THE DEVELOPMENT OF CHEMICAL SAFETY PROGRAMS IN CANADA

*P. Toft**

Presented at the Pan American Health Organization Regional Symposium on Problems Related to Chemical Substances and Environmental Health, Rio de Janeiro, Brazil, Sept 13–15, 1988

The extensive and ever increasing use of chemical substances in industry, in agriculture and in consumer products has brought many benefits to society. In Canada and many other countries, we have become a 'chemical society'. However, the use of certain chemicals in commerce has, on occasion, resulted in injury to man or the environment. In recent years, society has become aware of the potential for harm which certain chemicals may pose because of the improper use, handling or disposal of many of these substances. Sensational reports frequently appear in the news media about the alleged risks caused by chemicals, which have induced public anxiety. One of the main factors contributing to this anxiety is the inadequate knowledge of the possible adverse effects which a chemical can have on human health or the environment. As a result in Canada, the tide of public opinion favours a continual reduction in environmental hazards.

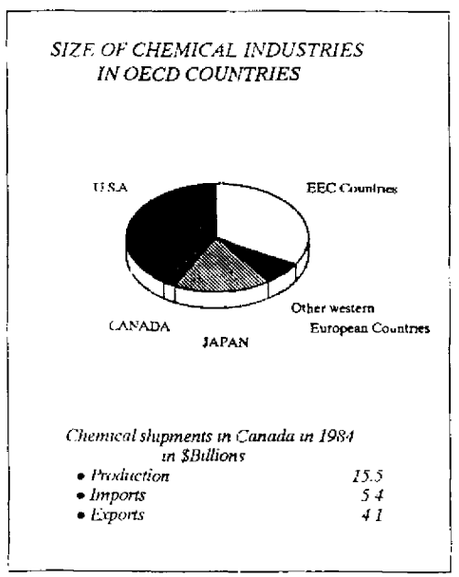

Figure 1

Canada is a partner in the international market in chemicals. For example, in 1984, Canada produced $ 15.5 billion worth of chemicals, imported $ 5.4 billion worth and exported $ 4.2 billion worth (Figure 1). There have been many estimates made of the number of chemicals in use around the world, ranging from 60,000 to over 100,000. Clearly it would be a difficult, if not impossible, task to determine the toxicity of each of them. It has been estimated that about 30,000 chemicals are used commercially in Canada, most of them being synthetic.

* Department of National Health and Welfare, Ottawa, Canada

Obviously, the task of governments in dealing with the issues presented by chemicals in the environment is not an easy one. Most of these chemicals have benefits associated with their use In an ideal world, the evaluation and control of risks from chemicals would be conducted systematically, so that each identified risk would be dealt with in a consistent and expeditious manner However, I am not aware of any government which has developed a consistent and adequate policy for the management of all aspects of risks due to chemicals.

FEDERAL-PROVINCIAL DIVISION OF POWERS

Canada has a federal system of government. The Constitution Acts of 1867 and 1982 specify the areas of federal and provincial jurisdiction (Figure 2). The **federal government**, through its criminal law powers and its jurisdiction over interprovincial and international trade and commerce, has the authority to regulate hazardous substances, hazardous products and environmental contaminants. The **provinces** have authority within their boundaries over manufacturing, the work environment, waste disposal, and the provision of health care services, as well as control over environmental management (through their ownership of natural resources). The **federal government** also has emergency powers and any residual powers not specifically assigned to provincial governments. In principle, control of toxic substances is required from manufacture to disposal, or, more colloquially, from "cradle to grave". Legislative control, both federal and provincial, can cover the following elements: manufacture, importation, occupational health, transportation, storage and handling, use or sale, discharge to the environment, waste disposal and spills. There are some 27 federal statutes which provide some form of control over toxic substances; in addition, the ten provinces have enacted about 100 pieces of legislation.

