vinyl chloride. These are only relevant to the vinyl chloride problem in relation to possible industrial accidents. They show the narcotic effects of vinyl chloride where death is preceded by convulsions, accelerated respiration followed by respiratory failure,

congestion of all the viscera, central nervous system depression and hyperemia of liver and kidneys.⁴

Until recently, very few (chronic) studies on the toxicity resulting from repeated exposure to vinyl chloride monomer have been carried out. In 1938, Schaumann found no liver or kidney damage in mice and rats that were lightly anesthetized for 4 hours daily on 5 to 8 consecutive days and 1 hour daily for 4 weeks. Dogs anesthetized for 3 hours with 10 per cent by volume also showed no liver and kidney injury but higher concentrations (20 per cent by volume) caused marked salivation, respiratory arrest and vomiting.⁵ In the early 1960s, Torkelson, Owen and Rowe exposed rabbits, rats, guinea pigs and dogs to levels of 500, 200, 100 and 50 ppm (1280, 512, 256, and 128 mg/m³) of vinyl chloride for periods up to 7 hours/day, 5 days/week, for up to 6 months. At 500 ppm (1280 mg/m³), rats showed increased liver weight and pathology. At 200 ppm (512 mg/m³) and 100 ppm (256 mg/m³) rats showed an increase in liver weight but no pathology. Rabbits exposed to 200 ppm (512 mg/m³) also revealed liver pathology. No changes were noted in dogs or guinea pigs at this level. All species tolerated 50 ppm (128 mg/m³) for 6 months without effect. Repeated exposure for 1 hour/day at 200 ppm (512 mg/m³) or 100 ppm (256 mg/m³) were tolerated in all species without effect.⁶

These studies comprised until recently all the significant animal toxicity data. On the basis of the animal data and the fact that vinyl chloride had been used as an anesthetic at concentrations of 7-10 per cent by volume, there was a general consensus among toxicologists that vinyl chloride possessed low toxicity. The principal industrial hazard was its flammability.⁷

In 1975 Prodan *et al* described chronic toxic effects after exposure of guinea pigs to 10 per cent vinyl chloride for 2 hours daily for varying periods of up to three months. Marked growth disturbances were noted and severe lesions were noted in the liver, spleen, kidneys and lungs.⁸

The U.S. Center for Disease Control conducted an epidemiological study for birth defects in the vicinity of vinyl chloride monomer plants and discovered 53 in the period 1970-73 as against the 31 statistically expected. The National Institute of Occupational Safety and Health had previously reported an excess of defects, still births and miscarriages in three cities having vinyl chloride monomer plants.⁹

Viola *et al.* observed (1970) that vinyl chloride produced tumours in rats. After exposure of 26 rats to 30,000 ppm vinyl chloride 4 hrs daily, 5 days/week for 10-12 months, Viola observed 17 skin tumours, 7 pulmonary tumours, which were mainly carcinomas and 5 osteochondromas. Maltoni and Lafemine who reviewed Viola's results interpreted the lung tumours as predominantly metastases from the skin cancers which arose from the gland of Zymbal (a sebaceous gland of the exterior acoustic duct). Maltoni and Lafemine embarked on an extensive study using mainly inhalation but also endoperitoneal injection, subcutaneous injection, ingestion and transplacental routes of vinyl chloride administration. The results of Maltoni's studies were impressive. He showed that vinyl chloride produced tumours in the three species studied — rats, mice and hamsters. A wide range of tumours was produced including Zymbal gland carcinomas, nephroblastomas, angiomas and angiosarcomas of the liver and other sites, trichoeplitheliomas, hepatomas, lung adenomas, mammary adenomas and lymphomas.

There was some variation in the range of induced tumours from species to species. Liver angiosarcomas were observed in all three animal species. In the liver, blood vessel ectasia, endothelial hyperplasia with or without cellular atypia and fibroblastic changes frequently occurred, in addition to angiosarcomas. Fibroangioblastic proliferation was also often observed in the spleen. Maltoni's studies showed a definite dose-response relationship as far as angiosarcoma and nephroblastoma were concerned. Dosages as low as 50 ppm have been associated with hepatic angiosarcoma. He demonstrated two subcutaneous angiosarcomas in the offspring of breeding animals exposed to vinyl chloride for 7 days during pregnancy, indicating the likelihood of a transplacental effect of vinyl chloride.¹⁰ Part of Maltoni's data (1974) is summarized in Table 6.

It is not surprising that studies of human toxicity from exposure to vinyl chloride monomer are not as extensive as animal studies. Ideally epidemiological studies should lead to dose-response curves correlating exposure data and tumour (or other responses) incidence. Because of the extremely high concentrations of VCM in plants with little or no reliable monitoring facilities, because of the turnover of personnel and lack of complete medical records, and because of unknown effects of ambient concentrations of other chemicals used in the process, which could also co-promote carcinogenesis, it is impossible to determine the shape of the human dose-response curves except in a roughly qualitative manner.

In workers exposed to an environment with a high concentration of vinyl chloride, symptoms begin almost immediately. After the first few breaths, there is a pleasant taste in the mouth, followed by euphoria. Dizziness, headaches, somnolence or complete narcosis commonly follow. Somnolence often persists long after the worker leaves the factory. The sleep is deep, dreamless, commonly lasting 9-14 hours; one worker slept for 3 days intermittently. This narcotizing effect led to consideration of vinyl chloride as an anaesthetic at one time. Vinyl chloride is detectable in air by its odour in concentrations of 1800 ppm. Acute exposure to 4000 ppm for five minutes or more leads to dizziness and confusion. Higher concentrations may lead to unconsciousness and death. Vinyl chloride monomer fell into disfavour as an anaesthetic because of the narrow range between the anaesthetic dose and the fatal dose.

Two deaths from accidental acute vinyl chloride poisoning have been reported. Cyanosis, local burns, congestion of lungs and kidneys and failure of the blood to clot were noted.

