CANADIAN TOXIC CHEMICAL POLICY

by

JOHN ROBERT STURDY

B.Sc., The University Of British Columbia, 1975

A THESIS SUBMITTED IN PARTIAL FULFILMENT OF

THE REQUIREMENTS FOR THE DEGREE OF

MASTER OF SCIENCE

IN BUSINESS ADMINISTRATION

in

THE FACULTY OF GRADUATE STUDIES

(Department of Commerce and Business Administration)

We accept this thesis as conforming
to the required standard

THE UNIVERSITY OF BRITISH COLUMBIA

April 1980

© John Robert Sturdy, 1980
In presenting this thesis in partial fulfilment of the requirements for an advanced degree at the University of British Columbia, I agree that the Library shall make it freely available for reference and study. I further agree that permission for extensive copying of this thesis for scholarly purposes may be granted by the Head of my Department or by his representatives. It is understood that copying or publication of this thesis for financial gain shall not be allowed without my written permission.

Department of Commerce and Business Administration

The University of British Columbia
2075 Wesbrook Place
Vancouver, Canada
V6T 1W5

Date April 21, 1980
ABSTRACT

This thesis examines the existing constraints and opportunities that shape present and future chemical control. It argues that a lack of adequate and accessible information is the limiting factor and presents steps to expand those limits.

Federal and provincial jurisdictions were examined. Governments were found to have adequate power to regulate all aspects of the problem including enabling legislation, regulations and guidelines, information access and compensation. The impediments to regulation are not therefore, constitutional but rather the large number of chemicals and the lack of a method to choose candidates for control.

A pre-market strategy is necessary to establish priorities for control among the many chemicals posing a potential hazard. Hazard was described as a function of the exposure to a chemical and the consequences of that exposure. Thus, chemicals with large exposure and harmful consequences would be candidates for control while, conversely, chemicals with little exposure and negligible consequences would not. The necessity for information on those in between would be determined from the extent of exposure or of hazard known.

Approaches to transform public opinion and scientific knowledge into standards for chosen candidates was examined. No method of arriving at an optimal standard was found. Therefore, judgment is necessary. To aid in arriving at acceptable standards a consultative approach with government, industry and
the public as participants was suggested. Rational decisions would be aided by the availability of adequate information.

To provide the necessary information an information system is advocated. Three model systems were reviewed. Deficiencies were analyzed and prescriptions for design improvements were made. Some of the key points discussed are compatibility, standardization of data, storage and retrieval problems, organization and confidentiality.
TABLE OF CONTENTS

ABSTRACT ................................................................. ii
INTRODUCTION .............................................................. 1
1. INSTRUMENTS OF CONTROL ............................................ 7
   1.1 Current Canadian Legislation ..................................... 7
   1.2 Legislative Constraints ........................................... 13
       1.2.1 Federal Jurisdiction ........................................ 14
       1.2.2 Provincial Jurisdiction .................................... 17
       1.2.3 Summary of Federal and Provincial Powers .............. 17
   1.3 Information Access .............................................. 18
       1.3.1 Summary of Information Access ........................... 21
   1.4 Compensation ................................................... 21
   1.5 Conclusions ..................................................... 23
2. ESTABLISHMENT OF PRIORITIES FOR REGULATION ..................... 28
   2.1 Exposure Determination .......................................... 29
   2.2 Environmental Dynamics ........................................ 32
   2.3 Analogous Consequences ......................................... 37
       2.3.1 Common Sense .............................................. 38
       2.3.2 Occupational Exposure ..................................... 38
       2.3.3 Epidemiology ............................................... 39
       2.3.4 Extrapolation from Animal Tests .......................... 40
       2.3.5 Extrapolation from In Vitro Tests ....................... 42
       2.3.6 Extrapolation from Radiation Data ....................... 43
   2.4 Chemical Behavior ............................................... 43
       2.4.1 Atmospheric Interactions .................................. 44
       2.4.2 Aquatic Interaction ....................................... 46
INTRODUCTION

There is strong evidence of a problem arising from chemical contamination of our environment. The International Agency for Research on Cancer estimates that 80% of cancer is caused by environmental factors (Higginson, 1968) and the plethora of new chemicals ranks at least as a significant minority on the list of potential carcinogenic factors (Bridges, 1976). In addition to the carcinogens, there are a host of chemicals with proven toxic affects which cause deterioration of nervous systems, of pulmonary functions, of cardiovascular efficiency and of activity of various other organs.

The potential health risk from chemicals becomes of grave importance when the number of chemicals is estimated. The American Chemical Society (1978) indicates that there are four million chemicals in existence with 6000 new ones being discovered each week. About 1000 of these new chemicals are added to the present 50,000 commercial chemicals each year (Devoret, 1979), circumstances indicate that some form of government intervention is required.

Market mechanisms can lead to efficient choices in some instances but in many cases the basic assumptions governing efficient market choices are violated. Some of the relevant assumptions that are not met severely inhibit the function of the free market process. For example, possession of adequate information by consumers is assumed. But in many instances the
lay public has little knowledge and less understanding of chemical side-effects. Indeed, many times the scientific community is only marginally more enlightened. The number and variety of chemicals produced precludes exhaustive study of each individual new chemical. Synergistic and stochiometric interactions between chemicals which can occur in an almost unimaginable number of combinations makes a thorough study of chemical effects even more difficult. Mercury, for example, was found to the surprise of scientists, to be converted in the presence of the metabolic enzymes present in certain bacteria to a more toxic form. A second assumption violated is the assumption of the independence of the consumption units. Negative externalities from the consumption of chemicals by one group are imposed on other groups without their consent. For instance, DDT found its way into virtually every earthly place including mother's milk (Lowrance, 1976). Because of the externalities and the lack of information, conscious choice between the levels of risk cannot be made. It is further aggravated by the heterogeneity of the risk levels of a population. The level may vary according to the sensitivity of the person exposed. A fetus exposed to thalidomide (a drug used for sleeping tablets and tranquilizers) is at far greater risk than a adult (Lawless, 1977). Thus, the free market system has theoretical failings which are borne out by the empirical evidence of substantial chemical hazard.

In addition, the present institutional structures and legislation were set up to deal with pollution problems recognized in earlier times. They grew in a piecemeal way and
may be unable to cope with the new problems. Earlier recognized chemical pollutants, or classical pollutants, as they are labeled by Page (1978) tend to be visible and immediate. They irritate eyes, burn throats, taint water and cloud the skies among other effects. Since these pollutants could be seen, tasted and immediately felt, their presence and effect were obvious. This acuteness facilitated the formulation and public acceptance of measures to counteract undesirable characteristics. Foam from detergents, smog from cars, sewage in potable water, all are examples of contaminants that are controlled by pollution legislation that is accepted by the public.

But new pollutants are different in several respects (Page, 1978). First, they are very potent. Concentrations measured in parts per billion (ppb) or even parts per trillion (ppt) can have disastrous consequences. For example, mercury at levels over fifty ppb is considered unacceptable (World Health Organization, 1967). Second, the time span between exposure and evidence of effect can be very long: Skin cancer from coal tar has a latency period of ten to twenty years (Heuper, 1959). Detection is often complicated because the effect may not be unique. It may be manifested simply as an increase in the number of anomalies which already occur. This makes the epidemiology of detection very difficult. Some chemicals found to be harmful were only discovered because they produced peculiar, rare consequences. For example, the terrible effects of thalidomide might have gone much longer without detection except for the characteristic and unusual deformity which
resulted (Lawless, 1977). Carcinogens often seem to produce an overall, small increase in a common cancer rather than a new tumor, a specific cancer or a marked increase in cancer of one area. Third, the uncertainty present in extrapolating from affects shown in an animal or bacteriological test system to an estimate of the potential danger to humans leaves much room for a wide divergence of opinion. The connection between animal and human cancer is only circumstantial. Thus, a nicety of balance in the trade-off between risk and cost is required including among other things, an implicit value on human life. Fourth, many chemicals have environmental and human affects that are essentially irreversible such as destruction of lakes by acid rain or some cancer forms. Finally, traditional mechanisms for dealing with costs, benefits and risks are not operating efficiently. Benefits of chemicals are transferred indirectly by the market while costs are distributed directly through environmental hazards. Since risk is so ubiquitous, the standard compensation methods fail. Insurance, for example, is ineffective in situations where many people are affected simultaneously. These factors, potency, latency, uncertainty, irreversibility and market failure, combine to limit the effectiveness of current institutional structures and legislation. Some kind of government intervention is deemed necessary. The extent and manner of the intervention are to be examined.

This thesis will examine the existing constraints and opportunities that may shape the future chemical control regulations. It will argue that a lack of adequate and
accessible information is the limiting factor and will present steps to expand the limits imposed by this constraint.

The first chapter reviews the instruments of control. Existing Canadian legislation is surveyed to provide a general background. From this base, the federal and provincial governments' potential and need to draft further legislation is examined. The governments' ability to legislate access to information and to compel participation of industry in compensation schemes is covered. Finally, some similarities with selected industrialized countries are noted.

Chapter two suggests that the number of existing and new chemicals is too great to allow a comprehensive examination of each substance. A screening system is necessary to designate chemicals for regulation. It therefore appraises the elements of a strategy to establish priorities for chemical regulations. The elements reviewed include determination of exposure, interaction with the environment, extrapolation from various tests and events, and determination of chemical behaviour. A strategy composed of these elements will require accurate and comprehensive data to make rational choices among candidates for regulation.

The thesis next examines approaches that may be utilized in transforming public opinion and scientific information into standards for chosen candidates. Chapter three is divided into two sections. The first section presents a series of techniques for constructing standards. These techniques are superimposed on a conceptual framework ascending from a no-risk approach to a risk-benefit trade-off. The factors of the second section
modify the techniques in the first section and introduce the effect of public risk perception. Emphasis is placed on the concept of acceptability as a necessary condition for successful standard setting.

Chapter four introduces the information system as a means of providing the data needed for choosing candidates and establishing standards. Some systems currently in use are described. Their deficiencies are analyzed and prescriptions for design improvements are made.

The last chapter provides a summary of the analyses and recommendations of the thesis.
1. INSTRUMENTS OF CONTROL

1.1 CURRENT CANADIAN LEGISLATION

Given that some change in government control of toxic chemicals is necessary, it is useful to examine federal and provincial powers to effect such change. In this light, the Canadian legislation regarding environmental and commercial chemicals and drugs will be examined. In addition, limitations on the ability to draft new legislation such as provincial-federal jurisdictional constraints will be reviewed. Finally, the approaches of other Organization for Economic Cooperation and Development (OECD) countries, notably the United States (US) and the United Kingdom (UK), to toxic chemical control will be surveyed for appropriate models applicable to the Canadian arena. In examining present Canadian statutes it is convenient to categorize them according to their purpose.

The Canadian legislation to control chemical hazards is classified by Franson et al. (1977) into ten categories. (1) The first category, General Pollution Control Statutes, contains both federal legislation and statutes from all provinces. The provincial regulation systems use two main techniques: (a) permits and approvals to control disposal of contaminants and pollution, the definitions being broad enough to cover most situations of discharge into the environment. For example, in Ontario, approvals utilizing standards derived from regulations concerning ambient air quality are used to control
air contaminants; (b) the second technique is the authority of the Environment Minister to use stop or control orders when he establishes to his satisfaction that a contaminant will decrease environmental quality. The main federal pollution control acts are the Canada Water Act the Clean Air Act, and the Fisheries Act. All three acts are general in nature but because of incomplete implementation, the latter two acts are limited in practice. (2) The second category deals with Industrial Safety, Workman's Compensation and Occupational Health Statutes. Although all provinces have industrial safety legislation, the statutes vary from general requirements of a common sense nature (e.g. prevent exposure to toxic chemicals, limit use or handling of dangerous substances, and provide proper ventilation or protective clothing), to specific limits to certain chemicals (e.g. lead, vinyl chloride and asbestos). (3) The third contains Special Statutes Regulating Particular Contaminants. A specific contaminant per se may be regulated, (e.g. provincial and federal pesticide controls) or regulations may pertain to a contaminant in a substance (e.g. lead in leaded gasoline). (4) Category four deals with Motor Vehicle Standards and contains federal and provincial legislation on motor vehicle emissions. (5) The fifth encompasses Public Health Acts. Here Franson et al. (1977) perceive little overlap between federal and provincial statutes. Federal health regulations are mainly concerned with specific areas like food safety and dangerous consumer products. Health acts affect other areas as well as public health. Some provincial acts pertain to occupational health to control the use of a
particular contaminant and other acts contain elements of pollution control. (6) The sixth category covers the Federal Food and Drug act which contains the fundamental controls for contaminants in food and drug products. Specific standards deal with quality and quantity of substances, packaging and toxic chemicals such as lead. (7) Only one piece of legislation is in the seventh category, General Contaminants Control statutes, and that is the federal *Environmental Contaminants Act*. It is used to supplement and reinforce, the predominantly provincial legislation in the area (OECD, 1976). For example, it may supplement the provincial pharmacy acts which regulate a more restricted range of chemicals.

The act allows for investigation of suspicious substances. If the suspicions are justified, i.e. "significant danger to health or the environment" (p. 32) exists, then the chemical may be added to the Schedule of the Act allowing restrictions respecting importation, manufacture or use to be applied after consultation with other authorities to establish the absence or presence of other applicable statutes (OECD, 1976) or in some other way. It is designed to act in two ways. It allows for the normal, measured flow of process providing due consideration during situations of everyday business but, is ready for immediate action in emergency situations (Ince, 1976).

The back-up nature of the legislation may present a problem. As with the legislation of the other OECD countries¹,

¹ A review and an analysis of the legislation of OECD countries is in the appendix.
the act is usually applied when other legislation will not suffice. Thus, before action can be taken under the Environmental Contaminants Act, considerable discussion between federal and provincial departments is necessary to determine whether other legislation is applicable (Ince, 1976). If the jurisdictions of the various departments are vigorously defended a substantial lapse of time can occur.

The Act represents a shift in emphasis from post-market monitoring to pre-market screening which is common to other OECD countries. However, a problem with the Act in this capacity lies in its lack of sensitivity to small amounts. The efficacy of the Act with regard to pre-market screening may be limited since the only notification of chemicals required are for those manufactured or imported in quantities over 500 kg. Even then the Act can only be used when the characteristics of a chemical suggest a potential problem.

The organizational aspects of the Act allow a great deal of flexibility in approach (OECD, 1976). Experts decide what substances to investigate, gathering all available information. The appropriate tests are to be carried out (after agreement with industry if possible) at industry expense and the results reviewed by the government. Conditions of sale are decided after consultation with industry, other governments and federal agencies to decide on the method of control. The Environmental Contaminant Act allows for whatever actions are required. Ince (1976) points out that the advantages lie in the political convenience of the statutes and in the potential efficiency of the resulting regulations. The existence of the Act gives the
appearance of a strong stand to satisfy environmental interest
groups while allowing input from affected parties before the
actual regulations are designed. (8) The eighth category is
Particular Resource Statutes containing legislation for
management of resources. It is usually quite detailed and
contains regulations to control pollution; e.g., The
Saskatchewan Pollution Prevention Regulation for the Mineral
Industry. (9) Category nine, Special Industry Regulation
Statutes, contains provincial and federal legislation. The
provincial legislation as noted by Franson et al., tends toward
the general, although laws dealing with areas such as mine
safety, and pesticides are more specific. Federal statutes of
principle interest are the Pollution Prevention Regulations
(part of the Canada Shipping Act) and the Fisheries Act dealing
respectively with discharge from ships and industrial discharge
into water such as pulp and paper mill effluent and petroleum
refineries. (10) The last category, number ten, contains
Consumer Safety Statutes. These range from those concerned with
food and drug safety (the federal Food and Drug Regulations and
provincial public health standards) to those concerned with
poisons (the federal and provincial pesticide acts) and
finally, to one concerned with other aspects of consumer
safety, the federal Hazardous Products Act. The latter deals
with the specific standards, for example, lead and asbestos in
a myriad of consumer products including childrens toys.

In examining the categories presented above, Franson et
al. identify two main control mechanisms. Both are used with
apparent randomness in federal and provincial statutes and
sometimes in the same statutes. One approach to regulation is distinguished by the use of agencies, officials or departments to issue licenses or approvals. Guidelines are established to outline procedures and qualifications necessary to obtain governmental sanction.

A guideline is defined as "an informal statement issued by a regulatory agency setting forth the standards of conduct that it expects those under its control to exercise" (Franson et al., 1977, p. 34). This is compared to a regulation which is defined as "a rule made by competent authority relating to actions of those in direct control (Franson et al., 1977 p. 34). The legal difference between guidelines and regulations is that regulations are specific laws, and as such are enforceable in court whereas guidelines are not enforceable in court. Also, regulations have a higher profile, being generally passed by Order-in-Council and published in the official Gazette, whereas guidelines are much less obvious. To uncover guidelines it is often necessary for an outsider to check with agencies who might produce them. However, they are sometimes considered restricted internal documents in which case even direct inquiry will not unveil them.