RESPONSBILITIES OF GOVERNMENT IN CANADA

Federal Government	*Provincial Governments*
• *jurisdiction over trade*	• *jurisdiction over work environment, manufacturing practices and waste disposal*
• *criminal law power*	
– *regulates hazardous substances, hazardous products, and environmental contaminants*	– *regulate workplace safety industrial emissions, and disposal of chemical waste*

Figure 2

LEGISLATIVE FRAMEWORK IN CANADA

The first Canadian legislation which allowed for some control of toxic substances, was passed in 1875, and was intended to combat the fraudulent practice, common at the time, of adulteration of food and medicines with foreign matter. From these early beginnings, Canadian legislation to control chemicals evolved towards resource protection, to consumer protection, to worker protection, and to protection of the environment and the public. The relevant federal legislation may be classified as follows:

i. *General Pollution Statutes* (intended to control contamination of water, air or soil).

The **Canada Water Act** (1969) enables the government, in conjunction with the provinces, to manage the quality of water bodies, and provides for monitoring and research.

The **Clean Air Act (1971)** was used to set specific air emission standards and national air ambient air quality objectives.

In June 1988 it was subsumed into the Canadian Environmental Protection Act (see below).

The **Fisheries Act** (1939) was the first Canadian environmentally oriented law, although its intent was not so much to protect the environment for its own sake, but rather to protect fish habitats. It is principally used to protect commercial fisheries, but also has the value of protecting the environment.

ii. *General Contaminants Control Statutes* (directed at controlling specific chemicals)

The **Canadian Environmental Protection Act** is a powerful piece of new legislation which was promulgated on June 30, 1988, and replaces the Environmental Contaminants Act. It provides the power to regulate toxic chemicals which cannot be controlled by other legislation. In particular, it provides for notification to the government of new chemicals before manufacture or importation.

iii. *Food and Drug Statutes* (intended to preserve and improve the quality of food and drugs)

The **Food and Drugs Act** was promulgated in 1920, and had broad powers to control food and drug quality. The Food and Drugs Act was last revised in 1953, and is now a mature piece of legislation. Over the years more than 175 pages of regulations have been developed. It provides for control of toxic chemicals in foods, drugs, cosmetics, and medical devices. For example, maximum residue levels for a wide variety of chemicals in food have been established. It is important to note, however, that the Food and Drugs Act focuses upon control of the product containing the toxic substance, rather than upon control of the contaminant itself.

iv. *Consumer Safety Statutes* (directed at particular products used by the public)

The **Hazardous Products Act** was enacted in 1968, and is directed at protecting the consumer from hazardous products, including hazards from toxic chemicals. It was a pioneering piece of legislation since, at the time, no other country had any comparable law

The Pest Control Products Act, also promulgated in 1968, is designed to control products used for the control of pests. Pesticides must be registered under this Act before they can be used in Canada, and detailed regulations have been promulgated prescribing information requirements for registration.

v. *Transportation Statutes* (to protect public health and safety and the environment during the transport of dangerous goods)

The **Transport of Dangerous Goods Act** (1980) mandates the application of certain safety standards for handling and transportation of goods as well as standards for containers and packaging.

vi. *Workplace Contaminants Control* (to protect workers' health and safety in specific industries)

The **Canada Labour Code**, enacted in 1967, affects workplace safety conditions for employees involved in federal works, businesses and undertakings. It provides authority to make regulations respecting the handling, transportation, storage, use and disposal of toxic substances. Similar legislation exists within provincial jurisdictions.

vii. *Statutes Regulating Specific Industries*

There are several groups of federal statutes, such as the Canada Shipping Act and the Fisheries Act, which can be used to establish specific standards for emissions from particular industries.

Traditionally, therefore, legislation in Canada has provided a dual approach to control of chemicals:

(i) the licensing before they are marketed of specific groups of chemicals, such as drugs, food additives and pesticides, which have the potential to be harmful, especially to human health, and

(ii) the control of existing chemical substances which have come to be regarded as toxic pollutants.

