REGULATORY SCIENCE IN CANADA

Introduction:

Governments have had a long, albeit for the most part, disinterested involvement with science. One major exception has always been in the arena of so called national security especially during times of warfare. Another was some public health measures, such as various sorts of public sanitation. Both had more to do with technology than with the underlying sciences involved. There certainly was an increased interest during and after WW2. In the 60s there was a realization that governments were devoting an enormous amount of resources to supporting scientific and technological endeavors. Out of this grew an appreciation that governments' role with respect to science and technology was enormous. In parallel arose the appreciation of the perils of technology as it affected and affects the environment and the workplace with consequences to human health that had never been considered.

In 1968 the Canadian government created the Science Council Of Canada to advise it on all aspects of the relationship between science and government. Thus the term Science Policy became somewhat prominent and became a hobby horse in the bureaucracy for the next twenty years or so. The Science Council has been disbanded and there are now no bureaucratic mechanisms that deal directly and holistically with Science Policy. Indeed what few remain are usually at the provincial level with an interest restricted to technological development with an eye to bettering the Canadian economy.

One area that government was and presumably still is devoting time and resources to is the protection of human health. Administratively it accomplishes this by regulation. It is obvious that to succeed at this endeavor an appreciation of the sciences involved in promoting and protecting human health is critical.

The Science Council had long been interested in the protection of human health and more particularly in the effectiveness of relevant government policy. "Policy And Poisons" and "Regulating The Regulators" are two Council policy reports that exemplify its concern about how well Canadian citizens have been and are being protected from hazards and risks about which they have no control and very often no, little, incomplete or false information.

Council was involved in this policy area because much of the protection afforded Canadian citizenry from invidious and often invisible perils is closely related to scientific research and the often resultant technological developments. Governments devote a great deal of resources to "Science" that assist officials in making regulatory decisions. For the purposes of this statement, this "Science" is labeled "Regulatory Science." A very significant percentage of the government's science budget is devoted to these endeavors. Because of its mandate, the Science Council, therefore, had a keen interest in trying to determine the size, shape, and, in general, the quality of these efforts. Based on such analysis the Council expects that it can make recommendations, that, at the very least, could lead to some improvement in their cost effectiveness and, at best, to greater real protection for Canadian citizens.

The activities that make up "Regulatory Science" consist mainly of identifying risks and measuring their severity. The sciences involved include toxicology, epidemiology,

analytical chemistry, field biology, atmospheric physics and chemistry, microbiology, etc. It is obvious that the quality of "Regulatory Science" is related to the quality of all these sciences, no matter whether they are located in government, universities or industry. The two most often considered key are toxicology and epidemiology. As such, a determination of their quality could serve as a bellwether. It is for this reason that the Council, as part of its examination of "Regulatory Science" engaged in studies of these disciplines and held workshops on each. An attempt to examine the science behind certain regulatory decisions was also undertaken, specifically those related to benzene, lead and the red dyes used as food colours.

What follows is a statement that attempts to outline the problem, arrive at some conclusions and make some recommendations. While it is mostly based on the work that was undertaken, it cannot help being influenced by certain tacit value judgments. In a free democratic society, such as ours. It is the right of both the collective and in certain instances, individuals, to accept or reject risks that are imposed by others. To properly exercise this right, unbiased, valid, relevant, and as complete as possible information about these types of risks should be made freely available, again as a right. The amount and quality of this information available for Canadians is, obviously, directed related to the amount and quality of "Regulatory Science" being carried out in Canada.

The Problem:

While it is impossible to calculate, with any degree of accuracy, the total number of chemicals and energy forms encountered by people who live in industrialized societies, it is known to be very large. Since WW2 the number has grown to be orders of magnitude greater than all of the chemical and energy forms, natural or artificial, that have been introduced into the overall environment in previously recorded human history. Many have been introduced into the natural environment, many into the work environment and very many make up ingredients in consumer products. We are exposed to them through the air we breathe, the solids and liquids we ingest and by direct contact via our skin, ears and eyes.

For a long time very little concern about these exposures was exhibited, mainly because no immediate, acute negative effects were discerned and the benefits, real or illusory, were considered to be many and major. In certain quarters this lack of concern is still de rigueur for the same reasons. In due course, it became apparent that continuous long term exposure to low levels of these chemical and energy forms poses a real risk in the form of carcinogenesis, mutagenesis, teratogenesis and other disorders of a somatic, circulatory, pulmonary, immunilogical, gastrointestinal, allergic, sensory and psychological nature. Over the last number of years, public concern about these exposures has grown dramatically resulting in much pressure to control these exposures to levels that are considered "safe."

