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MECHANISMS AND PRACTICES FOR THE ASSESSMENT OF THE SOCIAL AND CULTURAL IMPLICATIONS OF SCIENCE AND TECHNOLOGY

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SUMMARY

Introduction

As part of the review being conducted by Industry Canada on science and technology, this paper deals with the mechanisms and practices for the assessment of the social and cultural implications of technology. It examines the range and suitability of Canadian mechanisms and practices for assessing current and emerging social and cultural issues raised by science and the new technologies. It reaches the conclusion that, notwithstanding the vast resources applied to science and technology and their social and cultural implications, all is not well in this regard. The paper provides a discussion of what might be required to change the situation.

There is a vast literature dealing with the problems under review in this paper. It deals with assessment, with the various methods by which the assessment is carried out, with science and technology, with science and technology policy, and with the social and cultural implications of science and technology. To do justice to the literature, and to render the discussion manageable, the paper is structured in three parts. The first part uses four examples of conventional wisdom about science and technology or related matters as a foil, a means of arriving quickly at a focused synthesis of the literature. The second part draws on this synthesis to deal directly with the mechanisms and practices for the assessment of the social and cultural implications of science and technology. The focus is on three arenas of science policy. Each arena is analyzed in such a way as to make recommendations possible.

Finally, there are appendices containing case studies specially prepared for this paper. One discusses some aspects of biotechnology, and more particularly its use in agriculture. Its focus is on the social and cultural implications of science and technology, especially on how they have been dealt with in a variety of contexts. The second case study deals less with specific issues, and more with the range of mechanisms and practices used in Canada in dealing with environmental, safety and health risks attached to science and technology and its implementation.

Definition of Key Terms

A definition of some key terms is necessary.

- *Science and technology* are different but related activities, and are considered a single enterprise for the purposes of this paper. Emphasis is given to the natural and technical sciences, but science is understood to include social sciences and economics. Distinctions between basic, mission-oriented and applied sciences are not of concern in this paper.
- *Mandated science* is the body of science or technology — including basic science and applied research — drawn on expressly for the purposes of public policy and regulation.

- *Science policy* is defined as government-initiated policies intended to promote or evaluate science and technology because of their contributions to, or the problems created for, the general well-being of society. In this context, science policy always deals, explicitly or implicitly, with the social and cultural implications of science and technology, whatever other objectives are also intended.
- *The social and cultural implications of science and technology* include not only the social by-products of the applications of science and technology, such as are dealt with in technological or environmental assessments, for example, but also the roles played by science and technology in promoting or impeding the social and economic well-being of Canadians.
- *Social* and *cultural* are understood to include the natural environment, but are not limited to encompassing environmental, health or safety issues, and include changes to the social fabric, to the skills profile and to the working lives of all Canadians.
- *Assessment* refers to the many different approaches to the assessment of science and technology, and to a large literature debating the usefulness and limitations of various methodologies, including risk assessment, technology assessment, cost-benefit analysis and economic forecasting.
- *Mechanisms and practices* refer to initiatives taken by, or in conjunction with, government to facilitate the assessment of science and technology. This includes, but is not limited to, public inquiries and royal commissions, task forces, special panels and advisory committees, regulatory hearings, formal hearings designed for assessment of major economic, social, regulatory or environmental initiatives, and governmental organizations specifically mandated to conduct assessments of science and technology on a continual or occasional basis.

Overview of Analysis

It is all too easy to develop inappropriate expectations of both science and technology and of the mechanisms and practices for their assessment. Furthermore, without an overview, without constant monitoring of the environment and developments within it, and without rigorous evaluations of initiatives, it is quite likely that the benefits attributed to science and technology and their assessment will fail to materialize. Given the high level of dependence on science and technology which characterizes an advanced industrial economy such as Canada, this would be a serious problem.

Placing emphasis on mechanisms and practices seems to imply that an administrative solution lies in waiting to meet the needs of science policy. Whether one is speaking about risk assessment or about the promotion of science culture, it is all too easy to rely on models which, although increasingly sophisticated, are nonetheless confounded by the intransigent problems of melding science with public policy.

When responsibility for research is devolved to non-governmental bodies whose research reports are viewed as instruments for lobbying, when government research activities are

curtailed and when consultation replaces research as the only method for conducting assessment of the social and cultural implications of science and technology, assessment itself is seriously compromised. However beneficial the devolution of research might be for other reasons, and however important consultation is as a form of research in its own right, there is still an urgent need for research, conducted according to scientific values, to be used as background information for developing the overview and evaluating the implications of science and technology.

It is worth emphasizing that the policy process is an iterative one for science policy no less than any other form of policy making. The multiplicity of committees, mechanisms and practices for assessment, review procedures, etc., can be evidence of wastefulness, but often it reflects the needs of the political and legal situations facing policy makers, and the many conflicting needs and demands of their various constituent publics. Costly and sometimes inefficient or even counter-productive, the array of mechanisms and practices for assessment of the social and cultural implications of science and technology is likely to remain in place.

That said, there is often a need for specific and timely advice about issues involving complex scientific or technical questions, and for "overview" statements which gauge the status of scientific and technological development in Canada in relation to the needs and dictates of the new economy and the general well-being of Canadians.

The primary focus of recent attention in the literature has been on the policy side of the equation, with many groups and analysts concerned that the policy implications of science and technology and questions about social values will be neglected, and that science and technology will themselves be seen as sufficient to meet the needs of Canadians. Theirs is a legitimate concern, and it has led to increasing emphasis on processes for assessment of the social and cultural implications of science and technology. Even these new processes have their shortcomings, however. They easily become venues for public controversies about symbolic issues[1] or, alternatively, they demonstrate the worst aspects of adversary procedures: preoccupation with procedures over issues of substance, lack of adequate representation and undermining of democratic debate.

However legitimate the concern with the policy side of the equation, there is equal reason to be concerned about the quality and quantity of the scientific and technical research being used in conjunction with public policy. As studies of mandated science demonstrate, processes for assessment are often characterized by scientific work which does not meet the rigorous standards of science and which involves scientists (among others) in making judgments only peripherally related to their expertise — ironically, the kinds of judgments actually required for public policy.

Toward Recommendations

In the last two decades, a vast array of mechanisms and practices for assessment of science and technology have been put into place. Government departments now routinely draw on increasingly sophisticated methodologies for assessment, and the results are promising. That said, there are intrinsic problems in the mix of science and public policy, and controversies often erupt in spite of the best efforts of all concerned. Moreover, the best uses of assessment procedures depend on a highly rational administrative process, but the political process is never so rational that conflict, jurisdictional problems, procedural wrangling and political issues do not arise.

Suggestions included in this paper deal mainly with ways that the current assessment process might be better co-ordinated or supplemented to deal with the challenges posed by new developments in science and technology. They concern issues involving more than one agency or department of government and matters of such broad significance that an independent capacity for review is required.

Three arenas are identified in which the mechanisms and practices for social and cultural assessment take place. Each generates its own problems and requires its own recommendations.

Arena One: Assessing science and technology for the purpose of policy and regulation

To deal with the problems arising from the mix of science and public policy imperatives, and to support more informed debate on scientifically complex issues of considerable public urgency, it is suggested that a new practice be instituted involving scientific focus groups, whose task it would be (unlike that of current consultative committees, task forces, advisory councils or expert committees used routinely by government departments) to comment on the "state of the art" in the scientific literature with respect to particular issues likely to be considered for assessment.

The task of such scientific focus groups would be a limited one: to comment only on what is known, not known, uncertain and highly contestable about such issues to aid in preparing adequate background information to support informed assessments. Their contribution would not supplant conventional assessments nor lead to recommendations, which are more properly handled within government or through use of expert or consultative committees, routine assessment procedures or, in special cases, through inquiries. The use of scientific focus groups would render priority-setting exercises more effective and efficient. Their use would lay a foundation of credible information for debate, generating a higher level of public confidence in science and technology than is typical in controversies about scientifically complex issues. Scientific focus groups are relevant in both the natural and social sciences.

To establish such groups, a mechanism is necessary. Appropriate expertise must be located, a time frame set, a means of reporting established, etc. The paper argues that scientific focus groups must be, and be seen to be, independent of government departments. It discusses the advantages and disadvantages of using existing organizations in Canada, such as the disciplinary associations or independent research institutes, and of establishing something new to set up and oversee such focus groups.

Arena Two: Promoting science and technology

With respect to initiatives designed to promote science and technology, it is suggested that neither is there the basis for an adequate assessment of such initiatives (because existing evaluations are not made public or published), nor has enough attention been paid to establishing benchmarks for their success. Efforts are required to locate and co-ordinate existing evaluations and to provide an overview. The task to be done is difficult, and prior attempts to gain an overview have been inappropriately mandated and unsuccessful. A well-defined, delimited and strategically designed effort, focused mainly on evaluating initiatives to promote science and technology (as opposed to evaluating science development in particular areas), might prove more promising.

Arena Three: Assessing Canada's capabilities and position in the new economy

With respect to environmental scanning, i.e., the evaluation of Canada's position in relation to the new economy, there is even more serious need for a co-ordinated view. Some initiatives are promising, such as the regulatory review requirement embodied in the mandate of the Canadian Radio-television and Telecommunications Commission (CRTC), the emergence of sectoral councils of one kind or another and the development of new independent research institutes specifically dedicated to the task of environmental scanning. In the best of circumstances, one organization would assume responsibility for environmental scanning and draw on other institutions, programs, mechanisms and initiatives to complement its work. There are several successful examples in other countries. In today's situation in Canada, it is unlikely — although not impossible — that any new organization with such a broad mandate will be established. In its absence, much more strategic use needs to be made of the resources and initiatives that do or might easily exist.

Concluding Comments

Two last remarks reflect the preoccupations of the author of this paper. The first is a concern that the contributions of science not be compromised in the interests of promoting sound public policy, important though sound public policy may be.

In terms of assessment, scientists have a crucial but limited contribution to make. They can bring their expertise to bear to answer questions about what is known (with a reasonable degree of confidence), what is not known, what remains uncertain and what is subject to debate within any field and with respect to any issue. This is precisely the information needed by policy makers. But, all too often, scientists are called on to contribute to another debate, in this case about the implications of science and technology for particular policies under development. In the latter debate, scientists offer an informed view, but their expertise is not necessarily relevant to the types of questions being addressed.