The first of these is preventive in that it attempts to identify and evaluate chemicals that might be harmful before man is exposed to them. The onus is on the manufacturer or importer to apply for permission to sell a chemical for use in one of these regulated categories. The petitioner must submit evidence in support of his application which demonstrates to the satisfaction of the government that the chemical is efficacious and safe for the intended use. If successful, the chemical is then registered for a specific use, and often certain limitations are placed on the use of the chemical. In Canada, registration of chemicals is required by law for drugs and food additives, because they are intended for direct human consumption, and for pesticides, because by their nature they are toxic.

The second area is isually an attempt to control a chemical after it has become evident that some harm or damage has occurred, or is likely to occur. It can take the form of controls on release or emissions of the chemical, or the establishment of quality standards, usually maximum concentrations in various media or commodities, e.g. food items. In this case the onus is on the government to identify the existence of a risk to health or the environment, and to implement appropriate corrective action.

APPROACHES TO CONTROL OF CHEMICALS

Licencing Before Marketing	*Control of Existing Chemicals*
• *preventive - manufacturer must demostrate safety*	• *controls chemicals already in use after they are found to be toxic*
• *used where direct human exposure anticipated*	• *used where direct human exposure is not expected*
• *expensive*	• *less costly to industry*
• *traditionally used for food additives, drugs and pesticides*	• *generally used for all other classes of industrial chemicals*

Figure 3

REGISTRATION OF NEW CHEMICALS

The process for registering pesticides provides an example of the preventive approach for controlling chemicals. In Canada, the primary legislation is the Pest Control Products Act (P.C.P. Act), which is administered by the Department of Agriculture. The Act attempts to ensure that pesticides are not used which are unsafe to human health or the environment. It also tries to ensure that only pesticides are approved which are effective for their intended purposes. The review process is shown in Figure 4. The manufacturer must apply to the Department of Agriculture and provide a supporting data package. This Department coordinates the review of the data package by other federal Departments —Health and Welfare, Environment, Fisheries and Oceans, and Agriculture itself. For example Health and Welfare reviews the information as it relates to risks to health of people involved in manufacture, handling or application of a pesticide, as well the potencial risks to bystanders. Health and Welfare is also responsible for ensuring that the use of a pesticide on food crops will not result in residues on food that may be hazardous to health. The data package provided by the manufacturer can take up to 10 years to develop at a cost of up to $20 million The data for assessing the potential health effects is generated using laboratory animals. Four kinds of studies are performed: 1) acute studies (single exposure); 2) short term studies (multiple exposure 10% of lifespan); 3) long term studies (multiple exposure —two-thirds of lifespan); and 4) special studies such as teratology and mutagenicity studies. The manufacturer must also provide some indication of the likely exposure of applicators and bystanders to the pesticide during normal use —usually via the inhalation or dermal route. The Department of National Health and Welfare and the other Departments involved make their recommendations to the Department of Agriculture based on their review of the data package, and the Department of Agriculture makes the regulatory decision. Provision is also made in the P.C.P. Act for re-evaluation of established pesticides in light of new information. In this way, a registered pesticide can be withdrawn from the market, i.e. de-registered, if new data show that the risks outweigh the benefits A recent example is that of Alachlor which was de-registered in 1985, because of studies which showed it to be a potent carcinogen.

