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TESTIMONY OF

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ON
VINYL CHLORIDE
OCCUPATIONAL EXPOSURE STANDARD

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This testimony is presented as a result of discussions among various members of the Society of Plastics Industry Task Force on Monitoring and Analytical Methods for the determination of vinyl chloride in the work environment. It does, we feel, reflect the current "state-of-the-art" with respect to analytical procedures, techniques, and instrumentation for the accurate measurement of vinyl chloride in a variety of work environments.

Procedures for the determination of vinyl chloride can generally be divided into two rather different groups:

1. Procedures applicable to the examination of plant or production atmospheres and reporting the results of that analysis immediately. Devices which collect a sample from a large area for a short time and report the results of that analysis immediately are termed area monitors.

2. Procedures which are applicable to the examination of the atmosphere directly surrounding work personnel. Devices

which collect samples from this small area (usually in the worker's breathing zone) over a long period of time (e.g. 8 hours) and retain any collected material for subsequent analysis are termed personnel monitors.

In general, area monitoring provides information on what the concentration of suspected compounds is "right now" while personnel monitors provide information on what concentrations workers have encountered in the past.

Obviously, the time requirements for these two types of analyses are very different. The first, area monitoring, requires procedures capable of detecting vinyl chloride accurately, quickly, and reliably, since the area monitor generally is used to sample many locations (sequentially) and must operate with very little attention or maintenance. The second, personnel monitoring, requires that the method be able to accurately measure vinyl chloride in the presence of the many other gases and vapors with which the worker may come in contact

over the course of a day. Since the results are always ex post facto, speed of analysis is less important, but the accuracy and quantitative requirements are no less demanding than for area monitoring. Again, since examination of personnel monitors from many people may be required, and the analysis may be repeated at periodic intervals (annually, quarterly, etc.), the analytical procedure for the examination of personnel monitor samples must also not require high maintenance and must be very reproducible, since the most recent results are to be compared to previously analyzed samples (last month, last quarter, last year, etc.). Thus, the demands for accuracy, selectivity (the measurement of vinyl chloride with little interference from other compounds), sensitivity (to be able to detect concentrations as low as 1 part of vinyl chloride in a million parts of air), and reliability (to be able to make the measurement again and again and again without fail and without requiring extensive servicing or repair) are prime

requirements for both area monitor and personnel monitor procedures. Additionally, area monitors have the demands to be able to do the analysis as quickly as possible so that any hazardous situations can be recognized and the situation corrected.

The methods and procedures which I will describe are procedures which have been used, either in the laboratory or in production environments or both for the determination of vinyl chloride in "air" (i.e. work environment). I will describe each procedure in some detail with particular attention to the differences between them as regards the points I mentioned earlier: selectivity, sensitivity, speed, and reliability. I will discuss them more or less in order of their applicability, although some particular situations will recommend one procedure over the others.

In order to be consistent with the goal of accurately

reporting concentrations of vinyl chloride throughout the work environment, each of the techniques discussed as "area monitoring" methods has the capability of analyzing "air" samples from a number of different locations sequentially and automatically.

Analytical Methods

1. Gas-liquid chromatography (GLC)

This is a procedure which physically separates and quantitatively detects most individual components in mixtures. The principle upon which this method is based is that different compounds are absorbed into an organic silicone liquid to different degrees. If the silicone is deposited as a thin film on the surface of granular particles in a long tube and a carrier gas is forced to flow through the tube, when a sample mixture containing vinyl chloride and other compounds is introduced into one end, each compound, in the course of its travels through the packed column, will be absorbed by the stationary liquid and desorbed by the moving carrier gas in a unique manner. The result is that each compound will emerge from the tube at a unique time. If the temperature of the tube and the carrier gas flow rate in the tube are constant, each compound (including vinyl chloride) will emerge at its unique time reproducibly. Thus, when the emerging gas forms a part of

the fuel source of a small flame, the individual compounds can be detected and quantitatively measured by their "effect" on the flame. If the main fuel source is hydrogen gas, organic compounds will be detected by virtue of formation of carbon ions in the flame and are observed electrically. These types of detectors are termed Flame Ionization Detectors (FID) and are widely used for the detection of organic compounds.

The resulting instrument, a gas chromatograph with flame ionization detector, is an extremely useful device for detecting and measuring vinyl chloride in work environments. There are many different models and styles available from many different manufacturers. They have been in use in laboratories and plants for many years and have a good record of reliability. They do require pure hydrogen gas and an uncontaminated source of air (as well as electricity) for their operation. The "open" flame used as the detector does not allow them to be used in areas where explosion hazards exist. Generally a separate room is advisable when they are used in production plants.

There are several outstanding advantages of gas chromatographic methods. Primary among them is the ability of this technique to selectively determine vinyl chloride in the presence of many other kinds of compounds. The ultimate sensitivity of this method is also very good: about 1 ppm and perhaps as low as 1/10 ppm. This method is also applicable to both the analysis of "air" samples as an area monitor as well as being useful for the examination of personnel monitors.

The major disadvantage of this procedure is that somewhat longer times are required for the analysis; usually 5 to 15 minutes per analysis. This means, for area monitoring with 10 different areas or locations being sampled and the sample analyzed by one GLC-FID, each location is only monitored each 150 minutes. There is good evidence to suggest that the time required for the GLC-FID analysis could be reduced to about 5 minutes by means of additional valves but the long-term operation of these valves at these fast cycle times is not known and some maintenance problems can certainly be expected.

2. Infra-red Spectroscopy (IR):

Infra-red spectroscopy is another technique which has considerable applicability in the determination of vinyl chloride in "air" (i.e. work environments).

This procedure employs a device called an Infra-red spectrometer to irradiate the gaseous sample (contained in a sample cell) with radiation in the infra-red portion of the energy spectrum. Different molecules, by virtue of the chemical bonds comprising the molecule, will absorb energy at specific different wavelengths. For example, vinyl chloride shows rather strong absorption of energy at wavelengths of 6.15μ , 9.8μ , 10.9μ , and 13.9μ .

Since other common organic atmospheric contaminants have different arrangements of atoms, there is relatively little interference from most other compounds when the energy absorption is monitored at one of these wavelengths.

A major advantage associated with the use of IR as an

area monitor derives from the fact that a relatively short time is required to make the energy absorption measurement. In general, only about two minutes is required for the measurement, although some additional time may be required to remove the previous sample and introduce the next one. With long pathlength cells, sensitivities of 2-5 ppm can be expected and lower concentrations are obtainable with some additional modification of the sampling procedure.

A major limitation of IR for area monitoring is associated with the fact that the air sample can vary considerably with respect to content of other components, primarily water vapor. Water vapor does show some absorption at 6.15μ and, although this could be compensated, results in a decrease in sensitivity. There are some procedures which have been used to reduce the amount of water vapor in the sample stream but they are still being tested in several laboratories and their long-term reliability is yet unproven.

A secondary effect of water vapor as well as some other compounds is to slowly form a deposit or "mist" on the transparent end-windows of the sample cell. This too reduces the sensitivity and causes the instrument to be unstable. Again, the demonstration of applicability of several of the water vapor "traps" would reduce the magnitude of the problems. At the present time, there are several manufacturers of IR monitoring equipment.