After repeated or chronic exposure, the main neurological symptoms are headaches, irritability, dizziness, sleep disorders, diaphoresis, memory loss, general arthralgia and paresthesia. Skin sensations of formication and heat were noted as well as dyspeptic symptoms, epigastric pain and anorexia. Hepatomegaly with hepatic fibrosis, splenomegaly, hepatitis, ulcers, Raynaud's syndrome, allergic dermatitis, scleroderma, acroosteolysis, thrombocytopenia, restrictive pulmonary disease with lung fibrosis of linear type and emphysema on chest x-rays and dermatological conditions, especially contact dermatitis have been recorded. Laboratory findings reported include BSP retention, increased urinary excretion of monochloroacetic acid, an increase in peroxidase, indophenoloxidase and glutathione, increase in blood catalase, serum albumin, cholinesterase, and pseudocholinesterase. There is a correlation between the symptomatology and the degree of exposure to vinyl

chloride. Most of the severe clinical manifestations were found in workers who cleaned reactors. In one study by Suciu *et al.* a comparison was made of workers in 2 factories before and after the introduction of a 22-fold reduction of VC in the air. All the clinical manifestations of VC toxicity were greatly reduced (approximately by two-thirds) following the introduction of these measures.¹¹

In factory workers both VC and PVC cause a sensitization dermatitis which has been attributed to the plasticizers used. It is noteworthy that outside the factory, various reactions have also been observed. In consumers, hypersensitivity has been reported with PVC products containing epoxy resin plasticizers-stabilizers. In children, VC and dibutylphthalate release from floor coverings have caused an eczematous dermatitis. In infants and adults, irritation of the eyes and respiratory tract has been ascribed to liberation of volatile materials from polyvinyl chloride floor tiles. It has also been shown that the plasticizer, Di-2-ethylhexyl phthalate can migrate into stored blood and hence into tissues from polyvinyl chloride blood bags. The toxicological implications of this are not known.

Acroosteolysis deserves special comment because it was the first well-recognized toxic effect of vinyl chloride. The unusual disorder is a dissolution of the bones of the terminal phalanges of one or several fingers, and is accompanied by clubbing, swelling and shortening of the terminal phalanges and nail beds. The condition was associated with hand cleaning of polymerization reactors, although there is some evidence to suggest that it is not just a local disease. Rapid diagnosis to prevent progression of vinyl chloride induced scleroderma, Raynaud's syndrome and acroosteolysis is essential. Measures introduced included reduction in exposure of vinyl chloride in the air, water wash, gloves, a yearly physical examination, X-ray of the hands and periodic thrombocyte counts because thrombocytopenia occurred much earlier than any other sign.¹²

The first liver angiosarcoma cases in polyvinyl chloride workers were reported by Creech and Johnson in the United States in 1974. Angiosarcoma is a rare form of cancer and is not uniquely associated with vinyl chloride. Although at first disputed, the identification of vinyl chloride as a carcinogen in human beings has now been convincingly established.

As of March 1976, there are 48 known cases of VC-related hepatic angiosarcomas in the world; 45 are dead and 3 are still alive. They are distributed as follows: Canada 10, United States 17 (14 dead, 3 still living); Germany 9, France 3, Italy 2, U.K. 2, Sweden 2, Czechoslovakia 2, Yugoslavia 2 and Norway 1. All but one were workers handling large quantities of liquefied vinyl chloride under

TABLE 6
EXTRACT FROM MALTONI'S DATA, 1974

Exposure to Vinyl Chloride	Number of Animals Exposed	Number Developing Liver Angiosarcoma
6000 ppm	72	11
2500 ppm	74	9
500 ppm	67	7
250 ppm	67	2
50 ppm	64	0*

*Subsequently, hepatic angiosarcoma was found in this group. Studies are now in progress with 25, 10 and 5 ppm)
Source: Phillips, 1976, p. 1¹⁰

pressure; the exception was an accountant. Forty-six of the 48 workers in PVC polymerization plants had worked directly on the polymerization process and, for long periods, they cleaned reactors where vinyl chloride exposure would have been at its highest. Nine of the Canadian cases worked in one plant (in Shawinigan, Que.), and 9 of the U.S. cases worked in a single plant (Louisville, Ky.). These were old plants, but there are other plants in Western Europe and the U.S. (approximately 20), with equally long histories, with no known cases.

The ages of the 48 vinyl chloride workers at the time angiosarcoma was diagnosed ranged from 38 to 71 years with a mean age at diagnosis of 47.5 years. In the large series of angiosarcoma patients described by Makk *et al.* the most common symptoms were fatigue, weight loss and abdominal pain.²⁰ The most frequent physical findings were hepatomegaly followed by splenomegaly. Biochemical profiles (including bilirubin, SGOT, LDH, alkaline phosphatase, SGPT, GOT, fetoglobulin and CEA) yielded variable results and proved to be of little value in the detection or the diagnosis.

There is a strong indication from the clinical studies that a dose-response relationship exists with respect to the vinyl chloride exposure and human angiosarcoma. This serves as a basis for the current regulations concerning the atmospheric concentrations permitted in factories. Information, although incomplete, is available on the total years of exposure (ranging from 4 to 32 years) and years from first exposure to death (ranging from 9 to 32 years). *From these data, it is evident that there is a long latency period of about 10 years, which is usual with carcinogenic agents. This figure is of further significance since, predictably, new cases of vinyl-chloride-related angiosarcoma can be anticipated in workers exposed prior to the introduction of controls.* The deaths from angiosarcoma have occurred over a 14-year time period with an increasing number of cases occurring per year. This may be due to the rapid expansion of the polyvinyl chloride industry, and also to the awareness in recent years of this hazard so that all (or most) new cases are now being reported. The estimated figure of those still at risk in the U.S. from previous exposure is given as between 5000-6000 workers so that further cases of angiosarcoma can be anticipated.

However, the probability of diagnosing angiosarcoma may not be very good especially for those who have not been exposed to vinyl chloride monomer for quite a few years. There is very little chance of diagnosis being made if the pathologist is not aware of the relationship between angiosarcoma and vinyl chloride, if the hospital and diagnostic facilities are not sophisticated, if the person's medical and work history are not known and if an autopsy is not carried out.

In relation to human hepatic angiosarcoma, it is notable that two lesions, namely fibrosis and peliosis, precede the appearance of the angiosarcoma. There is also evidence that angiosarcoma of the liver is not the only tumour associated with vinyl chloride. Large cell carcinoma of the lung is now suspected, as is hepatocellular carcinoma. Also, angiosarcoma of the liver is not peculiar to vinyl chloride. Chronic exposure to insecticides containing inorganic arsenic has been associated with hepatocellular carcinoma and hepatic angiosarcoma.²¹

We have outlined the gross effects of exposure to vinyl chloride monomer. There are two remaining questions, what happens to VCM once it enters an organism (man or animal), and how are diseases related to VCM exposure

diagnosed so that effective treatment can be implemented?

Without going into detail, evidence from studies with rats, indicates that VCM is altered (metabolized) and that the resulting products (metabolite) are the carcinogens rather than the VCM itself. Further, there is evidence that the level of glutathione which normally serves to detoxify these metabolites is decreased by VCM, thus freeing them to react with other intracellular macromolecules such as DNA, RNA, proteins and lipids. This is one of the well-established experimental routes by which chemicals cause cancer. It should be emphasized that this evidence is based on studies made with rats and the applicability to human beings is unknown.