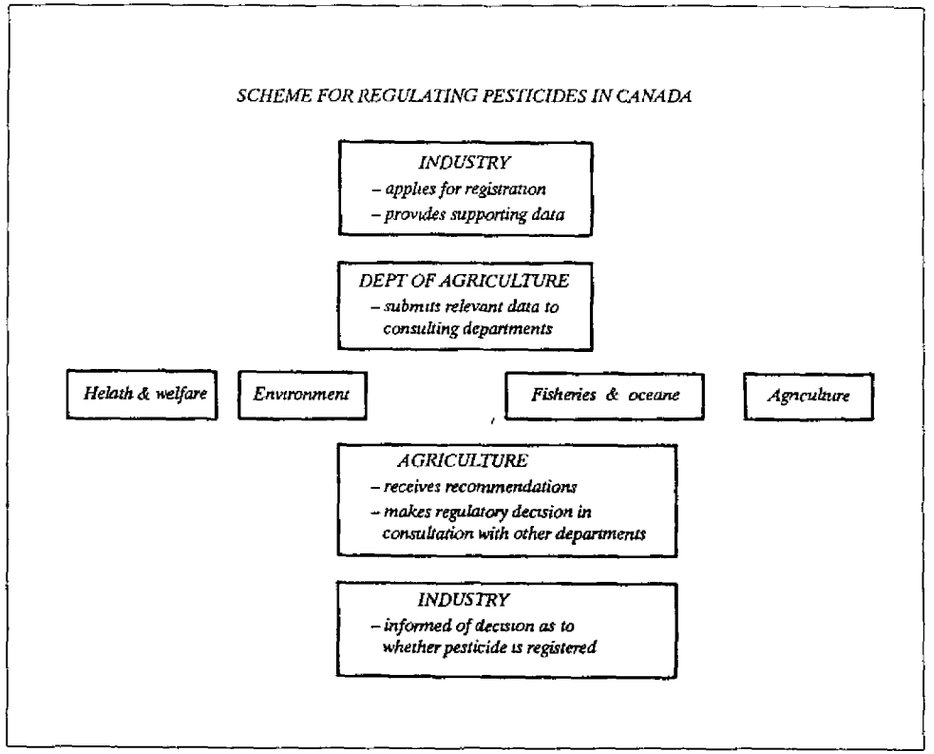

Figure 4

The preventive approach to the control of chemicals is also now being taken in Canada for all new chemicals, whatever their intended use. The concept of identifying and evaluating potential hazards associated with industrial chemicals **before** they are manufactured or imported has been incorporated into the new Canadian Environmental Protection Act (CEPA). This Act provides new powers that include the authority to regulate all phases of the life-cycle of chemicals from development, to manufacture, to storage, to transportation, to use and finally to disposal, where these aspects are not encompassed in other, more appropriate legislation. A few of the highlights of CEPA will now be discussed.

Firstly, under CEPA, new chemicals will have to be tested and evaluated before either manufacture or importation (Figure 5). The actual toxicity and other data to be provided depends upon the quantity of the substance to be manufactured or imported Quantity triggers are used

as a measure of potential exposure to man or the environment (Figure 6). As more exposure is foreseen to be likely, more test data will be required. Test requirements for chemicals made or imported between 5 and 300 kg per year are shown in the column 1 of figure 6. For chemicals in the range 300–1000 kg per year the data requirements are increased (column 2). For chemicals manufactured or imported in greater than 1000 kg quantities per year a full data package is needed (column 3). These data requirements are not as comprehensive as those required for registration of