The second principal mechanism is described by Franson et al. as "out-right prescription" (p. 46) in which case a particular chemical has a specific and definite standard associated with it. To enforce compliance with the standard the government has recourse to quasi-criminal sanctions which may include confiscation.

In some cases, the prescriptive regulations serve as a
backup for the more common, daily use of the licensing and approval mechanism. For example, the federal Food and Drug Act provides for standards and allows for quasi-criminal proceedings if the standards are not met. However, the daily order of business utilizes warning letters and other informal methods such as negotiation to encourage voluntary withdrawal of chemicals violating standards. Also, in practice, submission of product tests and information for review routinely results in "approval" for product manufacture and sales. In establishing the regulations, a fairly informal process involving information circulars and solicitation of industry views is followed.

1.2 LEGISLATIVE CONSTRAINTS

Having reviewed present legislation, the ability of the government to enable legislation concerning new areas is analyzed.

This section deals with the potential of the federal and provincial governments to produce and enforce legislation regulating toxic chemicals. It will cover the jurisdiction of the federal and provincial governments, the powers available, the governmental versus individual right to information and the right to compensation of individuals and corporations who have been harmed by toxic substances.
1.2.1 Federal Jurisdiction

The British North America Act (BNA Act) establishes federal jurisdiction (Franson et al., 1977). Some areas of exclusive jurisdictions are listed, for example, fisheries, shipping and navigation. As well, less specific powers are allocated federally under Section 91. General powers with the greatest potential for control of toxic substances exist in the two areas of criminal law and trade and commerce. These latter two will be examined first.

Criminal Powers

The powers that the federal government has under criminal law are very broad. In effect parliament has the power to recognize new crimes and enact legislation to prevent them. "in fact, it has been said that any time Parliament prohibits certain conduct and attaches penal consequences for engaging in it, that legislation may be sustained under the criminal law power" (Franson et al., 1977, p. 14).

Some limitations of the federal use of criminal law power exist in practice and are summarized by Franson et al. (1977). First, the courts tend to defend areas of provincial jurisdiction. These areas, however, seem to be confined to regulation of local trade which, in any case, would not be encroached upon by federal regulation concerning toxic substances. Also, the potential for federal criminal legislation is enhanced by a traditional posture of crime prevention. Legislation governing the production and distribution of
chemicals that may harm others fulfills the defined intention of such laws quite well. In fact, some legal precedent already exists (Franson et al., 1977) to support this contention. The second problem is that because of strong tradition in another area dealing with possible remedies and sanction under criminal law, some useful remedial action may not be allowed. Tradition has established that persons found guilty before ordinary Court of contravening the legislation should suffer a fine or imprisonment. Maintenance of, and limitation to these modes of action has been advocated. Franson et al. (1977) note that acceptance of this view would effectively negate the use of such beneficial actions as stop orders and advance rulings. Given the courts' inclination to limit federal use of criminal law, it may be wise to relate future toxic chemical regulations under this area to crime prevention and criminal punishment.

Trade and Commerce Powers

Federal powers under trade and commerce law may be somewhat limited although a large potential for the use of these powers exists because of the great number of toxic chemicals involved directly with commercial activities. Previously, the scope of federal powers was interpreted quite restrictively, however, recent interpretation has been broadened to effectively include interprovincial trade. But the courts have remained undecided on the ability of the federal government to expand its intervention from a traditionally economic focus to one including national health and safety. In
practice, Franson et al. assert, this may not be an important consideration for two reasons. One, since the very uncertainty which prevents legal affirmation of such legislation also provides a measure of protection from attack. A challenge to the law would be based on showing it to be unconstitutional, making resolution of the questions contingent upon the determination of the original intent of the legislation, a difficult task. Two, the majority of new toxic chemicals are imported into Canada and importation is an acknowledged federal jurisdiction.

General Powers

The general power likely to be most important in the regulation of toxic chemicals is the federal government's ability to deal with problems crossing provincial borders (Franson et al., 1977). Recent court decisions have added some credence to the federal argument for power over problems of national dimensions. Interprovincial pollution was likened to interprovincial trade with the implication of similar federal jurisdiction. Franson et al. State that the inference to be made from such decisions is future support from the Court on the issue of federal power over interprovincial contaminants.
1.2.2 Provincial Jurisdiction

Provincial powers

Franson et al. points out that provincial jurisdiction granted by Section 92 of the BNA Act is very broad with respect to control of toxic chemicals. Almost all aspects of domestic chemical production are concerned from manufacturing, to labour relations, to work environment, and waste disposal. Although this concerns most contingencies of interest some limitations exist, mostly with regard to federal powers. Provincial powers are constrained to their respective territories. Federal legislation takes precedence over conflicting provincial statutes and federal Crown property is exempt from provincial control. Finally, the BNA Act gives exclusive rights over many areas to the federal government. Because of the amount of conflict with federal legislation, delimiting provincial powers implies definition of federal jurisdiction.

1.2.3 Summary of Federal and Provincial Powers

In summary, fruitful federal legal powers lie in the areas of criminal law, trade and commerce law, statutes, general jurisdictions and indirect approaches. Criminal law has very broad uses and control of toxic chemicals has the potential to fit traditional requirements for such law. One problem, however, is the nature of the traditional punishments attached
to such law. Compliance may be better achieved through stop orders or advance rulings rather than the fines and imprisonments presently favoured by courts. Because the bulk of toxic chemicals are commercial, trade and commerce law is potentially useful. Here again, the focus has been characteristically economic rather than health and safety. However, enough ambiguity may exist to cushion any laws from the challenge of unconstitutionality. Legislative power may lie in arguing the analogous nature of interprovincial trade and interprovincial pollution. The courts seem inclined to recognize the similarity. Finally, the government may use taxation and fiscal policy to provide industries with economic incentives to comply. Unfortunately, the public may view such indirect methods with suspicion, making such a policy politically infeasible.

Provincial legislative powers extend over the production process and are constrained mainly by regional limits and federal-provincial jurisdictional boundaries.

1.3 INFORMATION ACCESS

Government appears to have ample power to enact legislation controlling toxic chemicals. A major residual consideration, is collection of information to guide selection of candidates for control. In addition, the ability to obtain and use information for monitoring or prosecuting becomes very important. Both federal and provincial governments have wide
powers to obtain information, although the provinces must often take a more circuitous route (Franson et al., 1977).

Federal powers to gather information lie in the section of the BNA Act dealing with census and statistics and in the ability to pay for research and surveys without constitutional limits on spending. The latter ability is shared by the provinces as well. It is in the ability to force release of information that a divergence of power occurs. The federal government has a direct method available in the statistics and census laws. As well, it can use the power of criminal law to compel the release of information relating to prosecution for criminal offense. The provincial governments must act more indirectly. For example, they can make approval of a licence contingent on the proposed activities. Information access might be limited to areas germane to the application.

Wide access to information does not extend to the individual. In fact, many factors militate against public access to government information about toxic substances. For example, the federal Official Secrets Act and the civil servants' Oath of Office both encourage secrecy (Franson et al., 1977).

Canada takes an approach opposite to that of the United States. The US Freedom of Information Act assumes information, except for that noted, will be open to public scrutiny. The trend in Canada is to resume information is restricted except for that specifically released. Guidelines for access to documents do exist in Canada, having been set forth by Cabinet, but they are for internal government use only. They are not...
useful to a private citizen.

In addition, Crown privilege (the ability of a minister to declare documents secret) and the threat of a libel suit should an agency reveal "defamatory" information further serves to increase a basic government reticence to disclose information.

Some valid reasons exist to support a policy of non-disclosure. For example, trade secrets regarding chemical structure and manufacturing techniques must be secret or industry cooperation will be lost. Other arguments reported by Franson et al. include a loss of "working rapport" and our social inclination for personal privacy.

Some limited procedures exist to compel release of information, i.e. for judicial proceedings or regulatory hearings. In general, however, public access to information is severely curtailed.

Once governments have the information, what can they do with it? In Canada, governments are not constrained by legislation regarding privacy. But, even though Canadians have no constitutional right there exist compelling political reasons for governments to act as if such an individual and corporate right to privacy existed (Franson et al., 1977). Generally they do so. These political reasons also tend to limit the amount and kind of information collected even in the absence of constitutional constraints.
1.3.1 Summary of Information Access

The federal government has powerful means of gathering and processing information. Besides the power of census taking and statistics procurement, criminal law allows for access to information relating to criminal prosecutions. Also, there are no constitutional restrictions on research or survey spending. Provincially, more indirect methods must be used for information gathering. For example, a license may be withheld pending information on its use.

Information is gathered more readily than it is dispersed. Broad access to information does not extend to the individual. Our common law tradition combined with ministerial privilege and secrecy laws strongly inhibit an outward flow. Often this predisposition is supported with policy arguments. An example of such an argument is that public access to pollution information would destroy the professional rapport between regulators and regulated.

1.4 COMPENSATION

Another important issue relating to toxic chemical control by federal and provincial governments is compensation for damages. Franson et al. (1977, p. 21) lists three general kinds: (1) compensation funds established from general revenue; (2) special compensation funds maintained by compulsory contributions levied against the industries likely to cause injury; and (3) private rights of action given to an injured
person to proceed directly against those causing the injury. Both governments seem able to establish compensation funds and the provincial governments, at least, have the power to levy industry within their respective borders. Federal power to raise a contributory fund is probably limited to industries under its exclusive jurisdiction. Generally, provincial powers encompass private right of action but recent cases have suggested Parliament may be able to ensure that violators of federal statutes pay compensation to those injured as result of the violation.

However, legal responsibility of companies and methods of compensating those injured must be examined. Recent events have stimulated such examinations. The chlorine spill at Mississauga, Ontario, for instance, has stimulated government consideration of this topic where accidents have resulted in acute hazard. A partial solution to the questions of responsibility and compensation may lie in the establishment of a central fund with payments made into it on the basis of production levels. This approach is well within federal and provincial powers.

Another aspect is responsibility for subacute damage. In the case of latent damage occurring, some legislation already exists (Ince, 1976). The Industrial Operations Damage Compensation Act allows for an agreement for compensation between the owner of land and a polluting company. The Act negates further responsibility of a company for any damage arising from the pollution. Also, should an agreement not be reached, agreement can be imposed on an owner by a judge,
resulting in the same loss of recourse to legal action should unexpected damages occur. In view of the limited knowledge about long term effects of toxic chemicals and numerous possible interactions, the ability of a judge to decide on present adequate compensation for further damages seems questionable. Although Ince (1976) predicts that judges are unlikely to use this act to remove personal rights, it may significantly reduce private access to legal action against polluters.

In any case, assigning responsibility for any environmental or health damage done in the past will prove a difficult problem. The final damage may be caused by a chemical resulting from many intermediate reactions with other natural or man-made chemicals over a long period of time. Thus, the initial contributor is effectively disguised. Here again, some central no-fault fund, contributed to by industry and administered by the governments, may be required to compensate victims of chemical hazards.

1.5 CONCLUSIONS

Existing legislation is broad and powerful. General Pollution Control statutes allow both the federal and provincial governments to use permits and approvals to control most situations of discharge into the environment. The statutes also allow the federal use of stop or control orders if contaminants are detrimental to the environment.
Other existing legislation deals with specific areas. The provinces can regulate public health, resource use and the workplace, while the federal government can control motor vehicle emissions, food and drugs, and consumer safety. Both can regulate specific chemicals or contaminants and specific industries.

Any gaps in environmental legislation can be covered by the federal Environmental Contaminants Act. It supplements provincial and other federal legislation. By design it is very flexible in application and effect.

In addition to the existing legislation, both governments have the ability to bring in new environmental legislation as needed. Such legislation can originate in any of several areas. The federal government can call almost anything a crime and enact legislation to punish those engaged in it. Also, because many toxic chemicals are used commercially, the federal government can apply the power of trade and commerce law. Finally, the federal government has control over problems of national dimensions.

The provinces, except that their powers are limited to their respective territories, can exert considerable influence on chemical production. This control is derived from the chemical industry's association with at least one area of provincial jurisdiction be it manufacturing, labour, the workplace, or chemical waste disposal. By working together, federal and provincial governments should be able to cover most situations with little trouble.

Between existing legislation and the ability to enact new
legislation, introducing regulations to fill a gap should present no problems. However, conflict between federal and provincial jurisdictions may occur. In many cases legislation overlaps. This may be preferable to gaps since if an emergency occurs it is advantageous to have the power to act immediately. However, overlaps also mean duplication of effort, potential conflicts between individual laws and added expense to industry to comply with duplicate statutes. Careful rationalization of conflicts, such as designating which legislation has precedence, may reduce the burden of overlaps.

It is evident, upon reviewing the existing legislation and the powers existing to formulate new laws, that few constitutional impediments restrict the introduction of toxic chemical regulations. Thus, the constraints on the promulgation of new policies are the large number of chemicals to regulate and the difficulty in controlling them. The number and variety of chemicals is so great that the determination of priorities and the efficient deployment of resources is difficult. In essence, the development of new policy revolves not around enabling legislation but in establishing priorities for developing specific legislation.

To aid in developing priorities, both governments have the ability to collect nearly any information desired. Federal powers originate with the census and statistics section of the BNA Act and with criminal law. It also has the ability to finance the collection of data without constitutional constraints. It thus has direct access to data and the power to force compliance. The provinces too have few limits on
information collection powers but must use a more indirect route in some cases. Licence approval, for example, can be made contingent upon provincial access to information.

Potential blocks to information collection are in the nature of political and economic constraints. Industry may not wish to divulge information if competitors have access to it. The use of government powers to force compliance may have the undesirable consequence of reducing the Canadian industry's economic contributions.

However, governments need not reveal information collected from industry. They can avoid the conflict. The tradition of Canadian governments has been to promote secrecy. In addition to tradition there is the Official Secrets Act and the civil servants' Oath of Office to ensure secrecy. Canadians have no constitutional rights to information so governments can assure industry of confidentiality if required.

Both governments have the ability to ensure compensation for damage caused by chemicals. This may be done in several ways. Federal and provincial governments can provide funds from general revenue or by levy of industry. The federal government can only levy industries directly under its control whereas the provinces can levy any industry within its borders. Finally, both governments can ensure private rights of action against responsible companies.

Two problems exist in administering a policy which includes a levy against industry. First, ascertaining responsibility for damage may be difficult if the damage is chronic and latent in nature. Time, environmental interactions
and personal mobility will tend to confuse areas of responsibility. In these cases, a general fund may be needed. The second problem arises because of the nature of the jurisdictions. Federal and provincial cooperation may be essential if levies are to be applied fairly and equally to industry. An intergovernmental coordinating mechanism may facilitate the administration of compensation policies.

Several points are raised by an examination of OECD countries' legislation but the focus here is the change in emphasis. The change in emphasis from post-market monitoring to pre-market testing implies a form of test system to determine candidates for control. Design of such a system may be difficult as evidenced by the divergent approaches of the US and UK. But, one point is clear: the pre-market test approach will require efficient and adequate information about chemicals, about their effects and about public perceptions of their hazards.

Governments have ample power to regulate toxic chemicals and to provide compensation for damages. However, information is needed to aid in the formation of actual regulations. Governments have both the ability to finance and collect such information and to provide industry with the assurance of confidentiality. The next step is to examine criteria for screening of candidates for control.
2. ESTABLISHMENT OF PRIORITIES FOR REGULATION

It has been established that utilization of legislative powers requires that suitable candidates for control be isolated from the thousands of new and old chemicals. At least two methods exist, fire fighting and establishment of a screening system.

An obvious strategy is to focus on fire fighting. Such a policy of concentrating on high profile chemicals has several good points to recommend it. First, public acceptance of restrictions is likely to be enhanced by the large amount of media hyperbole generated by a toxic chemical crisis. Two, the industry marketing or distributing the chemical is likely to be at a disadvantage in a crisis situation and therefore more amenable to government regulation. Finally, the fact that the chemical is drawing attention suggests that a significant level of information already exists. These factors will facilitate the design of suitable controlling statutes. Thus, known hazards can be dealt with.

Unfortunately, several drawbacks arise if a more comprehensive policy is not implemented. First, even with a receptive public and a compliant industry, legislation can require a long time to pass into law. Hastily composed legislation may be poorly conceived and difficult to enforce as well. Once a law exists, regulations must be designed and enforcement machinery must be placed in motion before law takes effect. Time can be an important constraint. Second, the nature
of contemporary commercial chemicals allows them to do much damage before discovery if they are not closely monitored. Chemicals are often toxic at low concentrations or may have latent effects. Once established in the environment, persistent chemicals may take many years to dissipate. Thus, there is an argument for testing chemicals before they are distributed in large amounts (pre-market control).