3. Combustion Conductivity

The technique called combustion conductivity has also been employed as an area monitor for vinyl chloride. This method is based on the fact that when vinyl chloride is heated in air at 1000°C (1800°F), almost all of the vinyl chloride is converted to carbon dioxide and hydrochloric acid (HCl). If the combustion products are bubbled into a "pure" water stream, the HCl may be detected by virtue of

the increase in electrical conductivity of the water (due to the hydrogen ions and chloride ions). This method is very rapid, only about 30 seconds being required to measure the conductivity.

It does not require a large amount of maintenance and is a relatively simple device to both install and maintain. The major disadvantage of this method is that there are many other compounds which would be detected as well as vinyl chloride. Particularly severe interference would be expected from such compounds as the various FREON[®] gases, common refrigerant gases. However, this device, when used to monitor plant atmospheres where interferences are known to be low, can provide a rapid indication of the concentration of vinyl chloride. The simplicity of the data collection lends this device to easy computerization to provide supervisory personnel with calculated time-weighted average exposures for different types of jobs within the area being monitored.

4. Total Flame Ionization Detectors (FID)

This method is similar to the previous combustion conductivity method in that the total sample is subjected to burning and the combustion products monitored (as in Method 1, GLC-FID). However, the sample is not physically separated into constituent compounds. This procedure, like number 3, is relatively fast; about 2 minutes per sample. It too has a relatively simple data presentation and is easily amenable to a variety of computer generated report formats (calculated TWA, etc.).

The major disadvantage, like number 3 above, is that it too is a non-specific analyzer.

In general, any organic compound (i.e. containing carbon) will be detected and generally with a sensitivity equal to that

for vinyl chloride. Thus, any contamination of the area being monitored from automobile exhaust, hydrocarbon vapors, etc., will be detected as vinyl chloride. Some correction of the signal from these interferences is possible but generally at the expense of simplicity and reliability.

5. Gas Chromatography - Mass Spectrometry (GC-MS)

This analytical method is not generally applicable to the problem of area monitoring of vinyl chloride. However, it is probably the most specific method for the determination of vinyl chloride. It also amenable to a wide variety of types of samples and is capable of sensitivities well below 1 ppm. It is discussed briefly here since it appears to be useful as a REFERENCE METHOD. As such, it can be used to determine the concentration of vinyl chloride in a variety of different situations and the results compared to one or more of the above area monitoring methods.

The principle of this method is the same as number 1, GC-FID; physical separation of sample components in a packed tube. However, in this procedure the compounds emerging from the tube are detected with a device called a mass spectrometer. This instrument subjects the sample gas in a rather high vacuum to bombardment by a stream of electrons. These electrons cause the formation of ions of the sample gas. These ions are then separated according to their mass by a magnetic field. Since each compound produces ions which are peculiar to its own atomic and molecular structure, the resulting ions are extremely characteristic of each different compound. When this characteristic ion spectrum is combined with the specificity obtained from the gas chromatographic column, the result is that there are almost NO interferences in the determination of vinyl chloride.

A major limitation to the use of GC-MS for area monitoring is that it is a fairly complex instrument which requires a

trained analyst for operation. Also, the maintenance is greater than any of the previously mentioned methods. Finally, the instrument is expensive to buy and maintain (\$50,000 minimum, \$5-10,000/yr. maintenance).

6. Personnel Monitoring Techniques and Procedures

As mentioned earlier, personnel monitoring is extremely useful for the examination of the immediate environment around workers. The normal procedure consists of collecting a sample of "air" from the worker's breathing zone continuously as the employee goes about his normal tasks. If the collected sample is then analyzed, the result yields the total amount of vinyl chloride to which the worker was exposed. At this time, there are no continuously-indicating devices which can be worn to provide an immediate indication of vinyl chloride concentration. Since this sort of monitoring serves the very useful purpose of permitting an actual "encounter" record, the analysis must be as fast and accurate as possible.

Since samples are collected over a long period of time (up to 8 hours), the collection device must retain essentially all vinyl chloride until the time of analysis and then permit essentially all the collected vinyl chloride to be removed for analysis. Additionally, the collection device must be sufficiently comfortable to wear so as to not interfere with the normal safe performance of each employee's job.

Components necessary for accurate personnel monitoring include:

- a) sample collection system, comprised of an "air" pump, sample tube, and adsorbent to hold the collected vapors.
- b) sample elution and analysis system consisting of equipment for removing vinyl chloride from the adsorbent and determining the amount.

The system components for collection should be components of well-tested reliability and performance. For example, silica

gel adsorbent must be used with caution, since high relative humidity will cause incomplete sorption of vinyl chloride, especially if high sampling flow rates are used. Activated carbon has shown extreme variability in its ability to adsorb vinyl chloride. Two types of carbon which appear to be successful are Pittsburgh PCB, 12/30 mesh and Westvaco WV-H, 8/30 mesh.

Elution of the vinyl chloride from the activated carbon for analysis can be achieved either by solvents or by heating. If solvents are used, carbon disulfide is the preferred eluting solvent. It, however, is extremely flammable and precautions must be taken to avoid exposure of fumes to open flames, sparks, and heat. Alternately, any vinyl chloride collected can be desorbed by heating the adsorbent tube to 430°C and flushing with 12 liters of dry nitrogen gas, collecting the gas in an appropriate bag. Both elution procedures appear to produce accurate, reproducible results. If the sample collection tubes

are not analyzed immediately, care must be taken to avoid additional contamination or loss of vinyl chloride. It is preferable to analyze the samples within several days of their collection. Obviously, all sampling and analytical instruments should be calibrated and tested before use and the initial results compared to duplicate samples taken for analysis by the reference method.

Sampling Frequency:

The number and frequency of samples required to insure a safe and healthful work environment requires judgement. Continuous area monitoring can be used as a processing aid to allow for early detection of leaks and losses so that equipment can be maintained. It can notify the employee of a contaminated area so that proper protective equipment can be worn to prevent exposure. With adequate continuous monitoring of the work area, less frequent personnel monitoring is needed to document employee exposure. If the continuous monitors

indicate that the work environment is in compliance with established standards, an annual personnel monitoring program should suffice. If continuous area monitors demonstrate that potentially hazardous areas exist, a quarterly personnel monitoring program by job classification should be done.

Summary and Recommendations

1. Reference analytical methods should be established in the permanent OSHA vinyl chloride standard.
2. Continuous area monitoring should be installed in those areas with potential employee exposure. Several different instruments and methods are acceptable, depending on each particular location and manufacturing situation. Whichever instrument or method is used, it should be checked no less than quarterly against the Reference Method using air samples as similar as practicable to those extant in the work environment.
3. Annual Personnel Monitoring should be done in those plants with continuous area monitors. Personnel monitoring

should cover each job classification, with potential exposure under typical operating conditions. Quarterly personnel monitoring should be done, by job classifications and under typical operating conditions, in those plants without continuous area monitors.

4. Gas chromatography, or where it is available, gas chromatography-mass spectrometry should be established as the instrument in the Reference Method. Specific analytical procedures which have been successful are given in the attached documents, particularly Dow Method ML-AM 74-12.