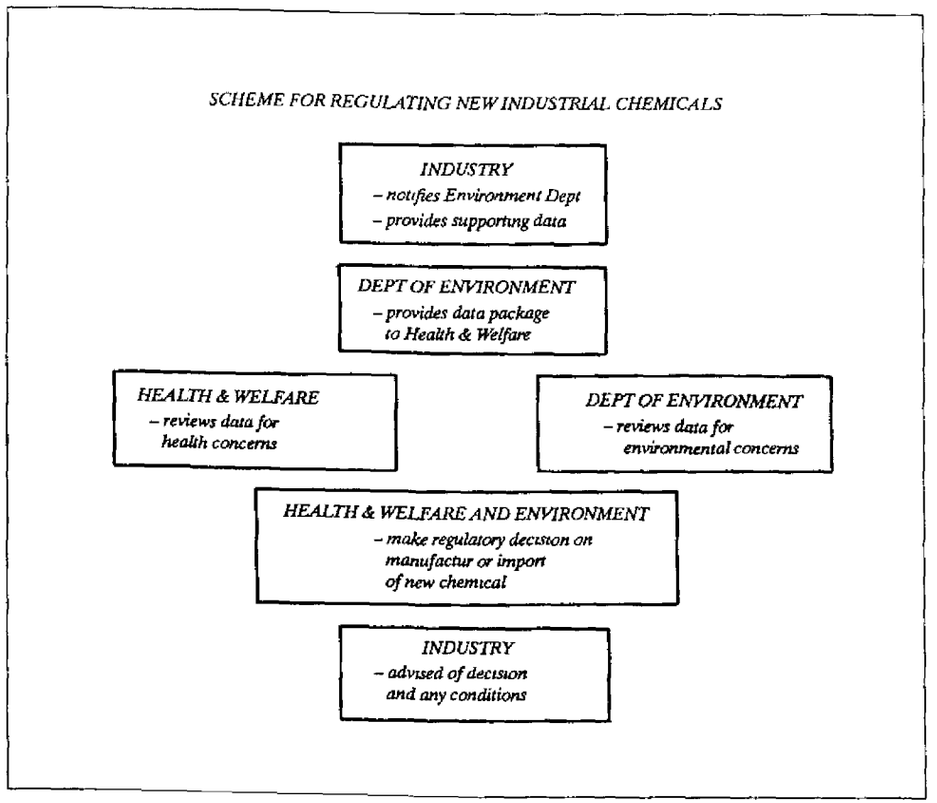

Figure 5

new drugs, food additives or pesticides. However, industrial chemicals are not intended for direct human consumption, nor, unlike pesticides, are they intended to be toxic or applied directly to the environment. These minimum data packages are therefore felt to be sufficient to provide for a

first meaningful assessment of the potential risk to health and the environment. If the data provided suggest that a risk to man or the environment may occur, the Act provides the power both to restrict the conditions of use and to require that more testing be done The scheme to be followed is similar to that used for new pesticides (Figure 5). In this case, however, only two Departments are involved —Health & Welfare and Environment.

The regulatory provisions for new chemicals will come into force once an inventory of chemicals currently in use in Canada has been developed —to be known as the Domestic Substances List. This will take about 2 years to complete and is necessary so that the government can determine what is a new chemical A chemical not on the Domestic Substances List will be treated as a new chemical for the purposes of the Act. Manufacture or import of **existing chemicals** will, of course, be permitted without further testing.

REGULATION OF EXISTING CHEMICALS

With respect to the control of existing chemicals, i.e. chemicals already in commerce, it was pointed out above that this is usually an attempt to control a chemical after it has become evident that some harm or damage has occurred. There are several Canadian laws which can be used to deal with specific aspects of problemas caused by existing chemicals. However, in addition to dealing with new chemicals, the new Canadian Environmental Protection Act also addresses the question of existing chemicals, and does so in a systematic manner. The Act requires that a list of priority chemicals be established for assessment to determine whether further controls need to be imposed on them. This priority list of chemicals for assessment is now being drawn up with the assistance of an advisory panel of persons from universities, industry, unions and public interest groups

Effective control of existing chemicals flows from a systematic examination of the risk, an evaluation of socio-economic factors, and finally management of the risk. A number of models for risk assessment and risk management have been proposed in recent years, but they are all generally similar. The one in figure 7 is that used by the Environmental Health Directorate, in the Department of National Health and Welfare, to assess risks to health from existing chemicals.

The first step in this risk assessment —risk management process is **hazard identification**, which means recognition that a particular hazard exists. A hazard may be identified in a variety of ways, including case reports, toxicological studies, and epidemiological investigations.

The next step is **risk estimation**, which involves quantitative estimation of risk or risks associated with the identified hazard. Such estimates are usually based on the analysis of epidemiological and toxicological data as well as estimation of levels of human exposure. It is often necessary to extrapolate information obtained from animal studies to man. And furthermore, it is also frequently necessary to extrapolate dose-response data from high to low doses, and mathematical models are often used for this purpose. Dose-response data is also, of course, the type of information used to develop exposure standards —essentially the reverse of determining the level of risk.

The third stage is **option evaluation**, which has two components **development of options** and **option analysis. Development of options** involves formulation of a number of alternative courses of action to deal with a problem. Options may be regulatory or non-regulatory, and can range from an outright ban of a substance to economic incentives or provision of advice to the public **Option analysis** requires consideration of potential options in light of other factors such as·

- health risk versus health benefits
- the acceptability of the risk to the public
- the technical feasibility of the proposed courses of action
- economic impact of options.