With the above points in mind, it becomes important to choose candidates for control even before extensive information is available. A suitable screening system must be developed to evaluate the relative importance of a particular chemical. Two factors can be integrated to determine the potential importance of a chemical. These are expected exposure to a chemical and the consequences of that exposure. Together these factors determine the impact a chemical will have on health and the environment and therefore, its importance as a candidate for regulation.

2.1 EXPOSURE DETERMINATION

The first strategy to be examined is exposure determination. Ideally, exposure should be easy to define. The questions to be answered are: Who is exposed? What are they exposed to? How long are they exposed? and What is the strength of exposure? To answer the questions the production process of a chemical is examined.

A typical product scenario might be as follows. Raw
material is removed from the earth in some way, for instance, mining or pumping. It is transported to a refining center, refined and sent to a manufacturing plant. A product or intermediate part is produced which is sold to a consumer. The consumer uses the product until it is finished or disposed of, possibly to be degraded to some basic, natural components. To define the exposure the consumers are simply traced and catalogued.

Obviously this scenario is over simplified. Closer examination reveals many possibilities for inadvertent or even routine exposure. In the mining of asbestos, for example, miners are exposed to the minute fibers every workday. The hitherto ignored chemical causes a chronic lung disease called asbestosis (Brodeur, 1979). Another example is the accumulation of dust in the lungs of coal miners which leads to black lung disease. Both are forms of occupational exposure.

During the mining process tailings are discarded, some into water used for other purposes. In 1973 the drinking water of Duluth, Minnesota was found to have billions of asbestos-like fibers suspended in it. The discharge from the mine was being disposed of in Lake Superior (the local water supply). Animal tests showed it to cause cancer (Lawless, 1979). This illustrates unintended exposure to others through industrial discharges and emissions. Other examples abound: lead and carbon-monoxide from car exhaust; sulphur dioxides from coal-burning electrical plants; and mercury compounds from the plastics industry concentrating in fish and causing the infamous Minamata tragedy (Smith and Smith, 1970).
Another point in the scenario where accidental exposure can occur is during transport between processors. Chlorine, for example, shipped by truck or railcar has spilled near population centers imperiling whole cities with poisonous gas; during a fire or flood which damages storage facilities; during illegal use either by a final consumer such as a drug addict or by an intermediate user such as a farmer using the wrong pesticide on crops; and during legitimate use of substances which contain impurities such as flame retardant chemicals in childrens clothing (Blum and Ames, 1977) or strawberry flavouring (Strawberry Aldehyde) (Butterworth, 1978).

Finally, unexpected exposure can occur by criminal design. Important factors to consider in estimating exposure are the very real probability of sabotage, subversion or vandalism. These factors can add significantly to the uncertainty of both the occurrence and the extent of exposure.

When the myriad of potential sources of exposure are recognized it is evident that the task of determining accurately who is exposed to what is beyond reasonable means.

Rather than actually measuring or calculating exposure, an index may be used to approximate it. For example, the European Economic Community (EEC) uses production levels as a proxy for exposure. In the EEC scheme, as the production level of a chemical passes certain thresholds, thereby increasing probable exposure, more sophisticated, complex and expensive toxicological data are required (McGinty, 1979). The use of production levels as the sole index of exposure is subject to
strong criticisms since there are many cases where exposure intensity to man and the environment is not reflected.

Other systems use a more complex index. The US Interagency Testing Committee (ITC), for instance, derived an index of potential exposure based on numerical scales for production volume, environmental release, occupational exposure and non-occupational human exposure. Such an approach improves the index's sensitivity to chemicals which may be highly toxic in small amounts or, conversely, only slightly toxic in very large doses.

2.2 ENVIRONMENTAL DYNAMICS

Another important consideration in estimating exposure is environmental dynamics. Two main areas are of consequence, the natural, external environment and the environment of the human body. The external environment can have a powerful effect on chemicals. Substances deposited there are eventually changed to some other form or compound. Some chemicals like DDT resist such changes and are classed as persistent (Lawless, 1976). Others like biodegradable soaps break down quickly. Depending on their solubility in water, the amount of sunlight and other conditions such as pH, temperature and endemic microorganisms, chemicals may be degraded, dissipated or concentrated.

The end product of degradation can be benign as in the case of ordinary soap or very toxic as in the case of mercury. Mercury was used in chemical plants mainly in the production of
chlorine and caustic soda (Chemical and Engineering News, 1971) or in smaller amounts as a fungicide with pulp and paper or agriculture applications. In 1969 consumption of mercury by main users was almost 6 million pounds (Chemical and Engineering News, 1971). Most of the mercury was in a low toxicity form as aryl mercury compounds (often used in pharmaceuticals). However, anaerobic bacteria in bottom sediment convert the aryl mercury compounds from industrial effluent into a far more toxic organic form, alkyl mercury (Bosen, Wood and Kennedy, 1968).

In addition, mercury tends to accumulate in animals as the food pyramid is ascended. For example, hawks fed on chicken livers with 3 ppm, accumulated up to 18 ppm (Chemical Engineering, 1970) and fish have been found with up to 5 ppm in the toxic methyl form (Lawless, 1977). Man is a predator at the top of the food chain. Mercury ingested at low levels accumulates to higher toxic levels in the food that man eats (biomagnification). It tends to concentrate in the brain (bioaccumulation) affecting the central nervous system and leading to permanent, crippling blindness and even death (Dorland's Illustrated Medical Dictionary, 1974).

Chemicals can also be dissipated as the natural flow of the environment transports it from place to place. Dust particles are carried by animals and wind, streams carry soluble substances or suspended matter and gaseous materials are condensed in the air to return as raindrops. The end result is a thorough dispersion of the chemical. An example of such a ubiquitous chemical is the pesticide DDT. Lowrance (1976, p.
in documenting DDT laments:

DDT was everywhere on the surface of the earth. DDT was in every body of air and water. DDT was in the bodies of virtually all living creatures. DDT was in man's own flesh.

The combination of mobility, persistence and extensive use had allowed it to permeate the world.

The number of sources of a chemical have been shown, and the action of the environment on chemicals that are deposited in it has been illustrated. To the possible combinations and permutations arising from these two factors can be added the action of the human environment: the effect that man's own physiology and microbiology have on substances with which they come in contact. For example, metabolic factors can influence mutagenicity of chemicals (mutagenicity is highly correlated with carcinogenicity). Chemicals can be metabolized from a non-mutagenically active chemical or vice versa (Council of the Environmental Mutagen Society, 1975) such an action could occur with sodium nitrites used to prevent the growth of Clostridium botulinum and other dangerous bacteria in meat. Microorganisms present in the human gut transform the ingested nitrites into nitrosamines which are carcinogenic (Lawless, 1977). Another example of physiological interaction is the synergistic effect of some chemicals which potentiates the action of a mutagen. Caffeine, for instance, increases the action of a mutagen by

1. See McCann et al. (1975), McCann and Ames (1976), and Purchase et al. (1978).
inhibiting the deoxyribonucleic acid (DNA) repair process. Thus, when a mutagen damages the DNA structure it remains faulty leading to errors in transcriptions and possibly to cancer. Other cases of potentiation occur when enzymes are altered. Such changes can increase the rate of enzymatic activation of a mutagen (Environmental Mutagen Society, 1975) since such reactions can vary with the genetic predisposition of individuals (people with the genetic condition Xeroderma Pigmentosum are more susceptible to carcinogens) even people subjected to the same kinds and amounts of chemicals from the external environment can be exposed internally to different dangers as a result of the various transformations and synergies peculiar to his or her body.

Finally, such demographic factors such as age and sex change the importance of exposure. Men and women differ in their susceptibility to mutagens which alter genetic material. In order to act on gonads, a sufficient concentration of active mutagen must pass the blood-testes barrier. Unfortunately, other than follicular cells surrounding immature ova, the female has no corresponding protection (Environmental Mutagen Society, 1975). However, as the female passes prime child bearing age the importance of such protection diminishes. After menopause, of course, it is inconsequential.

For somatic mutations, age also plays an important role because of the time element inherent in the probability of cancer. A child exposed to a carcinogen has a greater chance of developing cancer that a person exposed later in life simply because there is more time for it to develop. Thus, it is more
important that children not be exposed to such carcinogens as nitrophenylenediamines found in hair dyes than it is for a mature woman (Searle, 1975).

When all these factors are considered, exposure analysis appears very complicated. But, several points stand out. First, as in the case of mercury, the danger of many chemicals is not realized. They may interact with subtle biological and chemical mechanisms which are unknown or thought to be of little importance. Even in known systems, the particular combination of events that occurs may not have been perceived by scientists. For example, Clarke (1977) describes a mishap with the Apollo 13 spacecraft. Although the system was completely known and every conceivable hazard prepared for, a completely unexpected event occurred which destroyed the capsule. Exposure may be thought sufficiently controlled so that little risk exists. Second, the wide uncontrollable variation in the exposure of individuals and the wide range of susceptibility implies that a considerable safety margin is necessary if standards for particular chemicals are set to minimize the maximum risk.

What may be an insignificant exposure to one individual may be a lethal dose to another if his genetic disposition or metabolic state causes potentiation of that chemical. Unfortunately, setting standards in this way also implies added expense to consumers of chemicals as increased pollution control costs are passed on from industry.

Finally, pollution that is insignificant in small doses becomes of paramount importance when contaminants are in
amounts beyond the capacity of the body or of the environment to cope. A long latent period and high volume production capability means that contaminants may exceed the capacity of the environment or body and irreversible damage may be done before a hazard is recognized. The environment may be overloaded and permeated before sufficient study on low level effects can be done to predict the consequences of higher levels. Extended protection for the human and external environment necessitates sufficient screening of chemicals before large scale manufacturing is permitted. Thus, either rapid tests must be designed or the period between initial testing availability and high volume production must be lengthened if protection against this danger is to be established.

2.3 ANALOGOUS CONSEQUENCES

Imputations of consequence by analogy is based on the premise that if two or more things agree in some respects the inference can be drawn that they will probably agree in others. Mechanisms to aid in the discovery and formulation of an analogous situation range from a simple application of common sense to the sophisticated statistical analysis of epidemiological studies or mathematical models.
2.3.1 Common Sense

Applications of common sense have occurred in the food industry. The Food Protection Committee (FPC) of the National Research Council have developed guidelines as an aid to determining the appropriate levels of chemicals in food (Schlegel, 1978). One of the criteria for determining insignificant levels is based on the occurrence of the chemical in traditional food. If that naturally occurring chemical is recognized as safe, then by analogy, the synthetic chemical is considered safe if consumed in quantities of the same order of magnitude. An example of such an application is the addition of glycerides to processed foods to improve texture and other characteristics. Based on average consumption of glycerides in traditional foods, the additional glycerides were judged to be an insignificant additional hazard (FPC, 1965).

2.3.2 Occupational Exposure

A second use of analogy is the comparison of inadvertent and occupational exposure with expected exposure of a population overall. By inference, an approximation of expected consequences can be determined. Because exposure is relatively high and continuous, ill effects often come to light in a more obvious way. Such was the case with coal dust leading to black lung disease in miners. Information on possible effects of those rarely exposed would be severely limited without such an analogy.
2.3.3 Epidemiology

Epidemiological studies involve the comparisons of groups who have been exposed to a substance with control groups who have not. They have been used with notable success to establish the link between cancer of the jaw and workers in the watch-making industry (Castle et al. 1925). They have also been used, although with less success, to correlate lung cancer with cigarette smoking. Such a method has the advantage of utilizing human subjects without the ethical constraints of deliberate exposure to dangerous chemicals. The major drawback is that epidemiological studies can only indicate a relationship. They cannot prove cause and effect. For example, if one were to study the relationship between foot size and success as a basketball player, one may conclude, from the high positive correlation, that a large foot contributes to basketball skills. However, this is an indirect relationship. The correlation may be better explained by the direct relationship between height and success in the game. Thus, in less obvious circumstances, it is clear that where the mechanism of action is not known, spurious relationships may be hypothesized. A simple correlation cannot prove a cause and effect relationship.

This weakness of epidemiology has led to acrimonious debate between the tobacco industry and advocates of heavy restrictions on cigarette sales as well as between the mining companies and advocates of more stringent safety and compensation status for certain miners (Doren, 1978).
McGarity (1979) points out that secondary drawbacks exist. Since epidemiological studies simply indicate the probability of a relationship, scientists must judge the point at which data is statistically significant. Judgment is also exercised in the designing of experiments and in choosing the control cohort.

These methodological problems and others, such as the difficulty in controlling for confounding, irrelevant events during the course of the study pose strong threats to validity. Meaningful extrapolation to other populations becomes dubious. Despite problems, Wienstein (1979), considers epidemiological studies to be the source of best evidence to establish an association between exposure to a substance and a particular human illness.

2.3.4 Extrapolation from Animal Tests

Tenuous analogies can be drawn between animal tests and predicted human consequences from similar exposure (Storer 1972) or prediction of chemical damage from data on the damage caused by an 'equivalent' amount of radiation (Environmental Mutagen Society, 1975). Both these analogies are more tenuous as a natural result of the decrease in similarity on which to base the analogy. There are wide differences in the physical, physiological and metabolic structure between various animal species and man. A carcinogenic response in an animal is not wholly analogous to a response in a human. Life spans are
different, intestinal flora are different and body functions are different (Environmental Mutagen Society, 1975). Thus animal tests cannot be directly extrapolated to man.

However, the range of expected results can be narrowed down. Crouch and Wilson (1979) have developed a method of comparison to allow extrapolation of consequences within a factor of ten as a good first approximation of expected effect. At least one notable exception exists, unfortunately, since arsenic (and possibly other heavy elements) were not detected by tests with rats, as highly toxic to man.

Animal tests, as a means of determining a toxicological risk to man have other problems. First, they can be very expensive. A common testing methodology in the US uses a minimum of 600 animals, takes up to three years and costs up to $500,000 (National Research Council (US), 1979). Second, to obtain a result with a practicable number of animals, proportionately larger doses of chemicals than man would normally be exposed to are used. Results may not be valid if dose response is not linear or if a detoxification mechanism is overwhelmed.

In addition to these and other problems there remains the theoretical problems of extrapolating results from lower animals to man. Although the National Research Council (US) (1979) feels that extrapolation using dose per body weight is a reasonable approach, other researchers suggest the alternative of proportionality of surface area is a more reliable approach. Thus, there is not agreement on the appropriate methodology.
2.3.5 Extrapolation from In Vitro Tests

In vitro (short term) tests constitute a rapid and inexpensive means to determine the consequences of exposure to chemicals. Generally, such tests are based on the detection of genetic mutation, damage, and growth transformations in microorganisms or cultured mammalian cells. For example, changes in DNA such as chromosome damage or mutations are known to be highly correlated with the ability to cause cancer (McCann et al., 1975; McCann and Ames, 1976; and Purchase et al., 1978).

Over eighty in vitro tests have been developed, often with special adaptations to increase their ability to detect potential carcinogens. By using batteries of tests, the sensitivity to carcinogens can be further increased to different types of mutations or other anomalies. A battery of tests is therefore, likely to detect potential carcinogens missed by a single test. Unfortunately, increasing the sensitivity increases the probability that non-carcinogens will be labeled carcinogenic by mistake since the specificity of the test is reduced.

These test systems have only a remote similarity to human systems. Therefore, their use is generally confined to preliminary screening.
2.3.6 Extrapolation from Radiation Data

The extensive data on radiation effects could be very useful in determining the potential effects of a new chemical on man. The Environmental Mutagen Society (1975) has developed the concept of a rem-equivalent-chemical (REC) which is the dose of a chemical over some period of time which produces the equivalent amount of damage as one rem of chronic radiation. It relies on the assumption that the ratio between chemical and radiation mutagenicity remains constant and linear which, when genetic and metabolic factors are incorporated, is unlikely. Like the extrapolation from animal tests it is quantitatively useful only as an approximation.

2.4 CHEMICAL BEHAVIOR

This section deals with the ability to predict the behaviors of chemicals in the environment from their chemical structure.

After release into the environment, a chemical becomes dispersed through all mediums: air, land and water. Because of the complexity of the environment, the behavior and concentration in any geosphere depends on both chemical and geosphere properties (National Academy of Science, 1975).
2.4.1 Atmospheric Interactions

The three main factors affecting entry into the air and transport of chemicals through it are vapour pressure, heat of vapourization and the partition coefficient between the atmosphere and another medium, and the characteristics of air flow (National Academy of Science, 1975). In order to predict the probable path and the fate of a chemical a knowledge of the rate of exchange between the atmosphere and other geospheres is essential. The vapour pressure (the maximum pressure a chemical would exert in the gas phase in a closed container (Porterfield, 1972) provides insight into the process necessary for evaluation. Using pesticides as an example, it is evident that vapour pressure values differ widely (Hamaker and Kerlinger, 1969). Values range from the extreme of gases (oxygen, carbon dioxide and sulphur dioxide) to the volatile organophosphates and carbamates (Parathion and Sevin with vapour pressures of 0.03 mm Hg and 0.005 mm Hg respectively) to the less volatile pesticides (Triazines have a vapour pressure of $10^{-6}$ to $10^{-9}$ mm Hg) and finally to the other extreme of those with negligible vapour pressure.