5. All results should be recorded as the time-weighted average (TWA) for the period of actual sampling time.

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FOREWORD

This book on the law and public policy of toxic substances control is the second product of a modest grant made in 1976 by RFF to the *Ecology Law Quarterly*, Boalt Hall School of Law of the University of California at Berkeley. Our grant supported the extra expenses involved in preparation and publication of a special issue of the *Quarterly* on "Hazardous Substances in the Environment." This ambitious issue was published in the summer of 1978, just as the continuing public debate on this most important topic was heating up.

In reviewing the special issue, several of us at RFF concluded that the paper by David Doniger constituted such an excellent introduction to this evolving field that its wider circulation could be very useful. Accordingly, we have arranged to bring out this study alone, with the hope that it will be used in legal, economic, and other courses on environmental problems. The publication may also serve as an announcement of RFF's interest in this field for, while several staff members have written individually on toxic substances, a formal program on toxic substances problems is now developing here under the direction of Allen V. Kneese.

Doniger is currently an attorney with the Natural Resources Defense Council and was formerly with the Environmental Law Institute, both in Washington, D.C. He holds a J.D. and a master's degree in city planning from the University of California at Berkeley. While at Berkeley he was special issue editor of the *Quarterly*. In organizing the project, he had the support and cooperation of Richard H. Cowart (editor-in-chief 1976/77), Karl E. Geier (managing editor 1977/78), and members of the board of editors. For readers whose interest goes beyond this paper, we have reprinted the complete table of contents from the journal issue on page 179. Copies of the entire issue are available for \$10.00 from the *Ecology Law Quarterly*, School of Law (Boalt Hall), University of California, Berkeley, California 94720.

The case study of vinyl chloride regulation, the observations about the federal agencies' coordination efforts, and the analysis of the devel-

oping administrative law in the area of health and environmental regulation carry through April 1978. Naturally, as the government and the courts continue to work on these problems, there are further developments constantly. Nonetheless, it is likely that the basic structure and background this paper provides will remain valid for some years.

November 1978

Clifford S. Russell
Senior Fellow
Resources for the Future

INTRODUCTION

On January 22, 1974, the B.F. Goodrich Company revealed that three workers at its plant in Louisville, Kentucky, recently had died of angiosarcoma of the liver, an extremely rare and incurable cancer, and that a fourth had died of the same illness five years before.¹ The plant converts vinyl chloride, a petrochemical gas, into polyvinyl chloride, the second most widely used plastic in the United States.² The grouping of these rare cancers at this plant immediately raised the suspicion that vinyl chloride was the cause. This suspicion was soon confirmed by reports from other companies that some of their workers exposed to the chemical had developed the same cancer, and by disclosures that since 1970 vinyl chloride had induced a wide variety of cancers in experimental animals.³

Within a week of the Goodrich disclosure, the Occupational Safety and Health Administration and the National Institute for Occupational Safety and Health began preparing a workplace standard for vinyl chloride.⁴ This marked the beginning of the still incomplete regulation of this pervasive chemical, an endeavor that has involved five major federal agencies operating under 15 separate health and environmental statutes.

1. These events are summarized in Occupational Safety and Health Administration, *Standard for Exposure to Vinyl Chloride*, 39 Fed. Reg. 35,890, 35,890-91 (1974) [hereinafter cited as *OSHA Permanent Standard for VC*]. See also *Hearings on Dangers of Vinyl Chloride before the Subcomm. on Environment of the Senate Comm. on Commerce*, 93d Cong., 2d Sess. 39-42 (1974) (testimony of Dr. Marcus Key, Director, National Institute for Occupational Safety and Health) [hereinafter cited as *VC Hearings*].

2. See text accompanying notes 81-82 *infra*.

3. See text accompanying notes 124-129, 139-141 *infra*.

4. Dep't of Labor, *Possible Hazards of Vinyl Chloride Manufacture and Use, Request for Information and Notice of Fact-Finding Hearing*, 39 Fed. Reg. 3874 (1974) [hereinafter cited as *OSHA Hearing Notice*].

This Article examines the federal regulation of vinyl chloride, and through that experience, the complex law and policy of toxic substances control in the United States. Attempts to control toxic substances were begun seriously only in the 1970s. The law and policy in this area are in rapid growth and transition and are still deeply disorganized. The vinyl chloride problem is one of several chemical crises that has strongly influenced the growth of the field.⁵

Vinyl chloride gas (VC) and polyvinyl chloride plastic (PVC) permeate modern American living. PVC has hundreds of widely different uses, some very important and others completely frivolous. PVC is a major construction material, used in products such as water pipe, floor tile, and exterior siding. It is a major food packaging material. PVC is used to make consumer products ranging from household furniture to auto interiors, from credit cards to baby pants. Ironically, it provides a valuable coating for pollution control equipment, due to its resistance to corrosion. VC gas itself has been used as an aerosol propellant and a refrigerant. It was once even tested for use as a general anaesthetic.⁶

Hundreds of thousands of people are exposed to VC at their places of work. Millions are exposed to VC from living and working near the factories where it is made and processed, and near the routes over which it is transported between factories. VC leaches from many of the PVC products with which the consumer is in contact daily—from packaging into food, from pipe into drinking water, from latex paint into indoor air, and from many other sources.⁷

The primary threat from VC is to the workers. To date there have been at least 68 known cases of liver angiosarcoma among the roughly 30,000 workers most heavily exposed to the chemical in the three decades prior to 1974. The illness is occurring in these workers at a rate as much as 3,000 times higher than in the general population. VC is also suspected of causing an equivalent number of more common cancers in these workers. Moreover, many other workers are expected to develop liver angiosarcoma and other cancers as a result of their exposure in the 1950s, 1960s, and early 1970s.⁸

5. There have been several other studies of the regulation of VC: Krause, *Environmental Carcinogenesis: Regulation on the Frontiers of Science*, 7 ENV'T L. 83 (1976); N. Ashford, E. Zolt, D. Hattis, & J. Katz, *The Impact of Governmental Restrictions on the Production and Use of Chemicals: Draft Final Report* (appendices concerning regulation of VC in the workplace and as a food additive) (Dec. 1976) (report prepared for the Council on Environmental Quality); G. Adams, *Toxic Substance Control: Vinyl Chloride* (unpublished master's thesis, Washington University, St. Louis, Mo., Dec. 1976).

6. For a more thorough description of the uses of VC and PVC, see text accompanying notes 84-87 and Figure 1 *infra*.

7. For a more complete description of the sources of exposure, see text accompanying notes 148-167 *infra*.

8. See text accompanying notes 98, 125-135 *infra*.

Most of the victims known to date have been exposed to VC at levels higher than those experienced by most workers, consumers, and others. Even low doses of a carcinogen are a matter of serious concern. Presently, it is not possible to identify safe levels of exposure to carcinogens, and some scientists believe that as little as a single molecule of such a chemical, interacting with the appropriate portion of the genetic material of a susceptible cell, can cause a fatal cancer many years later.⁹

The adverse effects of VC are not limited to cancer. At relatively high doses it causes a variety of degenerative symptoms. At low doses it may cause birth defects and mutations.¹⁰

Unfortunately, VC is not an oddity. It is representative of thousands of chemicals that are capable of causing cancer, other long-term illnesses, and many subtle adverse environmental effects. Like VC, many of these chemicals were once thought to be safe, are important components of significant industries, and are manufactured, transported, consumed, and discarded in vast quantities. Nearly everyone is exposed to them in complex, possibly interactive combinations; nearly everyone is at some degree of risk.¹¹

These hazardous substances are only a fraction of the estimated 65,000 chemicals in commerce and the more than four million chemicals that are known.¹² But in absolute terms toxic substances are large in number, and they are responsible for a substantial portion of the illnesses, deaths, and environmental insults experienced today.¹³ The vast number of chemicals to be tested, evaluated, and regulated makes toxic substances control in many respects the major challenge of the health and environmental movement.