The three steps discussed above (hazard identification, risk estimation, and option evaluation) comprise the **risk assessment** portion of the model. The remaining steps comprise **risk management**.

Level 1 5–300 Kg/year	**Level 2** 300–1000 Kg/year	**Level 3** More than 1000 Kg/year
1 Identity (IUPAC nomenclature)	1. Identity (IUPAC nomenclature)	1. Identity (IUPAC nomenclature)
2. CAS number	2 CAS No	2 CAS No
3 Material safety data sheet and a label	3 Material safety data sheet and a label	3. Material safety data sheet and a label
4 All available information in the possession of notifier on health and environmental effects	4. All available information in the possession of notifier on health and environmental effects	4 All available information in the possession of notifier on health and environmental effects
5. Intended use	5 Intended use	5 Intended use
	6. Physico-chemical data excluding adsorption and hydrolysis data	6 Physico-chemical data as recommended by OECD
	7 *One* acute mammalian toxicity test representing most probable exposure route	7. *Two* acute mammalian toxicity test representing most probable exposure route —oral, dermal or inhalation
	8 Expected quantity to be used per year	8 Expected quantity to be used per year
	9. Estimated number of people likely to be exposed	9. Estimated number of people likely to be exposed
	10 Expected emissions and discharges to the environment	10 Expected emissions and discharges to the environment
	11 Recommended disposal method	11. Recommended disposal method
		12 Mutagenicity data
		13. Ecological data – fish LC_{50} – *Daphnia* LC_{50} – biodegradation – bioaccumulation
		14 Repeated dose mammalian toxicity test (28 day study)