Any chemical with a vapour pressure can be in the atmosphere but the rate and the extent are mediated by other factors. Dust particles increase the entry rate by absorption of vapour to the greatly increased surface area while air currents interact with the partition coefficient to increase the rate of diffusion through the partition by decreasing the concentration (Hartly, 1969). An important factor influencing
the rate of chemical entry into the atmosphere from the soil is the pressure of moisture. The evaporation rate of many chemicals, for example DDT, is increased through co-distillation with water (Acree et al., 1963) so that loss from soil is accelerated when the soil is damp (Freed et al., 1962). Other factors mediating the influence of vapour pressure are temperature, humidity, pH and physical properties of the chemical.

Activity in the atmosphere is modified by general physical properties of the chemical molecule. Molecular weight (MW) tends to limit the dispersal of molecules in the atmosphere. Molecules over 200 to 300 MW tend to exist as aerosols rather than as random dispersions. Molecules, such as 2,5-dinitroanaline, which are made of a basic carbon framework with electronegative atoms like nitrogen, oxygen, fluorine or chlorine incorporated in the structure tend to have an electric dipole moment. That is, one end of the molecule is more negative than the other (Porterfield, 1972). This characteristic causes a configuration with a high degree of stability and tends to lower the volatility leading to less evaporation.

Another effect of the molecular dipole moments pointed out by the National Academy of Science is the effect on solubility. Polar solvents tend to dissolve other polar chemicals thus water, a polar solvent, dissolves polar substances like NaCl (table salt) an ionic crystal with strong charges, easily and covalent or metallic substances less so. This phenomenon leads to selective accumulation of polar and ionic substances in
aqueous clouds through absorption and dissolution. As well, the close proximity of the chemicals in this situation facilitates aqueous and heterogeneous chemistry resulting in reactions transforming the original constituents into something quite different.

Other chemical properties having atmospheric implications are crystal structure, light sensitivity, ring structures and multiple bonds (National Academy of Science, 1975). Crystal structure, for example, can have profound effects on weather since a substance with a structure similar to that of ice can be incorporated into snow and hail or can provide nucleus around which cloud droplets or ice form. This can lead to precipitation. Furthermore, many chemicals, depending on light sensitivity and structure are susceptible to photochemical oxidation sequences. Such chemicals, containing oxygen, hydrogen or halogens can interact with ultraviolet light (UV) to form smog. Other contributing chemicals are those with double bonds or aromatic and hetrocyclic rings or especially strained 3,4 or 7 member rings.

2.4.2 Aquatic Interaction

Many or the chemical activities in the atmosphere are shared by terrestrial and aquatic ecosystems as well. Of the many chemical characteristics affecting solubility, of prime importance in an aquatic system, the hydrophobic nature of many organic compounds causes a unique result. Besides the very low
solubility which can make accurate measurement difficult, some of the compounds are attracted to the air-water interface where they cluster into discrete particles (Bowman et al., 1959). As a result of this selective process, a marked accumulation of pesticide can occur at the surface.

Other factors affecting solubility and stability are pH and temperature. A decrease in pH can often lead to increased solubility: triazine solubility is an inverse function of pH (Ward and Weber, 1968). Temperature has the opposite effect. As temperature increases solubility increases.

As mentioned, the other major characteristics of chemicals such as polarity, MW and vapour pressure have a similar effect in water as in air.

2.4.3 Terrestrial Interaction

The National Academy of Science (1975) points out that the major influencing factors on chemicals in the soil are adsorption and leaching. Those chemicals which are strongly ionic such as inorganic salts or organic cations tend to be adsorbed onto clay soil through an exchange mechanism making them less mobile than neutral organics adsorbed from an aqueous solution through a physical process. Adsorption is inversely related to solubility and to leaching. As adsorption increases, leaching decreases.
2.4.4 Microbial Interaction

Microbial action on chemicals is probably the most important factor to consider in the aquatic and terrestrial geospheres and their interface. The importance is derived from the ability of microorganisms to cope with naturally occurring toxic compounds through synthesis and degradation. An anaerobic bacterium (Yamada and Tanomura, 1973) and a strain of fungus (Landner, 1971) for example, were shown to change inorganic mercury to methylmercury (a far more toxic form for humans). Of further importance is the ability of organisms to reduce or oxidize heavy metals to all valence states. The National Academy of Science (1975) uses the example of mercury detoxified from Hg$^{2+}$ to methyl and dimethyl mercury or to Hg$^{0}$ and methane. The implications of the ability to alter metals through their full valence range are ominous to man. The valence states have a significant effect on the toxicity of substances. As pointed out above, mercurous oxide has limited toxic potential whereas methyl mercury is very toxic in comparison.

The behavior of totally synthetic compounds may be more amenable to prediction because the ability of microorganisms to transform natural toxins comes from the selective pressure of exposure over many generations (National Academy of Science, 1975). Since the organisms have not been exposed to synthetic toxins, there is a strong chance that the microbes have not evolved an efficient means of degrading them. However, if a synthetic substance is an analogue of a natural metabolite, it
may be actively accumulated in organisms. In time, organisms can be expected to evolve the necessary enzymes and mechanisms to process synthetic toxins as well. An approximation of the time this would take may be possible by increasing mutation rates under invitro lab conditions to simulate the natural evolution on a compressed temporal scale (National Academy of Science, 1975).

Other factors relating to accumulation of synthetic chemicals are a high degree of lipid solubility causing the chemical to concentrate in fat and the tendency of metallic compounds to form organo-metallic complexes. These factors can increase the exposure of predators to toxic substances.

2.4.5 Prediction Capability

The National Academy of Science (1975, pp. 56-57) feels that the ability to predict chemical reactions in the environment is sufficiently developed now.

On the basis of existing knowledge, it is generally possible for microbiologists, biochemists and chemists working together to determine metabolic sequences for both natural and totally synthetic compounds and to identify those that may pose environmental problems.

A large assumption is implicit in their attitude. Current information must be available. Chemicals previously used for commercial purposes are probably familiar enough to scientists to predict their environmental rates and behaviors. However,
new, complex chemicals are produced at an astounding rate. Consequently, all scientists will not have sufficient information.

It is imperative, if full use is to be made of available expertise, that information be accessible. Necessary data would cover: oxidation; reduction; hydrolysis; alkylation and dealkylation; conjugation with metabolites such as amino acids, polypeptides or saccharides and the rates and extent of reactions (National Academy of Science, 1975). Also, basic characteristics of the chemical must be known: melting point; boiling point; decomposition temperature; flash point; physical state; vapour pressure; and crystalline form. Finally, for the monitoring and testing of micro amounts, absorption spectra for the various light wave frequencies must be known.

One further point must be made. Since commercial chemicals are not a single, pure chemical, impurities may have a significant impact on behaviour. The introduction of foreign matter through handling, storage or transportation, the residues of reactants and solvents and the products of side reactions are all probable contaminants of industrial chemicals. They may be more dangerous than the principle chemical. For example, tetrachloro-p-dibenzodioxin in the pesticide 2,4,5-T is far more toxic than the pesticide itself (Wilson, 1971). Thus, care must be taken to test both the chief chemical and its impurities.
2.5 CONCLUSIONS

A review of the foregoing analysis reveals that there seldom is complete information on any of the elements presented. Exposure is a useful criterion for a screening system when used in concert with other criteria. But, the analysis reveals the near impossibility of determining actual exposure accurately by measurement or calculation. Accidents, inadvertent exposure through misuse and environmental factors such as persistence tend to mitigate against such an approach. Also, the effect of the exposure can differ because of synergistic interactions or variations in personal susceptibility. Finally, the cost in time and dollars of obtaining detailed information may be prohibitive. The use of an exposure proxy, such as the ITC index, partially solves the problems. It is relatively inexpensive and straightforward to use. As well, necessary information is available. It does not, however, deal with the variation in individual sensitivity to chemicals.

The use of analogy as an aid to establishing priorities is of direct use in many cases. A direct examination of the effects of a naturally occurring chemical may yield significant information. Epidemiology and occupational exposure provide a check on chronic and acute hazard in such cases. However, in most cases such approaches are limited to feedback after exposure to new chemicals has occurred. In spite of their failings, animal and in vitro tests provide the main source of information on the chemical effects on living systems.
The National Academy of Science feels that it is possible to at least predict the major aspects of the environmental behavior of chemicals through structure and physical characteristics. The major factors affecting chemical behavior are strongly related to a chemical's attributes. For instance, the principal factors influencing chemicals in soil are adsorption and leaching which depend in turn on the solubility and charge of a chemical. Similar influencing factors in other geospheres depend on other characteristics. It is therefore important to obtain basic information about a particular chemical. The National Academy of Science suggests that necessary data should cover at least basic reactions and basic characteristics.

A rational approach to designing a screening system involves making the best use of information. To this end the following decision framework is discussed.

A major focus of concern should be the minimization of chemical hazard to man and environment within the constraints imposed by limited resources (or maximization of the net benefit if a cost/benefit approach is taken). The impact of a chemical is a function of two variables, exposure and consequences. Thus, an obvious candidate for regulation is a chemical with high exposure and disastrous consequences. Conversely, a chemical with low exposure and negligible consequences is of little interest. These cases are straightforward.

It is the cases that have insufficient information to clearly categorize a chemical that cause difficulty. An
appropriate strategy for these cases would be to examine the information that is available for indications of high exposure or high hazard. If, for example, a chemical is produced in large amounts, is widely distributed and is persistent, prudence dictates a close examination of health consequences. Similarly, a highly toxic chemical warrants further information about exposure.

In summing up, a screening system could be a weighted composite of the three approaches. A rational approach to control could involve an index for exposure: a high index would mean stricter testing for toxicity. A scheme for determining the effects of a chemical on living tissue would utilize animal and in vitro tests. Because of time and expense, preliminary screening for health effects may be done with in vitro tests which are cheaper and faster. A built-in bias (toward detection of carcinogens, for example) could reduce the chance of missing toxic chemicals. Those chemicals which test as toxic would be tested further.

Similarly, knowledge that a chemical is toxic would indicate the need for careful review of existing information and possibly further research to determine persistence or distribution etc.

Epidemiological studies could provide feedback on those potentially toxic chemicals tentatively cleared for large scale manufacture. This would allow a check on the accuracy of the screening system and of individual tests. Of course, chemicals whose structure indicated a potential hazard would require careful review as well.
The analysis has indicated the complexity of the two variables, exposure and consequences. To assess probable impact, the many aspects of each variable must be examined and weighed. Given the size and complexity of such a system, most chemicals cannot be dealt with by the use of a formal decision making model. Even though weights may be assigned to specified criteria to generate a formal decision model, knowledgeable scientists will be needed to integrate and interpret data derived from different sources and through different methodologies. This has two implications: one, an attempt to process large numbers of chemicals will necessarily require many trained scientists and decision makers who may not be readily available; two, an extensive information system will be needed to provide relevant data to aid in the decision process.

Another major factor to consider is the cost of control. Weinstein (1979) points out that the ITC, although putting great effort into establishing "reasoned" priorities has considered "control cost only implicitly at the end" (p. 371). Consideration must be given to establishing the economic worth of further information so that a rational decision about further research and other information costs can be made.
3. STANDARD SETTING

3.1 STANDARD SETTING APPROACHES

Once a candidate for control is chosen, the question of what standards to apply must be answered. Burton and Whyte (1978) note that it is through the design of standards that scientific evidence and public opinion are melded into laws and regulations. Various methods exist to guide the development of standards. Acceptance of such standards by both industry and the public is important.

Ultimately, any useful standard must be "acceptable" since public rejection may have profound effects. In our society rejection may range from political lobbying to law suits or civil disobedience. Such results are generally undesirable to a public decision maker.

Unfortunately, a problem becomes evident when an attempt is made to substantiate the elusive definition of acceptable. Lowrance (1976, p. 78), in searching for a functional meaning, quotes the US Congress Joint Committee on Atomic Energy.

'Acceptable' is used to mean such different things as (a) a conscious decision perhaps based on some balancing of good and bad or progress and risk, (b) a decision implying a comparison, possibly subjective, with hazards from other causes, these latter being 'acceptable' in turn in one of the senses given here, or perhaps just historically and possibly unconsciously, (c) the passive but substantive fact that nothing has been done to eliminate or curtail the thing deemed 'acceptable'.
Although failing to discover a circumscribed definition, Lowrance offers 'guides to acceptability' augmented with further 'considerations' which are in present use. These factors are utilized by decision makers in varying circumstances as an aid to choosing an appropriate standard. A comparative analysis of these alternative standard setting techniques follows. As a conceptual framework, the analysis will be roughly ordered between the two extremes: no risk and risk-benefit trade off.

3.1.1 The Delaney Principle

The Delaney principle, which has been applied to food, is the embodiment of the no-risk approach. Its essence is that "no additive shall be deemed safe if it is found ... after tests which are appropriate for the evaluation of the safety of food additives to induce cancer in man or animal" (Lowrance, 1976, p. 82).

Although it is superficially a useful tool for decision makers since it automatically bans carcinogenic additives from food, it has been invoked sparingly in actual practice. Its main effect seems to be as a guide, representing as it does, the spirit of the law which is to provide food at the lowest possible risk.

Food is accepted as a special case by decision makers and regulatory agencies. Three of the main elements that make it unique are the facts that exposure is universal, involuntary
and without alternatives (Upton, 1979). Given these factors, there is a strong public feeling that confidence in the quality and purity of food should be maintained even at high cost. However, the same status is not granted to water.

Implementing the Delaney principle is fraught with difficulty and contradiction. First, Lowrance points out that it applies only to carcinogenic food additives. Other toxic agents are excepted. Second, closer examination reveals that it requires 'appropriate' tests to indicate carcinogenicity. Third, it precludes the explicit use of cost-benefit judgments although trade-offs are made implicitly.

If the objective is to minimize hazard in food, why is the Delaney principle not applied generally, instead of only to carcinogenic food additives? One of the main arguments against a general application is that everything seems to have a little of everything else in it. As scientists develop micro-techniques that can detect and measure progressively smaller amounts it becomes infeasible to remove all known toxic chemicals that can be detected. The concept of purity stands only until a more sensitive detection technology leads to the discovery of infinitesimal amounts of contaminant in the food.

The second point mentioned questions the meaning of 'appropriate' tests. The wording, perhaps purposefully, leaves the meaning open to discussion, a reflection of limited knowledge in this area. At any rate, much uncertainty exists as to what is appropriate since many factors can influence the results of a test. Kraybill (1979) lists eleven such factors including route of administration, test species chosen,
influence of dose on metabolic pathways and contaminants in test chemicals. All these elements are thought to impinge on the assessment of carcinogenicity and judgment of its significance to man. With such a high level of uncertainty, just selection of the required test by a decision maker requires a significant level of effort.

Finally, Lowrance (1976, p. 83) quotes the President's Science Advisory Committee regarding the exclusion of cost-benefit trade-offs by the Delaney principle.

The rigid stipulations of the Delaney Clause, springing from presently inadequate biological knowledge, places the administrator in a very difficult position. He is not allowed, for example, to weigh any known benefits to human health, no matter how large, against the possible risks of cancer production, no matter how small.

Such a decision must be, in reality, dealt with in some manner, the Delaney Clause not withstanding. In order to contend with problems such as the use of nitrites in meat (they are necessary to reduce the risk of botulism from preserved meat) the Delaney principle must be subverted. Nitrites in combination with certain amines become nitrosamines (Lijinsky and Epstein, 1970) a known carcinogen, so the dilemma exists. A trade-off must be made between the risk of cancer and the risk of botulism. The fact that nitrites are still used turns on the fine point of legal interpretation: The chemical is deemed not to be a carcinogen at the time of addition and it is therefore permissible (Kessler, 1977). Other chemicals, possibly carcinogenic, remain in food by virtue of being ignored
Contamination of water is among the other complications that exist. Water meeting public health standards in other respects does not meet the requirements of the Delaney clause when added to food during processing. This anomaly arises because of the presence of complex organic compounds which are carcinogenic in their own right (Kraybill, 1979) or become so when combined with the chlorine added to reduce bacterial content. Thus, the context in which a carcinogen is found affects the application of the Delaney clause.

Also, some risk/benefit trade-off may be possible, although a heterogeneous population may not have a threshold below which a contaminant would not cause detrimental effects (Calabrese, 1978) it is possible that individuals do. Stokinger (1972) shows that the body has enzymes which can detoxify some foreign materials. Urbach (1975) lists three repair mechanisms that can reduce or remove the effect of DNA damage. These facts support Cornfield (1977) who maintains that the existence of a threshold depends on whether or not detoxification and repair mechanisms become saturated, a level which differs from person to person. This may imply that some small amount of toxic contaminant may be safely consumed by most people, allowing some latitude for cost-benefit trade-offs.