One focus of this Article is the staggering complexity and fragmentation of the federal programs to control these toxic substances. About 20 separate health and environmental statutes empower five major agencies to regulate such substances. (See Table 1) The patchwork of statutes grew piecemeal, mostly over the last two decades, as Congress perceived additional, relatively narrowly defined needs for controls. Together the laws cover virtually all the avenues through which people can be exposed to dangerous chemicals, and most of the avenues through which such substances can harm natural systems.¹⁴

9. See text accompanying notes 22-80, 148-167 *infra*.

10. See text accompanying note 138 *infra*.

11. On the vast number of hazardous substances needing regulatory attention, see Slesin & Slesin, *Categorization of Chemicals Under the Toxic Substances Control Act*, 7 ECOLOGY L. Q. 359 (1978); Page, *A Generic View of Toxic Chemicals and Similar Risks*, 7 ECOLOGY L. Q. 207 (1978). As an example of the numbers problem, see NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY & HEALTH, *SUSPECTED CARCINOGENS* (2d ed. 1976), which identifies 1,500-2,000 chemicals that animal experiments have implicated as possible carcinogens.

12. Maugh, *Chemicals: How Many Are There?* 199 SCIENCE 162 (1978).

13. Between 60 and 90 percent of human cancers are estimated to be caused, wholly or in part, by chemicals in food, water, workplaces, cigarette smoke, and the general environment. See COUNCIL ON ENVIRONMENTAL QUALITY, *SIXTH ANNUAL REPORT* 32-33 (1975). See also text accompanying note 33 *infra*.

14. Two possible exceptions are the components of cosmetics and of substances harmful

TABLE II

FEDERAL AUTHORITY OVER VINYL CHLORIDE EXPOSURE

AGENCY STATUTE	YEAR ENACTED	USES OR SOURCES OF EXPOSURE COVERED
<i>Occupational Safety and Health Administration</i>		
Occupational Safety and Health Act	1970	Exposure in factories and in transportation (workers only)
<i>Environmental Protection Agency</i>		
Clean Air Act	1970	Factory emissions
Federal Environmental Pesticide Control Act	1972	Insecticide aerosols
Federal Water Pollution Control Act	1972	VC discharges to water
Safe Drinking Water Act	1974	VC in drinking water, PVC water pipe
Resource Conservation and Recovery Act	1976	PVC sludge wastes
Toxic Substances Control Act	1976	Possible to use in lieu of multiple separate actions under other laws
<i>Food and Drug Administration</i>		
Food, Drug, and Cosmetic Act	1938	Cosmetic aerosols, PVC cosmetic packaging
Food Additives Amendment	1958	PVC food packaging, PVC water pipe
New Drug Amendments	1962	Drug aerosols, PVC drug packaging
Medical Device Amendments	1976	PVC medical devices
<i>Consumer Product Safety Commission</i>		
Federal Hazardous Substances Act	1966	Household aerosols, household plastics and paints
<i>Department of Transportation</i>		
Hazardous Materials Transportation Act	1975	Rail and truck tank vehicles
Federal Rail Safety Act	1970	Rail tank cars and roadbed
Ports and Waterways Safety Act	1972	Barges and tank vessels
Dangerous Cargo Act	1940	

But although the coverage of these statutes, taken together, is nearly complete, it is highly fragmented. As noted above, to address all of the sources of human exposure to VC would require action by all five agencies acting under 15 of the statutes. Few chemicals are as widely used as VC, and therefore few will fall under so many authorities. Nonetheless, there are already more than 20 chemicals undergoing regulation by two or more agencies.¹⁵ This is likely to be the rule rather than the exception, at least for chemicals currently well established in commerce.¹⁶

A serious problem is that in many cases the boundaries between agencies' jurisdictions are not clear. Sometimes authorities overlap, empowering two agencies to regulate a given source of exposure.¹⁷ In some areas where two agencies have abutting jurisdiction—i.e., where together their statutes cover a type of hazard without overlap—the dividing line is uncertain, and it is uncertain into which bailiwick a particular source falls.¹⁸ Jurisdictional complexity and confusion often discourage agencies from stepping forward to deal with a problem; each waits for another to act.

Even when jurisdictional issues are resolved, the fragmented system discourages comprehensive assessment and balancing of all of a substance's risks and benefits. No agency has the responsibility to consider the net social gain or loss from different levels of control. Such a holistic consideration might yield a different result than the sum of partial analyses. Moreover, in the case of VC, some risks have been seriously understated and some control costs seriously exaggerated because of the fragmentation of assessment of both hazards and economic benefits.¹⁹

The final drawback to the current balkanized system is the duplication of decision making. Many separate, essentially identical proceedings must be held. The duplication wastes the resources of all concerned—government, regulated industries, and health and environmental groups. Some industries may prefer the fragmentation because it slows the speed with which the government places controls on the profitable use and sale of

to the natural environment which are components of food and drugs. See generally Page & Blackburn, *Behind the Looking Glass: Administrative, Legislative, and Private Approaches to Cosmetic Safety Substantiation*, 24 U.C.L.A. L. REV. 795 (1977); EPA, *Fully Halogenated Chlorofluorocarbons, Proposed Rule*, 42 Fed. Reg. 24,544, 24,545 (1977).

15. See Interagency Regulatory Liaison Group, Joint Regulatory Developments, March 1, 1978, reprinted in 1 BNA CHEM. REG. REP.—CURR. REP. 1916-21 (1978) [hereinafter cited as IRLE List of Substances of Common Concern]. The list includes VC. For some of these substances, such as VC, some regulations are already in effect and more are under consideration.

16. The problem may be avoided for new chemicals, which under the Toxic Substances Control Act (TSCA) must be tested by manufacturers and evaluated by the Environmental Protection Agency prior to their entry into commerce. TSCA § 4, 15 U.S.C. § 2063 (Supp. V 1975).

17. See text accompanying notes 672-674, 753-771, 793-795 *infra*.

18. See text accompanying notes 557-561, 608 *infra*.

19. See text accompanying notes 347-348, 470-472, 803-804 *infra*.

hazardous substances. But in many cases uncertainty over the ultimate scope of regulation probably outweighs the industries' advantages in delay.

In response to problems encountered in the control of VC and several other substances through this fragmented system, the agencies recently have begun efforts to coordinate their many programs and to increase the consistency of their actions. The promise and pitfalls of these efforts are surveyed at the end of the Article, on the basis of the lessons of the VC experience.²⁰

The second focus of this Article is how agencies cope with problems of uncertainty and competing, dissimilar interests that are inherent in toxic substances control decisions. As is explored in Part I, the regulation of any of these substances involves complex decision making under uncertainty, and controversial value judgments concerning the weighing of health and environmental values against economic interests. The VC case study permits one to see how the many statutes and agencies approach these problems, in a relatively constant scientific, technological, and economic context.