Furthermore, scientists have no exclusive claim to expertise about the implications of their research, or of science in general. Occasionally, they are poorly prepared to offer useful insights because of the narrowness and rigour of their own work and expertise. In other words, while scientific assessment has an important contribution to make to public policy, it is crucial that the capacity of science to address policy-related questions not be overestimated or wrongly understood. The price of both is not just (or necessarily) poor public policies, it is sometimes poor science.

Second, while there is no one model of how scientific assessment should be done, especially with respect to new technologies and the new economy, there is ample room for change. There are many approaches to accomplish the goal of assessment of the social and cultural implications of science and technology, and, indeed, there are now many examples of successful efforts in this regard. In today's political climate, it is safe to assume that whatever is put into place will involve both consultation and research, and will probably develop partly outside departments of government. Anything put into place should probably also be reasonably independent, not just of government but of policy research institutes associated in the public mind (properly or not) with particular political perspectives. Anything put into place should enhance the assessment capacity of government and its many constituents without adding to their administrative burden or to the cacophony of public controversy. The initiatives discussed in this paper offer promising avenues of approach, but they do not exhaust the possibilities.

INTRODUCTION

It seems unexceptional to say that science and technology hold the key to social and economic development. From this, it would logically follow that every effort is, and should be, made not only to promote science and technology, but also to integrate their benefits and monitor their effects. This paper examines the range and suitability of Canadian mechanisms and practices for assessing the social and cultural issues raised by science and the new technologies. It reaches the conclusion that, notwithstanding the vast resources applied to science and technology and their social and cultural implications, all is not well in this regard. The paper provides a discussion of what might be required to change the situation.

There is a vast literature dealing with the problems under review in this paper. It deals with assessment, with the various methods by which assessment is carried out, with science and technology, with scientific and technological policy, and with the social and cultural implications of science and technology. To do justice to the literature, and to render the discussion manageable, the paper is structured in three parts. The first part uses four examples of conventional wisdom about science and technology or related matters as a foil, a means of arriving quickly at a focused synthesis of the literature. The second part draws on this synthesis and deals directly with the mechanisms and practices. Again, however, one could spend many pages simply describing the mechanisms used in Canada with respect to many different issues. This is not the purpose of the paper. The focus is instead on three arenas of science policy, and each arena is analyzed in such a way as to make recommendations possible. Finally, there are appendices containing two case studies specially prepared for this paper.

As noted, two new case studies were prepared for this paper. One deals with some aspects of biotechnology, and more particularly its use in agriculture. Its focus is on the social and cultural implications of science and technology, especially on how they have been dealt with in a variety of contexts. As might be expected given the controversial nature of the topic, the case study takes a point of view; different views are easily located through its references. The second case study deals less with specific issues, and more with the range of mechanisms and practices used in Canada in dealing with environmental, safety and health risks attached to science and technology and its implementation. In this case, it is possible to present a more detached view of the situation. Another review was conducted of a few of the agencies and organizations used in the United States and Britain to conduct assessments and evaluate the social and cultural implications of science and technology. It is not included here because most of the information is readily available elsewhere. These case studies do not exhaust the background material by any means. A further case, drawn on extensively but not reported in detail, is that of the new communication and information technologies.

A definition of some key terms is a necessary preface to the discussion. *Science and technology* are different but related activities, but will be dealt with as a single enterprise for the purposes of this paper. Emphasis will be given to the natural and technical sciences, but science

should be understood to include social sciences and economics. Distinctions between basic, mission-oriented and applied sciences are not of concern in this paper. Reference will be made, however, to *mandated science*, which is the body of science or technology — including basic science and applied research — drawn on expressly for the purposes of public policy and regulation.[2] Reference will also be made to *science policy*, which is defined as government-initiated policies intended to promote or evaluate science and technology because of their contributions to, or the problems created for, the general well-being of society. In this context, science policy always deals, explicitly or implicitly, with the social and cultural implications of science and technology, whatever other objectives are also intended. In turn, *the social and cultural implications of science and technology* include not only the social by-products of the applications of science and technology, such as are dealt with in technological or environmental assessments for example, but also the roles played by science and technology in promoting or impeding the social and economic well-being of Canadians. *Social* and *cultural* are understood to include the natural environment, but are not limited to encompassing environmental, health or safety issues, and include changes to the social fabric, to the skills profile and to the working lives of all Canadians. The term *assessment* will be frequently used. There are many different approaches to the assessment of science and technology,[3] and a large literature debating the usefulness and limitations of various methodologies.[4] In this paper, assessment refers to all of these approaches and methodologies, including risk assessment, technology assessment, cost-benefit analysis and economic forecasting. *Mechanisms and practices* refer to initiatives taken by, or in conjunction, with government to facilitate the assessment of science and technology. They include, but are not limited to, public inquiries and royal commissions, task forces, special panels and advisory committees, regulatory hearings, formal hearings designed for assessment of major economic, social, regulatory or environmental initiatives, and organizations specifically mandated to conduct assessments of science and technology on a continual or occasional basis.

1. CONVENTIONAL WISDOM UNDER SCRUTINY: A LITERATURE REVIEW

Conventional wisdom abounds in any discussion of science and technology and its assessment. Little-examined assumptions about the importance of science and technology and about their usefulness for public policy are used to support policy measures involving major commitments of financial and human resources. To be sure, as will be indicated shortly, these assumptions contain a measure of truth. It is not wrong to suggest that the future health and prosperity of Canada depends on the quantity and quality of its science and technology. Neither is it mistaken to suggest that assessment is critical, and that members of the public, and stakeholders, should be consulted before any initiative is undertaken. Granting the merit of these contentions, there is something more to be said. It will be useful to clear the air by identifying the little-examined assumptions, their usefulness and limitations. Four deserve special mention.

(1) The first such assumption is that there is a cause and effect relationship between resources spent on science and technology and the benefits accruing to Canadians. Furthermore, it is generally assumed that, within the limit of available resources, greater application of resources will result in more benefits.

It is unassailable that, in the current era at least, the social well-being of Canadians and the economic development of Canada are both contingent on adequate research and, consequently, on high levels of support for science and technology. This is self-evident in the case of health, safety and the environment. Health and environmental problems cannot be identified nor solutions found, nor even new products and processes made available, without a continuing commitment to supporting science and technology and their assessment. It is less evident, but easily argued that by increasing the general stock of knowledge (i.e., basic research) as well as applied research, innovation is spawned.[5] Adequately developed and diffused throughout society, such innovations are crucial to economic growth and social well-being.[6]

There is a further aspect to the benefits accruing from investments in science and technology and their assessment. It is bound up with the phrase, *the new economy*. In many instances, the new economy is equated with the phenomenon of globalization, seen as the outcome of the increased integration of financial markets and trading regimes over the last two decades.[7] Yet, this concept of the new economy is too narrow on its own, for the growing integration of the world economy has been a steady feature of capitalism since the mercantile era of the 16th and 17th centuries.

A more adequate concept of the new economy focuses on the dynamic role that new technologies are playing in altering the economic calculus of the existing production paradigm and managerial practices, as well as the prevailing balance between the state, its citizenry and the economy, on one hand, and the different sectors of the economy, on the other.[8] At the heart of the new economy is the convergence of an integrated set of computer, communication and

video technologies, which are based on semiconductors and have in common the capacity to process and transmit data in digital form. The spreading application of microelectronic technologies to a wide range of information-handling activities generates data at the same time as it reduces cost and other barriers to automating existing processes. While the microelectronics revolution is exponentially increasing the capacity to handle information, knowledge-based inputs are simultaneously becoming an increasingly salient component of every aspect of production. These combined developments lead to the characterization of the emerging period as one of "knowledge-based" capitalism. Together these new information technologies constitute the key factors powering the emergence of the new economy.

The use of the "new economy" assumes that today's changes in the underlying technology system are so far reaching in their effects that they exert a transformative influence on every aspect of behaviour, throughout the industrial economy and in all areas of social life. What distinguishes the new economy from less pervasive changes is the relatively low (and constantly falling) cost curve, plentiful supply and ease of application of the technology.[9] Technology does not diffuse throughout a modern society as an isolated input, but rather has become the core of a rapidly growing system of technical, political, social and managerial innovations.[10] Clusters of these innovations have cumulative effects, altering virtually every aspects of social and economic relations.

To the extent that the current era is properly understood as a new economy, then, it ill serves any country, especially a highly industrialized one such as Canada, to fall behind in science and technology and, more particularly, to underestimate the importance of the assessment of science and technology. To miss seeing or mistakenly read the contours and effects of science and technology in the new economy is to be sidelined.

Unfortunately, the converse is not true. It does not follow that increasing commitments to science and technology and to assessment necessarily produce benefits for Canadians. It is entirely possible to spend money, even wisely, yet to garner few results, even in terms of establishing a research or science culture. Sometimes, instead of benefits, the result is serious problems, such as labour displacement or environmental degradation, which are costly to rectify. Innovation can be spawned, but unless innovations are adequately developed and diffused they remain bright ideas. Furthermore, as extensive experience with scienctific and technological assessment in the health and environmental fields demonstrates all too clearly, further research and assessment are not only costly,[11] but also muddy the waters, making it more difficult, instead of easier, to reach sound public policy decisions.

Lest this point be mistaken, it should be put quite forcefully. The uncertainty of outcomes attendant on increasing commitments made to science and technology and their assessment is not a reason for avoiding such commitments. On the contrary, the case is easily made that, in the absence of such commitments, seriously negative consequences follow. Without an adequate and strategic overview of the situation, and without monitoring the goals, effectiveness,

consequences and expenditures of resources on science and technology and on assessment, the equation between increasing commitments and benefits will fail to materialize.

(2) The relationship between science and policy is an easy one, adequately dealt with by current innovations in administrative process and by risk and technology assessments.

In theory, this second assumption is also unassailable. There can be little question about the usefulness for policy makers of drawing on both scientific and technical information and assessments of science and technology.[12] Even in an era of increasing public cynicism about both science and public policy, consensus exists that policy makers should rely on the best available scientific and technical advice and assessment. Moreover, in the last decade, a vast array of mechanisms has been put into place, largely funded by government, to accomplish this task. Inquiries, risk assessment, technological assessment, government department-contracted research, etc., are all designed to bring the best available information to the table before policy decisions are made.