What follows is a list of questions that sketches the overall problem facing regulatory authorities, as they attempt to respond to the public and sometimes contradictory political forces that push for better promotion while promoting deregulation. (In the next section, titled, Conclusions and Recommendations, this statement will focus mostly on those questions that deal with "Regulatory Science." The others are included to illustrate

the complexity of the problem and to provoke more needed study, discussion and thought to underline the importance of Regulatory Science.)

1. From the tens and possibly hundreds of thousands of chemical and physical entities that humans are now exposed to, let alone the hundreds of new ones that are introduced annually, how can those that are dangerous be identified at a reasonable cost? However, implicit in this question is a fallacious assumption, which is that all these entities work in isolation from each other and that there is no antagonism nor symbiosis between them. Is it possible that when chemical X, harmless by itself, becomes the latest in a long list of chemicals to which we are exposed, it is transformed into the straw that breaks the camel's back? How do we deal with this horrific potential?

2. How can a greater degree of certainty about the nature and degree of risk involved with exposure to these potentially dangerous entities be established in the regulatory process? The uncertainty referred to here is of the scientific variety. While science is replete with uncertainty, the amount of it that appears to be endemic to risk measurements is relatively high. For example, epidemiological studies often suffer from a lack of relevant input leading to statistical results that are doubtful. The often long gestation period between an exposure and the manifestation of a deleterious effect further complicates matters. The inability of epidemiologists to carry out human experimentation, for ethical reasons, further hampers that discipline.

Toxicology is no better off. Since most of its work is based on cellular, microbiological and animal studies, the deduced human effects are based on somewhat uncertain extrapolations from cells, microbes and animals to man. In light of all this, is a greater effort needed? If so, how much and where? Are there new developments that need to be explored such as in the areas of pollution abatement, immunological and allergic responses, genetic predispositions and protective technologies?

3. When there is uncertainty, controversy usually follows. How can relevant scientific arguments be resolved? Through a Science Court? A Mediation Process? Arbitration? How can the regulatory process be rational and effective when such controversies occur? How can such controversies be prevented from spilling over into the political arena?

4. How can the strengths and limitations of Regulatory Science be made clear to everyone concerned so that unrealistic expectations can be avoided and false information from being disseminated? One notion that needs to be dispelled is the thought that "safe" is synonymous with "zero risk." There is no such thing as "zero risk." There is only "risk," which, sometimes, is so small it cannot be measured.

5. How can the regulatory system be altered to ensure that public input is meaningful and bureaucratic and political accountability is real, without turning the regulatory system into a political football and without compromising its ability to protect the Canadian public with countless delays due to litigation, public forums, task forces, etc.? This question is based on the idea that "safety" is not a scientific concept but rather socio political in nature and analogous to "acceptable risk." If this is so, who decides which risks are acceptable? What criteria should be used? How can all the factors, conflicting or otherwise, be balanced so that the best decisions are made? How can we be sure that regulatory standards reflect this approach?

6. How much weight should be given to the scientific aspects of a regulatory issue as opposed to those of an economic, social and political nature?

7. Finally, how can the credibility of Regulatory Science and the Regulatory System be improved so that Canadians can feel secure in the knowledge that they are being well and reasonably protected? The system must not only work well, it must be perceived to be working well.

In summary, all the above can be condensed into the following somewhat complex and difficult query. In light of the plethora of chemical and physical entities in our society and the uncertainties associated with determining how dangerous or safe they are, how can the regulatory process properly identify those that are dangerous, either singly or collectively in groups, then make regulations that will protect Canadians while taking into account all the relevant, economic, social, political and technological factors? While a completely satisfactory answer would require the wisdom of Solomon, a tentative partial answer is offered. With no apologies intended, many of the conclusions and recommendations that follow are not new, are probably obvious, and particularly with the measures recommended, have been considered, are being tried or are already in place. If this is the case this statement becomes one of support for those endeavors.

Conclusions and Recommendations:

Generalities.