Part II, the case study, makes up the major portion of this Article. It begins with a survey of the uses of VC and PVC, the technology and economics of associated industries, and what is known of VC's toxicity. This is the factual background for all the regulatory proceedings; additional data peculiar to individual areas is given in those discussions.

The next three sections in Part II analyze in depth the actions taken to date respecting three of the major sources of VC exposure. The first section considers the development of a standard for workplace exposure by the Occupational Safety and Health Administration (OSHA). The second addresses standard setting for emissions from factories to the surrounding air, by the Environmental Protection Agency (EPA). The third considers the proposal by the Food and Drug Administration (FDA) to regulate the use of PVC food packaging. Each of these sections illustrates central legal and policy problems in toxic substances control and a range of responses by agencies and interested parties. Considered together, the OSHA and EPA actions also illustrate the underweighting of risks that can result from jurisdictional fragmentation.

The extremes of jurisdictional complexity are illustrated in the next two sections, on VC-propelled aerosol products and the transportation of VC between factories. Authority over aerosols is divided among three agencies: FDA, EPA, and the Consumer Product Safety Commission (CPSC). Authority over hazardous material transportation is divided among OSHA and three agencies within the Department of Transportation (DOT). Because very small economic interests were at stake over aerosols, regulation proceeded relatively smoothly. However, the aerosol episode reveals the potential for serious jurisdictional conflict in those future cases when more money

is at stake, when decisions are more difficult, and when the results for a given product might depend on which statute and agency it falls under. In the transportation area the economic interests are greater and the balancing of risks and benefit is more difficult. The jurisdictional lines also are unclear. Moreover, historically none of the agencies concerned has regulated the movement of carcinogens and other substances with long-term or subtle effects. Each is reluctant to assert its authority vigorously and is content to wait for another to step forward.

The last section of the case study briefly surveys the authorities for identifying the remaining sources of VC exposure. Principally, these are exposure routes connected with water, consumer products, packaging other than for food, and medical devices. The agencies involved are EPA, FDA, and CPSC. No controls of these exposure sources have yet moved beyond the proposal stage. The control of these sources leads to several more examples of jurisdictional overlap, of underweighting of risks, and of conflicting statutory responsibilities.

The final section also considers how the Toxic Substances Control Act, administered by EPA, relates to the control of VC and to future instances in which authority over a dangerous chemical is seriously fragmented. The Act was passed only in 1976, after some standards for VC already had been set under prior laws or had been proposed, and therefore it is of minimal use to control this chemical. But EPA might use the Act in the future to reduce the number of separate, fragmented actions that are needed to regulate similar substances.

Part III of this Article has two purposes. First, in light of the VC episode and similar experiences, it surveys past and ongoing efforts to deal with jurisdictional fragmentation and to coordinate federal action and policy on toxic substances control. It discusses the agencies' internal coordination efforts, interagency agreements, cooperative regulation of particular substances, and two new interagency groups created to foster broader forms of cooperation. Serious coordination efforts are only just beginning.

Second, Part III of the Article confronts the capacity of certain characteristics of the legal framework for toxic substances regulation to deal with the other central policy problems noted above: decision making under uncertainty and balancing of dissimilar, competing interests. The statutory formulations, which are analyzed individually in detail in the appropriate sections of the case study, are considered here in general terms.

From the case study it becomes clear that in view of the problems of factual uncertainty and conflicting values, each agency faces a wide range of rational choices in setting exposure limits and other standards, but no one choice can be said to be objectively "correct." Each agency must make judgments about what to assume when the true facts are uncertain and about

20. See text accompanying notes 836-868 *infra*.

21. 15 U.S.C. §§ 2601-2629 (West Supp. 1978).

which interests to favor among competing ones. The policies or norms that drive these judgments are difficult to state clearly and difficult to apply precisely to the circumstances at hand.

The statutes that delegate responsibility to the agencies for making these judgments provide certain limitations, along with some measure of guidance for decision making. The statutory formulations differ in many particulars, but certain themes and basic alternatives emerge clearly.

First, virtually all the statutes are precautionary; *i.e.*, they direct the agencies to act on the basis of uncertain, suggestive indications that a substance is dangerous. Because many substances can be shown definitively to be harmful only after serious harms have already occurred, these statutes reject the view that control measures must await proof of actual, past harm.

On the balancing problem there is substantial division among the statutes. Most of the statutes require agencies to weigh health and environmental concerns against economic considerations, but several statutes prohibit agencies from considering anything but health factors. Depending upon which approach is used, the results of regulation will differ dramatically. Because of the severe results of the health-only rule, the prohibition is acknowledged more often in the breach than in the observance.

The toxic substances control statutes also differ in the allocation of the burden of persuasion. Most place the burden of showing that a substance should be regulated on the government. Several important statutes, however, place the burden of showing that a substance should be allowed in commerce on the proponent of use. The difference in the burden of persuasion can affect fine judgments at the margin, such as where an agency is deciding between alternative levels of exposure.

Finally, the statutes call for searching judicial review of agency decisions, although ultimately they leave to the agencies a large measure of discretion. Although the statutory formulations regarding standards of judicial review vary, the courts are developing consistent principles for scrutinizing decisions.

Through these devices the statutes give some guidance and offer some control, but they leave the agencies a wide range of legitimate choices. This Article contends that these legal tools are not instruments of finely-tuned control, and that the agencies and advocates waste considerable energy in unproductive attempts to draw from the statutory differences fine distinctions in the agencies' obligations. Ultimately, regulations emerge from the interplay of available facts, the advocacy of interested parties and the predispositions of the agencies. The dynamics of this process are best seen in operation, as in the VC case study. Before analyzing the actions of the agencies in the regulation of VC, it is necessary to examine the central policy problems of uncertainty and balancing that the agencies have had to face. These problems are considered in the next section.

BASIC POLICY PROBLEMS IN TOXIC SUBSTANCES CONTROL: DECIDING UNDER UNCERTAINTY AND BALANCING INCOMMENSURABLE INTERESTS

Two cardinal problems are endemic to any scheme for regulating substances that cause cancer or other long-term, serious health or environmental effects of relatively low probability. First, all decisions must be made under substantial uncertainty about the medical and ecological risks, technological difficulties, and economic costs associated with different degrees of exposure. Second, all decisions involve trade-offs among groups with interests that are not readily comparable. These two problems form serious "boundaries of analysis" that prevent regulatory agencies from making exact, objective, and noncontroversial decisions.²² This section explores the problems of uncertainty and balancing generally, as a preface to the exploration of agency response to the VC hazard, and to the discussion of the legal framework within which the agencies make decisions.

Cancer is the primary adverse effect of VC, and the disease is the chemical hazard most on the public mind. For these reasons, this section explores the nature of scientific uncertainty in the management of hazardous substances through the example of cancer risk assessment. This section also discusses the technological and economic uncertainties of estimating the difficulty and cost of toxic substances control. Finally, the section examines the difficulty of determining what risk-benefit trade-offs are acceptable to individuals and to the society as a whole. Only with an understanding of the boundaries of our scientific, technological, economic, and ethical knowledge is it possible to evaluate fairly the analytical efforts and normative choices of the agencies that have regulated VC.