As for diagnosis and treatment, a number of reports dealing with the clinical management of workers exposed to vinyl chloride and polyvinyl chloride have been published. It is agreed that a good medical surveillance program should include a comprehensive medical and occupational history, and a review of all the systems and information concerning alcohol intake, past history of hepatitis, past exposure to hepatotoxic drugs and chemicals, blood transfusions, etc. A physical examination by a physician, a chest x-ray, x-ray of the hands, a pulmonary function test (forced vital capacity and forced expiratory volume, 1 sec.) and a panel of laboratory tests including complete blood count, a complete blood chemistry profile.²²

The special problem of all these examinations lies in the fact that the individual symptoms of all pathological manifestations brought into connection with vinyl chloride are not in themselves specific to vinyl chloride. Thus, for example, acroosteolysis, Raynaud's syndrome, scleroderma and thrombocyte changes have occurred in people who have not been exposed to vinyl chloride monomer. The thrombocyte count of a person can fluctuate considerably within a very short time. Wrong diagnoses are readily made if one relies on that symptom alone. The changes in the liver of vinyl chloride workers are very specific disturbances — so-called fibroses of the liver can only be recognized as such by means of microscopic tissue examination of the liver (biopsy).²³

Liver function tests, liver scans, angiography and liver biopsy deserve special comment. It is well known that the "liver function tests" used in medicine, are not tests of liver function. They only provide crude information on the function and dysfunction of the liver and no information on its cause. Moreover, since a large segment of the working population drinks, if an abnormality is found, it is not easy to exclude an ethanol aetiology for this abnormality. Liver function tests are too crude to detect lesions such as the hepatic fibrosis which seems to be the precursor lesion of angiosarcoma; they are also too crude to detect early angiosarcoma. The use of invasive techniques such as angiography and transjugular liver biopsy seem too extreme, ordinary liver biopsy is hazardous in suspected angiosarcoma. Popper recommended the liver scan as the best single test, it should be done annually (along with the medical examination) on those workers at risk. It would seem reasonable also to do a scan of workers with abnormal liver function tests especially if an ethanol cause can be excluded. If a liver scan is positive, it should be followed by angiography and if this is positive, then surgery is recommended.²⁴

Although it seems unlikely that anyone entering the vinyl chloride work force today will develop angiosarcoma because of the controls that are in force, new cases are anticipated in workers previously exposed: continued med-

ical surveillance is important. Since a minimum of 4 years exposure (initiation phase) is required and since the promotion phase takes about 10 years, it is likely that new cases will develop over the next 14-15 years in this previously exposed worker population.²²

There are essentially three sources of exposure to vinyl chloride monomer. It is emitted into the outside atmosphere (environment) during the manufacturing process, workers are exposed to it in the contained atmosphere of the workplace, and polyvinyl chloride consumer products under certain circumstances can release vinyl chloride monomer into the atmosphere, foods, or solvents such as alcohol.

Vinyl chloride emissions into the atmosphere in Canada have been estimated at 6,000 metric tons during 1973, about 5 per cent of production. Of this total, it is thought that 89 per cent was released by PVC manufacturing plants and 10 per cent by VCM plants. The remaining 1 per cent was released by the plastics industry during the processing of PVC into finished products and is due to monomer trapped in the PVC resin. Emissions for 1976 are less since efficiency has increased to 98 per cent or better. Release of vinyl chloride from the degradation of PVC is insignificant due to the great stability of the polymer. The estimated total entry into the North American environment in 1973 was 126,000 metric tons.

The physical properties of the compound (low boiling point, high vapour pressure and low water solubility) indicate that it would migrate rapidly to the air and not be found in appreciable amounts in water or soil. Photolytic decomposition in the atmosphere is thought to be the only significant route for removal of vinyl chloride from the environment. The photodegradation half-life under real conditions is about two days.

It is possible to calculate the expected concentration of vinyl chloride in ambient air in the Northern Hemisphere by using the release figures and the half-life of vinyl chloride in the atmosphere. For 1973 the calculated ambient steady state concentration in the atmosphere is 1.4×10^{-6} ppm by volume (3.6 nanograms/m³).²³

Total emissions from the three basic industry sectors for the year 1973 were reported as 0.4 per cent from VCM manufacture, 3.5 per cent from PVC manufacture and 0.05 per cent from PVC fabrication, based on 1973 total production of PVC. Technology and work practices could reduce these emissions by as much as 95 per cent.

Vinyl chloride monomer emissions are further categorized as captive and fugitive. Captive emissions are those from continuous or periodic vent streams to maintain process control and product quality. Fugitive emissions are those which can come about through leaking flanges, valves and pump seals, and losses during sampling, monomer loading, and unloading. Captive emissions relate directly to the intrinsic process or capability of equipment. Fugitive emissions relate primarily to equipment maintenance, operating procedures and discipline.

Table 7 shows typical emission rates (as percentages of vinyl chloride monomer emitted to the atmosphere) for captive and fugitive losses. The quantitative data are based on industry performance in 1973, prior to implementation of recently-developed technology.

How vinyl chloride monomer is dispersed outdoors is unknown. Measurements show a concentration of vinyl chloride monomer of 0.1 ppm two-thirds of a mile from a plant, and no detectable VCM one mile from a plant. The relationship between emission rates and ambient

air concentrations of VCM is not known. On occasion a universal dispersion calculation is used by engineers to calculate the ambient concentration of a particular pollutant at ground level. Factors included in this calculation are stack height, ambient temperature, wind, emission rates, half-life of particular substances, etc.

Occupational exposure to vinyl chloride may occur in the manufacture of the monomer and also during the manufacture of PVC. Loading and unloading of tank cars and trucks containing VCM and PVC constitute an exposure risk. During the manufacture the greatest risk of exposure occurs to workers when cleaning the polymerization kettles. The polymer usually contains unreacted monomer which is partially given off in the drying process, packaging operation and storage. Residual monomer may be given off during mixing, compounding and extrusion of PVC. Excessive heat leads to decomposition of PVC and the formation of hydrochloric acid gas, carbon monoxide, carbon dioxide and possibly traces of phosgene and other gases.²⁴

Prior to the emergence of the VCM health problem, little data were available on the concentrations of VCM to which workers were exposed. However, it is generally accepted that levels up to 3000 ppm were frequently encountered, particularly in the older resin plants. More specifically and according to industrial sources, exposure levels during the year 1970-73 ranged from 35 to 50 ppm with a weighted average of 28 ppm. In June 1974, 5 per cent of tests read under 5 ppm and 79 per cent over 10 ppm. By December 1975, the situation had changed: 92 per cent under 5 ppm while only 8 per cent read over 10 ppm and the average had fallen to 4 ppm. Today, following numerous process improvements and the development of new technology, personnel exposures in Canada are reported to be below 5 ppm.