Indeed, a new academic discipline has developed, with its own literature and journals. Risk studies address questions about how to organize the assessment of science and technology for the purposes of public policy in as administratively rational and publicly responsible a manner as possible.[13] Generally speaking, and with some notable exceptions among authors in the field of risk studies,[14] it has now been concluded that the process of scientific and technical assessment (the assessment of risk) can and should be separated from legal, policy and regulatory matters (risk management).[15] Furthermore, two sub-specializations of risk studies have developed, one dealing with the public's perceptions of risk[16] and the other with communication problems among experts, policy makers and the public.[17] Models for incorporating scientific and technical information into public policy making now abound in the literature.[18]

In practice, as any seasoned bureaucrat will attest, the relationship between science and technology and public policy is more likely to be stormy and unproductive than the models suggest.[19] Policy makers function in a world not entirely, or even often, of their own making and must be responsive to pressures other than the viability of academic models and the administrative procedures of their departments. Legal questions are always relevant, because proprietorial and other interests are involved even if such questions are sometimes put aside in assessment of science and technology.[20] Pressures other than the pursuit of knowledge set the agenda for research, and influence the timing, flow and availability of data.[21] Demands are placed on science and scientists which are incompatible with the values of the scientific community. Those who respond are not less able scientists, but they are oriented to the particular demands being placed on them, the demands of mandated science. Such scientists are regularly asked to comment on the broad implications of their findings, for example, and to combine studies from different disciplines or with different methodologies, to arrive at conclusions which are pertinent to policy makers but of little scientific significance. Citizens, some quite expert and others ill informed, demand the right to participate even when complex

scientific issues are involved, arguing that judgments are required to deal with the many uncertainties of scientific information, and that such judgments are neither strictly scientific in nature, nor properly the exclusive prerogative of those with scientific training.[22]

Controversies often develop, and once they do, the opportunity for separating risk assessment from risk management vanishes.[23] A single chemical, forest, hydro dam, power installation or new technological innovation becomes a lodestone for a more general debate about such things as the trustworthiness of science and government, the adequacy of regulation, the values inherent in government policies and industry or advocate actions.[24] This broader debate is no less legitimate than the assessment of the chemical at hand, but it has the effect of fusing risk assessment with risk management and rendering both amenable to perception and communication problems affecting all parties to the controversy.[25] The cost of assessment spirals, because everyone properly has a right and responsibility to contribute to a broader debate about the values to be reflected in public policy. The original topic of the assessment is lost to view, and even those with a strong commitment to science are drawn into a debate which is only peripherally about science or technology, a debate which renders their research expertise irrelevant except as it contributes to their general status as experts.

Lest this point also be mistaken, it too should be stated clearly. The relationship between science and public policy is a crucial one. Great strides have been made, especially in the last decade, in understanding this relationship and in reordering administrative processes to increase the level of public confidence in science and government. This relationship remains complex and difficult nonetheless. It is confounded by issues no less important than science, and no less legitimate than any detailed assessment under way. However, there can be no definitive administrative solution to what is not, in essence, an administrative problem: the problem of how best to combine the needs of scientific assessment with those of public policy and regulation.

(3) The social and cultural implications of science and technology can be gauged from consultations and public participation.

It is difficult to imagine that only two decades ago, there was little commitment among policy makers to either consultation or public participation. To be sure, extensive discussions were usually held between government officials and members of industry, and advocate groups of one kind or another influenced policy making through formal and informal channels.[26] But the formal processes of consultation, today considered to be an intrinsic part of proper policy making, are of recent vintage. Moreover, formal requirements for public participation, now usually embodied in the mandates for inquiries or committees and in legislation (for example, for regulatory or environmental assessment), have become commonplace only in the last two decades in Canada.

No one should dispute the importance of consultation and public participation in policy making. Policies or regulations developed without extensive consultation easily miss their mark, adding to the administrative burden placed on all citizens without delivering adequate benefits in

return. Clients of public policies and those affected by individual policies, standards or regulations often have crucial information; they are likely to be in the best position to forecast the effects of any initiative accurately. Furthermore, given today's widespread preoccupation with democratic accountability, it is no longer possible or desirable to consider the social and cultural implications of any policy without providing the opportunity for democratic debate.[27] Whatever the limitations of current approaches to consultation and participation, it is unimaginable that either will become less important to policy making in the future.

It would be all to easy to conclude that the social and cultural implications of science and technology can be gauged exclusively from consultations and public participation, and to assume that they will always provide the needed information. Recent experience with royal commissions, special task forces and environmental assessments provides an important lesson about how costly consultation and participation can be. No one should expect such bodies to deliver public consensus on critical issues, or even agreement among the stakeholders about a limited set of recommendations.[28] New techniques for stakeholder mediation and alternative dispute resolution have been applied in some cases, to render controversies about science and technology amenable to efficient and effective resolution,[29] but only some have been successful and there is considerable resistance to their application.[30] If the issues to be determined about science and technology are understood to involve questions about social values and broad social policies (as they often are today) or if the "will to settle" is absent among those consulted (as is often the case), the result of extensive consultation or participation is yet another layer of ineffective decision making.

In theory, consultation and participation bring important information to the table about the social and cultural implications of science and technology. Cross-examination, the representation of interested parties by lawyers or formally constituted advocate groups (including both environmental groups and industry trade associations) and effective adversarial debate can ensure that debates among scientists about controversial or uncertain issues in their fields of study are canvassed properly and that all relevant information is brought forward for consideration. In practice, the formal and often court-like nature of the assessment process — whether conducted through public hearings or simply involving parties with specific legal interests at stake — confounds the assessment. Adversarial debate often obscures the search for background information necessary for policy making by focusing on questions of procedure and rights as opposed to the situation at hand. Any adversarial debate is also only satisfactory if all the affected parties (stakeholders) can be, and are, represented. Whether because of a lack of resources or because the issues of concern are of broad and overarching concern, or because those speaking for different points of view are not considered properly representative, authoritative or accountable, it is often the case that adversarial debate is limited in its ability to capture the democratic debate demanded in today's political climate.

It has been argued that an adjudicative process, adversarial or not (whether it takes place in a committee or a court, involving extensive review or a debate between expert witnesses), provides benefits roughly comparable to peer review for science and technology.[31] In an

adjudicative process, many of the prerequisites for adequate peer review are met. For example, research is made publicly available, assessed and debated by people other than its authors or sponsors who nonetheless have appropriate expertise to evaluate its methodologies and conclusions. That a committee or court conducts its assessment for purposes other than the furtherance of knowledge is beside the point, as long as the research itself is adequately evaluated. Furthermore, it is argued that subjecting research to broader scrutiny in an adjudicative process to determine its broader implications is entirely appropriate, because the actual researchers are unlikely to have special expertise in this regard. Consultation and participation, committee deliberations, the involvement of interested parties and advocate groups all extend and enrich the review. Given the well-documented problems with traditional peer review in science,[32] it is always worth exploring new approaches for assessing scientific research, including adjudication in its various guises.

There is merit in all these arguments, and yet studies of the adjudication of science and technology also document how easy it is to lose sight of the science in such cases.[33] The actual process of research is slow. It requires painstaking effort, rigorous attention to detail and highly systematic methodologies. Questions amenable to research are quite different from those best debated in a wider arena. They are usually narrow and specific. Research reports are often misinterpreted by people other than researchers in the same field. Scientific uncertainty is the norm, and debates about founding premises of different analytic frameworks are common.[34] What appears highly productive in a research context is often of limited value when the broader policy implications of science are the focus of attention, as is always the case when adjudication occurs in the courts, inquiries and committees, and so on. Conversely, committees, courts, etc., are often required to address questions which are handled inadequately using the conventional methods of science.[35] Thus it is not surprising that, given access to enough resources, royal commissions regularly commission research studies in addition to holding hearings and that they rely heavily on their findings to complement information garnered through their hearings.[36] Both are seen to comprise the necessary research to support recommendations. The assessment of the social and cultural implications of science and technology requires both research studies which are narrowly focused, properly conducted according to the tenets of science and rigorously peer-reviewed by those with appropriate expertise, and a broader evaluation of this same research (i.e., consultation of one kind or another) conducted through the by-play of debate among experts, among adversarial groups, among policy makers with different responsibilities and among the citizens and groups most directly affected.

It is a widely held perception that no government can afford the luxury of doing both kinds of research — traditional research studies and consultation — in today's economic climate. There is obviously some truth to this perception. The demise of the Science and Economic councils and of the federal Law Reform Commission is a good case in point, because each was engaged in some combination of research and consultation on a variety of topics of public importance.[37] Budget cutbacks within government departments have often been felt most acutely in their research capacity, even as the importance of research has been stressed, while consultation has been pressed into service as an alternative to research. When funding has been

made available, it has sometimes been assumed among policy makers that consultations adequately replace the need for conventional research studies. Moreover, in the current context, even the funding for consultation has been curtailed. To the extent that both consultation and traditional research are required for an adequate assessment of the social and cultural implications of science and technology, the current situation is a problem.

This problem is worth examining further. Even if government departments have curtailed some of their own research activities, funds remain for research contracted to outside researchers, consultants and industry. There is also a large array of research institutes (many with an express political point of view) which garner funds from government, industry and occasionally unions or a partnership between two or more of these groups. While many would argue that their funding is seriously deficient, the research granting councils (the Natural Sciences and Engineering Research Council of Canada, the Medical Research Council of Canada and the Social Sciences and Humanities Research Council of Canada) sustain a large volume of research, and all have taken steps to improve their administration of research funding in a period of government cutbacks. Furthermore, some of their research funding is now designated for initiatives with direct applicability to industrial development or to policy making. In other words, research is still being done, and research reports are being produced, even in the face of diminishing resources.

What is noteworthy about this situation is that *direct* responsibility for research has diminished within government. The larger proportion of research activity now takes place outside government (although often funded with government resources) — in industry, in consulting houses, through strategic research partnerships and similar initiatives, through contracted research or in policy research institutes. Research is largely conducted by bodies operating with their own mandates, priorities, political predilections, decision-making procedures, interests and agendas. Even in the case of the Centres of Excellence (and other examples of partnered research) a large grant is given (often by government) to an autonomous body made up of researchers and their industrial and government partners. It then acts as if it were an independent granting agency, making decisions according to its own agenda, predilections about the funding, end-products and evaluation of specific research studies.

Equally noteworthy, however, is the number of mechanisms and practices for the assessment of the social and cultural implications of science and technology initiated by government departments. Consultation about science and technology has increased, not decreased, in the last decade. In other words, consultation flourishes and has remained the prerogative of governments, while research opportunities have been constrained, and direct responsibility for research has been partly devolved onto industry, private contracted researchers, consulting houses, and research centres and institutes.