In summary, the Delaney clause appears to be a comfortable myth, unsubstantive in form, of the type postulated by Zeckhauser (1975) confirming the idea that life cannot be traded off for other considerations at any cost. This may be changing. Smith (1979b, p. 1221) reports that a majority of the
Institute of Medicine and National Academy of Science panel recommends that "health risks of a hazardous food be balanced against the economic benefits to food supplies and others". Even the minority dissenters tend to see it more as a symbol of an ideal to be strived for (Abramson, 1979) than as a realistic principle since it was introduced when detection of minute quantities was not possible. Thus, as a standard-setting tool it provides a symbolic ideal rather than a scientific reality. However, in that sense, it may serve as a guide for decision and a restraint for hazardous actions.

3.1.2 No Detectable Adverse Effect

The next three standard setting guides that Lowrance suggests have been linked together for purposes of analysis on the basis of their similarity. They are: (1) no detectable adverse effect, (2) toxicologically insignificant level, and (3) the threshold principle. These three guides admit some specific level of a toxic substance but accept that level as benign. This contrasts with the no-risk approach of the Delaney clause used as a benchmark.

The 'no detectable adverse effect' approach is liberally applied at present. For example, the Union of Soviet Socialist Republics uses such a principle in setting their maximum permissible concentrations (MPC) (Roschin and Timofeevaskaya, 1975 p. 32) for occupational exposure. The definition of MPC is given as:

the concentrations which, with a workday of not more than 8 hours through the whole of the service record, do not cause any disease or have any other adverse effects on the health status of the workers that could be detected by the modern methods of investigation either directly in the course of work or at later dates.

To illustrate some of the difficulties in establishing a level of no detectable adverse effect it is noted that there is no consensus on what the level is. The Soviet MPC's are generally lower than the US threshold limit values (TLV) applied to the same chemicals, a major reason being that most TLV's are weighted mean concentrations rather than maximum single time exposures (Roschin and Timofeevskaya, 1975). Another major consideration is the sensitivity of those people tested. Naturally, if those most sensitive to the chemical are not tested, the permissible level will be higher than it would be otherwise, allowing a small percentage of workers to suffer adverse effects. These points show that although the principle may be useful, in operationalizing it, factors such as who is tested, the type of exposure (average versus maximum single dose) and the state of development of the testing technology employed can influence the standard chosen.
3.1.3 Toxicologically Insignificant Levels

Many of the criticisms which apply to the above guide are applicable to the principle of 'toxicologically insignificant levels'. Lowrance comments that this approach is sometimes taken with some types of food chemicals. Administrative discretion would be exercised in setting the toxicologically insignificant levels. Chemicals subject to this regulation might be: those that have existed commercially for an adequate period of time without evidence of hazard; those about which little is known but whose structure has certain characteristics. Such an approach considers lack of negative information as an indication of a lack of negative effects. In the absence of knowledge about a mechanism of action for a chemical this assumption may be dangerous. Other criticisms could revolve around the state of the technology, the effort expended on looking for toxic effects, the time elapsed for toxic effects to appear and the arbitrariness of the standard set.

3.1.4 The Threshold Principle

One of the most controversial standard setting techniques is the last of this group of three, the 'threshold principle'. As pointed out "The threshold hypothesis assumes that there is a no-effect dose of carcinogen below which induction of cancer cannot occur or occurs with extremely low probability." (Maugh II, 1978, p. 37). As pointed out earlier and reiterated by
Lowrance (1976), the determination of a threshold for the individual for certain substances seems possible. Indeed, Kraybill (1979) presents instances where substances present naturally in metabolic cycles of the body become toxic at higher levels. However, because of the extreme variability of a general population (Calabrese, 1978), thresholds for carcinogens and other toxic chemicals are not likely to be a useful standard setting device.

Infact, using standard animal tests, which are at present the accepted method of 'proving' carcinogenicity, it may be impossible to resolve the threshold question. The experimental and human error is too large to make such studies useful for defining the existence or absence of a threshold by statistical means (Maugh II, 1978).

3.1.5 Standard of Usage

The next standard setting technique to be analyzed is 'custom of usage'. This technique is of major importance to the flavour industry (Schlegel, 1978). It is based on the principle that if a substance is consumed in traditional food whose safety is confirmed, then an identical synthetic substance can be consumed safely in other foods as long as ingestion remains on the same order of magnitude. (The FDA reviewed the hundreds of food additives that it established as 'generally recognized as safe' in 1958 but aside from cyclamate had found no toxic substances (Spiher, 1974)). There are two main points to be
made about this approach. It should be subject to periodic review (Lowrance, 1976) and although no evidence has yet come to light, there remains the potential for a synthetic chemical to be hazardous. This may result from a contaminant produced during the production process as occurred in the manufacture of the fire retardant tris-bp and its impurity 1,2-dibromo-2-chloropropane a proven carcinogen in rats and mice. Strawberry aldehyde flavouring was also found to contain an impurity (suspected to be the cause of paralysis of the hind limbs of rats) (Butterworth, 1978).

3.1.6 Practical Constraints

Next in order of increasing acceptance of risk trade-offs is Lowrance's guide: best available practice, highest practicable protection and lowest practicable exposure. Here again the utility of this approach varies with the context of its use. In the context of food where the aim is to reduce risk to a minimal amount with little regard to cost, its use has substantial value. Its adoption, however, must integrate with the enforcement technology and resources available since there is little use in promulgating laws when infractions cannot be detected. (An exception to this may occur if the objective of the decision maker is to decrease public pressure by the appearance of action without actually attempting to change the situation.) its main drawback in this instance is that definitions of 'best' and 'practicable' are vague guides for an
administrator (Lowrance, 1976).

Such vagueness in legislation leaves many questions open to interpretation. Burton and Whyte (1978, p. 168) list four such questions.

1. What factors are to be included in the assessment?
2. From whose point of view is practicality to be defined?
3. Who defines what is practicable?
4. Does the 'best practicable means' include the extreme case of prohibition of the cause in order to reduce pollution to zero?

Thus, this approach places the burden of interpretation on to the administrator who is then forced to make political decisions. Companies disagreeing with the ruling may go to the courts for clarification is no other appeal system is available.

3.1.7 Degree of Necessity of Benefit

Reflection on 'degree of necessity of benefit' reveals that in the context of environmental pollution, explicit evaluation of risk/benefit trade-offs is acknowledged. However, with food, the connotation of efficacy is added. The Environmental Mutagen Society (1970, p. 509) states:
given a reasonable calculation of the genetic hazard posed by an environmental mutagen, it then becomes necessary to consider how acceptable such a risk will be to the population at large. Guiding principle in all cases should be that no risk whatsoever is acceptable when the mutagenic compound presents no clear benefits, or when an alternative nonmutagenic compound is available.

Lowrance (1976) gives an example of the application of the principle relative to DDT. William Ruckelshaw of the EPA reviewed the benefits and costs of DDT and concluded that costs out weighed benefits with the existence of other "equally effective pesticides available" (Lowrance, 1976, p. 77) playing a significant role in the decision.

With regard to food, in addition to meeting the requirements of safety, the additive must also be efficacious, less toxic, improve supply or nutritive value, or decrease cost.

This criterium at last offers the decision maker a sharp delineation of what is acceptable and what isn't. Unfortunately, few chemicals are so obliging as to fall within this narrow scope.

3.1.8 Reasonableness

'Reasonableness' is called by Lowrance (1976, p. 79) "the most commonly cited and most unimpeachable principle in safety judgments". This, with the last of Lowrance's guides to acceptability 'prevailing professional practice' is characterized by serious weakness. Lowrance points out that
reasonableness may differ considerably with the point of view of those deciding. What is reasonable to industry may not be reasonable to a community or a union. Also, such factors as ignorance, familiarity, age and the necessity of taking the risk can influence reasonableness (National Commission on Product Safety, 1970). Thus, from the point of view of a decision maker, this guide has little validity.

3.1.9 Prevailing Professional Practice

The prevailing professional practice guide suffers from the lack of a rational basis. Although it is in growing use, unless the soundness of present practice is evaluated and justified, such acceptance of conventional wisdom is questionable (Lowrance, 1976). In fact a tendency may exist to restrain from upgrading standards if excess reliance is placed on this approach since the support traditionally provided by employing a common practice is lost if innovative methods are introduced. Its main appeal seems to be in the sense of process that established procedures bring about. This may be as important as efficiency to a decision maker. Zeckhauser (1975) asserts that it is sometimes as important how you do something as what you do. Decision makers sometimes prefer a procedure that can be justified and explained rather than a more efficient but esoteric approach whose methodology is not obvious (Slovic et al., 1975).
3.2 MODIFIERS OF STANDARD SETTING APPROACHES

The former standard setting techniques represent some of the major approaches that have been used. Decisions about acceptable levels may be made on the basis of these methods alone but usually the choice of a technique and the final determination of the level is modified by what Lowrance (1976, p. 86) terms "an array of considerations". These represent in part a manifestation of people's perception of risk which varies with the attendant circumstances and in part a measure of the extent and probability of the consequences of a potential hazard. Although these factors are known to modify the standard setting techniques the amount of their effect and their direction is sometimes uncertain. For example, the probability of an event, perhaps a disaster, is often judged according to our ability to recall a similar event. However, Newell and Simon (1972) point out that our ability to assimilate conceptual data is limited by the extent of our short term memory and the speed at which long term memory is laid down. Thus, when judging an improbable event we may overestimate the probability of its occurrence because the news media has recently brought it to our attention. Slovic et al. (1975) labels this availability bias. Is sometimes reversed, perhaps because of cultural bias. A study comparing Austrian perception with Canadian perception of risk showed that the Austrians tended to increase their perception of probability of events they could not remember while Canadians decreased their perception of probability as memory of the experience faded
3.2.1 Voluntary Versus Involuntary Risk

The first consideration introduced by Lowrance is the concept of involuntary or voluntary risk. Starr (1969, 1972) asserts that risk assumed voluntarily is deemed more acceptable than risk assumed involuntarily. He gives the example of public participation in highly hazardous sports and pastimes contrasting with public resistance to the nuclear hazards which are calculated to be less risky.

The concept of voluntary and involuntary risk is more complex than is first apparent. Rowe (1977) recognizes at least three important elements: "(a) equity of risk and benefit distribution, (b) the avoidability of risk and availability of alternatives and (c) the manner in which risk is imposed on the risk taker" (p. 119). In examining the equitableness of risk he contends that for a risk to be voluntary the risk taker must be the recipient of both risk and benefit. If exposure to risk brings no concomitant benefit, allowing only the alternative of flight to avoid or reduce risk, then it is neither equitable nor voluntary. In addition, the extent of knowledge available to the risk taker modifies the situation. If a person at risk does not have sufficient information about the amount of risk exposure, then even if benefit is received, the risk is inequitable and involuntary since no means to balance risk and benefit exists. The lack of information may result from
deliberate withholding by an informed (possibly exploitative party) or lack of interest in available information on the part of the risk taker. Howe, in explaining the significance of the manner in which risk is imposed, differentiates between self-imposed risk and externally imposed risk. In some cases inequitable risk can be self-imposed such as the case of a person who risks injury to save a life. Externally imposed risk can arise by fiat (e.g. compulsory military service), by natural causes (e.g. earthquakes) or other causes. The last element posed by Rowe and by Lowrance (1976) is the availability of alternatives and the avoidance of risk. In determining if a risk is voluntary the presence of viable alternatives is critical. In addition to flight from risk, alternatives with less risk even at higher cost must be available.

Thus, all these factors act to characterize voluntary and involuntary risk. Rowe contents that when a risk taker is informed and alternatives exist, risk, whether self-imposed or equitable and endogenously imposed is voluntary.

3.2.2 Temporal Distribution of Risk

The second consideration introduced by Lowrance is the temporal distribution of risk. Fischhoff et al. (1978) found that perception of risk seemed less when, among other factors, consequences were immediate. This contrasts with the findings of Rowe (1977) who takes the view that risk is discounted over
time. That is, the further away in time the consequences are the greater is the discount effect. An illustration is young people's penchant for smoking, knowing that the consequences will not be manifest for many years. The discrepancy may be at least partially explained by the building of anxiety about the consequences once a risk is taken. Zeckhauser (1975) speculates that anxiety plays a large part in risk perception. The longer the time between exposure and consequences the greater the anxiety can become. However, the large amount of apparent discounting behavior needs further examination and clarification.

3.2.3 The Certainty of Risk

The next consideration involves the extent of our knowledge about the certainty of risk. An example of this is the increased perception the public has of new technologies e.g. nuclear electric plants versus bicycles. Old risks are often perceived as less than unfamiliar new ones even though the new risk may be statistically less. Fischhoff et al. (1978) found familiarity with the risk to be one of the major factors influencing perception of risk.
3.2.4 Necessity of Exposure

An adaptive coping mechanism may operate in conjunction with this next consideration, necessity of exposure. Otway and Pahner (1976) point out that the public often exhibits dichotomization in its behavior when excessive risk is perceived. One action is to withdraw and ignore the threat. The other is to form interest groups generally with the intent of removing the source of the risk. Withdrawal behavior may be appropriate when risk is unavoidable. Rowe (1977) supports this contention with observations of man's ability to rationalize when confronted with the inescapable consequences of war and terminal disease. The perception of consequences is reduced to a manageable size through the coping mechanism.

3.2.5 Occupational and Non-Occupational Risk

The divergence between occupational and non-occupational exposure to hazard has been justified on the grounds that the extra risk is paid for (Lowrance, 1976). Indeed, many workers incurring high risks are paid large amounts e.g. 'high-steel' workers on the steel frame of skyscrapers or daredevil performers performing improbable feats. Unfortunately, the economics of the work place often encourage poorer workers to accept high risk for low pay. Economic theory suggests that the risk rejected by the rich is accepted by the poor because their marginal utility for the benefit is much higher. Empirical studies show that the job risk a worker will accept is
negatively related to wealth and supports the concept of increased pay for increased risk (Viscusi, 1978).

The USSR states their intention to equalize occupational and common public exposure (Roschin and Timofeevkaya, 1975) but even with the best of intentions, the extent and complexity of occupational environments combined with traditional attitudes means that attainment of such a goal is improbable in the foreseeable future.

3.2.6 Common Versus Dread Risk

When the comparison between common and dread hazards are considered the influence of perception becomes of major importance. News media build-up of particularly terrible accidents or feared diseases like cancer can cause resources to be expended out of proportion to its actual benefit to society. As Lowrance (1976) observes, this inefficiency means that hazards more efficiently reduced go unattended resulting in an overall risk that is unnecessarily high. Cardiovascular diseases take more lives than cancer (National Center for Health Statistics (US), 1979). But cancer is often perceived as being the more hazardous and therefore receives more attention. The perception of dread hazards as having greater risk can seriously skew our approach to risk management.
3.2.7 Varying Susceptibility to Risks

The sensitivity of the persons affected is a factor particularly important when considering standards for toxic agents. As pointed out previously and supported by Lowrance (1976), the variability of a population makes it virtually impossible to protect everyone. Calabrese (1978) states that sensitivity is modified by exotic factors like blood disorders (e.g., Methemoglobinemia), homeostatic-regulatory disorders (e.g., Cystinuria) and magnesium deficiency, and by such common factors as age, sex and living habits.

3.2.8 Chemical Propensity for Misuse

Other considerations such as the propensity for misuse and the reversibility of the consequences can help to arrive at an acceptable standard. Some of the points discussed by Lowrance include the amount of extra protection that must be built-in for the few that might misuse a product compared to the cost imposed on the rest of society. Flame-retardants in fabrics, for example, may protect people smoking in their beds from fire at the expense of exploiting others' sensitivity to cancer. Blum and Ames (1977) have shown that a major fire retardant in fabric is carcinogenic to mice. Here is a situation in which two life threatening forces must be balanced. Must flame retardants expose others to the risk of cancer to protect those who choose to abuse fire in their homes? How far should such a trade-off go?
3.2.9 Reversibility of Effects

In examining the potential hazard from a chemical, the reversibility of its effects and its persistence are of major interest. To illustrate a worst case, suppose a chemical was utilized in large quantities in a way that allowed dispersion throughout the environment. If the chemical were found later to cause irreversible effects, e.g., cancer, and was persistent, a double bind would exist. Such a chemical would not only cause irreparable harm by would be actively present for generations after its use has been discontinued. Such a situation was feared with DDT (Lowrance, 1976). Because of its great persistence this ubiquitous chemical was severely restricted on the basis of merely suspected deleterious long term effects. Decision makers felt that the consequences would be catastrophic if DDT caused toxic effects and judged the risk too great in light of the availability of suitable substitutes. On the other hand, a situation in which a widely used chemical was transient in nature would likely leave decision makers more amenable to controlled use. In this case it is clear that if post market monitoring revealed chronic effects, removal of the chemical from the market would constitute effective immediate control not possible in the case of a persistent chemical. Thus, the threat of irreversible damage perpetuated by a persistent chemical must be considered.