At first glance the problem appears to be insurmountable and perhaps it is. We have become addicted to a, "technological fix," in which chemicals play a very large part. The hundreds of thousands of chemicals already in our environment and the rapid rate of introduction of new chemicals make it impossible to test them all for their hazardous properties in a reasonable time frame even if all the industrialized countries work in concert. If anything, we are more than likely taking one step forward and two backwards.

The first thing needed is a widespread recognition of the problem. It is a problem that will not go away by itself. It may even be further exacerbated by exotic new technologies such as microelectronics and biotechnology. There must be political will and resolve to acknowledge and face the problem squarely despite the fact that the risks involved are not as dramatic as those related to plane and train travel. It needs immediate and ongoing attention. While the problem will probably never be completely resolved, it can be contained and prevented from growing into a situation where irreversible damage has occurred. Much can be done, should be done and remains to be done. The need to know should not be used as an excuse for doing nothing. Obviously recognizing that a problem exists is a good first step. However, while it is necessary, it is not sufficient.

Herewith further recommendations of a general and specific nature.

1. The regulatory sciences need to be strengthened in Canada wherever they exist. The granting councils, including the SSHRC, have a major role to play. Industries that are contributors to the problem should be encouraged, by whatever means the government deems necessary, to either fund or conduct studies of a relevant nature. Resources that

were taken away from the NRC Associate Committee On Scientific Criteria and Environmental Quality should be returned to it. The federal government should reconsider its decision to cancel its partial sponsorship of the Canadian Centre of Toxicology, (Toronto/Guelph Institute of Toxicology). "Canada lacks an organization that has the critical mass of multidisciplinary scientific personnel necessary to undertake broad based toxicological problems." (1)

Contrary to what has been occurring recently, the regulatory scientific apparatus in government departments such as, Health and Welfare Canada, Agriculture Canada, Environment Canada, the Department of Corporate and Consumer Affairs and the Department of Energy, Mines and Resources, to name the most important ones, should, at the very least, be maintained. In those areas where "Contracting Out" is impossible, these resources should be improved. To ensure greater efficiency, MOSST should undertake an inventory of regulatory scientific resources with an eye to maximizing their utility.

It is impossible to determine how much resources should be devoted to improving the situation vis a vis regulatory science. The old saying is operative here. "You get what you pay for." While we may be accused of ducking the issue, how much is needed and how much we are willing to spend and where, are very subjective questions.

This statement argues that more is needed. The argument is partially based on some recent surveys that suggest that the capacity, in Canada, to meet the needs of toxicology is wanting. (2) That argument is reinforced, not only by the views of just about every scientist with a stake or interest in risk analysis (3), but also by some recent events, such as the acid rain debate, the pollution of the St. Clair river and lake, the spills of PCBs, the recent rise in the incidence of lung cancer amongst uranium miners and the growing concern about the quality of our drinking water.

At a 'Science Council National Workshop On The Status Of Toxicology In Canada', industry and government participants pointed, out that today's needs are for, "applied toxicologists, people with abroad knowledge in the related areas like product safety, environmental protection, industrial hygiene, customer relations, etc. " and for "evaluators of toxicological data developed by other countries that is required for the preparation of regulatory submissions within government departments, particularly Health and Welfare." (4) It has become evident that an indepth study of Canada's capacity in the regulatory sciences to meet its needs is required. Perhaps singly or jointly, the Ministry of State for Science and Technology (MOSST), the Science Council of Canada (SCC), and the Canadian Council of Resource and Environmental Ministers (CCREM) should be asked to undertake this venture by some of the more involved government departments, such as Health and Welfare, Environment and Agriculture.

Enhancing the regulatory sciences is not always a question of money. The following four recommendations illustrate this: (5)
Federal and provincial governments, in consultation with concerned advisory bodies, should enact legislation and/or formulate a set of ethical guidelines for the provision of access to data bases about individuals in the population to bona fide researchers, which should take account of both the detailed needs of these researchers and the rights of individuals to confidentiality and privacy.

Access to all regulatory information presently subject to permission from commercial enterprises should be granted to bona fide researchers with suitable precautions regarding the confidentiality of proprietary information.

Consideration should be given to the development of mechanisms whereby the producers and distributors of toxic products would contribute explicitly to the cost of post marketing epidemiological surveillance.

Government agencies involved in product regulation should give a high priority to the development of data on the distribution and use of products so as to facilitate post marketing epidemiological surveillance.