Figure 6

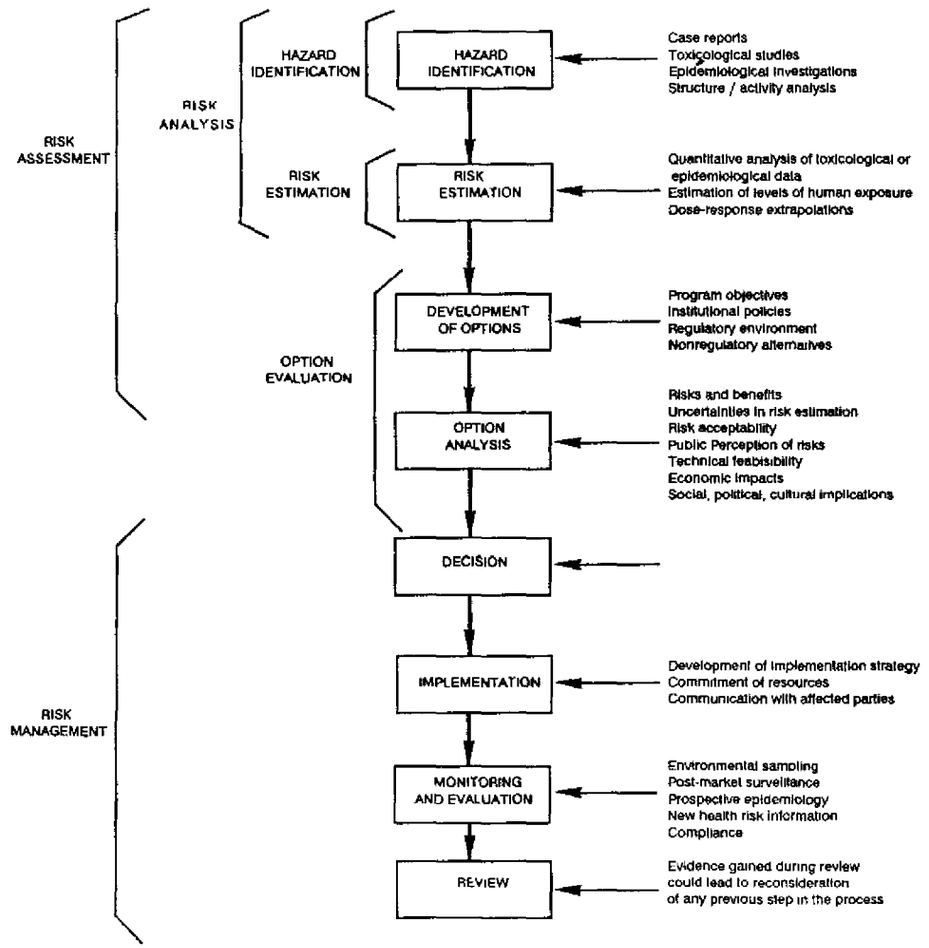

Figure 7

Risk management begins with the **decision** as to which particular strategy or option will be chosen to deal with the perceived risk. **Implementation** of the **decision** will usually require commitment of resources, and should in most cases be conducted in consultation with the affected parties. Once the strategy to control the perceived hazard is in place, feedback on the suitability and impact of the process can be obtained through compliance **monitoring and evaluation** Techniques such as environmental monitoring or market surveillance can be used for this purpose. Finally, a review of the whole process, after a suitable period of time, may provide valuable information on each step and a new insight into the decisions taken.

STANDARDS

Regulatory agencies generally need to use standards in order to implement regulations to control risks from existing toxic chemicals, unless, of course, the risks are so great that no use of the chemical whatsoever can be permitted. Standards used by regulators are usually expressed as numbers, and in the case of chemicals, usually some sort of concentration value No matter what sort of regulatory action is being considered, a standard provides a reference point for enforcement and surveillance. In reality, the standard enables the regulator to make a judgement between what is safe and what is harmful or criminal —or, more correctly, between what is an **acceptable risk** and what is an **unacceptable risk.** Even the best standards, however, will only be an approximation for the purposes of health protection and will not give an absolute guarantee of freedom from risk.

Types of Environmental Standards

In general there are three types of environmental-standards environmental quality standards, emission and effluent standards, and product standards (Figure 8).

TYPES OF ENVIRONMETAL STANDARDS

- *Environmental Quality Standards*
- *Emission and Effluent Standards*
- *Product Standards*

Figure 8

Environmental quality standards prescribe the maximum allowable levels (or sometimes the minimum allowable levels) of pollutants in media such as air, water or soil. They may be designed to cover certain geographical areas e.g. national, provincial or local. However, in some instances, it may not be wise only to set a maximum allowable level for a chemical pollutant in the environment. It may be used as a licence to pollute to the maximum level. It may, therefore, be useful to designate a lower level as a long term objective for environmental quality. This concept is incorporated, for example, into the National Air Quality Objectives which have three levels: 'tolerable', 'acceptable' and 'desirable'. The first sets the concentration which poses a threat to human health, the second provides adequate protection to human beings and the environment, while the third is a long term goal for sound environmental quality.

Emission and effluent standards specify the maximum amounts or concentrations of pollutants that may be released into the environment In some instances, a particular process or mode of operation may be specified as the means to achieve an emission standard.

Product standards specify limits based on the properties of the product, its packaging or its emissions Examples are pollutant limits in food products for heavy metals and pesticides

Derivation of Exposure Standards

In order to establish accurate, defensible, health-based exposure standards, it is essential to determine the quantitative relationship between a given pollutant and its effects, i.e. the so-called **dose-response** relationship. Because of ethical considerations, it is usually difficult to obtain such information from studies on human populations. Rather regulatory agencies use laboratory animals and generally attempt to determine a level of exposure below which there are no apparent adverse effects using laboratory animals — the No Observed-Adverse-Effect-Level (Figure 9). An uncertainty factor is then incorporated in order to derive a regulatory standard or guideline. The size of uncertainty factor depends upon the type and quality of the available data, and is generally in the range of 100 to 5000. The use of this approach implies that there is a threshold dose below which an adverse effect is presumed not to occur.