A second view of reversibility considers acute effects. In this case reversibility can be effectively coupled with the potential for misuse. An agent which may cause an ailment which
is passing or treatable may be marketed with less stringent standards and with greater potential for misuse than an agent causing permanent harm.

3.3 CONCLUSIONS

All of these considerations and others such as people's cognizance of a hazard and the familiarity of the technology of a hazard, have a sense of scale in them. At one end of the scale a hazard is unacceptable but, at the other, it is likely to be accepted. Decision makers try to assess the point on the scale at which a hazard is perceived as acceptable. This point often has little connection with the actual risk of any given hazard because of the influence of a variety of psychological and physiological constraints which distort perception. Methodology to establish the point of acceptance is currently being researched. Two of the approaches used are derived from historical behavior (Starr, 1969) and from a survey of present preferences (Slovic et al., 1975).

Other influencing factors can exist. To illustrate, the evolution of the US Public Health Service water standards will be examined. Borchard and Walton (1971) point out that the composition of the advisory body affects the substantive nature of the recommendation. Personal limitations and views of the participants often dictate the outcome of a meeting. Borchard and Walton (1971, p. 17) comment on one of the first committees to set water quality standards.
It is also evident that the recommended and accepted standards were limited to the bacteriological quality only because the commissioners had been unable to agree on specific physical and chemical requirements.

A second factor influencing what standards are set and at what level, is the simple fact of awareness of a hazard. For example, standards for lead were set very early while others were included later as scientists became cognizant of a new threat and gathered enough information to initiate action. This awareness of risk is tied directly to technology.

Technology is important in two respects. First, the technology for reproduceable and sensitive testing must be available. If the standard is more rigorous than can be reliably tested by current techniques then the standard is useless. Second, in some cases, water in particular, the necessary technology to meet stringent standards was simply not available. Here again it was not practicable to set standards at a lower level than could be met by the industry since the water was needed. The answer was to let standards become progressively more stringent as technology was developed and the industry became more sophisticated. Such a strategy is still being implemented with time limits being imposed to encourage the use of the best available technology (Environment Reporter, 1978).

A third influence is the logistics of testing. It may not be possible to test for every potential contaminant. Borchard and Walton point out that when bacterial levels in water were being developed it was not feasible to test for the presence of
every organism. The strategy finally adopted was to use the presence of the most numerous, robust organism as an indicator. If these organisms were not detected it was assumed that the other more virulent but labile organisms were also absent. Such a strategy may work for chemicals also if a production process always produces a certain group of chemicals together so that a reliable indicator exists. In any case, with the multitude of different chemicals present in water, it is not possible to test for all of them that may be harmful.

Finally, reactions to a standard must be considered. The reaction of the public and the industry are important. Public reaction to regulations intended to protect it may, in fact, increase the risk to which they are exposed. The construction of dams to control flood waters is an example of such an occurrence. Since the dam was perceived by inhabitants of the flood plain to control the water and reduce risk, population and development on the flood plain increased. When a major flood, beyond the capacity of the dam occurs, the loss of life and property will be larger than the potential loss before the construction of the dam (Slovic et al., 1975). If an increased sense of safety leads to increased public use or consumption of a hazardous product, a standard may cost more than it benefits society.

Industry actions can also negate the purpose of a standard. Borchard and Walton (1971) point out that one of the factors considered in the setting of water quality standards was industry's reaction to it. The fear was that a standard limiting pollution to amounts below a certain level would cause
industry to just meet the maximum level allowed, slowing efforts to reduce contamination below that level. Present day experience shows that this sometimes occurs. Larger, more established firms with, perhaps, their reputations in mind, tend to meet and exceed minimal requirements so that company standards may be more rigorous than government requirements (John Wessel, FDA, 1979). However, smaller firms, with a more tenuous existence, have less to lose and may tend to just meet government standards.

Many factors, considerations and methods impinge on standard setting decisions. These include: the people setting the standards as well as the beneficiaries, the technology for detecting transgressions of standards and the technology for complying to them, and the many moral and philosophical approaches to establishing an operating principle. Some provide more guidance than others but most serve simply to increase awareness of the ramifications of any particular decision made.

Few of the approaches and modifiers are definite administrative aids to the control of toxic chemicals. Modern analytical methods have challenged the effectiveness of the Delaney principle and turned it into only a useful myth. The validity of other approaches such as 'no detectable adverse effect' and 'toxicologically insignificant levels', which depend on technology, are being challenged as well. Often, what is acceptable in one country is not acceptable in another. In fact, with the exception of 'degree of necessity of benefit' and perhaps, 'reversibility of effects', which provide fairly objective guidelines, all of the approaches and modifiers rely
If 'judgment' is the only useful method to combine scientific knowledge of chemical hazard with public opinions of tolerable levels of hazard, strategies to ensure an acceptable judgment should be implemented.

A rational approach could utilize risk/benefit methodology. The end result could be the reduction of overall risk and increased benefits. Unfortunately, the methodology necessary to apply risk/benefit analysis to questions involving human morbidity and mortality is not fully developed. Public misperceptions caused by factors such as temporal distribution, certainty, and dreadness of risk make it difficult to define the elements of risk/benefit analysis. For example, what discount rate would make a death in the future equal to a death at present? Should a lingering death by cancer have the same value as a sudden fatal accident? These deficiencies prevent a total application of this method of analysis but risk/benefit analysis may still be used as a guide to aid rational decision making.

A second approach to standard setting emphasises the need for a process to assist the judgment procedure. The objective of the process would be the accumulation of as much of the relevant information as possible as an aid to rationalizing decisions. An important consideration here is the cost of regulation versus the benefits. A full study may not be possible, however, even a partial examination of the costs and benefits of various methods of control may be helpful in choosing the best available approach. Submissions from
industry, from the public and from government agencies would be sought. The accumulation of information would ensure at least that decision makers were exposed to relevant data. An independent body, acceptable to the three participating sectors could review appeals where participants were not satisfied with an original decision.

The success of such a process would depend on the availability of information to the participants. Organizations already exist to present industry's point of view (e.g. The Canadian Chemical Producers' Association and The Manufacturers' of Chemical Specialties Association). Such associations have access to industry's information and the resources to argue a case. The public, having more diffuse interests, has more difficulty in assembling the resources necessary to gather information or to present a case. The success of this consultative process therefore, would require government assistance. Both information and financial help may be required.
4. INFORMATION SYSTEMS

4.1 INFORMATION SYSTEMS

4.1.1 Necessity

The foregoing analysis indicates that decisions concerning the regulation of toxic chemicals requires access to a structured and efficient data base. Economical information development and access requires the creation of an appropriate information system.

The problem facing chemical information systems is often not a lack of information but rather a lack of the right information. Burton and Whyte (1979) point out that we are being overwhelmed by data and that what is needed is a method of choosing pertinent information from the glut of irrelevant data.

The word "information" is used rather loosely as a synonym for data. However, strictly speaking, data are not information until a user has located and assimilated them. In many cases, potential users are not even aware of the existence of data. Adams (1978) points out that not only are potential users not aware of the 'universe' of data but they cannot locate specific data within the 'universe'.

It seems this is not only a contemporary problem. Fifty-two years ago scientists were lamenting the lack of an efficient
The precise extent to which research workers are wasting energy repeating experiments that have already been made is difficult to estimate; but those who have given much attention to the study of the literature of their special subjects are aware that the proportion of labour which is wasted for lack of information on previous work is very high. ... perhaps it is less well perceived that the same proportion of useful work is published only to be buried out of sight. ... Attention should be concentrated on the indexing of recorded information so that hard won data may be found at need and play their part as a basis for further progress.

It is obvious that duplication and inaccessibility of data are expensive in terms of time, money and lost opportunity. The existing multitude of data sources have many faults which contribute to that excessive expense. Data are often stored in information systems which are incompatible in their access methodology. Also, different systems were built to meet different needs. Therefore, no common nomenclature is used. Chemicals are stored under different names and, indeed, in completely different ways. For example, chemicals may be stored according to chemical structure in contrast to storage by commercial or common name (TSSC, 1979). This heterogeneity makes efficient data exchange very difficult.

There are important social consequences of inefficient data systems as well. For example, it is usual in Canada for the Department of National Health and Welfare to alert physicians to food and drug problems. This has not carried over to the dissemination of information about carcinomas of
chemical origin (Science Council of Canada, 1977) in this case, recent data linked vinyl chloride to a specific type of liver cancer, yet the Department of National Health and Welfare failed to alert pathologists to these findings. Given this information, it is possible that much could have been done to reduce the vinyl chloride hazard to Canadians.

Information dissemination is an important tool to combat such hazards. The latent and subtle effects of some chemicals requires a comprehensive data base as one of the few effective means of detecting and distributing information to control such hazards as vinyl chloride. Data from medical research, workers compensation, occupational settings and various applicable provincial agencies must be known to exist and be accessible to other relevant users if it is to be exploited to its potential. A properly programmed and efficient data system could be an important and significant step toward such a goal.

Efficient chemical data systems can offer many advantages to government and private sectors. Reduced duplication of research and data reporting save time and money. Not only is information available faster, but in some cases, uncertainty can be reduced and new ideas stimulated by the new combinations and associations possible through computer use (TSSC, 1979). Information systems could do for scientists and regulators what the Polaroid camera system did for photographers. It could decrease the time spent on research and allow effort and creativity to focus on synthesizing and developing innovative ideas.

International cooperation can improve information
dissemination and hazard detection by increasing the utilization of present information. Use of computers to search and cross-reference the expanded data base should prove useful to private and public agencies both nationally and internationally.

Various methods of chemical data compilation, storage and retrieval have been tried. These systems, ranging from standard manual methods to sophisticated computer models (some even able to translate data from foreign languages (Dubois, 1979)) are designed to minimize certain problems and maximize certain advantages to a particular user. Depending on the user's needs, parameters such as access methods, cost, speed of retrieval, type of information and system capacity can be adjusted. Three example models in various stages of development will be outlined and their common and unique problems discussed to illustrate the present state of the information systems field.

4.1.2 Systems Models

Port (1978) outlines three information systems as examples, describing methods of access, capacity, potential users and information handled.
The national system has the acronym DESCNET standing for Network Of Data On Environmentally Significant Chemicals. It was originally designed by the Department of the Environment of the UK to provide the government and others with information on chemicals. The structure resembles a spider's web in that it is organized as a network around a centre. The peripheral nodes store data on chemicals in a common format to facilitate information exchange with each other and with other information systems. The centre would act as a reference for sources and questions. A pilot project has been initiated to determine answers to questions of feasibility and of the needs of users.

The European system described by Port (1978) is being developed at the Joint Research Centre of the European Communities (Norager et al., 1978). Its name, ECDIN is the acronym for European Chemicals Data and Information Network. The information system can be visualized more as a spoked wheel than as a network since it stores its data in a single data bank at the hub of the wheel. Users with compatible computer terminals will have access through the EURONET which links users through phone lines at post offices.

Data on about 30,000 chemicals will be segmented into ten categories of information on each chemical and each category will be divided further into fields and subfields to a total of 200 properties. Each will be retrievable separately. The
categories include scientific information on structure and properties as well as production information such as use, transportation methods and dispersion in the environment. The design of the data base is such that simple information such as solubility can be retrieved or a sophisticated retrieval program called ADABAS can oversee the retrieval of cross-referenced information such as a breakdown of chemicals that: (1) are pesticides; (2) are found in milk and; (3) are carcinogenic to rats (Port, 1978).

As part of the pilot project a portion of the Registry of Toxic Effects of Chemical Substances data from NIOSH (National Institute of Occupational Safety and Health) was incorporated into the data base (Norager et al., 1978). The data on the approximately 5000 chemicals (Johnson, 1978) were taken at face value from the Registry: their integrity unquestioned. "of necessity we rely on editing provided by the scientific community before publishing." (Norager et al., 1978, p.135).

International

The international information system model described by Port (1978) is under the auspice of the United Nations Environmental Program (UNEP) and is tied into the UNEP Global Monitoring System (O'Sullivan, 1976). The organizational structure of IRPTC (International Registry of Potentially Toxic

1. The question of validity and cross certification of data and inferences is addressed later in this thesis.
Chemicals) is a network with a centre but it has more emphasis on secondary data bases than the UK DESCNET. Although the centre at Geneva will carry out administrative duties such as providing referrals and answering questions as well as acting as a computer data storage centre, the peripheral nodes of the network named 'National Correspondents' will be encouraged to build up a selective semi-autonomous data base. This will develop a capacity to answer questions pertinent to a particular geographic area (Huismans, 1978) without going through the centre at Geneva.

IRPTC will cover a geographically larger area and have a somewhat broader mandate than most other information systems. Users will be globally distributed and will include such institutes as the World Health Organization and the International Agency for Research on Cancer as well as divers member countries. As a result of this width and breadth IRPTC has unique goals and constraints. Huismans (1978) points out four functional objectives of IRPTC.

IRPTC will not attempt to centralize all data but rather may refer requests for information to the appropriate National Correspondent. Thus, a National Correspondent may participate in two ways: the data base may be stored centrally at the Program Activity Centre as has occurred with data from NIOSH in the US; information may be released directly from individual files on request. In any case, an additional function of each National Correspondent will be to search out required information from his specific sector and to make it available throughout the network.
A second function of IRPTC takes advantage of the extensiveness of the network to in order to reveal global information deficiencies in toxic chemical data and to direct research to reduce the gaps. This will be accomplished through the cooperation and collaboration of various programs worldwide.

The third function will revolve around the identification of potential chemical hazards. Here the agencies will utilize the network to achieve a fan-out of data on current chemical hazards and controls of global interest. Members will be alerted to current chemical risks throughout the world and to steps taken to control such risks.

Finally, Huismans (1978) expects that IRPTC will disseminate data on the regulatory approaches and policies of member countries by whatever means seem appropriate. This might range from regular bulletins for routine information to special alerts for more urgent information.

According to Port (1975) the actual chemical data base is expected to be smaller than the 30,000 chemical capacity of ECDIN. The organization of the files also will be slightly different. They will be comprised of only eight categories divided into 140 attributes. The information will include chemical characteristics (molecular formula, molecular weight and toxic dose) and regulatory information (reviews, standards and regulations) (Huismans, 1978). To aid identification and cross-referencing of chemicals, approximately 80,000 synonyms will be stored in the files.
Other Systems

Other systems have been developed in response to the specific needs of a particular user. The US Council on Environmental Quality has formed CSIN (Chemical Substances Information Network) (TSSC, 1979). It will have a large capacity (about 500,000 chemicals) and is expected to serve federal agencies as well as private groups in industry and public interest groups. Software, management and funding are some of the areas with questions pending.

The US has several other systems which provide specialized data bases. Merian (1978) mentions: MEDLABS, TOXLINE, CHEMLINE and TOXBANK administered by the National Library of Medicine; data banks maintained by NIOSH, CPSC (Consumer Product Safety Commission) and EMIC (Environmental Mutagens Information Centre); and also the extensive files of the EPA.

Other existing systems are the German UMPLIS (Umweltplanungsinformationssystem), DABAWAS (Dataenbank fur wassergefährdende Stoffe) and DIMI-systems (Deutsches Institut fur medizinische Dokumentation und Information) (Merian, 1978).

These are but a few of the many systems in the chemical information system field. As mentioned, most are not compatible with others and so represent not only duplication of effort but also limited access to unique data. However, rationalizing such systems presents several problem areas.
4.1.3 Problem Areas

Many of the advantages and disadvantages of computerized data systems are the same as those brought by a computer to any system. A computer can scan a tremendous amount of data in a short time with greater accuracy than a manual searcher can. However, the computer adage 'garbage in garbage out' still applies.

Several problem areas are evident when a system design is attempted. The data itself must be of good quality. The program to handle the files must be sound and efficient. The needs of the potential users must be met in such areas as access, structure, funding and confidentiality. Finally, experts must be available to prepare data and run the system.

Data Quality

Different data are important to different users. This has a profound effect on the criteria used to develop a comprehensive, current and accurate data base. For example, a user seeking only information to physically characterize a chemical requires stable data which is fairly easy to obtain. The accuracy is simple to verify and not subject to excessive distortion as it passes through the data gathering system. Such data may include molecular weight, melting point, structural formula and other 'hard' facts. Since these data are obtained through the physical sciences using established procedures, there is little judgment involved. The field is limited so it can be covered comprehensively and data can be gathered easily.
on thousands of chemicals (Port, 1978). However, other data users such as regulatory agencies or public interest groups are interested in the implications of data. Port (1978) points out that in these cases summaries and interpretations are needed. What are to be treated as relevant data becomes a policy question involving judgment. Because of this subjectivity, a complete coverage of the field is difficult if not impossible to obtain.