There is a strong possibility that this point will also be misunderstood. To be sure, there are strong arguments for and against devolving responsibility for research from governments onto the non-profit and private sectors, as well as for and against the introduction of consultation

as the primary instrument of government policy making. These arguments do not concern us here. Two interrelated problems are of concern in this context. The first is that, by devolving responsibility for research onto non-governmental bodies, there is a danger that the research itself will be perceived as simply a form of lobbying. Rather than viewing research studies as necessary for the proper assessment of the social and cultural implications of science and technology, or indeed of any policy, all research reports will be regarded as instruments, generated and used by groups with agendas or interests.[38] The second danger is that it will be assumed that consultation is sufficient to deal with the social and cultural implications of science and technology.

(4) Co-ordination and consultation is good; more co-ordination and consultation is better.

The case for consultation has just been made and need not be repeated. Little discussion is required to support the argument that co-ordination within government is also beneficial. Two decades ago, conflicts between levels of government and among government departments about pesticides, for example, were relatively commonplace.[39] Today, many memoranda of understanding exist to deal with contributions legitimately made by various levels of government and departments with respect to specific issues.[40] Increasing commitments to, and resources for, consultation and co-ordination are not always beneficial, however.

Science policy, like any other policy, involves an iterative process.[41] Any proposed initiative normally goes through several rounds of assessment, many committee reviews, multiple consultations, etc. The recommendations from a senior government official (speaking for the department), an inquiry, expert or consultative committee are only rarely accepted immediately.[42] Much more frequently, they themselves become subjects for further deliberations, inquiries or studies. In part, these multiple assessments result from jurisdictional issues which confront all levels of government and all departments within government, and which require resolution in their own right. Political issues also intervene; governments must respond not only to the directions set within the political process, but also to public controversies.[43] Furthermore, notwithstanding the frequent demands for government rationalization, i.e., for greater co-ordination and consultation, the fact is that each advocate's and interest group's notion of what constitutes a properly rational process differs. Given sufficient resources, no group seeking to change, eliminate or establish a government policy, standard or regulation would be satisfied with a commitment to a single policy-making process (say, one committee's deliberations), a single process where all decisions on specific issues were made and all decisions were final. Each group seeks out the many avenues of influence[44] most collegial to its own agenda or interests, and attempts to keep the policy process in motion until a resolution is found compatible with its goals.

In this context, consultation and co-ordination can easily become synonyms for keeping the policy process in motion and avoiding a final decision, at least temporarily, until a favourable resolution to the major participants is found. That this does not always occur does not lessen its importance as a potential pitfall in the current era. Increasing co-ordination is not

necessarily viewed as a benefit, especially given the fact that participation in consultations or co-ordinating bodies involves costs which often exceed the benefits or the ability of some groups to bear them. Industry groups, for example, often view such things as new co-ordinating councils or committees and consultative studies as an imposition on their time and resources.

2. LAYING A FOUNDATION FOR RECOMMENDATIONS IN THE THREE ARENAS OF SCIENCE POLICY

Thus far in this paper, science policy has been used as a general term to deal with all government-initiated policies intended to promote or evaluate science and technology because of their contributions to, or the problems created for, the general well-being of society. It has been noted that science policy always deals, explicitly or implicitly, with the social and cultural implications of science and technology, whatever other objectives are also intended. In turn, the social and cultural implications of science and technology always include not only the social by-products (good and bad) of the applications of science and technology, but also the roles generally played by science and technology in promoting or impeding the social and economic well-being of Canadians.

In the first part of this paper, some of the academic literature on science policy was reviewed in some detail. In the second part, this same material is drawn on again but used for a different purpose. No longer is its role to indicate what is now understood about the relationship between science and policy making. Rather, the emphasis is on recommendations, and the literature serves only as means to the end of arriving at feasible proposals. For the purposes of recommendation, the definition of science policy used in the first section is far too broad. A more nuanced appreciation is needed of the various tasks to be accomplished through science policy. In this context, it will be of assistance if science policy is understood to refer to three different arenas of policy making.

The First Arena

The first arena is that reflected in risk, technological and environmental assessments. It involves the use of scientific and technical information, in conjunction with other kinds of information drawn from policy makers and their constituent publics, to assist in the planning, introduction or regulation of products, standards, production processes and economic developments. Science and technology have two roles to play within this first arena of science policy. Scientists provide necessary background information for policy makers dealing with, and in some cases avoiding, the possible consequences of actions taken within their jurisdiction, by governments, industry or private citizens. These actions might include the introduction or review of a pesticide or drug, a proposed hydro-power installation, a proposal to log new areas of a province, the routing of a public transit line, etc. *Any* product, development, standard or production process can be subject to an assessment requiring scientific and technical information. In practice, only a few are, but risk, regulatory, environmental and other assessment processes are now commonplace. The introduction, design and operation of these assessment processes all represent activities in the first arena of science policy.

Science and technology themselves can come under scrutiny within the first arena of science policy. For example, proposed new applications of biotechnology in agriculture,[45] the introduction of new reproductive technologies, the patenting of life forms or the intrusion of the information highway into private homes all reflect pioneering new developments in science and technology. All of these generate consequences, much in the same way that a hydro dam generates consequences, and these consequences also require scientific assessment. No routine process exists in Canada for the assessment of new developments in science and technology, but inquiries, royal commissions, special consultations and task forces are sometimes called into being on an ad hoc basis to carry them out.

To understand the strengths and limitations of science policy as it has developed in Canada in this first arena, it is important to recognize some characteristics of the arena. For any single issue there is almost always more than one government department, and often several levels of government, with some degree of responsibility or jurisdiction.[46] Not surprisingly, because often so much is at stake even in a single decision, there is normally an array of mechanisms and practices used for conducting assessments, including departmental committees, advisory committees, task forces, assessment procedures,[47] review panels, interdepartmental committees, parliamentary committees and the like. Furthermore, there are usually many groups seeking influence. In most cases, legal responsibility for making final decisions rests with someone other than those who conduct these assessments — often with a minister or with Cabinet. Although, in most cases, the assessments proceed without much public comment or notice from the political process, it remains a possibility that any assessment will be overtaken by a political process or overturned by a decision from the minister or Cabinet.

The science in this first arena of science policy is uneven with respect to the quality, quantity and scope of research. Often, research is contracted by parties seeking to influence a decision and, as such, reflects both the narrow demands of the assessment methodologies in use and the interests of the party which contracted the research. Seldom is research carried out in this first arena of science policy which is designed for, or applied in, a broader context, either as part of the environmental scanning process[48] or as a contribution to academic research. Most research reflects the constraints of mandated science. At best, it is only one element in a process oriented to public policy or regulation and involving hearings, consultations or other forms of policy making.

A great many of the mechanisms and practices for assessment in this first arena of science policy make specific reference to social, cultural, ethical or similar considerations.[49] Costs or risks are intended to be gauged against benefits. Social and economic studies are required as part of formal environmental assessments. Methodologies exist for social and regulatory impact-assessments, both of which require attention to the social and economic consequences of whatever is being proposed and evaluated.[50] The case studies done for this paper and other research indicate that very limited notions of what constitutes "social" and "economic" are often used in this first arena of science policy.[51] This results from the fact that most social and economic research (with some notable exceptions) is not amenable to being incorporated easily

in the types of assessment being done.[52] It results, as well, from the pressures placed on scientists and policy makers alike to arrive at decisions quickly, with due regard for the interests of those directly affected. Finally, it results from a widespread misapprehension that engaging in a consultative process is itself sufficient as social and economic research.

Controversy abounds in this first arena of science policy, but controversial issues are often not resolved by the mechanisms and practices of assessment, and rarely if ever are they resolved by reference to the scientific literature. Yet those engaged in policy making have an urgent need for scientific input. They need to know the status of knowledge of particular issues — i.e., what can be said about the issue with a high degree of confidence, what information has little basis in science, what is still scientifically uncertain about the issue and what is highly controversial among those with expertise about the issue in question. Ironically, this is precisely the kind of information which is so difficult to garner from the scientific assessments done in the first arena of science policy. In part, this occurs because of the adversarial nature of the processes, but equally because the dictates of policy making and the contingencies of the political process overtake scientific assessment.

Clearly, it is unrealistic to expect any assessment process, whether existing, new or revised, to address all the situations requiring assessment. Even if it was possible to overcome the difficulties caused by controversy, jurisdictional complexity and inadequate methodologies, it would still remain the case that only some of the new potentially dangerous or deleterious products or activities would come under review, and fewer still of the previous decisions would be revisited. For example, reproductive technologies are only some of many potentially disruptive new developments in science and technology, and it is unrealistic to expect that full-scale inquiries will be held about all of them. The cost and burden of comprehensive review far exceed the capacity of both governments and their many constituents to bear them. Yet scientific assessment is definitely needed.

A solution may be closer at hand than it first seems. There are two problems to be resolved. The first arises when scientific issues are inadequately canvassed. Convinced that something is lacking in the scientific assessment, advocate groups broaden the debate, even to the point where it no longer focuses on science or technology at all. Inadequate scientific work becomes a proxy for social issues not being addressed. Controversies about scientific issues are transformed into controversies about the status of science, the trustworthiness of scientists or regulators and the capacity of science to respond to social values of critical importance to members of the public. Much could be accomplished if before any assessment, even before a decision on whether assessment was required, an independent review of the scientific issues could be undertaken.

The point is important and easily misunderstood. There is no question about whether social values impinge on many aspects of the science. Moreover, there is an urgent need to canvas the social, political and policy issues involved if any assessment is to be undertaken. What is of concern is the possibility that everything about the science will be rendered

debatable, even those aspects about which there is little disagreement in the scientific community. Controversies and adversarial processes tend to polarize scientific debates, focusing only on the end-points of the continuum of views among scientists. Issues are rendered controversial in such cases which otherwise are legitimately taken for granted. Furthermore, those engaged in assessment (from outside government) tend to assume that they must begin with the basic information, having little appreciation for how far the debate has progressed within the scientific community. Better information made available from an independent source about the status of debate would obviously be helpful in promoting a constructive discussion of even the most controversial issues. Finally, much of the tension and adversarial relations within assessments arise because non-scientists perceive that uncertainties and disagreements within science have not been brought to the fore, but rather science is presented in idealistic terms as having answers to most questions. Scientists themselves contribute to this perception, as happened when a nuclear scientist engaged in an environmental assessment of the Point Lepreau nuclear power station stated: "those who are experts have no questions." Faced with this attitude, scepticism about the scientific work underlying any assessment seems justified.