The manufacture of VCM involves a continuous process which for the most part is open to the atmosphere. Incidents of worker exposure are primarily limited to infrequent fugitive emissions. Vent stacks are usually elevated and workers are not formally affected.

Advanced technology and modified work procedures have resulted in personnel exposures below 5 ppm with good prospects of further reductions. Readings below 1 ppm were recently reported for Dow's Sarnia operation.²⁵

TABLE 7

ESTIMATED VCM EMISSIONS PRIOR TO NEW TECHNOLOGY

Emission Type or Source	Emissions (In Per cent) In The Manufacture of:		
	VCM	PVC	Fabricated Products
I Captive			
Reactor/Mixer	.05	.1	.04
Intermediate Recovery	.04	.9	—
Product Purification/ Recovery	.21	1.05	.1
Product	—	.05	—
Total Captive	.3	2.1	.14
II Total Fugitive	.1	1.4	—
III Total Emissions	.4	3.5	.14

Source: Arnold 1976, p. 11

The danger of exposure to vinyl chloride monomer gas exists mainly within plants which produce polyvinyl chloride resin. Due to the nature of the "batch" PVC resin production process and the frequent need to open vessels, atmospheric contamination by vinyl chloride monomer gas emissions occurs.¹⁰ In the polymerization process the conversion of vinyl chloride monomer is only 85-90 per cent complete. Most of the unreacted VCM is recovered but amounts of up to 1000 ppm residual monomer are retained in the resin and are transferred downstream to the fabrication plants with the resin shipments. A good portion of the recycled monomer and the remainder is lost to the atmosphere inside and outside the plant.

There is very little evidence that VCM has been a problem in plastic fabrication plants where PVC resin is used. Individuals employed by processors are not exposed to the levels of VCM which are present in VCM or PVC plants. Resins with low residual monomer content and good plant ventilation control are responsible for the low risk in the plastics fabrication industry.¹¹

However, until recently, a number of the PVC powder grades produced by the suspension and bulk polymerization processes contained over 1,000 ppm residual, unreacted vinyl chloride. Despite degassing after polymerization and high temperatures during drying, it is not possible to remove residual vinyl chloride from PVC. This residual is partly liberated during storage and during subsequent processing. Consequently increased concentrations in the work area cannot be ruled out.

By adopting a completely new mode of operation, decisive improvements in industrial safety and reductions in the vinyl chloride monomer emissions are possible.¹²

A critical operation in the use of PVC is its transfer from the rail car to the fabrication plant. A recent report prepared by the University of Washington's Department of Environmental Health states,

"Of the 13 polyvinyl chloride operations located in the state, only the extrusion plants appeared to present potential exposure problems. It should be mentioned that the six extrusion plants employed 398 workers or approximately 80% of the total work force exposed to vinyl chloride. Five of the six extrusion plants were subject to general atmospheric vinyl chloride concentration in excess of the permissible exposure limit of 1 ppm. Vinyl chloride concentrations in plant 12 were all well below 1 ppm. The only plant, however, in which personnel samples exceeded the permissible exposure limit was plant 11. The blender in this plant exhibited a 6-hour time weighted average concentration of 4 ppm. The extruder, the beller, and the laboratory technician were at or above the action level of 0.5 ppm.

"The railroad car at plant 10 indicated a vinyl chloride concentration of 814 ppm when sampled through the plastic cover. Twenty-four hours after the car was opened and partially unloaded, the interior concentration was still 70 ppm. The rail car at plant 1 showed 77 ppm 1 vinyl chloride immediately after being opened and 12 ppm 1 hour after opening."¹³

In a general environmental health context, concern has been expressed on the possible effects of using PVC products containing unreacted releasable monomer. Studies have shown the resulting exposures are insignificant and no ill effects are known to have occurred.¹⁴

In its final form, PVC is an inert material. That is, it will not revert or depolymerize to vinyl chloride mono-

mer gas. Both the Ontario Ministry of Health and the U.S. Occupational Safety and Health Administration have stated that finished PVC products "Do Not Constitute Any Known Health Hazard." No evidence to the contrary has been discovered. Products made from PVC have been used by consumers for almost 40 years.¹⁵ In the same context, retrospective studies have been conducted on certain Ohio cities with PVC production facilities in order to ascertain the oncogenic and mutagenic risks to the population. The results are inconclusive.¹⁶

Detectable levels of VCM have been discovered in PVC bottles. Residual VCM gas is known to have migrated into products which are mainly alcohol based. For example, unreacted VCM has been found in certain PVC bottled wines, distilled spirits and vinegar. No evidence is available to indicate that the occurrence has endangered the health of users.

Unreacted VCM has not been found in food wrap when measured by sensitive instruments which detect vinyl chloride monomer down to 50 parts per billion.¹⁷

Actions Taken as the Result of the Perception of the Vinyl Chloride Monomer Hazard

Three areas illustrate the response to the perception of the hazards associated with vinyl chloride exposure:

1) setting of standards, 2) industrial activity such as the development of better abatement technology and monitoring, and 3) research.

Vinyl chloride monomer and polyvinyl chloride were introduced in the United States in 1937 and in Canada in 1943. For many years VCM was considered as only slightly toxic, from both single and repeated exposure.¹⁸ The high flammability of VCM was considered a more serious hazard. The first concentration standards were based on this criterion of hazard.

In 1949, an early Russian study revealed a high incidence of liver disorders among men handling VCM. As a result, a maximum acceptable concentration of 12 ppm was established in the U.S.S.R. Whether this standard was enforced is unknown. The results of this study remained unnoticed because they were inaccessible to other countries and they are still not available in detail.¹⁹

Until 1962, the American Conference of Governmental Industrial Hygienists (ACGIH) recommended that the long-term exposure of workers to vinyl chloride should not exceed 500 ppm with a time weight average of 8 hours daily. The recommendation was based on single exposure studies on animals and human beings.

In spite of ACGIH recommendations, Dow Chemicals Limited, reduced exposure levels to 50 ppm on the basis of animal experimentation.

In the 1960s industry was alerted by reports of occupational disease among PVC reactor cleaners, namely acroosteolysis and Raynaud's syndrome. A Manufacturing Chemists Association (MCA) study could not define the role of VCM in causing this condition. However, the vinyl industry adopted industrial hygiene controls and work practice changes as recommended and new cases of this disease are almost never seen.