A. The Limits of Cancer Risk Assessment

Cancer is a group of illnesses characterized by the unrestrained multiplication of cells that somehow have lost an essential self-regulatory mechanism.²³ The uncontrolled growth of these cells eventually threatens the life of the host organism. Presently, cancer is the second leading cause of death in the United States.²⁴ One American in four is expected to contract some type of cancer,²⁵ and one American in five is expected to die of it.²⁶

22. The quoted phrase is taken from the title of a study of water project planning and, more particularly, from an article on similar issues in cost-benefit analysis in that context. See Bradford & Feiveson, *Benefits and Costs, Winners and Losers in BOUNDARIES OF ANALYSIS: AN INQUIRY INTO THE TOCKS ISLAND DAM CONTROVERSY* 125, 144 (H. Feiveson, F. Sinden, & R. Socolow eds. 1976).

23. See COUNCIL ON ENVIRONMENTAL QUALITY, SIXTH ANNUAL REPORT 13 (1975) (ch. 1, *Carcinogens in the Environment*) [hereinafter cited as CEQ SIXTH ANNUAL REPORT]. For explanations of the essentials of cancer directed to the lay reader, see M. SHIMKIN, *SCIENCE AND CANCER* 1-6, 43-54, 87-98 (1973) [hereinafter cited as *SCIENCE AND CANCER*]; Cairns, *The Cancer Problem*, *SCIENTIFIC AMERICAN*, Nov. 1975, at 64 [hereinafter cited as *The Cancer Problem*].

24. CEQ SIXTH ANNUAL REPORT, *supra* note 23, at 9, table 2.

25. *Id.* at 12.

26. *The Cancer Problem*, *supra* note 23, at 66.

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Most forms of cancer are difficult or impossible to cure; less than one-half of all cancer patients survive longer than five years from the discovery of their illness.²⁷ The elusiveness of cures largely is due to the fact that cancer's basic biological mechanisms at the cellular level are not well understood.²⁸

The causes of cancer are, however, somewhat better understood than the cures. Studies of cancer incidence in particular groups have shown strong statistical connections between exposure to certain chemical substances and particular cancers. The connection between tobacco smoke and lung cancer is the most widely known.²⁹ Markedly elevated cancer rates are also found among certain occupational groups in the United States and in other highly industrialized countries.³⁰ Cancer rates are elevated where air and drinking water are contaminated with industrial organic chemicals.³¹ In general, cancer rates are higher than average in American urbanized areas.³² From comparisons of different rates of different cancers throughout the world, the World Health Organization and other prominent institutions and individual experts have concluded that 60 to 90 percent of all human cancers are caused by exposure to chemical substances (and, to a lesser extent, radiation) present in our air, workplaces, food, water, and the rest of our environment.³³

The causal relationships underlying the statistical connections observed in humans have been confirmed for many substances by controlled experiments on animals. With one possible exception, all substances related to cancer in humans have been shown to cause cancer in animals.³⁴ In addition, animal experiments have implicated 1,500-2,000 other chemical substances

27. CANCER PATIENT SURVIVAL, REP. NO. 5, U.S. DEPT. HEALTH, EDUC., & WELF. PUB. NO. (NIH) 77-992, at 3 (1976).

28. *The Cancer Problem*, supra note 23, at 72.

29. See Hammond, *Tobacco in PERSONS AT HIGH RISK OF CANCER: AN APPROACH TO CANCER ETIOLOGY AND CONTROL* 131 (J. Fraumeni ed. 1975) [hereinafter cited as *PERSONS AT HIGH RISK OF CANCER*].

30. CEQ SIXTH ANNUAL REPORT, supra note 23, at 23-26; Cole & Goldman, *Occupation in PERSONS AT HIGH RISK OF CANCER*, supra note 29, at 167.

31. EPA, *Interim Drinking Water Regulations: Control of Organic Chemical Contaminants in Drinking Water*, 43 Fed. Reg. 5756, 5758 (1978), citing NATIONAL ACADEMY OF SCIENCES, *DRINKING WATER AND HEALTH* (June 1977); Pike, *Air Pollution in PERSONS AT HIGH RISK OF CANCER*, supra note 29, at 225.

32. CEQ SIXTH ANNUAL REPORT, supra note 23, at 19; Hoover, Mason, McKay, & Fraumeni, *Geographic Patterns of Cancer Mortality in the United States in PERSONS AT HIGH RISK OF CANCER*, supra note 29, at 343-44 & table 1, at 345.

33. CEQ SIXTH ANNUAL REPORT, supra note 23, at 17; Higginson, *Importance of Environmental Factors in Cancer in ENVIRONMENTAL POLLUTION AND CARCINOGENIC RISKS* 15, 17 (C. Rosenfeld & W. Davis, eds. 1975) [hereinafter cited as *ENVIRONMENTAL POLLUTION*]; Boyland, *The Correlation of Experimental Carcinogenesis and Cancer in Man*, 11 *PROGRESS IN EXPERIMENTAL TUMOR RESEARCH* 222, 223 (1969); Epstein, *Environmental Determinants of Human Cancer*, 34 *CANCER RESEARCH* 2425 (1974). See also R. DOLL, *PREVENTION OF CANCER: POINTERS FROM EPIDEMIOLOGY* (1967) [hereinafter cited as *PREVENTION OF CANCER*].

34. CEQ SIXTH ANNUAL REPORT, supra note 23, at 30-32. The apparent exception is arsenic.

as potential human carcinogens.³⁵ Many of these substances are synthetic organic chemicals that have been in commercial use only since the 1930s. Because cancer is a latent disease that typically manifests itself only 15 to 40 years after exposure begins, it is too early to know the effects of chemicals that have been in widespread use for only this short period.

This evidence suggests that cancer rates could be cut significantly by reducing human exposure to the disease's chemical causes. Even though it may be quite expensive, preventing human exposure to carcinogens often is a more effective and economically efficient method of reducing cancer rates than attempts to cure patients who already have the disease.³⁶ In order to make the best use of the resources available to prevent cancer, precise data on which substances are carcinogenic and on how dangerous they are at various levels of exposure would be helpful. Unfortunately, the causal relationship between a chemical and cancer is often difficult to establish. Even where a qualitative relationship is visible, precise quantitative estimates of risks to humans cannot be made reliably, particularly for low risks in the order of one case in 10,000 or more subjects.³⁷

In the first place, not enough is known about how chemical carcinogens operate, especially at the cellular level. There is general agreement that the substances cause changes in the genetic material of an individual cell or in the mechanisms through which the genetic material controls a cell's behavior, inducing it to multiply wildly.³⁸ There is uncertainty and disagreement on whether only one such "hit" need occur or whether a certain sequence of independent hits by the same or different substances is needed.³⁹ Further uncertainty stems from the complexity of cellular metabolism—the system of chemical and physical processes that occur within a living organism. Opinions differ on whether there are chemical reactions that detoxify certain amounts of a carcinogen by converting it into a harmless substance, or that repair genetic changes after they have occurred.⁴⁰ The metabolic "pathway" of a substance from its point of entry (e.g., lungs, skin, or digestive system) to its point of damage is also often uncertain.⁴¹

35. Occupational Safety and Health Administration, *Identification, Classification and Regulation of Toxic Substances Posing a Potential Occupational Carcinogenic Risk*, 42 Fed. Reg. 54,148 (1977).