There is merit in having independent scientists speak directly with other scientists outside the context of an adversarial process as a precursor to the debate, and as a means of getting adequate background information on the table. To do so would only generate public confidence, however, if it were clearly understood that the scientists were to confine their discussion to the areas of their expertise, addressing only questions for which their research skills were appropriate. It would generate confidence only if the purpose of the exercise was to determine, and make explicit, that which was uncertain and contested within the scientific community, as well as that which was generally accepted. Any document produced by this *scientific focus group* would itself have to be subject to review and debate within a process designed to deal with the close links between science, values and public policy.

In other words, if a mechanism were to be put into place to permit governments to draw on the best available scientific or technical expertise for each issue potentially subject to a more comprehensive assessment, this would be of considerable assistance, at the very least in determining what resources should be made available for assessment. Were such experts then given a very limited time frame and asked to report only on the state of knowledge with respect to the issue at hand (something which people working in the field should have at their fingertips), this would solve some of the problems arising from the mix of scientific and policy advice normally occurring in expert or consultative committees. If the final product addressed only matters about which research experience is relevant, those designing any later assessment could tailor it to matters requiring genuine debate, relying on a foundation of information about which relatively little comment was required. The trustworthiness of this information would be enhanced if it was publicly acknowledged that some of the science was uncertain and controversial on particular aspects of the issue at hand.

No one would seriously suggest that such a scientific agenda-setting exercise — a scientific focus group on scientific issues potentially subject to controversy and assessment —

would always short-circuit the legal, adversarial and often politically oriented debate which now accompanies almost all assessments. What it might do, however, is establish a better basis for the debates. It might also contribute positively to the current priority-setting exercises that have not had much success in determining which, among the vast number of issues potentially requiring assessment, should take priority in terms of resource allocation.

The second problem to be resolved lies with the impoverished state of much social and cultural assessment accompanying most science policy reviews, notwithstanding the emphasis given to social and cultural questions in discussions of public policies. This problem might be ameliorated by using the same approach: scientific focus groups. All too often, expertise is applied only to the natural science and technical aspects of any issue, and it is assumed that consultation is adequate to deal with the social and cultural implications. Yet social scientists and ethicists are not without expertise and can make a major contribution, acting in capacities other than as consultants. They, too, have detailed knowledge about research, for example, in the fields of ethnicity, mass media, social development, ethics. Were a mechanism in place to draw on this expertise quickly, to mandate a timely review of the social scientific dimensions of various issues, this would also aid in setting an agenda for assessments, in deciding when full scale application of resources was justified and in establishing a foundation of information for future assessments. As is the case with natural and technical scientists, such scientific focus groups might best not consider issues outside their particular domains of research expertise nor deliver policy recommendations.

Several bodies exist which might be used to implement these recommendations. All are independent, and seen to be independent, of government, capable of taking a longer-term perspective, highly respected within the scientific community and in touch with those who are likely to have research expertise on a variety of very different issues. For example, a refashioned Royal Society could perform the task, were it to undertake it as part of a new mandate. There is precedent in the national academies of science in many countries, but significant changes would be required if the Royal Society were to undertake this task in Canada. Alternatively, it may be possible to draw on the professional or academic societies, or their federations. Again, each would need to reconsider the totality of its mandate, going beyond its current role as lobbyist for the discipline. It should be noted that such societies regularly schedule conferences and workshops to review the state of the art in particular sub-fields, and thus have immediate access to the expertise required. Finally, another option would be to rely on one or more of the existing research institutes, particularly those with no discernable political affiliations. The advantage of this last option is that the research institutes are designed initially to be in touch with experts in particular fields and are accustomed to providing ready responses to the demands of policy makers. The difficulty with this option lies in distinguishing consulting (which is the normal activity of research institutes and which does require the combination of science and policy) from the task just described. While such institutes now are involved in non-consulting activities, their orientation has been to conventional research and its particular deadlines, not to the speedy production of state-of-the-art reviews on specific issues. There is always the possibility of establishing a new institutional mechanism for this (and related) purposes. What is not likely to

succeed is reliance on the current model of expert committees. They are too closely allied with particular government departments to perform this particular task (although they play a valuable role otherwise) and normally are mandated to provide policy recommendations in addition to reviewing scientific studies. Similarly, although major consultative initiatives such as the Information Highway Task Force can be of great assistance to policy makers, their contribution lies elsewhere, mainly in canvassing the constituent groups about possible public policies.

The Second Arena

The second arena for science policy involves promoting both research and science culture. In this arena, science is not a means to an end, as is the case when scientific information is sought to evaluate the consequences of a new product or development. Science and technology are ends in themselves, worthy of understanding and promotion in their own right. In this second arena, assessment refers to something beyond the consequences of actions or new developments. It refers instead to the evaluation of initiatives taken to promote research, in particular, and science and technology in general. The focus of evaluation is to determine four things: whether initiatives have achieved their intended effects, whether the status (quality, quantity and state of development) of research in particular fields and of the diffusion of science and technology in Canada is appropriate for an advanced industrialized country operating in the new economy, whether scientific literacy and expertise among Canadians has increased and whether a greater appreciation of science and technology has been developed.

Major initiatives have been undertaken in this second arena of science policy in the last few years. Many programs are devoted to scientific education and culture. Funding has been made available for state-of-the-art status reports on fields of study in science and technology conducted under the auspices of the Royal Society. With the institution of Centres of Excellence grants, with the establishment of "Chairs" in designated research fields, with strategic granting programs and partnered research, and with the support given to the Canadian Institute for Advanced Research, there is much to evaluate.

To comment on the first of such initiatives, the programs designed to enhance scientific education and culture, goes beyond the scope of expertise reflected in this paper. One assumes that each initiative in this regard has been subject to an evaluation, either as part of the current review being conducted by Industry Canada or in conjunction with its own funding and final report. If this were not to be the case, it would constitute a serious problem, because no easily defined boundaries can be drawn around either scientific education or culture. Without standards and benchmarks for evaluating such initiatives, they easily command all available resources without necessarily having much influence.

More is known about the second initiative, the evaluation of the state of the art of research in important fields of study. Efforts by the Royal Society have not been entirely successful, in part because the Society has not been organized properly to perform such tasks.[53]

The Society has used a site-visit committee-based approach, which has proven costly and unwieldy. The granting councils are likely to be reluctant to assume the responsibility for state-of-the-art reviews except in connection with new strategic granting programs (see below). All of the granting councils have had reasonable success with designating areas of research for special promotion through designated funding (strategic research), but each has been properly reluctant to interfere, or be seen to interfere, with the normal practice of scientific evaluation — that is, with the peer-review process. Peer review in science is, generally speaking, limited to reviewing either specific research after the fact and before publication, or to the quality of research proposals (and members of research teams) before they are funded. Any state-of-the-art study reviews many studies, after they have been published. It must be simultaneously independent and expert, it must evaluate new developments at the margins of the field as well as the established literature and must not ignore innovative or ground-breaking work which is not yet reflected in the "consensus" of the field or the mainstream of its research program.[54]

With respect to the third initiative — strategic research initiatives, strategic partnering with the various Centres of Excellence — information has not been collected and analyzed, or rather the evaluations are not available in the public domain. Experience with several of these programs suggests some problems may exist. The efforts to secure the collaboration required to obtain funding seem to overwhelm efforts to identify the research problems most urgently in need of study. Collaborations are sometimes best described as marriages of convenience with little more than administrative co-ordination among the researchers. Innovative research undertaken by researchers who have "yet to make a name for themselves" can easily be undervalued when, as is almost always the case, the adjudication of the proposals is done by people with differing expertise and priorities, who depend on the seniority of the researchers as their only evidence of the importance of the research. The administration of research commands a significant proportion of the resources, but because it is done within the project and not through universities, industry, government departments or the granting councils, its full costs are nonetheless difficult to identify. Fund-raising to garner support for continuing research after the funding period commands a significant proportion of time, especially if the research is intended to be (and contingent on) partnering with industry, government departments or others. Industrial and government partnerships with university researchers are often limited. These partners do not expect significant benefits to flow from the research and sometimes contribute only a small portion of the costs.[55] Social and cultural issues are often lost to view, unless they are designated to be of special concern. Peer review is often inadequate and the funded programs often act as delegated research councils, performing all the functions of a research council (in a designated area of research) without the administrative and quality controls employed by such councils.

None of these problems is intractable; nor should this discussion be taken as an indication of failure of any of these programs. Rather, these observations legitimately serve as warnings about the pitfalls in the second arena of science policy and the need for an overview and proper evaluation of initiatives taken therein. It appears as though too much of the evaluation has occurred in house and, thus, is not available either for academic or policy purposes. It may be that inappropriate evaluation models have been used whenever independent reviews have been

undertaken by national research bodies with international credentials. Major strategic initiatives seem to have been undertaken with too little attention being paid to the benchmarks. Science and technology are unlikely to be promoted by major strategic granting programs unless, among other things, sufficient time and resources are allocated for genuinely collaborative research; there is adequate peer review at each stage of the research process by those with specific expertise who are familiar with debates within the fields; there is a commitment to continual interaction among researchers, inclusion of social and cultural issues in the primary agendas for research; provision is made for the inclusion of new research topics, approaches, methodologies and researchers; and there is continual supervision by the research funding bodies or councils. In general, problems have arisen in this second arena of science policy because all the initiatives have been, by and large, unco-ordinated and, in some cases, poorly supervised.

The Third Arena

The third arena for science policy develops in conjunction with the new economy. In this context, science policy refers both to the environmental scanning necessary to gauge the nature, shape and implications of the new economy, particularly as it is likely to affect Canada, and to measures undertaken to promote Canadian participation in the new economy. This includes ensuring that industry and labour adjustments are made, training opportunities are provided, industry opportunities are taken advantage of, the social well-being of Canadians is protected and the strength of the economy is fostered. For simplicity's sake, both are referred to here as environmental scanning. Several major programs have focused their attention on this third arena of science policy. Special programs promoting adjustment, training and development opportunities have been established by federal, provincial, regional and municipal authorities.

As best can be determined, systematic evaluation of many of these initiatives is lacking, and relatively little has been published in the academic literature to contribute to an assessment. Most of the literature is either descriptive or prescriptive. In general, environmental scanning appears to have been done mainly in conjunction with reviews contracted by specific government departments. Often it employs policy research institutes or consulting houses, which operate with their own priorities and agendas. There seems to be little capacity for developing an overview from materials available in the public domain. No one should underestimate the complexity of the environment, the new economy and its implications, however, nor the difficulty of conducting even a limited environmental scan. Nonetheless, a few developments related to environmental scanning bear watching. They are new developments in regulatory practice, sectoral councils and science policy research institutes.