2. There is an aspect of the problem that must be clearly understood so that it can be dealt with. Uncertainty is part of the fabric of science. It is even more so in the occupational and environmental health sciences. While it cannot be eliminated it can certainly be reduced and efforts to accomplish this should be undertaken. Such efforts should include;

a) Regional epidemiological studies carried out by local and regional University Faculties of Health Sciences. The Appendix to this statement contains a list of human health problems that should be addressed by these studies.

b) The taking into account of the results of negative studies. These are often ignored. They should not be. A positive study is usually terminated when an effect has been identified, whereas, a negative study must be far more thorough to prove that a given level of exposure does not increase the risk to those exposed. Perhaps an international database fort negative results can be established by a body such as the World Health Organization (WHO).

c) Research into methodology with the aim of improving toxicological and epidemiological studies. For example, linear extrapolation is used in risk assessment to extend the dose response curve from a high exposure level to a low one, assuming that the risk of contracting a disease, such as cancer, exists as long as the substance is present. As practiced, linear extrapolation does not differentiate between the possible causes of tumours found in laboratory animals and ignores the possibility of a threshold effect. Thus the potential exists for misuse of data or biased interpretation. While linear extrapolation has been a useful regulatory tool, it will remain little more than a statistical exercise as long as we do not understand the mechanisms of cancer induction. Research into both to establish their links is needed. Another example is the need for research to illuminate the relationship between allergic sensitivities and genetic profiles. This has arisen because of the growing appreciation of the importance of idiosyncratic responses. A third example is the need for further study of neurotoxic effects as underlined by questions as; Can normal statistical techniques be applied to subjective assessments of subtle changes in IQ and behavior? Have we developed techniques to measure memory?

Further, given the infinite number of combinations and concentrations in which chemicals may be encountered, some means other than the traditional laboratory toxicity studies are needed to predict the effects of interactions. The best approach seems to be fundamental work in chemical interactions and the identification of patterns for similarly acting chemicals. Complementary to this, an approach to parallelism between effects observed in laboratory studies and human health implications by identifying the particular animal study which most closely mimics the response of a particular human subpopulation should be undertaken. In addition, a process of overcoming institutional

obstacles towards gaining access to existing proprietary data and related studies produced by pharmaceutical houses for various classes of chemicals should be initiated. The skills of engineers, physicists, chemists and biologists would be needed for an overall study, which could take up to 4 years. (7)
d) Extensive exploration about the feasibility and development of record linkage systems, connecting such things as census data with residential, occupational, medical, hospital and mortality records. Birth documents should be revised to capture; paternal occupation maternal occupation, both during and/or prior to pregnancy presence of a birth defect with specification of its nature.

Excellent capabilities for record linkage have and are being developed in Canada. They should be recognized as a major epidemiological resource to be fully utilized by Canadian investigators. (8)

3. Canada should get as involved as possible in international cooperative regulatory scientific efforts. As with many other areas, it is obvious that Canada cannot go it alone. Canada's current efforts the international sphere are applauded, particularly its role in the O.E.C.D., I.L.O., W.H.O., I.A.R.C., F.A.O. and the UN Environmental Program. More should be encouraged. Strong international links are obviously essential to ensure that we are kept up to date on all the latest developments. Every effort to promote international joint ventures and to participate in them should be undertaken.

However some precautions should always be kept in mind. They were voiced by some participants at the recent Science Council Toxicology Workshop. (9)

"How are you ever going to find out, for example, the environmental degradation rate of certain substances under Canadian conditions when you import them from offshore?"

"We cannot be totally dependent on imported science to settle Canada's toxicological problems."

"We need the ability to make sure the information we are getting is really what we are looking for."

4. A Risk Agency should be created. Currently there are just too many bureaucratic actors from various departments and agencies involved in regulating risk. They often have different agendas which often lead them to pull in opposite directions. While the exact format and mandate can be worked out the agency should;
a) Be completely independent from from any government department. It should be responsible only to parliament through the Prime Minister.
b) Its mandate should be defined as clearly as possible and should include measuring risks, anticipating them, developing the appropriate measures to deal with them and designing a hierarchy of risks which in turn could lead to a system of prioritizing the testing of hazardous materials and needed research.
c) It should have the authority to make regulations and standards that transcend those already in force.
d) While there should be representation from the key government departments, preferably at the ADM level, that representation should not have any decision making power but should make needed inputs into the agency.
e) It should be run by a Board of Directors with members from provincial governments, public interest groups, trade unions, industrial management, and academics from both

the natural and social sciences. In the long term much of the regulatory functions of the federal government designed to protect human health could come to reside in this agency. Further the regulatory scientific institutions that currently exist inside various departments could acquire an independent status and do their work under contract for any interested party, including the risk agency, relevant government departments, the private sector and provincial governments. The kernel of such an agency exists. The Interdepartmental Committee on Toxic Chemicals, which appears to be seeking a raison d'etre, could serve as a starting point.