In 1963, the ACGIH modified their recommendation so that 500 ppm became a maximum concentration (or ceiling) rather than a time weighted average. It is this value that was in the 1970 threshold limit value list promulgated by the Occupational Safety and

Administration on May 29, 1971 as a national consensus standard. The ACGIH proposed in 1970, and affirmed in 1972, reduction of their recommended TLV to a time-weighted average of 200 ppm.⁴⁰

In Germany, at about the same time, the threshold limit value was reduced to 100 ppm following the outcome of animal experiments in which liver changes had been noted after exposure to vinyl chloride.⁴¹

Dr. Viola's work in 1969 was the first indication of cancer in connection with the exposure to vinyl chloride. Little attention was paid by industrial hygienists to Viola's report of the carcinogenic potential of vinyl chloride because his investigations were conducted with extremely large dosages.⁴²

A year later in Europe, the Manufacturing Chemists Association (MCA), Montedison, Imperial Chemical, Solvay and Rhone-Prolig, initiated research to be conducted by Dr. C. Maltoni with the agreement that the information discovered would be shared among them, but not revealed without their consent. Even though Maltoni's results were available in August 1972, and shared with U.S. scientists in January 1974, the National Institute of Occupational Safety and Health (NIOSH) was not notified nor was any attempt made to warn the public or workers of risk. Further experimental results in November 1973 and in May 1974 confirmed Maltoni's 1972 findings.⁴³

In January 1974 when B. F. Goodrich reported three cases of angiosarcoma in workers exposed to VCM at their plant in Louisville, Kentucky, the problem received worldwide attention and concentrations for occupational exposure were reduced all over the world.

During May 1974, West Germany adopted a standard of 50 ppm. Shortly afterwards the threshold limit value regulation for vinyl chloride was discontinued and a technical guiding concentration of 5 ppm as an annual average was fixed.⁴⁴

In Britain, a time-weighted TLV of 50 ppm in the work environment was imposed. A comprehensive code of practice in February 1975 was issued as a result of the formation of a joint working group of unions, management and the Inspectorate. In October 1975 a new hygiene standard was adopted: a ceiling level of 30 ppm; a time-weighted TLV for VCM of 10 ppm, and a policy that exposure of workers should be brought as near as possible to zero concentrations. To evaluate the extent of the hazard within Britain, three studies have been set up: a prospective study of PVC manufacturers, a prospective study of PVC fabricators, and a retrospective study of primary angiosarcoma.⁴⁵

In the U.S., after the Goodrich announcement, the most expensive and comprehensive measures ever undertaken to deal with an industrial health hazard were mounted. Virtually all of the U.S. National Institute of Occupational Safety and Health (NIOSH) field teams were mobilized to undertake epidemiological (group health) studies of various PVC plants.⁴⁶

An emergency standard of 25 ppm time-weighted average with 50 ppm maximum exposure was set by June 1974. Permanent levels were then set by OSHA, NIOSH and trade unions (IUD of the AFL/CIO, OCAW, URW) in February 1974. It was recommended in the U.S. that the acceptable threshold level of VC to be allowed in air be set at no detectable level (in reality a 1 ppm standard).⁴⁷

OSHA proposed a standard for personnel exposure to VCM of 1 ppm, time weighted average over eight hours, in October 1974, including a maximum, peak level of 5

ppm over 15 minutes. This regulation became effective in April 1975, and in April 1976 the peak limit was reduced to 5 ppm before the use of respiratory equipment becomes necessary.⁴⁸ Therefore, the U.S. value went from 500 ppm to 50 ppm and then to 1 ppm between 1968 and 1974. The EPA has promulgated final standards limiting air and water emissions of vinyl chloride from new and existing plants. Vinyl chloride emissions will be limited to 10 ppm under the final standards and require the use of the best available technology.⁴⁹ However, the EPA standard for vinyl chloride has been challenged by the Environmental Defence Fund (EDF) which has filed a petition in the U.S. Court of Appeal. The petition is based on Maltoni's latest findings which suggest that mammary carcinomas can be induced in laboratory animals at 1 ppm or less. According to the EDF, the EPA standard is based on the degree of control which can be achieved through use of best available control technology and not on the degree of control which is necessary to protect public health. This is contrary to the Clean Air Act.⁵⁰

Generally, Canadian response occurred after the 1974 B. F. Goodrich announcement. Canadian regulators became aware of the vinyl chloride hazard through their American counterparts and the Canadian subsidiaries through their American parent companies. The media provoked a response, as well as scientific publications and exchanges.

At the federal level in Canada, because of a more limited workplace jurisdiction, the response has been slow. The Product Safety Branch of the Department of Consumer and Corporate Affairs, after learning of the decision early in 1975 of the U.S. Consumer Product Safety Commission on harmful effects of household sprays using VCM as a propellant, immediately banned the importation, sale, and advertising of aerosol packaged chemical products which contained vinyl chloride as a propellant gas. Infant toys and pacifiers emitting detectable amounts of VCM were also banned.

The Bureau of Chemical Hazards of the Department of Health and Welfare also responded in 1975. After its researchers discovered traces of vinyl chloride in plastic vinegar and peanut oil containers, it asked the packaging industry to modify their packages and then banned the use of packaging in which vinyl chloride monomer could be found.⁵¹ Further, all foods containing detectable amounts of VCM due to PVC wrapping is to be rejected when analyzed using the official method of analysis (May 1976).

Environment Canada is in the process of developing criteria to establish an emission rate standard for VCM and PVC plants that is distinct from an ambient air standard.⁵²

In Canada, the provinces generally have jurisdiction over conditions in the workplace and over health delivery and health protection systems. Thus, it is possible that provincial responses do vary as shown in Table 8.

TABLE 8
CANADIAN VCM EXPOSURE LIMITS

Province	8 Hr. TWA - ppm	15 Min. Peak - ppm	Effective Date
Alberta	5	10	Oct. 1975
British Columbia	1	5	In Draft Stage
Ontario	10	25	Oct. 1974
Quebec	1	5	In Proposal Stage

The Ontario Ministry of Health established vinyl chloride exposure limits guidelines. Upon recommendation from the Ministry of Labour it will enforce such guidelines in the workplace. The Ministry of Health issued an occupational health data sheet to industry and industrial associations which includes precautions to be taken in the workplace. Inspectors have the power, under the Public Health Act, to enforce recommended precautions. The Ontario Ministry of the Environment has set up and is enforcing an ambient air guideline for vinyl chloride emissions of 0.1 ppm over a 24-hour period with a peak limit of 0.2 ppm over 30 minutes. Plant directors have been informed of this guideline and given time to allow them to develop adequate controls to comply with the standard when it is set. The guideline will be in force until adequate information is gathered to set appropriate standards.