36. Schneiderman, *Sources, Resources, and Trends in PERSONS AT HIGH RISK OF CANCER*, supra note 29, at 451, 452, 459.

37. See generally Schneiderman, Mantel, & Brown, *From Mouse to Man—Or How to Get from the Laboratory to Park Avenue and 59th Street*, 246 *ANNALS N.Y. ACAD. SCI.* 237, 243 (1975) [hereinafter cited as *From Mouse to Man*].

38. *SCIENCE AND CANCER*, supra note 23, at 45-54, 87-92.

39. See generally Mantel & Schneiderman, *Estimating "Safe" Levels, a Hazardous Undertaking*, 35 *CANCER RESEARCH* 1379 (1975) [hereinafter cited as *Estimating "Safe" Levels*].

40. See Cornfield, *Carcinogenic Risk Assessment*, 198 *SCIENCE* 693 (1977) [hereinafter cited as *Carcinogenic Risk Assessment*].

41. See, e.g., Watanabe & Gehring, *Dose-Dependent Fate of Vinyl Chloride and Its Possible Relationship to Oncogenicity in Rats*, 17 *ENV'TL HEALTH PERSPECTIVES* 145 (1976).

Whether or not there are defense or repair mechanisms has profound implications for strategies for cancer prevention. If the "one-hit" model is accurate, and if there are no detoxification, repair, or other defense mechanisms, then as little as one molecule of a carcinogenic substance, interacting with the appropriate portion of the susceptible cell, can cause an irreversible cancer. If multiple hits by different substances are needed, any one substance alone may not be carcinogenic (or may be only weakly so) but together these substances may be potent causes of the disease. If detoxification or repair mechanisms or other defenses exist, there may be safe doses—"thresholds"—below which no cancers will be caused. More important, than the question of whether a threshold exists is the question of what risks to expect from a range of doses. Different propositions about cancer causation lead to different conclusions about the rate of cancer to expect from each dose.⁴²

The second major source of uncertainty is a result of the limitations of available research techniques. Current methods for investigating the carcinogenicity of substances do not permit the verification or disproof of alternative theories of cancer causation. The methods are themselves also the subject of great controversy. Observation from direct human experiences is of limited utility. Purposeful experimentation on humans is ethically unacceptable, since the results often would be fatal. Human evidence of carcinogenesis usually comes from observation of occupational groups exposed, often unwittingly, to chemicals in the industrial economy.⁴³ Some connections can be drawn in the general population, but for the most part humans are exposed to too many different substances at unknown doses for unknown periods to permit statistically reliable conclusions to be drawn.⁴⁴ Moreover, there are synergistic and antagonistic interactions between chemicals that drastically complicate drawing conclusions about the effects of each chemical. Finally, because latency periods run 15 to 40 years or

42. Some assumptions lead to the conclusion that threshold doses exist and that the risk at doses approaching the threshold declines to zero. See Kotin, *Dose-Response Relationship and Threshold Concepts*, 271 ANNALS N.Y. ACAD. SCI. 22, 25-27 (1976). See also *Carcinogenic Risk Assessment*, supra note 40; *DNA Repair: New Clues to Carcinogenesis*, 200 SCIENCE 518 (1978). Other models decline to decide whether there are thresholds. One major model has dose and response in a logarithmic relationship, with risk declining more rapidly than dose at low doses. This model yields higher risks for given doses than those which posit thresholds. See *Estimating "Safe" Levels*, supra note 39.

Other researchers argue that the dose-response relationship at low doses is likely to be linear, i.e., that decreases in risk are probably proportional to reductions of dose; This approach yields a risk for a given dose higher than the risks estimated by the other two approaches at least at low doses. See Crump, Hoel, Langley, & Peto, *Fundamental Carcinogenic Processes and Their Implications for Low Dose Risk Assessment*, 36 CANCER RESEARCH 2973 (1976) [hereinafter cited as *Fundamental Carcinogenic Processes*].

The issues are summarized briefly in NATIONAL ACADEMY OF SCIENCES, *PRINCIPLES FOR EVALUATING CHEMICALS IN THE ENVIRONMENT* 86-88 (1975) [hereinafter cited as *PRINCIPLES FOR EVALUATING CHEMICALS*].

43. CEQ SIXTH ANNUAL REPORT, supra note 23, at 23-26.

44. *Id.* at 26-28.

longer, definitive studies of effects on humans are impracticable.⁴⁵

Studies on rodents are the major source of data on the carcinogenicity of chemicals.⁴⁶ Their response characteristics are considered essentially similar to those of humans, so that a substance carcinogenic to one is likely to be carcinogenic to the other.⁴⁷ But although the qualitative inferences are sound, there are limitations on the ability of the animal tests to indicate the magnitude of human risks. It is difficult both to detect small risks in test animals and to translate risks for animals into risks for humans.

The difficulty in detecting small risks is statistical in nature. For practical and financial reasons, nearly all experiments on animals involve small numbers of subjects, usually no more than a few hundred.⁴⁸ In so small a group, a chemical must cause an effect at a relatively high rate for the relationship to be confidently distinguished from random occurrences of the same event.⁴⁹ The dose of a substance that induces cancer at rates detectable in such tests is often far higher than most people experience.⁵⁰ The critical question is whether lower doses cause cancer, and at what rates. An effect occurring at a very low rate stands a good chance of not being observed in so small a test group, so that the failure to observe an effect in such a test is not a reliable indication of the substance's safety for a larger population.⁵¹ Thus, no test has confirmed the existence of any threshold or detoxification mechanism or resolved any other basic aspect of the theoretical controversies discussed above.⁵²

45. *Id.* If the effect is mutation rather than cancer, the effect will not manifest itself for one or more generations.

For a general description of the nature of epidemiological evidence and of the uses and limitations of such research, see PREVENTION OF CANCER, supra note 33, at 15-29.

46. CEQ SIXTH ANNUAL REPORT, supra note 23, at 28-32; In re Shell Chem. Co., 6 ERC 1007, 1032 (EPA, FIFRA Docket, 1977); PRINCIPLES FOR EVALUATING CHEMICALS, supra note 42, at 135-39; T. LOOMIS, *ESSENTIALS OF TOXICOLOGY* 206 (2d ed. 1974) [hereinafter cited as *ESSENTIALS OF TOXICOLOGY*].

47. CEQ SIXTH ANNUAL REPORT, supra note 23, at 30-32; *Estimating Safe Levels*, supra note 39, at 1381.

48. See *From Mouse to Man*, supra note 37. On the trade-off between the sensitivity and cost of tests, see Bates, *Laboratory Approaches to the Identification of Carcinogens*, 271 ANN. N.Y. ACAD. SCI. 29, 30-32 (1976).

49. For an explanation for laymen of the statistical issues, see W. LOWRANCE, *OF ACCEPTABLE RISK* 60-64 (1976) [hereinafter cited as *OF ACCEPTABLE RISK*].