DERIVATION OF STANDARDS FOR CHEMICALS

- *need to determine the "dose-response" relationship*
- *generally have to use laboratory animals*
- *determine exposure level below which no effects occur*
- *incorporate a safety factor to derive standard*

Figure 9

For carcinogenic substances, it is assumed that there is some probability of harm at any level of exposure. Consequently, there is no threshold of exposure below which adverse effects will not occur, and therefore it is not appropriate to derive standards using the approach just described. Nevertheless, the incremental risk which a carcinogen poses to health decreases as the degree of exposure decreases. At sufficiently low exposures the risk posed by a carcinogenic chemical may be so small as to be **essentially negligible or de minimis**, especially in comparison to other risks commonly encountered in society. In recent years, a variety of quantitative risk estimation methods have developed for dealing with carcinogenic effects. It is possible to calculate the degree of risk which is associated with a given level of exposure to a chemical. However, there are many uncertainties in the quantitative risk assessment process In Canada, therefore, we do not use risk estimation techniques to derive standards for carcinogenic substances. Rather, we try to keep exposure to carcinogens as low as possible, and use quantitative risk estimation to put a standard derived in this way into perspective

Multimedia Approach to Standard Setting

The widespread use of chemicals has led to their dispersion throughout the environment, such that they can be found in air, food, water and soil. Legislation, however, has usually been developed to deal with chemical contaminants on a medium-by-medium basis. Recently, we have been paying attention to controlling risks to health on a **multimedia** basis. This approach is designed primarily to ensure that human exposure to a toxic chemical from all possible pathways does not exceed an **acceptable** or **allowable** value. It implies that when a chemical is under assessment, all routes of exposure should be evaluated and controls or regulations should be developed taking into account the principal exposure pathways.

STANDARDS FOR CARCINOGENIC CHEMICALS

- *some probability of harm at any level of exposure*
- *cannot use A D I approach to derive standards*
- *risks to health depends upon degree of exposure*
- *set standards to keep exposure as low as possible*

Figure 10

EXPORT RESTRICTIONS

Finally, the new Canadian legislation has also recognized that toxic chemicals are a global problem There are new restrictions on the export of chemicals from Canada to other countries (Figure 11). A chemical which is banned in Canada cannot now be exported to another country, except for the purpose of disposal and with the permission of the importing country. A chemical which is severely restricted in Canada can only be exported after the Canadian government and the government of the importing country have been informed. It is hoped that this will enhance international cooperation among countries for safe handling and disposal of toxic chemicals.

CANADIAN ENVIRONMENTAL PROTECTION ACT
Section 41 (2) "Export of Toxic Substances"

No person shall export any toxic substance specified on the List of Prohibited Substances in Part I of Schedule II except for the purpose of destroying the substance or complying with a direction under subparagraph 40 (b) (iii)

Figure 11

BIBLIOGRAPHY

HICKMAN, J R. & GILMAN, A P, "The approach to safety evaluation and control of chemicals in Canada", in Homburger, 2nd Int. Conf. on Safety Evaluation and Regulation of Chemicals, Cambridge 1983. Published in Safety Evaluation and Regulation of Chemicals 2, pp. 11–18 (Karger, Basel, 1985).

KREWSKI, D. & BIRKWOOD, PL, "Risk assessment and risk management," *Risk Abstracts*, 4, 53–61 (1987)

MUNRO, I C & KREWSKI, D R, "Regulatory considerations in risk management", in Stich, H.F. (ed) "Carcinogens and Mutagens in the Environment: Naturally Occurring Compounds," Vol II, 155-166 (CRC Press, Baton Rouge, 1983).

PUGSLEY, L.I. "The administration and development of federal statutes on foods and drugs in Canada," *Medical Services Journal*, Canada, 23, 387-449 (1967)

SOMERS, E & MACDONALD, G E, "Regulatory control of chemicals. the Canadian experience," in Homburger, 1st. Int Conf on Safety Evaluation and Regulation of Chemicals, Cambridge 1982. Published in "Safety Evaluation and Regulation of Chemicals", pp. 16–25 (Karger, Basel, 1982)