The Quebec Ministry of Labour under the Industrial and Commercial Establishments Act is responsible for standard setting and enforcement. The Environment Protection Service inspects the workplace and recommends when enforcement action should be taken by the Ministry of Labour. The Ministry of Social Affairs is responsible for conducting medical examinations of workers if requested. When and if an already proposed regulation on the quality of the "occupational environment" is made into law, the Ministry of the Environment will be responsible for standard setting and enforcement. This draft regulation contains a series of standards and regulations among which is the proposed standard for vinyl chloride of 1 ppm, time weighted over 8 hours with a ceiling value of 5 ppm for 15 minutes. Currently, the Environment Protection Service is monitoring the B. F. Goodrich plant at Shawinigan and reports that the average exposure levels are 3 ppm. They have also given the company an informal objective of 1 ppm to be reached by July 1977. The legal standard according to the regulations of the Industrial and Commercial Establishments Act is still 200 ppm.

Industry's response to the vinyl chloride monomer situation, especially since the B. F. Goodrich announcement in 1973, has been dramatic in actions to reduce exposure to vinyl chloride monomer. In 1974 in the U.S. when a standard of no detectable level of exposure was recommended, industry responded by suggesting such a standard was unrealistic and if imposed would cost the industry right out of business. However, industry was subsequently able to meet exposure levels that were far less than they claimed could be met without altering the market price of PVC resin. The U.S. standard as promulgated by OSHA is 1 ppm time weighted over 8 hours with a 5 ppm maximum over 15 minutes.

In Canada and especially in Ontario, the controversy over standards does not appear to have taken place. Industrial spokesmen have indicated that the 10 ppm guideline for Ontario can easily be met and in fact actual exposure levels have been reduced to about 3 ppm using best practicable technology. Spokesmen from Canadian industry feel that the U.S. standard cannot be met unless gas masks are used or unless exposed workers are placed in pure air chambers for a few hours each day.

After the B. F. Goodrich discovery, the three vinyl chloride producers in Ontario met to discuss what steps to take. They initiated meetings with the federal and the Ontario governments in July 1974. The departments involved were the Ministries of Health, Labour and Environment at the provincial level and the Ministries of Health and Welfare and Environment at the federal level.

the Ontario Cancer Treatment and Research Foundation participated in the meetings. In March 1975, representatives of the Province of Quebec, and in mid-1975 of the Alberta Government, were included.

The Society of the Plastics Industry of Canada drafted a paper on vinyl chloride which was sent to government, industries and the media. That started the process of establishing pertinent regulations. In Ontario where the standard is 10 ppm, efforts were exerted to decrease actual levels to 0 ppm. In the last three years, levels have decreased from the hundreds to under 3 ppm.

In 1974 the Society of the Plastics Industry of Canada established a Canadian Industrial Committee composed of the industries producing and using vinyl chloride. An open exchange of monitoring and control techniques took place. Since B. F. Goodrich spent \$42 million on vinyl chloride technology, it is available only on a licensing basis. Information meetings on the subject of vinyl chloride and angiosarcoma have been held not only with plant and maintenance personnel, but with people from outside trucking firms handling the product. VCM gas and PVC resin producers today provide or are implementing continuous round-the-clock monitoring of vinyl chloride monomer gas levels within the plant work environment. Similarly, work is going on to reduce exposure levels through a combination of engineering changes, new work practices and personnel monitoring devices carried by workers on the job. Improved systems to minimize VCM emissions, either in plant or outside, are being installed.

In the U.K. developments that have occurred were improvements in monitoring techniques and control engineering. Prior to the B. F. Goodrich announcement monitoring was carried out irregularly, and was accurate to about 200 ppm. More accurate techniques of gas chromatography were soon introduced, and could measure to about 10 ppm. Eventually the accuracy was improved to 50 ppb. Monitoring is now carried out continuously, in such a way that the levels are known to workers immediately. It is intended that "alarm" systems will soon be introduced. Control engineering concentrated on improved ventilation systems, reducing leakages at valves, and finding ways of cleaning the kettles by high pressure water systems. These developments are continuing slowly, due to delays and shortages of the necessary pieces of equipment.

In early 1974 techniques to measure vinyl chloride monomer in the low parts per million range were not generally known. New instruments, methodology, and methods to collect air samples had to be developed. Over the past two years numerous pieces of equipment have been introduced and/or applied to VCM measurement. Gas chromatography appears to be the most popular technique and is now sensitive to 0.01 ppm or better.

Selected employees in the vinyl chloride unit at Dow Chemical's VCM and Esso's PVC plants in Sarnia wear personal monitoring devices (badges) which measure their exposure to vinyl chloride during an 8-hour period. Analyses of the badges are done at the end of each day so that any excessive exposure is quickly spotted and appropriate remedial action can be rapidly taken. Augmenting this procedure is an automatic area monitoring system which checks 30 points throughout the plants on a quarter-hour, half-hour or hourly basis. Results are compiled by a computer and are made available to all employees working in the area through monthly operating reports, monthly safety meetings and periodic communications meetings. In addition, VCM and PVC resin production work-
once per year,

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medical examinations developed by experienced liver and cancer specialists to detect early signs of disease. Extensive industry-sponsored medical research to better understand the pathology and early warning symptoms of VCM related disease has begun.¹⁰

Polyvinyl chloride resin producers have made and are continuing to make progress in reducing residual vinyl chloride gas trapped in PVC. This will eventually eliminate potential workers exposure in processor plants. There is an intensive international research and development program sponsored by companies and industry associations.¹¹

Improved recovery of the unreacted monomer was given priority for three basic reasons: to reduce the risk of employee exposure; to reduce emissions of VCM to the outside atmosphere; and to reduce the level of residual monomer in resins and compounds, which lowers the possibility of exposure at fabricators plants and in finished products.

Worker exposures were first reduced by providing improved plant ventilation, probably because it was the fastest and simplest thing to do. New technology had to be developed for monomer recovery and reduced levels of residual VCM in the finished resins.

It appears that significant changes have been made in sampling techniques and rail car loading procedures. Continuous monitoring systems throughout the plants provide an early warning system of fugitive emissions and process upsets enabling quick remedial response.

Refinements are being made in automatic reactor cleaning devices to reduce the frequency of vessel entry for manual cleaning. New technology designed to reduce or eliminate a polymer build-up on reactor walls is in place or is being introduced in varying degrees throughout the industry. This will reduce the frequency of opening vessels and will cut down or eliminate cleaning time. Further, in April 1973, Esso introduced an instripping process which will shortly be installed in all Esso and Goodrich plants in Canada.

The basic technology is not new but advancements are being made in the elimination of resin build-up or skin on the reactor walls which is the major cause for the need to open and manually clean the vessels by the addition of chemicals which prevent this build-up. This development trend coupled with automatic cleaning facilities that use water under high pressure have permitted the industry to advance to larger reactors. In recent years reactors have increased in size from 2000 gallons to 50,000 gallons.¹² Special provisions are in place to accommodate emergency situations such as run-away reactors and rupture disc failures. The ultimate impact of the new technology and process changes is reported to enable a 95 per cent reduction from 1973 levels of VCM released into the environment.