First, there is one example of a regulatory agency itself undertaking the task of environmental scanning. The CRTC (Canadian Radio-television and Telecommunications Commission) is a somewhat unusual regulatory agency in the Canadian context. In both areas of its responsibility, broadcasting and telecommunications, legislation requires that social and cultural implications be taken into account as a first priority in decision making. To be sure, this

is most evident in the broadcasting legislation, but the new telecommunications legislation contains more, not fewer, requirements for the agency to deal with telecommunications in the broader context. Unlike many regulatory agencies, the CRTC has designed its procedures and hearings to take account of the need for environmental scanning across the two areas of its mandate. Given the importance of recent developments in the technologies involved and the importance of communications generally for the new economy, this is entirely appropriate. From time to time, the agency has chosen to stand back from applications at hand, to assess the future of the industry and the policies best attuned to its future development. Furthermore, this agency has taken on itself to subject its own regulatory methodologies to scrutiny, both on a case-by-case basis and in general, with hearings devoted to "structural" issues, and regulatory practices and procedures. In effect, the CRTC has made it part of its deliberations to canvass the new economy and the place of communications within it in terms of how such developments affect, or should affect, regulatory mechanisms and practices.

There is no doubt that the CRTC's efforts to understand and position itself within the new economy are highly productive ones and that its actions in this regard should be considered a model for all regulatory bodies, especially with the current emphasis on regulatory review. To reiterate, theirs has been a continual review, conducted from within, with specific reference to the role of regulation and promotion of new technologies in the new economy. The CRTC has dealt not only with the new technologies, but also directly with their social and cultural implications.

At the same time, the CRTC's efforts provide some indications of the limitations and pitfalls of environmental scanning. First, as might be expected, the agency deals with some social and cultural issues more adequately than others. The CRTC does not deal with labour adjustment, for example. Second, while research about the new technologies, including forecasting studies, is cited regularly in the "structural" and other policy hearings, the CRTC's environmental scanning generally reflects the efforts of interested parties to influence specific decisions. Third, the issues canvassed by the CRTC are of general interest, and are themselves subject to public debates outside the confines of CRTC hearings. They concern the role of regulation, the nature of free markets, the role for governments and industrial policies and the analysis of the new economy. On these matters, there are distinct schools of thought, each with its own protagonists. The debate outside the CRTC has become highly predictable, occasionally even ideological in tone. Not surprising, the debate in the CRTC's context reflected the limitations of the broader debate in that it, too, seems to be somewhat predictable and occasionally ideological. While there is nothing amiss with canvassing the same issues or approaches inside as well as outside the CRTC, the predictability of the debate and its lack of specific application (to the situation in Canada with respect to particular issues relevant to broadcasting and telecommunications) can be a problem. It may well be true, for example, that the new satellite technologies render national boundaries (and thus national regulation) obsolete in the general case. It does not follow that the situation in Canada has yet to resemble that spoken about in the public debate. The threat to national regulation from satellite technology is real, but it is not necessarily a clear and present danger. One expects the CRTC to address the

specific case, as well as the general one, but sometimes it appears that, notwithstanding the CRTC's commitment to environmental scanning, its attention has been focused primarily on the general case.

A second method of environmental scanning worth watching occurs through the new sectoral councils.[56] Those represented on the sectoral councils have useful experience to be drawn on, because they are directly affected by the new economy in one manner or another. They have information which would become available to researchers only some years after the fact. Sectoral councils take many forms.

One example is the new Information Highway Task Force. It has the advantage of operating at the leading edge of new technologies, of involving people from different locations within the sector and of including social and cultural implications as part of its mandate. It is too early to say how successful this initiative will be, but some problems have already emerged. First, the topic is so complicated, the issues so numerous and the groups represented so diverse that much effort is expended just co-ordinating the initiative. Second, little provision seems to have been made for research or technical support staff, and there is a danger that the council will run aground on the technical complexity of the issues. Third, those involved are not only committed full time elsewhere, but they import into the council's deliberations many of the debates (for example, about competition within the sector) which are also occurring elsewhere. Consultation is constrained because of the manner in which the council is structured and resources made available. Even given these problems, the work of the Task Force bears watching as to whether it constitutes a model for assessing the social and cultural implications of science and technology.

Another example worth studying is that of the Ontario Telecommunications Advisory Council. Individuals, more or less representative of the different interests and expertise in the field, were invited to sit as volunteers on a council whose mandate was to produce recommendations for the Ontario government on telecommunications. This council worked with a tight time frame, but its agenda included several seminars. It was not a consultative body, in the sense of involving the public, but public advocate groups and unions were included among its membership. The intention was to develop a strategy for the sector as a whole, especially its industrial participants. But, because the council was established and maintained by government, the orientation of discussions was often only to what might be recommended for governmental action. The final recommendations are a testimony to this orientation. They include few intra-sectoral initiatives and many suggestions for new government initiatives and programs. Nonetheless, the council was remarkably thoughtful in its deliberations, and the process is likely to have been useful in supporting co-operation among its participants (even in the face of continuing debates about such issues as competition) who represented the major actors in the sector, regardless of the fate of the recommendations.

A third example is that of the sectoral labour adjustment and training boards, which, at their best, have been remarkably constructive in environmental scanning and generating

initiatives. Insufficient attention has been paid to evaluation of these boards, however, with the result that they vary from one to another. Several controversies have erupted with respect to poor management practices and controls in conjunction with a few of them.

In Canada, sectoral councils are usually convened on an ad hoc basis, which is useful to prevent their becoming trade associations in disguise and to promote concrete recommendations. In the best examples of sectoral councils, labour and management have proven their capacity to address common problems, and erstwhile competitors have been able to reach a consensus about their common needs by addressing broader issues including the social implications of developments in their particular sector. At their best, sectoral councils offer a cost-efficient (especially compared with inquiries and royal commissions) way of handling the consultation aspects of assessment, but sectoral councils do not offer a panacea. They have their limitations and weaknesses. They rarely have adequate evaluation or self-evaluation procedures in place; they tend to focus on developing recommendations only for governmental action, leaving aside what might be done by the members themselves; they fail when competitive issues are at stake or when labour-management relations are seriously strained; they function best when those who should be represented are organized into effective groups. They are not, in essence, public processes and they do not respond well to the demand for democratic debate and accountability.

By definition, sectoral councils bring together interested parties. Their contribution is valuable but it cannot take the place of systematic study: forecasting, formal environmental scanning, technology reviews, etc. It cannot take the place of properly conducted research. A third initiative promoting environmental scanning arises in conjunction with several university or university-government-industry research centres specifically dedicated to assessing the implications of science and technology for the new economy . Such diverse bodies as the Science Policy Research Unit in Britain, the Office of Technology Assessment in the United States, the Berkeley Round Table on the Economy, the Maastricht Economic Research Institute on Information and Technology (MERIT) (Netherlands), the Centre de Recherche Informatique de Montréal (CRIM) (Quebec), the Canadian Institute for Advanced Research (CIAR) (Canada: *see*, particularly, the Economics and Law programs of the CIAR) are good cases in point. Each of these bodies is (or is associated with) a research organization engaged in environmental scanning of the new economy. Each supports a major publication effort, takes on work directly related to policy, carries out research with a more long-term perspective and holds workshops with those directly involved in various capacities with scienctific and technological policy.

It is worth noting how diverse these bodies are from each other. Some operate under the auspices of government, others are research centres at universities; some are "research universities without walls," others yet are most closely akin to consulting houses. What draws all these bodies together is their preoccupation with assessment of science and technology and with the new economy (assessment defined broadly to include social and cultural assessment of science and technology), and their lack of ties to policy institutes which have, or can be seen to have, political philosophies or specific agendas of any kind.

There is no question about the importance of environmental scanning, of the assessment of the longer-term implications of science and technology. It appears that there are several ways in which this goal might be realized, ranging from mandating a regulatory agency to take on the task or establishing councils of one kind or another, to supporting research centres with these goals. All are important but, taken together, they do not fully meet the need. Missing from these initiatives is any mechanism for developing a comprehensive view, for bringing together the necessary background research and expertise, and for developing an overview. It is highly unlikely that Canada will develop something akin to the American Office of Technology Assessment because of the resources required. It does seem feasible to consider means by which the various existing initiatives can be better co-ordinated and strengthened, their research deepened and extended to meet the challenge, their outreach efforts improved, their security of tenure (where appropriate) made less dependent on the latest consultancy contracts or the good will of their participants and their work supported by better quality scientific research.

CONCLUDING REMARKS

Trying to capture all the mechanisms in Canada for the social and cultural implications of science and technology is to engage in the impossible. So many initiatives, programs and activities can be included or not, depending on the inclinations of the author. Despite significant attempts at administrative rationalization within government, little co-ordination exists among the various mechanisms and practices for assessment of science and technology, especially in connection with the many issues they raise. The term "policy community" is sometimes used to convey the fact that there are very many different groups seeking to influence any one policy decision and that they function like members of a large and dynamic community. Science and technology are themselves never a single phenomenon, but infuse virtually all aspects of social and cultural life in one way or another. Social and cultural implications are never fully contained by national boundaries, even less so when the new economy and leading-edge developments in science and technology are taken into account. The phrase "science policy" does not represent the problem any better. It has an uneven history, and seems to mean something different whenever it is used.

This paper has chosen two strategies to bring a sense of order to this chaos. The first strategy has been to use four examples of contentional wisdom as foils for a discussion of the literature. The second strategy has been to identify three arenas of science policy, suggesting that different problems, needs and opportunities for assessment exist in each. It remains to close the discussion with a few general remarks. It has been relatively easy to see where the problems lie with existing mechanisms and practices. It is much harder to identify approaches for dealing with these problems without encountering at least as many limitations as have been encountered with current efforts. The analysis offered here suggests that a variety of different tasks need to be performed to support assessment of scientifically and technically complex issues, to foster the development of scientific literacy and scientific research and to conduct environmental scanning of the new economy.

In the best of circumstances, one body might take charge of all these needs, and draw on existing institutions, programs, mechanisms and initiatives to complement its work. In today's environment, it is unlikely — although not impossible — that any new body with such a broad mandate will be established. In its absence, much more strategic use needs to be made of the resources and initiatives that do or might easily exist: of scientific focus groups and the organization which might convene them when required, of the Royal Society (assuming some internal reform) and the professional and academic associations, of the strategic granting councils and the research they sponsor, of politically unaffiliated research institutes such as the Canadian Institute for Advanced Research, and of sectoral councils in all their many guises.