Another problem is the difficulty in keeping information current since limited resources constrain the fields of new data that can be examined, as well as the selection and the entry speed for that data that is considered relevant. The bibliography data base, TOXLINE, for example, lags months behind current journals (Port 1978). So in addition to reduced currency and comprehensiveness, accuracy may suffer in two ways. One, since much of the information for regulatory decisions and public use requires interpretation of data, a substantial amount of judgment bias can be introduced into the the final data base. The data chosen for entry or exclusion as well as the manner in which data is worded becomes the product of the researcher and subject to his proclivities (National Academy of Science, 1975). Two, yet, any errors made in transcribing the data are difficult to detect. The volume of data to be covered makes errors unavoidable. The difficulty of maintaining data quality will vary with the complexity, subjectivity and volume of the data stored.

Some suggestions have been developed to improve data quality and to reduce the impact of errors and omissions. Port
(1978) advocates the establishment of data bases in conjunction with institutes doing research in the same subject area. This would increase data quality by providing expert advice on the interpretation and the inclusion or exclusion of data for the bank. Adams (1978), in summarizing the results of the National Forum on Scientific and Technical Communications, stresses the need to educate those concerned with the system (from data generator through data provider to data user) about the standards of the system. Adams also points out the need for the people entering the data to understand both the scientific area involved and the information system being used.

Design Problems

Much work is being done on data storage and retrieval methods with the result that systems are improving. However, problems remain. Some of the blocks in the chemical data systems are: (1) a universal method of referring to a particular chemical does not exist; (2) the optimal organizational structure of a system is uncertain; (3) there is a problem in characterizing the uses of chemicals; and (4) methods available to tie other files to computer systems raise other questions.

A standardized method of referring to a chemical must be established if inter-system and inter-agency data exchange is to occur. At present, a chemical may be referred to by formula, by commercial or trade name, by common name or by any of several chemical names in English or a foreign language. To
rationalize chemical data systems it is important that all the information attached to various names be retrieved when only one chemical name is given. One solution to the problem is to assign a unique number to each chemical no matter what synonym is used. The American Chemical Society has been using such a system for its Chemical Abstracts Service (CAS) and has already assigned numbers to four million chemicals. Adoption of such a plan seems feasible (TSSC, 1979).

A portion of the problem not addressed by the CAS numbering system is that raised by mixtures. TSSC (1979) points out the difficulty of identifying and categorizing mixes such as tar. Many other complex organic mixes such as flavouring chemicals may fall into this problem area (Schlegel, 1978).

The problem of system organization is unlikely to be solved until the potential users are identified. However, some of the considerations may be delineated.

One consideration is whether to use a data centre or a network approach to organization. Each has its advantages. A network allows a base to be geographically closer to major users or data generators. Proximity to data generators may improve data quality by increasing the availability of subject expertise, as mentioned earlier, while proximity to users may reduce cost of access. A single data centre, on the other hand, allows greater utilization of the computer's capability to manipulate data for cross-referencing and linking (Port, 1978). Such a system conserves scarce expertise and provides a more stimulating and supportive environment. In addition, greater control over the data generally is possible.
The third problem involves a method to categorize chemical use in a standard way. At present the TSSC (1979) points out that a Standard Industrial Classification code exists but it fails to provide enough detail. However, they report an alternative method developed by the EPA which uses chemical function and application to generate about 800 terms. Used singly or together, the terms can characterize a chemical use in a uniform and unique way. One example is the function 'adhesive' which is subdivided into sixteen applications of 'adhesives'.

Finally, a method is needed to tie existing and future files together. Techniques like epidemiology need methods of relating extensive personal files containing demographic, medical and occupational data on individuals to chemical use and exposure data. This is difficult because of personal mobility and name changes. An obvious answer is the use of the Social Insurance Number (SIN). Unfortunately, it is felt by many that use of the SIN presents severe threats to personal privacy since it represents a potentially powerful tool to suppress personal freedom by both government and private parties. Possible use and potential effects are now under study in Canada by a federal commission.

Private companies have expressed concern about the confidentiality of computer data. Duetgen (1979), speaking for a private company in the US, recognizes the value of computer information to the private sector, but emphasizes the cost of unauthorized disclosure of proprietary data. He points out that
possession of manufacturing data on chemicals may be a significant market advantage to other companies in the industry. He questions the legal status of data in such areas as accuracy and proper use. Dueltgen feels at present, that the chemical industry in the US inclines to non-disclosure of sensitive information pending satisfactory resolution of the confidentiality question.

A similar industry attitude appears to exist in Canada (Neff and Mutton, 1980). The Canadian problem may be compounded by circumstances in the US since Canada depends heavily on US data bases and information services (Werdel and Steele, 1978). Canadian companies may not wish to risk their information in US data banks if the American attitude to data confidentiality creates greater risk of disclosure.

One method of handling the problem of proprietary or other restricted information is to segment a file system as the EPA has done. Information for TOSCA is split into public information available to all and information available to the EPA only (TSSC, 1979). Thus, the public and other companies are refused legal access to proprietary data through security mechanisms.

Such mechanisms restrict access to computer files through three broad methods designed to verify the identity of an authorized user (Lowe, 1976). Verification may be based on some physical possession such as a key or magnetic card, some property of the user such as a fingerprint or signature, or some knowledge of the user such as a password or answers to a series of questions. However, no security system is perfect. At
best these features, when combined with others provide "a high degree of security" (p. 17). A trade-off between cost and difficulty of operation on one hand and the importance of data security on the other must be made, keeping in mind industry's reluctance to reveal trade-secrets without adequate security.

Funding and Users

Satisfactory methods of funding information systems have yet to be developed.

A given system cannot meet all the needs of diverse users (Adams, 1979). Potential users such as government, private corporations, scientists and the public all make different demands of a system (Port, 1978). The attempted reconciliation of user's needs and fund sources makes conflict evident. If the needs of the private sector are met then it is unfair to use large amounts of public money to fund the system. Yet, if a system is designed only for government use then much of the economic benefit will be lost if the private sector cannot exploit the system to advantage. Furthermore, private users are integrally involved in the information system, being the source of much of the data and a principal reason for the system's existence in the first place. If a system does not meet the needs of private users then the cooperation required from the private sector may not be forthcoming.

Even if government is the main user problems exist. Within government, scientists and regulating agencies have different
requirements. Scientists need full data and references while regulators need summaries and interpretations of relevant data. Given limited resources, a system may be compromised so that neither group is satisfied.

Technical Expertise

It is obvious that a great deal of technical expertise is required to extract a fair return from information system expenditures. Krentz (1978) points out the need for operators to be well trained in both information systems and in a clients' subject area if data is to be entered and retrieved effectively. As well, the demands for data quality, especially in the areas of interpretation and summarization, highlight the need for expert reviewers able to select, and evaluate data in the various relevant fields. Thus, a requirement for highly trained professionals will be generated with the introduction of information systems.

4.2 CONCLUSIONS

Computerized information systems can provide the information necessary to aid in decisions about priorities for chemical screening and about acceptable standards for the chemical candidates chosen. Although there are advantages, some questions remain to be answered.

The main advantages of information systems are those
derived from computer use. The speed of the computer allows a user to scan available data quickly for those which are relevant, avoiding duplication of previous research. The high speed also allows for increased use of data and a broader database. In turn, the enlarged data base can provide more relevant information for decision making thereby reducing uncertainty. Finally, the unique characteristics of computers offer two other features; by allowing cross references and new associations of data, innovation can be stimulated.

Difficulties with computerized information systems are typically concerned with the human elements. One important question is data validity. To be very useful, a system must provide data that is current and correct. Unfortunately, judgment must be used in deciding what is to be placed in files and how it is to be recorded. Such judgment can introduce a bias to the data. Bias when combined with entry errors, produces a substantial potential for misrepresentation. Thus, techniques must be introduced to maintain data validity. One approach to improving data validity is the establishment of data entry points at research centres where expertise is available to monitor entries.

A second major concern is the categorization and retrieval of data. Storage and retrieval of chemical data entered under many synonyms can be achieved through the use of common CAS numbers. Unfortunately, this approach does not apply well to the categorization of chemical mixes. However, the problem of categorizing chemical uses can be reduced by utilizing the EPA approach of functions and applications.
Also, unanswered questions about data exchange and use remain. Different users have conflicting requirements. A system that efficiently meets one set of needs may not meet others. The cost of providing duplicate data in two or more different forms may be very high. Thus, in meeting the needs of different users (e.g. regulators and scientists) a compromise may be needed.

To reduce this conflict a network approach may be taken. A system organization similar to that of IRPTC may be used. A federal system would serve as the centre of the network, providing a centralized data base while provincial computer systems would serve as 'National correspondents' to meet specialized needs and provide regional information.

Confidentiality is a fourth major concern. Standard setting and screening will require industry to provide the federal government with proprietary information it wishes to keep confidential. However, the regulation of chemicals requires federal and provincial cooperation and information exchange as well as interaction with public interest groups. Confidentiality will be threatened. Thus, although the federal government may share most information, some information must remain restricted. One method to do so is utilized by the EPA and involves splitting the data base. Data in one part of the base would be restricted for the use of authorized users only. A second element of confidentiality revolves around the status of Canadian information in American data banks. Canadian information in the US may be subject to American freedom of
information laws in which case industrial proprietary information may be divulged. Understandably, Canadian industries may not yield confidential information under these circumstances. Further implications of transferring information across international borders must be examined.

Compatibility among information systems, both national and international is important. Since most provinces maintain their own computer systems is important that their systems be compatible with a federal system. The overlapping and integrated federal and provincial environmental legislation necessitates cooperation among governments. Efficient information exchange is a significant step toward such an objective.

Information systems improve decisions only if their data are valid. To ensure validity, systems must have a means of cross verification and validation. This implies that data from different sources will be compatible for exchange and comparison among systems. Thus, methods of data collection and storage must be standardized.

Besides the steps taken to rationalize the information systems themselves, attempts are being made to standardize national and international research techniques to facilitate data comparison. For example, the OECD is currently engaged in reaching international agreement on uniform laboratory practices. In any case, it is important that information systems include a mechanism to identify data that has been proven robust, ie. has been validated by comparison with data from different sources. Conversely, less reliable data should be designated as such. Users of the data would then be able to
give a datum the proper weight in a decision.

International compatibility may be as important to a functioning system as national compatibility. The US, for example, in addition to providing much relevant, general scientific information, is also a major exporter of chemicals to Canada. Specific information from US tests of imported chemicals will aid in screening and standard setting decisions. Therefore, the design of any Canadian information system should consider compatibility at least with the American system.

An important aspect of screening and standard setting is feedback about the effects of previous decisions. Epidemiology, the main method of detecting and tracing chemical effects depends on extensive, current data. These data are obtained from sources including occupational and medical records. Modern mobility makes the maintenance of such data bases difficult. Although the use of the Social Insurance Number to tie personal files together is not presently accepted, procedures to reduce the danger of misuse and ensure privacy must be developed to improve acceptability or a substitute method must be found.

One further aspect of the operation of a Canadian information system remains for discussion. The efficient functioning of such a system depends on trained people able to make knowledgeable judgments about interpretation, selection, relevance and retrieval of data. Without valid data and proper use, correct decisions cannot be made. The users of the system must be familiar with its strengths, weaknesses and operation and be able to interface with scientists from many disciplines. The training of sufficient numbers of scientists and other
professionals associated with the information system must be encouraged and facilitated if a Canadian system is to reach its potential.
The instruments of control have been reviewed and existing Canadian legislation surveyed to provide a general background. Such legislation provides for federal and/or provincial control of most general and specific contaminants. The *Environmental Contaminants Act* supplements the legislation of both governments and covers most gaps. Little new legislation seems necessary, however both governments have extensive powers to enact needed legislation.

Few constitutional impediments restrict the introduction of toxic chemical regulations. Instead, constraints on regulations arise from the large number of chemicals to regulate and the paucity of information. The development of new policy revolves not around designing legislation but in establishing priorities and gathering information for developing specific regulations.

Both governments have the constitutional ability to collect nearly any information or to finance any research required. Constraints on information gathering are of a political or economic nature.

Some constraints can be avoided by the governments' power to restrict public access to government information. Thus, industry's reluctance to yield proprietary information to governments may be reduced.

Governments have powers to ensure compensation for damages from chemicals. Compensation funds may be set up and financed
either from general revenue or from levies on industry. In addition, governments can assist those harmed by chemicals by ensuring private rights of action against responsible companies.

To ensure effective chemical control policy, federal and provincial cooperation is needed since much of the legislation overlaps. Cooperation would be assisted by information exchange. Also, pre-market screening and regulations will require adequate information.

The elements of a strategy to establish priorities for chemical regulations were appraised. Exposure to chemicals and the consequences of that exposure are found to determine the extent of the impact on health and the environment. Adequate information on both elements would make screening a trivial exercise. However, such information seldom exists; therefore, judgment must be used. The complexity of the system makes the use of a formal decision model unlikely. If reliance is to be placed on the judgment of scientists and regulators, then careful training and as much relevant information as possible are necessary to reduce uncertainty.

The approaches to transform public opinion and scientific knowledge into standards for chemical regulations have been presented. The factors affecting the standard setting procedure have been reviewed as well. These include personal limitations of standard setting bodies, technology available, resources available, logistical constraints and reaction to policies. No clear method is available to establish optimum standards. Therefore, a consultative process and participation of the
three sectors (public, government, and industry) is necessary to ensure acceptability. An appeal to an independent board may be necessary to resolve some issues. Governments may also provide assistance in the form of information and finances to public interest groups to increase meaningful participation.

Finally, information systems were reviewed as a means of providing data for screening and standard setting processes. The main advantages of a computerized information system are speed, capacity and cross referencing ability.

Disadvantages such as problems with data validity and currentness arise principally from human limitations. Considerations must be given to cross indexing synonyms for the same chemical and categorizing chemical uses. These problems can be reduced by adoption of the CAS unique numbering method and the EPA functions and applications approach to categorization respectively.

A system organization must be decided on. A Canadian system may incorporate a network approach similar to the IRPTC organization with the federal government acting as a central data base and the provinces as peripheral nodes catering to specialized, regional needs. This compromise utilizes the computer ability to cross reference data while allowing specialized needs to be met. However, the sharing of cost, compatibility and methods of maintaining confidentiality requires federal/provincial cooperation.

Compatibility with other systems is stressed. National compatibility is a necessity. Also, compatibility with the systems in other countries, notably that of the US, must be
given thorough consideration. Such information exchange implies examination of the status of Canadian information in other countries and standardization of international testing and research methodology.

Such an approach to chemical regulation will require trained personnel. To benefit from the system operators and users must understand each other's fields and the system's capabilities and weaknesses. Also, they must be able to disseminate appropriate educational information to government, industry and public participants.

Without adequate information, rational decisions cannot be made about screening and standards. Establishment of an efficient information system is a necessary first step in this process.
BIBLIOGRAPHY

Abramson, Dr. Fred, Member of Institute of Medicine/National Academy of Science, Personal Communications, September 1979.


Blum, Arelene; D. M. Gold; Bruce Ames et Al. (1978), "Children Absorb Tris Flame Retardant from Sleepwear: Urine Contains the Mutagenic Metabolite, 2,3 - Dibromopropanol", Science, 201 (No. 15):1020-1023.


Brodeur, Paul (1974), The Expendable Americans, New York:
Viking.


Devoret, Raymond (1979), "Bacterial Tests for Potential Carcinogens", *Scientific American*, 241 (no. 2): 40-49


Evans, Lindsay A.; Michael F. Lynch and Peter Willett (1978), "Structural Search Codes for On-Time Compound Registration", *Journal of Chemical Information and Computer Science*, 18(no. 3): 146.

Franson, Robert T.; Alastair R. Lucas; Lorne Giroux; Patrick Kenniff (1977), Canad-
ian Law and the Control of Exposure to Hazards, Science Council of Canada Background Study No. 39, October 1977.


Food Protection Committee (1965), The Safety of Monoglycerides and Diglycerides for use as International Additives in Food, National Academy of Science/National Research Council, Food Protection Committee.


Gerster, Helga B. et Al. (1977), "Information Analysis Center Concept", American Laboratory, 9 (no. 7):41.


Heuper, W. C. (1959), "Environmental Cancer" In F.


Kilpatrick, J. J. (1973), In the *Kansas City Star*, October 18, 1973, P. 34.


Lichtenstein, Sarah and Baurch Pischhoff (1977), "Do Those Who
Know Also Know More About How Much They Know", Organizational Behavior and Human Performance, 20:159-183.


Otway, Harry J. and Philip D. Pahner (1976), "Risk Assessment", Futures, 8:122-134.


Port, Geoffrey Norman James (1978), "Information Systems for the Control of Toxic Chemicals in the


Sub Committee on Oversight and Investigations (US) (1978), *Cancer Causing Chemicals in Food*, Committee on Interstate and Foreign Commerce 95th Congress, Second Session.