Concluding Remark:

This type of statement is easy to ignore and because of that may be so treated. There appears to be two reasons for this. First, it can be accused of being alarmist and as such is cheerfully discarded. The plea to that charge is not guilty. It is not an alarmist statement. If anything it understates the case. Why is it that we are not willing to critically examine the disasters we create? Why do we continue to pretend surprise when they occur?

The second reason can be stated as follows. Policy statements that are put together by groups of interested parties are so frequently characterized by any or all of the following, that the old cliche, "familiarity breeds contempt" is translated into reality.

- At the very least the situation is serious and requires immediate action.

- Because of the seriousness of the situation more resources are needed and should be deployed immediately in these essential areas.

- Because of the novel characteristics of this situation a new mechanism is urgently required to deal with it and to integrate, coordinate and render more effective the whole operation.

This statement is guilty of the above three counts with an explanation. We really feel that the situation is serious enough to warrant action. However, if the public and political sectors of society perceive that the problem is not so perilous, or that the costs of remedial action are too high, relative to the problem, than a do nothing, or at the very least, a maintenance of the status quo approach is advisable. We are aware that this statement flies in the face of what the government has been doing. We can only conclude with the question, "Of what use is a society with a booming economy, which was made so by the health sacrifices of its citizens, who are now too ill or gone so that they cannot appreciate the benefits of their supposed new found wealth?

NOTES AND REFERENCES:

1) Proceedings of a National Workshop On The Status of Toxicology In Canada, sponsored by the Science Council of Canada. Page 18.

2) The Status Of Toxicology In Canada; A Science Council Study by I. Hoffman and R. Roberts.

3) This view was and is being expressed publicly and privately by every concerned citizen and scientist from all walks of life and from all societal sectors ion every possible occasion. Certainly such sentiments were expressed by the participants at the Science Council workshops on toxicology and epidemiology and by the panel of experts that the Council put together to broadly evaluate regulatory science.

4) Proceedings of a National Workshop On The Status Of Toxicology In Canada, sponsored by the Science Council Of Canada. Page 14.

5) Proceedings of a National Workshop On The Role Of Epidemiology In The Risk Assessment Process In Canada, sponsored by the Science Council Of Canada. Page 36.

6) The appendix to this statement is taken from Science Council Study, "An Appraisal Of The Role Of Epidemiology In The Regulatory Risk Assessment Process In Canada, by C. Chappel, H. Grice, A. Miller, R. Willes. Pages 91 93.

7) The Status Of Toxicology In Canada. A Science Council Study by I. Hoffman and R. Roberts. Pages 109 110.

8) Proceedings Of A National Workshop On The Role Of Epidemiolgy In The Risk Assessment Process In Canada, sponsored by the Science Council Of Canada. Page 37.

9) Proceedings of a National Workshop On The Status Of Toxicology In Canada, sponsored by the Science Council Of Canada. Page 14.

Appendix

Potential Human Problems That Should Be Addressed by Epidemiological Investigations from D. Wigle, Health Protection Branch, Health & Welfare, Canada

The major health problems identified by premature death (PYLL), hospital patient days and self reporting are summarized in Table 1.

Heart disease was the only health problem to rank high on all indicators. Conditions which ranked high on most or all indicators other than PYLL included digestive diseases (as a group), accident, mental disorders and arthritis and allied conditions.

The indicators should not be "weighted" equally. For example, PYLL is a far more severe outcome than consultations or drug use. It is proposed that serious health problems be

defined as broad disease groups in the top ten by one or more of PYLL, patient days and long term disability. Those included in this definition are asterisked in Table 1 and include cardiovascular diseases, cancer, respiratory diseases, digestive diseases, accidents and violence, neonatal conditions, nervous system diseases, diabetes, mental disorders and arthritis and allied conditions.

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