50. This is not always the case, however. Some carcinogens are potent enough to cause cancers in experimental animals when administered at the dose levels to which people have been exposed. See text accompanying notes 133-146 *infra*.

51. Three examples illustrate the point. In a test involving 100 animals each in an experimental and a control group, if no tumors are detected in either group, there is a 1.0% chance that the real rate of cancer is as high as 4.5%. With 1,000 animals in each group and no tumors, there remains a 1.0% chance that the real rate is as high as 0.46%, or 4.6 animals out of each 1,000. If only ten animals are used in each group and the results show no tumors, the potential error increases drastically; there is a 1.0% chance that the real rate is as high as 37.0%. See *OF ACCEPTABLE RISK*, supra note 49, at 62.

52. For a clear discussion of these points, see Saffiotti, *Comments on the Scientific Basis for the "Delaney Clause"*, 2 PREVENTIVE MEDICINE 125 (1973) [hereinafter cited as *Comments on the Scientific Basis for the "Delaney Clause"*]. See also World Health Organization, *Assessment of the Carcinogenicity and Mutagenicity of Chemicals*, Technical Report Series, No. 546, at 9-11 (1974); *Estimating "Safe" Levels*, supra note 42, at 1382-83.

To investigate the effects of low doses directly would require experiments involving enormous numbers of animals. To demonstrate with 95 percent confidence that a given low dose of just one substance causes fewer than one cancer in a million subjects would require a test involving at least six million animals. Such "mega-mouse" experiments generally are considered impracticably expensive and vulnerable to laboratory errors that can destroy the statistical reliability of the results.⁵³

Limited to observations at unrealistically high doses in unrealistically low numbers, the scientist's recourse is to use mathematical models of dose-response relationships to extrapolate from experimental results downward to the effects of low doses. However, like the theories on which they are based, the models yield widely divergent estimates of the risk associated with each low dose. The extent of the differences is astounding. For example, the major models differ by a factor of 100,000 on the size of the dose that creates a risk of one cancer in a million subjects.⁵⁴ The models do provide credible outer limits for the risk associated with each dose,⁵⁵ and they do permit the ranking of carcinogens in rough order of their potency. But they cannot provide the regulator with precise estimates of the risks of low doses.

More uncertainty is added to risk estimates by our ignorance of how to translate dose-response data across species lines. There simply is not enough known to determine if humans are more or less sensitive to a given dose of a carcinogen than the test animals.⁵⁶

Several new techniques for assessing carcinogenicity are developing, but these do not yet hold out the promise of yielding quantitative risk estimates or of answering the basic questions about how cancer is caused. There are "quick" tests—such as the Ames test—of chemicals' abilities to mutate bacteria or other single-celled organisms. There is a high correlation between the ability to cause such mutations and carcinogenicity.⁵⁷ Currently, however, the value of the "quick" tests is primarily qualitative; they may be able to distinguish strong from weak carcinogens, but cannot give more precise risk estimates.

One important consequence of the uncertainty about the size of small risks is that a regulator agency does not know the *marginal* risk at each

53. Estimating "Safe" Levels, *supra* note 42, at 1383. See also *From Mouse to Man*, *supra* note 37, at 241.

54. *Carcinogenic Risk Assessment*, *supra* note 42, at 694.

55. For example, Schneiderman and his colleagues estimated on the basis of the animal experiments on VC completed by May 1974 "that a dose as low as 1 ppm [part per million] is almost certain to have a risk of less than 1 in 10,000" for animals. *From Mouse to Man*, *supra* note 37, at 241-42.

56. See Rail, *Problems of Low Doses of Carcinogens*, 64 J. WASH. ACAD. SCI. 63 (1974).

57. McCann & Ames, *A Simple Method for Detecting Environmental Carcinogens as Mutagens*, 271 ANNALS N.Y. ACAD. SCI. 5 (1976). See also Note, *From Microbes to Men: The New Toxic Substances Control Act and Bacterial Mutagenicity/Carcinogenicity Tests*, 6 ENV'T L. REP. 10,248 (1976).

dose; that is, the agency does not know how great a difference in risk is caused by small changes in dose. If there is a large difference, then small changes in the allowable exposure will have a significant impact on human health and must be considered carefully. If the difference is small, these differences are not so important, and extensive efforts to obtain compliance with a small change in a standard might not be worthwhile.

Purely scientific problems of risk assessment are aggravated to some degree for regulatory agencies by their incomplete access to information. Most toxicological research is carried out or sponsored by the industries that make or market the substances being evaluated; industrial researchers have incentives to withhold negative information or to perform poorly designed and executed experiments incapable of revealing negative information.⁵⁸ To some extent, this behavior can be controlled by the use of standard test protocols and other means.⁵⁹ The problem of unequal access to data and of incentives to misinform or misrepresent is more serious with regard to the assessment of costs.⁶⁰

In sum, because the nature of chemical carcinogenesis is unknown, and because available research techniques are limited in their ability to predict human risks from exposure to carcinogens, the only conclusion that may be drawn with complete certainty is that no level of exposure to a chemical that causes cancer in animals is sure to be safe. Neither experimental nor theoretical analysis can give the agencies precise estimates of the risks associated with low doses of substances that are known to cause cancer in humans or animals at higher doses. Nor can regulators be sure how sensitive risks are to changes in dose. At present, the best available techniques produce only broad estimates of the outer limits of risk.

B. The Limits of Economic and Technological Assessment

The costs of controlling exposure to a toxic substance are shrouded in

58. See NATIONAL RESEARCH COUNCIL, DECISION MAKING IN THE ENVIRONMENTAL PROTECTION AGENCY 54-57 (1977) [hereinafter cited as DECISION MAKING IN EPA].

59. As an example of standard protocols for cancer testing, see Sontag, Page, & Saffiotti, *Guidelines for Carcinogen Bioassay in Small Rodents*, National Cancer Institute, Carcinogenesis Technical Report Series No. 1 (1976), summarized in Shubik & Clayson, *Application of the Results of Carcinogen Bioassays to Man in ENVIRONMENTAL POLLUTION*, *supra* note 23, at 241, 242. See also PRINCIPLES FOR EVALUATING CHEMICALS, *supra* note 42, at 134-55.

One other means for controlling the quality of data is to certify laboratories that meet minimum standards for their performance. See DECISION MAKING IN EPA, *supra* note 58, at 54-57. In addition, there are penalties in certain of the regulatory statutes for a company's misrepresenting or withholding toxicological data. Currently, the Food and Drug Administration is developing such certification procedures as part of "Good Laboratory Practice" regulations, and the agency has referred at least one case involving misrepresentation of data to the Justice Department with a recommendation for criminal prosecution. See *Creative Penmanship in Animal Testing Prompts FDA Controls*, 198 SCIENCE 1227 (1977). In addition, Velsicol Chemical Corporation has been indicted for withholding data from EPA regarding animal cancer tests on heptachlor/chlordane. See *Indictment Charges Velsicol, Six Persons, Withheld Chlordane, Heptachlor Data*, 1 BNA CHEM. REG. REP.—CURR. REP. 1413-14 (1977).

60. See text accompanying notes 67-71 *infra*.