B. F. Goodrich is licensing its stream-stripping process which removes VCM from PVC suspension resins. Monsanto has been licensing its PVC reactor cleaning know-how. Lonza, a Swiss company, is offering a procedure for preventing suspension resin polymer build-up on reactor walls. Tenneco has developed a carbon absorption method aimed at recovering the residual VCM in vent gas streams. The economics of installing another method of scrubbing VCM from stack gas, called oxyphotolysis is being evaluated.

It is unlikely that companies will reap great financial benefits from licensing new technology but they hope to defray part of the development costs.¹³ There is no question that the various VCM abatement programs have added

to increased costs in all manufacturing segments. Research and development, capital expenditures, operating costs, maintenance and continuing medical surveillance of the workers have all contributed to higher production costs.¹⁴

Most vinyl chloride related research in Canada is conducted by Dr. F. Delorme at Hôpital Régionale de la Mauricie and Dr. G. Thériault at Université Laval. They are focusing their research on the epidemiology of VCM-related diseases and on diagnosing pre-angiosarcoma tumors.

H. Plugge, a graduate student in the Department of Chemistry at the University of Guelph, working for Dr. S. Safe, is studying how vinyl chloride and its metabolites might interact with nucleic acids to produce cancer. In other words they are trying to determine the causal links between exposure to vinyl chloride and cancer development.

Health and Welfare Canada is not researching any specific aspects of vinyl chloride. By amalgamating information and data from a variety of sources, Health and Welfare alerted Environment Canada and provided it with necessary background information to assist that agency in establishing emission standards.

The Ontario Ministry of Health receives and surveys data from the medical surveillance of workers by the companies producing VCM and PVC.

Most other vinyl chloride research including epidemiological work, animal studies and abatement technology is carried out by U.S. university laboratories sponsored by industry and by U.S. industrial in-house research facilities. The information which results from these research activities is distributed to their Canadian subsidiaries.

The Manufacturing Chemists Association, the Society of the Plastics Industry, individual companies, and producers in the U.K. and Europe have all embarked on research programs. Within the North American plastics industry alone, hundreds of scientists and technicians are employed full-time on intensive research programs aimed at developing new technology which will reduce VCM exposure and residual VCM in PVC resin. The combined cost of these programs is estimated to be in excess of \$100 million over the next three years.¹⁵

Maltoni, in Italy, is still actively engaged in establishing dose response curves using animal studies.

Summary Conclusion

This overview has attempted to outline, as factually as possible, the nature and scope of the problems associated with exposure to vinyl chloride monomer, as well as what has been done. We now summarize the vinyl chloride story and attempt to draw some conclusions by denoting some of the deficiencies in the system, by suggesting some "lessons learnt" from the VCM experience, and by arguing for some reform.

Polyvinyl chloride is a resin used in the fabrication of a wide variety of plastic products, with tremendous commercial success. It is manufactured by the polymerization of vinyl chloride monomer, a relatively simple synthetic organic chemical. Since World War II, production of both VCM and PVC has grown at a tremendous rate. Worldwide production of PVC in 1974 exceeded 18 billion pounds.

Up to 1973 vinyl chloride monomer was considered relatively safe even though effects such as acroosteolysis, Raynaud's syndrome, had been noted. Removing workers from exposure often eliminated or lessened these effects. In December 1973, B. F. Goodrich in the U.S. received a

medical report that one of its workers had died of a case of liver cancer, angiosarcoma. Upon checking, the company found that two other employees had died from a similar cause. After further research, VCM was identified as the causative agent. Toward the end of January 1974, the company publicly announced these findings. A worldwide search has so far revealed forty-eight victims, ten in Canada. Others who may have died of angiosarcoma are unknown because of difficulty in diagnosing the disease.

Prior to the announcement, studies had shown that VCM had chronic effects on human beings at high levels of exposure. VCM causes a specific occupational disease known as acroosteolysis in which there is both Raynaud's syndrome and sclero-dermiform lesions. Actually, as far back as 1949, Soviet studies had shown a higher incidence of liver malfunction among workers exposed to VCM. In May 1970, Dr. Viola in Italy announced that VCM caused cancer in test animals. His findings were virtually ignored. Dr. Maltoni's findings, in Italy, that VCM is indeed a carcinogen, were made public by industry only after the B. F. Goodrich announcement.

The B. F. Goodrich announcement precipitated a flurry of publicity in the media. Response from governments, industry and labour was quick and generally cooperative. More stringent standards were set, abatement and monitoring technologies were either put in place or efforts to develop them started, and a wide variety of research in areas ranging from biomedical to technical was funded and initiated.

Is the Vinyl Chloride story a success story? If one views it from late 1973 on, it appears to be a partial success story. It has shown how weak federalism and different configurations of economic factors and organizational power result in different standards and responses. It does not tell us much (yet) about actual compliance to workplace standards, since most of the new, recently lowered, standards are still being implemented. Their effectiveness and sustainability are still questionable. One thing appears certain — if the current standards are being met (there is no reason to believe that they are not being met in Canada), the risk associated with exposure to VCM has been substantially reduced. Whether the risk has been eliminated or is at an acceptable level is difficult to determine since a dose response curve for worker exposure to VCM has, as yet, not been established. It has been argued that exposure to any amount of a known carcinogen is unacceptable. In any case, anyone now entering the workplace, where exposure to some vinyl chloride is probable, suffers a very small risk of contracting a VCM-related disease, or at least a much lesser risk than those who entered the workplace prior to 1973.

From this point of view, the vinyl chloride story is a success. However, are the future victims from past exposures, going to be identified and compensated? This is a complex issue because of the long latency period before angiosarcoma becomes evident, because of the difficulty in diagnosing the disease, because of the relatively poor records of exposure that were kept in the past, and because of the transitory nature of employment in contemporary society.

Viewed holistically, the claim that the vinyl chloride story is a success becomes rather dubious. It has long been known that nearly all halogenated hydrocarbons represent a hazard to human health. In 1949, 1958 and 1965 reports from the Soviet Bloc revealed a variety of disorders in workers exposed to VCM; in the mid-1960s a number of reports dealt with changes in VC reactor cleaners; in 1970, Dr. Viola reported

in animals. Despite these reports, up to 1973, it was the general conclusion that exposure to VCM was not a serious health hazard.

If blame is to be apportioned for ignoring the signs that VCM is a carcinogenic hazard, it should be shared by nearly everyone involved. Governments by their relative apathy and lethargy in the occupational health arena; business and labour by turning a blind eye toward this problem area, usually because of commercial and economic motives (profits and employment); and the scientific world, because of its ivory tower approach to these problems, have all been equally guilty of neglect.