Upton, Arthur (1979), Director, National Cancer Institute, Personal Communications, September, 1979.


Wessel, John (1979), Representative of FDA, Personal Communications, September, 1979.


A. OECD LEGISLATIVE MODELS

To aid in developing a focus for potential Canadian legislation, the legislation of other OECD countries is reviewed. Attention will centre mainly on the United Kingdom (UK) and the United States (US). The UK is important because of Canada's historical, constitutional and legal commonalities. As a result, both Canada and the UK have adopted a similar consultative approach to chemical control with an emphasis on consensus. This is in contrast to the approach of the US which uses adversary proceedings and relies heavily on the courts to resolve conflicts. However, cultural similarities, geographical proximity and economic ties make examination of US legislation important. The legislation enacted by other industrialized OECD countries will be reviewed as well to provide a more complete overview.

A.1 United Kingdom

The Control of Pollution Act of 1974 was enacted to cover situations where existing legislation is not applicable, especially where emergency action is required (OECD, 1976). It enables the administrator, the Department of the Environment, to control or ban the import, commercial use or distribution of any chemical to prevent environmental or human damage. Before
regulations are promulgated, consultation occurs with those affected.

To control pesticides, the UK has instituted a non-statutory agreement between manufacturers and government agencies. The agreement allows for government notification of new pesticides. Recommendations, in conjunction with an Advisory Committee, are made with respect to restrictions on marketing and use. The title is Pesticides Safety Precautions Scheme.

The OECD report points out that the control of environmental contaminants has occurred in three main areas, general pollutants, specific chemicals, and certain uses. The control approach to general pollutants of air and water and to waste disposal has been to allow local autonomy. Authorities consider all factors, local conditions not excepted, and then set type and level of controls to suit. As a result, controls in different areas of the country vary considerably. The control of specific chemicals is achieved through a mix of statutes and agreements. For instance, on the one hand, detergents are regulated by a voluntary agreement covering the screening of new chemicals to be used in domestic detergents. Sulphur, on the other hand, is regulated under Section 76 of the Control of Pollution Act which provides for limits on the amount of sulfur in fuel oil. Finally, certain uses are covered, for example, in the work place the manufacturer is bound to ensure that only chemicals safe under normal conditions are used. Under the Health and Safety At Work Act (1974), constant monitoring by the Health and Safety Executive
(HSE) is aimed at regulating potentially harmful chemicals. These chemicals are controlled by official guidelines reinforced by health and safety statutes as required.

In a recent release, designed to elicit industry response, Notification Scheme for Toxic Substances, HSE outlined its approach (Hay, 1979). The philosophy is to keep test costs down by requiring the minimum amount of information necessary to move to the next step of chemical development if more than 100 kg/yr is marketed. The idea is that preliminary toxicity testing will be carried out at a sub-acute level for 28 days. Should this raise suspicions, long term research must be implemented. This contrasts with the US Environmental Protection Agency (EPA) requirements for a rigid series of tests before a chemical is registered (registration is required for marketing).

The UK changed its approach to the control of pharmaceuticals with the introduction of the Medicines Act of 1971. The Act introduced formal procedures for pre-market screening of new drugs (Grabowski et al., 1978). These included proof of efficacy and an approved plan for testing in animals and humans. This represented a major shift in emphasis from a post-market, largely voluntary program to pre-market formal screening.
A.2 United States of America

In 1976, after six years of effort, the Toxic Substances Control Act (TOSCA) was passed. The reason for its inception is summed up by President Carter (1977).

...the presence of toxic chemicals in our environment is one of the grimmest discoveries of the industrial era. Rather than coping with these hazards after they have escaped into our environment, our primary objective must be to prevent them from entering the environment in the first place.

The Act gives the EPA an extensive range of authority to institute pre-market controls (Cleary et al., 1978): Existing chemicals are being catalogued and the EPA receives notice of all new chemical and existing chemicals with new uses; Industry tests of chemical and chemical mixes can be required; Chemicals with insufficient information and significant exposure can be withheld from the market; Chemicals, new or existing, presenting unreasonable risk can be banned or restricted and; The Act requires extensive record keeping and report production.

Already industry is objecting to EPA proposals under the Act (Hay, 1979). The proposed approach requires a rigid battery of specific tests, long and short term, before allowing a chemical to be marketed. Industry anticipates high cost, decreased innovation and a shortage of skilled technicians to carry out the work as a result of such a policy.

The US has specific legislation designed to control pesticides although TOSCA may be applied if the administrator
feels it is in the public's best interest (Cleary et al., 1978). The legislation requires the registration of all pesticides with the EPA and their examination for efficacy and for safety to man and environment. Present regulations pertain to classification and provide guidelines concerning user safety, proper procedures and permits for experimental use. As with TOSCA, potential hazard is emphasised.

Various other laws are germane to the control of toxic chemicals. Some of the major legislation administered by the EPA follows. The Clean Air Act and amendments requires the establishment of national emission standards for various contaminants. The Water Pollution Control Act and amendments has stated goals: "(1) to obtain, by 1983, an interim level of water quality that provides for the protection of fish, shellfish and wildlife and recreation; and (2) to achieve the elimination of the discharge of all pollutants into the waters of the United States by 1985" (OECD, 1976, p. 82). A significant point made by the OECD report is that standards are based on future technology and not on presently available technology. The Marine Protection Research and Sanctuaries Act limits or prohibits the disposal of harmful materials into the ocean e.g. chemicals, biological warfare agents and radioactive wastes. It specifically includes consideration of potential environmental damage as well as danger to human health and welfare. Finally, the Resources Conservation and Recovery Act deals with the dumping of toxic chemicals or other dangerous material in landfills, disposal through incineration and other means. Introduced in 1970, the Act was to encourage recycling
of waste material. The EPA provides guidelines for recycling and designs programs for waste management under the law.

The Food and Drug Administration (FDA) administers an important piece of legislation, the Food, Drug and Cosmetic Act. Containing the Delany clause, it prohibits the addition of any carcinogens to foods and cosmetics, although hair dyes are specifically exempt from its provisions. Also, in 1962, following the Thalidomide tragedy, the Kefauver-Harris Amendments were introduced requiring firms to substantiate the efficacy and safety of new drugs. Some economists have claimed a substantial loss of innovation and a rise in industry concentration as increased product cost and risk force the closing of the smaller firms (Grabowski and Vernon, 1977).

Various laws under the Department of Transport (DOT) are designed to promote the safe transport of toxic chemicals (OECD, 1976). Chemical and oil spills from ships are covered by the Oil Pollution Act of 1976. Most other aspects of transportation are covered by the Dangerous Cargo Act, Transportation Safety Act of 1974 and others. They give the Secretary of Transport power over all facets of transport e.g. packaging and labelling.

The use of chemicals in the work place is regulated through the Occupational Safety and Health Administration (OSHA) (OECD, 1976). Broad powers are given the Secretary of Labour through the Occupational Safety and Health Act of 1970. It has provisions for the setting of standards, recording of employee exposure, inspections and investigations. Immediate corrective action may be taken if danger exists. Also, in
consultation with Health, Education and Welfare (HEW), research of occupational safety and health factors may be carried out leading to the formation of criteria and standards for handling toxic chemicals. Examples of actions taken are the emergency vinyl chloride unit standards set in 1974 and the arsenic standards in 1975.

Laws for the protection of consumers are administered by the Consumer Product Safety Commission (CPSC). Four major acts allow for the control of products and the enforcement of earlier laws. The Consumer Product Safety Act of 1972, although it excludes tobacco, foods, drugs and cosmetics, has the authority to set standards on a variety of products as well as the mandate to enforce previous laws. Other acts are the Federal Hazardous Substances Act of 1927, the Flammable Fabrics Act of 1953 and the Poison Prevention Packaging Act which respectively regulate dangerous or irritating chemicals in consumer products, domestic fabrics and clothing, and child-proof caps.

A.3 Other OECD Countries

France

The purpose of the Control of Chemicals Dispersed in the Environment Bill is to complement existing legislation which governs only post-market use of chemicals. The bill introduces screening of chemicals before large scale manufacture is
commenced (OECD, 1976). Under the Bill, a manufacturer of a new chemical or an existing chemical coming under suspicion must provide information to allow an estimation of potential hazards. The evaluation uses specific criteria e.g. LD50 (the dose lethal to half of the test animals) to assess the risk to man and environment. On the basis of the risk, the chemical will be placed in Category I (absolute ecological danger) or Category II (potential ecological danger). Various restrictions regarding sale, use, storage and disposal may be applied and chemicals in Category I may be totally banned. Expenses incurred in providing the information are borne by the manufacturer in the case of new chemicals but in the case of existing chemicals are shared among producers in proportion to the amount marketed in the preceding two years.

A similar classification system provides for the control of agricultural pesticides under the administration of the Ministry of Agriculture (OECD, 1976), various commissions: set and revise standards in consultation with industry; examine data in order to set restrictions; and classify and determine the efficacy of the chemical. The intent of the legislation has broadened to include protection of the general public and the general environment from its previous narrower focus on efficacy and user protection.

According to the OECD report other French legislation has organized controls according to the point of distribution in the environment, type of industry, method of transport and forms of use. The drawback of this legislation is that it is directed at specific substances thereby leaving possible gaps
in coverage. For example, industrial discharges are chemically complex whereas regulations are enacted only for a few specified substances such as a small number of the many electro-plate plant chemicals discharged. A more general approach is being developed.

Japan

The Chemical Substances Control Act was enacted in 1973 to answer the need for control of persistent chemicals dramatized by such disasters as the Minamata disease (caused by mercury) and the Kanemi rice bran oil disease (caused by polychlorinated biphenyls) (PCB) (OECD, 1976). The intent of the act was to allow for pre-market examination and control of new chemicals. Its provisions include submission of information and review with regard to persistence, accumulation and toxicity before production or importation is permitted. Testing is quite thorough, involving micro-organisms, solubility, condensing rate in fish, toxicity (broadly and specifically) using in vivo tests on metabolic defects, and pharmaco-dynamics. Those chemicals considered dangerous are labelled "specified substances" and are liable to be banned or restricted in use as well as in manufacture and importation. The cost of the research is distributed under the Pollution Control Public Works Cost Allocation Law.

The aim of the Agricultural Chemicals Regulation Law is to provide stable production and human and environmental safety through standardization of chemical quality and assurance of
proper use. Regulations cover restrictions, prohibitions, safety criteria concerning toxicity and persistence, and detailed instructions on the use to which certain chemicals are to be put. All agricultural chemicals must be available for inspection before marketing.

Other regulations allow for post-market and pollution monitoring (OECD, 1976). The Basic Law for Environmental Protection allows the use of broad powers to implement measures necessary to control pollution. More specific laws are in the areas of: pollution control with responsibility for establishing and revising standards, monitoring and introducing pollution control programs; air pollution control with responsibility to designate and enforce controls on all gases from combustion, certain toxic chemicals and auto exhaust; water pollution; marine pollution; and others.

B. Analysis of OECD Models

The two approaches in toxic chemical control most apparent over the last few years have been (1) legislation to cover gaps in jurisdiction of legislation and (2) the shift in emphasis from post-market monitoring to pre-market control. In this respect Canada has taken similar action. The Environmental Contaminants Act is designed to fulfill those two functions.

In contrast to the US TOSCA, but in accordance with the UK approach, consultation with industry is explicitly included. This contrast between US and Canadian legislation is perhaps
due to the difference in legal structure since, in general, Canadian courts do not serve the same purpose as US courts do in testing agency decisions. Confrontations between government agencies and industry are avoided as much as possible by the consultative process. Thus, the approach is politically accommodating while extensive interaction with affected groups should enable the design of acceptable and efficient legislation.

As mentioned, all of the selected OECD countries have implemented some form of pre-market control to detect hazards before production. This is, perhaps, in recognition of the insidious nature of many of the toxic chemicals produced (as mentioned earlier, they are often toxic in very small amounts, persistent and have latent effects). It is the implementation of the regulations attached to the acts which have caused controversy. The regulations accompanying TOSCA for example, have caused an acrimonious debate between the EPA and the chemical industry (Hay, 1979). The EPA proposes a rigid and extensive series of tests conducted before registration is permitted. The chemical companies (who bear the cost) feel the cost of this approach is exorbitant and much favour the UK approach which includes a more flexible schedule of tests. In the UK, if preliminary results prove acceptable, the chemical can be marketed. Only if suspicions are aroused are long term tests necessary.

The principle drawback of pre-market testing is the cost incurred in processing each of the large number of chemicals introduced. The US has committed vast resources to simply
establishing a list of chemicals for registration. In addition to direct costs of testing, reporting and record keeping, there may be indirect international cost and domestic costs (Ross, 1978). The US has a $6 billion dollar chemical export industry which may be jeopardized. TOSCA could force foreign companies to test their products to meet American requirements just to retain the US market, making TOSCA in effect, a non-tariff barrier. If other countries were to react by banning US imports the American industry's export business could be destroyed. But, Canadian exports are not as extensive and are generally less refined in nature reducing the importance of such factors. However, some agreement on international standards may be a step toward resolution of the problem for the future.

Domestic cost that may occur are the decrease in innovation and the loss of smaller companies leading to decreased competition. Grabowski et al. (1977, 1978) investigated the effect of legislation requiring pre-market proof of efficacy and safety on the American drug industry. They contend that the increased cost of testing and of risk of failure resulted in fewer useful new drugs and reduced the number of companies in the industry without a balancing rise in social benefit. In the chemical industry, the direct cost of testing, reporting, record keeping and time delay may have a similar result. In addition, the risk of failure or loss of a competitive edge could lead to a reduction in the amount of money spent on research and development. Extensive and costly research may go into a chemical that is then designated as requiring more testing. Not only is its introduction delayed,
perhaps for years, but each agency handling it represents a possible leak of trade secrets to competitors. These extra "costs" may force otherwise competitive companies from the industry.

Also, this domestic cost may be sufficient to inhibit the growth of secondary chemical industry in Canada. But because research and development in the Canadian chemical industry is not as extensive at that of its American counterpart, the effect may not be as strong. Canada's industry deals largely in bulk chemicals which involves only a small amount of research and innovation, however, expansion of the more innovative part of the industry may be inhibited.

With regard to standard setting, strategies employed can be categorized into at least three areas: (1) guidelines versus fixed statues, (2) central versus local control, and (3) meeting standards by present versus future technology.

The UK, in an occupational context, uses guidelines backed by statutes as necessary. This approach allows for flexibility in content and procedure with the hint of more rigid regulations should they be necessary. A weakness with this approach is the inability of independent third parties to monitor the compliance of industry. Since, in Canada, information is difficult for the public to obtain, there may be a tendency for enforcers to identify with the regulated rather than the regulators. The public may perceive this as lax enforcement. On the other hand, problems with standards written into law are: first, the difficulty in providing precise wording to guide administrators; second, the inflexibility
should change be required; and finally, the amount of time necessary to pass such laws. Both environmental and industry interest groups are likely to confront government with strong lobbies on each issue causing delay and increased court costs.

In considering the benefits and costs of local versus central control of environmental standards, a compromise seems possible. There is much variation in local conditions across Canada and therefore, much variation in each area's ability to absorb pollution without excessive damage. Also, the benefits to local areas may vary considerably. Economic inefficiency is likely to result if strong standards prevent regions from adjusting their own levels. However, some minimal guidelines seem desirable to prevent irreversible damage to socially or geographically isolated areas. Thus, minimal federal standards could be applicable in the absence of other more rigorous standards.

An unusual aspect of this area lies in the existence of a "territorial imperative". The present political trend in Canada seems to be away from central control and toward provincial autonomy. The territorial imperatives of both the federal and provincial governments can lead to a competition to control polluting companies. Such a competition can be manifest as alternating increases in standards as each government vies with the other to have the most stringent and therefore controlling standards.

One of the fears of setting standards is that they become maximum as well as minimum requirements (Borchard and Walton,
As mentioned later, this tends to occur more with smaller, less permanent companies than with established companies who have a reputation to protect. This is explained by the fact that the smaller companies have less to lose in terms of capital and business and therefore, have limited liability for damage. The larger companies have correspondingly more to lose and greater liability.

One way of insuring against such abuse is to write more stringent standards into law ahead of available technology such as the US has done with its water act. The danger of course is that the technology will not evolve rapidly enough to meet the standards or that it will prove uneconomical. Such strategies require constant surveillance to ensure that an industry is not over or under regulated. A second approach which may be effective is the introduction of personal liability for corporate executives. Knowledge and control of company policy would then carry with it the responsibility for the results of such policy and make senior executives personally liable for damages and penalties. Drawbacks to such a policy could be the difficulty in establishing the degree of control each executive might have (hence the amount of responsibility) and the difficulty in providing insurance to responsible executives. Such a policy may then act to constrain entrepreneurial activities as well as decreasing public risk. A net loss of social benefit may occur.