Two last remarks reflect the preoccupations of the author of this paper. The first is a concern that the contributions of science not be compromised in the interests of promoting sound public policy, important though sound public policy may be. In terms of assessment, scientists

have a crucial but limited contribution to make. They can bring their expertise to bear to answer questions about what is known (with a reasonable degree of confidence), what is not known, what remains uncertain and what is subject to debate within any field and with respect to any issue. This is precisely the information needed by policy makers. All too often, scientists are called on to contribute to another debate, in this case about the implications of science and technology for particular policies under development. In the latter debate, scientists offer an informed view, but their expertise is not necessarily relevant to the types of questions being addressed. Furthermore, scientists have no exclusive claim to expertise about the implications of their research, or of science in general. Occasionally, they are poorly prepared to offer useful insights because of the narrowness and rigour of their own work and expertise. In other words, while scientific assessment has an important contribution to make to public policy, it is crucial that the capacity of science to address policy-related questions not be overestimated or wrongly understood. The price of both is not just (or necessarily) poor public policies, it is sometimes poor science.

While there is no one model of how scientific assessment should be done, especially with respect to new technologies and the new economy, there is ample room for change. There are many approaches to assessment of the social and cultural implications of science and technology, and, indeed, many examples of successful efforts in this regard. In today's political climate, it is safe to assume that whatever is put into place will involve both consultation and research, and will probably develop partly outside departments of government. Anything put into place should probably also be reasonably independent, not just of government but of policy research institutes associated in the public mind (properly or not) with particular political perspectives. Anything put into place should enhance the assessment capacity of government and its many constituents without adding to their administrative burden or to the cacophony of public controversy. The new initiatives discussed in this paper offer promising avenues of approach, but they do not exhaust the possibilities.

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APPENDIX 1
A Case Study of Canadian Approaches to Social and Cultural Implications of Biotechnology

by Judith Miller
November 1994

The development of biotechnology, a field where research and development are paramount, illustrates strengths and needs in Canadian mechanisms for assessing the social and cultural implications of science and technology. *Biotechnology* is defined as the use of living organisms in the production of goods and services. Biotechnologies include new enzyme capabilities, fermentations, cellular fusion and genetic engineering with recombinant DNA. The processes may be applied to micro-organisms, plants or animals.

Biotechnology is a potent set of techniques which can be used in a vast array of fields, e.g., agriculture, forestry, health sciences, mining, energy production, pollution control. The real and future potential benefits are well acknowledged, and recent listings of biotechnology articles in the *Canadian Periodical Index* attest to its value. The promise of biotechnologies is the basis for extensive national and international commitments to biotechnology. Canada's National Biotechnology Strategy, instituted in 1983, aims to develop a strong national capability. About $12 million, annually, are devoted to maintaining a strong research base for biotechnology development, to increasing the supply of highly qualified personnel, to enhancing scientific co-operation and technology transfer among government, university and industrial laboratories, and to fostering an economic and commercial climate conducive to the commercialization of biotechnology. Major elements of the strategy include the following:

- The National Advisory Biotechnology Advisory Committee provides independent advice to the Minister of Science on issues and policy needs to support development of biotechnology.
- The Interdepartmental Committee on Biotechnology co-ordinates federal activities in biotechnological research and development and other activities relevant to providing an appropriate infrastructure for the commercial development of biotechnology.
- The National Biotechnology Networks facilitate communication and co-operation in application and commercialization of biotechnology by sector.
- A federal cost-shared program, administered through the Industrial Research Assistance Program of the National Research Council of Canada, promotes technology transfer.[1]

As with the introduction of any new wide-ranging technology, biotechnology raises social and cultural questions which need to be addressed in tandem with its commercial development and implementation. Rapid advances toward commercialization for a wide range of products, and the prospect of continued and growing applications, have focused attention on the potential health hazards and environmental, social and cultural impact. Some claim, for example, that biotechnology could upset the ecological balance, threaten natural biodiversity or harm the

economic integrity of farmers or of the third world.[2] Concern over the impact on biodiversity led to a commitment by 157 nations at the Rio Earth Summit in 1992 to consider the need for a protocol on the safe handling and use of genetically modified organisms. There is significant controversy about release of biotechnologically modified organisms. Advocates of biotechnology argue that the release of transgenic organisms produced by biotechnology closely resembles the release of non-transgenic organisms and that the magnitude of risk is far less than the anticipated benefits. In contrast, some ecologists see significant risk.[3] There are also divided opinions among the scientific community as to the level of risk of assessment need in view of the finding that plants which are genetically engineered to resist viruses could become the breeding ground for new pathogens.[4] The biotechnology articles listed in the *Canadian Periodical Index* illustrate concerns as well as benefits. The appropriate role of biotechnology in the development of agricultural science is likewise debated.[5]

This paper focuses on some concerns and the means to address them, which have been far less well defined and explored than mechanisms to promote the development and use of biotechnology. This orientation in no way should be taken to deny the many benefits of biotechnology which are extensively documented in the literature or to suggest that all the concerns are justified. The paper is not intended to extol or condemn biotechnology, simply to explore the Canadian capacity to address social and cultural concerns raised by biotechnology and, thus, to build toward a sounder infrastructure for its development and use.

The focus on concerns stems from the continuing controversies around the potentially negative impact of biotechnology and its importance in understanding the issues in context. By stepping back from the thrust for commercial development and recognizing other ways to conceptualize the developments, we may be able to evolve improved strategies for the wise use of biotechnology for the benefit of humanity and the environment, and to enhance communication among all involved. Without such understanding and attention to public concerns, we may arrive at unmarketable biotechnology products[6] or, perhaps, expose the environment or humanity to unnecessary risks. As well this focus is important because, while the infrastructure for commercial development is well defined, the mechanisms and authority for addressing social and cultural issues is not. In exploring this topic, it is important to recognize that potential benefits and hazards of biotechnological applications differ from case to case and are unlikely to be amenable to a monolithic approach.

The exploitation of biotechnology has led to changes which are viewed by some as a source of concern for society. Large volumes of organism cultures with new genetic natures are handled by workers, and the wastes from such applications processed. An increasing number of genetically modified organisms are being released into the environment. Consumers are encountering a new generation of health products, animal-growth promoters and food additives. Scientists, industrialists, regulators, environmentalists and others recognize the need for regulation with appropriate assessment to protect against potentially adverse effects. From an industrial policy perspective, regulations also serve to promote a stable environment for research

and development, investment and marketing and to define limits of liability for any problems which might ensue.

Many countries, including Canada have examined the adequacy of existing legislation, mechanisms and practices to regulate biotechnology as well as the need for new approaches and frameworks. Suggestions have been made for comprehensive new legislation to regulate and bodies to oversee all areas of biotechnology. These often stem from those who perceive the area as fundamentally new and of high risk, and may focus on the need to regulate the process of biotechnology.[7] Following this approach, for example, Britain (along with other European Community member countries) has adopted what Levidow and Tait call "a precautionary approach" to potential hazards from intentional release of genetically modified organisms, anticipating, as best as possible, conjectural harm to the environment, both in its voluntary approach and in its *Environmental Protection Act* 1990, part VI. The multi-stakeholder review committee in Britain's voluntary approach considers the product, its intended use and the acceptability of the risk that the two in combination would pose.

Acknowledging the vast array of applications and of potential harms and benefits entailed in different instances, others have advocated a case-by-case approach which regulates the product rather than the process and applies and extends existing laws and assessment tools. Such an approach assesses and regulates for documented risks. Proponents of this approach tend to view biotechnology and genetic engineering as a natural extension of the more traditional use of naturally occurring organisms, production of comparable products by other than biological means and genetic manipulation by classical breeding and selection. Taking this perspective, industry has opposed the UK and EC precautionary position as inappropriate. It argues a process-based precautionary approach is unnecessary and detrimental, fostering a public fear of genetic modification and hampering the international economic competitiveness which the EC claims to support in its biotechnology regulatory policy.[8]

Faced with the degree of uncertainty, the range of applications with variable risks and the need for more predictive tests, Canada, among others, has adopted a case-by-case approach to assessment.[9] Canada opted formally in January 1993 to regulate the final product of biotechnology, largely through application and extension as necessary of existing legislation and of internationally developed guidelines,[10] rather than by developing a whole new framework for oversight for a process-based approach to regulation. This product-oriented approach does not preclude some preventive strategies.[11]

The range of the potential impact on environment, human health and the economy requires a co-ordinated approach from departments and players and special efforts to orchestrate efficiently. Co-ordination through interdepartmental groups such as the Interdepartmental Committee on Biotechnology is critical for coherent and workable control of biotechnology. Interdepartmental workshops on aspects of biotechnology which cut across departmental boundaries are another.[12]

To help work through the complex labyrinth of products and regulations and to facilitate a co-ordinated approach, Agriculture Canada, Environment Canada and Health and Welfare Canada produced *Biotech Regulations: A User's Guide*, published by the Ministry of State for Science and Technology Canada in 1988. This handbook, which serves as a road map to regulations, was updated in 1991 to include Labour Canada and Transport Canada and to reflect reforms such as those related to the environmental assessment process in Canada. While helpful in principle and although improved in its first revision, the document is in need of further revision in view of subsequent changes. For example, it does not mention the requirement for a Regulatory Impact Analysis under Treasury Board regulations to consider the socio-economic impact of any new regulation.[13] The document does provide contact persons for the various departments so the interested reader has the opportunity to pursue more recent developments. For those seeking assurance about the assessment of the social and cultural impact of biotechnology, either the regulations themselves or the presentation of them in the *Biotech Regulations* would benefit from revision also. The summaries of requirements under the various acts and regulations indicate attention to environmental and human health and safety, but most do not prescribe assessment of social effects and public concerns with the exception of the Environmental Assessment and Review Process Guidelines.[14] The *Canadian Environmental Protection Act* (CEPA) and Regulations specifically address products created through biotechnological processes and the use of any micro-organism in a biotechnological application. In general, however, existing regulation has been viewed as adequate to encompass biotechnologically created instances as well as naturally occurring ones. In turn, this means that a selection of the wide panoply of mechanisms and practices for risk assessment in a variety of areas may be used to assess applications of biotechnology, rather than regulations or mechanisms specifically designed for biotechnology products and processes. While not always interpreted as addressing social and cultural elements of a new technology, some of the mechanisms and assessment procedures may include social and cultural implications in their impact assessment and are hence a reasonable approach to look at the methods available, and used, in Canada for these elements. This paper refers to some of the key mechanisms and practices pertinent to particular applications of biotechnology. It speaks principally to a few regulations and mechanisms in Agriculture and Agri-Food Canada, in Environment Canada and in Health Canada. It does not attempt to define the panorama of potential governmental, quasi-governmental and private sector assessment tools which might be used. Christina Chociolko describes these in "A Case Study of Canadian Mechanisms and Practices for Risk Assessment," a companion study to this paper (*see* Appendix II). Her paper also provides additional detail on the mechanisms mentioned in context of this more issue-oriented study.