Occupational health has not been ignored, but the major emphasis has been given to dramatic, acute effects and not to the long-term sub-chronic effects of low levels of exposure. With hindsight it is evident what should have been done — the signs should have been heeded. Much more research, epidemiology and testing should have been undertaken. Information flow should have been facilitated and obligatory so that information was readily available. Occupational medicine (diagnosis and treatment of occupational disease), industrial hygiene, and monitoring need to be given added emphasis. Most important, attitudes toward industrial chemicals (whether new or old) and processes must take into account, when costing an industrial development, the potential for harm over the long term.

Testing a chemical for its potential as a carcinogen is lengthy and costly. A hierarchy of tests based on a sense of priorities needs to be established. Research directed toward developing quick and relatively inexpensive means of identifying chemicals that are harmful over the long term should be initiated. Promising developments are taking place.

There are two prime "lessons to be learnt." The first is that vinyl chloride is only one of a great number of chemicals harmful to human beings which have been or are thought to be safe. It is startling to note that the correlation between exposure to vinyl chloride and angiosarcoma was made only because that form of cancer is rare. Had the cancer been more common, it is likely there would still be no awareness of a linkage. Studies have shown that there is a relationship between primary cancer of the liver and the presence of chemicals in the environment.²² Thus, determining the frequency of carcinoma due to exposure and identifying those chemicals that cause carcinoma in the work and market places are questions of prime importance. Recent estimates by the World Health Organization indicate that 60 per cent of all cancers are induced by pollutants which are not viruses. However, cigarette smoking, admittedly, is probably responsible for a large but unknown proportion of environmentally-caused cancers.

The second "lesson to be learnt" from the vinyl chloride experience is that there is an urgent need to improve our anticipatory capacity. For far too long, the prevalent practice has been one of reaction. The existing method of using people, whether workers or the public, as guinea pigs for the hazards of industry, although it is not done overtly, is insupportable and unacceptable. Chemicals must, as far as possible, be tested prior to their introduction into the work and market places, particularly because of the delayed appearance of cancer. This emphasis on anticipation should not de-emphasize epidemiological research. On the contrary, this sort of research must be strengthened to enable us to determine what already exists and to confirm that future precautionary measures are satisfactory. The problems, obstacles and difficulties in conducting epidemiological studies are formidable, but must be overcome. For

relying on routine health records and death

certificates as they are currently constituted would probably provide "false negative" findings and incomplete information.

The study of the vinyl chloride case naturally leads to a number of other lessons and arguments for change."

- International recognition and acceptance of just what constitutes an industrial hazard should be established. Since the field of industrial hazards is so vast, some attempt at rationalizing an international effort should be made — possibly through the auspices of the United Nations, multinational corporations and international trade unions. The latter group should have a particular interest since workers usually do not receive compensation unless such recognition is given.
- Basic research carried out by people with no vested interest internationally and nationally must be established. The information should be made readily available to all concerned in any nation.
- Some of the research on industrial chemicals must be conducted in a manner which is related to the work environment. Most chemicals are tested in isolation from other chemicals and in a manner unrelated to the worker's dietary and non-work-related, physical conditions, some of which may predispose him or her towards a particular hazard. Both retrospective and prospective research should be initiated. The former will attempt to identify and verify all diagnosed cases of primary angiosarcoma of the liver and to evaluate their association with occupational exposure to vinyl chloride. The latter will evaluate the effects of exposure to vinyl chloride in terms of mortality and cancer registration rates, by including all past workers who may as yet have no symptoms, from every factory manufacturing polyvinyl chloride."
- Adequate and appropriate medical services (including diagnostic) must be made available to workers so that occupational diseases can be identified at the earliest stages.
- The worker, the unions and the public should be directly informed of the type of harmful effects that could result from substances, processes or phenomena to which they are exposed. This will assist them in deciding whether the risk associated with such exposure is acceptable. Further, this information needs to be made available so that the people involved will be able to recognize occupational and environmental illnesses when they occur and thus be able to identify, record, investigate and correct the conditions.
- Information flow between the medical-scientific, governmental, industrial, labour, and public communities should be as free and as open as possible, especially in all matters pertaining to human health. Governments having two major responsibilities in this regard. They must ensure that the information they have obtained is available and accessible. Secondly, they must obtain the release of information held by others. It is suggested that the Department of Labour be responsible federally for information pertaining to the health of workers; perhaps by some amendment to the Labour Code. In the broader area of public health, the Departments of Health and Welfare, and Environment should hold responsibility.
- Reliable exposure data must be included in the analysis of the correlation between the degree of exposure to chemical hazards and subsequent health effects. This is required as a basis for revealing what effects on

health occur at different levels of exposure. It also helps determine the nature, type and comprehensive-ness of the control measures required.

- There should be no restrictive definitions of what constitutes an industrial disease. For example, it would be unfair to confine the recognition of an occupational cause to a single histological type, which would deny compensation to a worker suffering from another related type. The identification of new occupational cancers underlines the need for a restudy of compensation laws. One particular concern is that the latency period of occupational cancers often exceeds the Statute of Limitations for the filing of workmen's compensation claims.
- Workers and the affected public must participate fully at every level of discovery of the variety of industrial hazards. They should be kept informed of the latest developments in industrial and environmental safety. Trade unions and labour organizations, in particular, should participate as equals with management in meetings dealing with the latest developments in industrial hygiene, in monitoring and controlling the exposure to hazards and, in certain instances, in the design of a new technological development to ensure that all needed safety precautions are included.
- Finally, standards of exposure should be promulgated and enforced by governments. While a standard should reflect what has come to be perceived as an acceptable risk, it should be flexible so as to adjust easily to new findings. Also there must be a capability to monitor a standard if it is to have any meaning. The prime requirement must be protecting public health rather than exhibiting the degree of control existing technology can achieve.

Conclusion

This overview emphasizes the occupational aspect of exposure to VCM, because that is where the major problem is. Exposure to VCM outside the workplace, does not, as yet, appear to be a threat to health. This does not mean it should be ignored. Recent findings by Maltoni, that concentrations of VCM of 1 ppm or less can cause mammary cancer, indicate it may be necessary to review emission and ambient air standards.

If the vinyl chloride story tells us anything, it is that we may be facing a crisis, one brought on by the plethora of new chemicals that are being introduced in the market and work places and about whose hazardous properties little if anything is known. This is a challenge that must be met by a dedicated effort by all involved — unions, management, health authorities, governments and the scientific community. The lessons from the vinyl chloride experience should be learned. Safety costs money — its neglect often costs lives.

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