Public participation is one indicator of attention to social and cultural elements in an assessment. It does not necessarily guarantee their inclusion or a sufficiently broad perspective for consideration of priorities. Marketing strategies to create public acceptance of new products may also entail public participation and be presented as addressing public concerns, yet may provide no meaningful input into policies for science and technology.

Public participation has been used in development of regulations under the *Canadian Environmental Protection Act* by Environment Canada and Health Canada (then Health and Welfare Canada) through invited consultation with environmental groups and in establishing policies for gene patenting by Consumer and Corporate Affairs (now part of Industry Canada). Agriculture and Agri-Food Canada has also used public consultation to develop its new biotechnology regulations. Yet some see such positive instances defined within the overall government policy framework as extremely limited in scope.[15] As with any public consultation, defining and informing the appropriate audiences is critical. Public participation may necessarily be limited at this time as surveys on public attitudes to biotechnology are reported to suggest limited definition of public issues and, hence, amorphous policy debate at the public level.[16] As well, the relatively few organized groups who might speak for the public are not necessarily representative.

Given the Canadian regulatory decision to apply controls developed primarily for chemicals rather than for living organisms which can reproduce, mutate and migrate,[17] it is important to explore the adequacy of the mechanisms in place to address the issues raised in biotechnologically generated products. A survey result that two thirds of the Canadian public believe biotechnology poses dangers to society, suggests the importance of considering the social and cultural impact as part of the assessment of biotechnology products.[18]

Continued concern can be viewed as an expression of social and cultural aspects which have not been well enough integrated into the current mechanisms and practices of assessment. It can be seen as an indicator of the importance of attending to and integrating assessment of the social and cultural impact in the development and implementation of biotechnologies. In what way is the concern a social and cultural expression? Sheldon Krimsky describes three reasons for what he names "the cultural selection of genetically engineered products as a special area of concern."[19] First he argues that prior concerns about recombinant DNA research, which have now been largely put to rest for laboratory research and for limited and contained field trials,[20] colour the public's perception of environmental risk today from genetically engineered organisms. Second, he notes concern for the specificity of recombinant DNA techniques and their capacity to create new life forms that cross species boundaries and are subject to fewer natural constraints than new organisms developed spontaneously in nature or by traditional techniques. Others hold that the specificity actually leads to greater safety and more predictable changes than the random gene mixing in conventional genetics. Finally the power of the technique, the basis for a perceived technological revolution, amplifies concern over humanity's wisdom in transforming nature. He emphasizes a natural relationship between technological power and risk anxiety in a world sensitized to technological failure. These kinds of concerns might best be addressed by assessment of biotechnology as a process, rather than the product-oriented approach adopted by Canada.

The adequacy of means to assess social and cultural implications of some applications of biotechnology will be explored particularly with regard to biotechnologically engineered pesticides, a specific instance of the heavily debated issue of environmental release of

genetically engineered organisms. The ability to engineer genetically, to create new combinations of genes and to transfer genes between species, has been the focus of most public concern and, hence, an appropriate case study.

Biopesticides, a Biotechnological Opportunity

The biotechnology industry has promoted the potentially increased capacity to replace environmentally and occupationally hazardous, broad-spectrum chemical pesticides with biological alternatives that are safer and species specific. A number of companies have engineered plants to include genes from *Bacillus thuringiensis,* a micro-organism which produces proteins toxic to insect pests.[21] The pesticide gene can now be transferred into other host bacteria, into plants and into insect viruses.[22] Biological pest-control agents, both naturally occurring and engineered, are thought to be environmentally friendly approaches with distinct advantages over chemical solutions. The biological safety features resulting from their specificity and short field life also limit the effectiveness and commercial appeal vis-à-vis chemical solutions. On the other hand, stringent and increasing regulation of, and the growing resistance to, chemical pesticides[23] provide incentives for development of more biological pesticides. To date, biological pesticides represent only a small proportion of the global pesticide market.[24]

In Canada, biological pesticides, whether naturally occurring or engineered, are regulated under the *Pest Control Products Act*. This Act governs all "control products . . . defined as any product, organism, device, substance or thing that may be used directly or indirectly to control, prevent, destroy, mitigate, attract or repel pests. This includes any compound or substance that enhances or modifies the physical or chemical characteristics of a control product to which it is added, and any active ingredient used to manufacture control products."[25] The Act is administered by the Minister of Agriculture with advice from Health Canada, Environment Canada and, as needed, the Canadian Wildlife Service and others. The Act, and the Pest Control Products Regulations based on it, lay out the technical requirements for registration, labeling, record keeping, storage, display and the like, but do not specifically address social and cultural concerns.

The Act requires assessment of the safety, merit and value of a proposed product for registration. Safety includes risks to human and environmental health: value should not be construed as referring to social and cultural values. One individual who works with pesticide regulations in the federal government interpreted the term to mean economic value for use of the pesticide. Another explained that it refers to whether the proposed pesticide would be valuable in Canada to address a need in an efficacious way and whether the value is sufficient to encourage users given the specific conditions for its use.[26] The Canadian Labour Congress notes, "We object to the use of ‘value assessments' in the model. We believe that value assessments are basically benefit studies and will lead to a process of risk-benefit comparisons. Whether a pesticide should be used should be based on whether it is hazardous, rather than whether other parties will benefit."[27]

The *Pest Control Products Act* does not define a specific role for the public, or for social and cultural factors, in pesticide assessment at the federal level. There are currently no guidelines to aid in interpretation of the regulations with respect to biological pesticides, and proposed uses are considered on a case-by-case basis in a co-ordinated effort by Agriculture and Agri-Food Canada, Environment Canada, Health Canada and the Department of Natural Resources. There are no special provisions for genetically engineered pesticides, which are subject to the same assessment criteria to establish safety as any other pesticide.

Pesticides controlled under the *Pest Control Products Act* are not subject to the new *Canadian Environmental Protection Act* (CEPA) Regulations or to the Environmental Assessment Review Process (EARP), the federal acts which most explicitly address biotechnologically modified organisms and which call for attention to environmental and social effects as well as public concerns. Some hold that this exemption is appropriate because they view the regulatory requirements under the *Pest Control Products Act* as at least as stringent. Yet it is not obvious that biological pesticides should be exempt from assessment such as that called for in the EARP requirements as applied by the Food Production and Inspection Branch of Agriculture and Agri-Food Canada as part of its assessment procedure for field tests of new biotechnological products, or that they will be subject to the same explicit social impact assessment under the *Pest Control Products Act* as they would under CEPA.

Biological pesticides are a special instance of environmental release of genetically modified organisms. Hence, it is important to review the concerns and assessment tools in that more general area. Risks of wide-spread deliberate release of genetically engineered organisms in the environment and appropriate risk assessment and management tools remain subject to intense debate.[28] Sound assessment is seen to rest on knowledge about such aspects as ecological interactions, infectivity, pathogenicity, toxicity, host range and environmental transport of the novel organism to be introduced, whether genetically engineered or naturally occurring. In the case of genetically modified organisms, the information base must also address the nature of the modification, any loss of normal function, genetic stability, potential for inadvertent introduction of new material and capacity for genetic exchange with other members of the ecosystem. The intentional release of organisms which can reproduce, mutate and exchange genetic material is recognized to require controls and data beyond those evolved primarily to deal with hazards from inanimate nuclear and chemical products. Development of unexpected pathogenesis through, for example, fusion of two non-pathogenic strains is another documented possibility.[29] Yet while genetically engineered organisms require some additional testing of aspects such as genetic stability, the fundamental questions remaining in the science of predictive ecology apply to environmental impact assessment of the release of any new organism, regardless of its origin. Instances of low probability of risk with significant magnitude of harm, the kind of risk often attributed to deliberate release of novel organisms in the environment, present special policy challenges.

It is important to recall that most introductions of new strains into the environment are benign. Most of the agricultural crops in North America are non-native, and microbial pesticides

have been used since the late 1940s. While both naturally occurring and biotechnologically modified organisms are capable of ecological disruption and of harm to human or environmental health, any seed catalogue attests to the routine release of new strains. In some cases, biotechnology simply streamlines the process to arrive at a new strain, which could have been developed with classical genetic selection.

Why then does concern continue to arise? Some point to a few disastrous attempts to introduce new organisms for beneficial goals which have backfired dramatically.[30] Introduction of the Japanese kudzu vine in North America to control erosion, and of the rabbit in Australia where it has no natural enemies, are often cited examples.[31] Such examples do not prove that most modified organisms present unreasonable risk, but rather indicate that a small unidentifiable proportion of deliberate releases could result in a significant problem.[32]

Canada has developed some new assessment procedures to safeguard against the risks of environmental release. Modifications of existing assessment practices include new guidelines for field tests of genetically modified plants. Information is required about the genetic nature of the plant to be tested, particularly any new traits, the trial site and procedures to be followed. Precautions required to prevent transfer outside the test area include reproductive isolation, disposal and use of seed and pods and restrictions on post-harvest land use.[33] Draft regulations for a proposal for unconfined release are in preparation.[34] Since the problem with introduction of genetically modified strains is often making them sturdy enough to survive well on release in the natural environment, risks of environmental release and dispersion may be less severe than imagined.[35]

Genetically engineered biopesticides may generate the same kinds of risks connected with environmental release of other genetically modified products. *Bacillus thuringiensis* has been shown to release spores into the environment which can affect non-target organisms and introduce new genes into the environment. While this particular toxin has not been shown to have detrimental effects on mammals or birds, some argue that even if biopesticides are more specific than chemical, and genetically engineered ones more specific still, nonetheless there is a possibility that biopesticides may contribute to the decline of rare species in the environment.[36] Direct risks include the potential for unintended side effects of biological pest-control agents. Released organisms, including genetically engineered biopesticides, may persist in the environment and damage existing ecosystems.

Biopesticides also may raise health risks and cultural issues in the way they are used or, as some believe, overused. The recent public hearings on *Bacillus thuringiensis* (Bt) spraying and chemical pesticide use in Quebec, conducted by the Bureau d'audience publique en environnement, arose out of public concern by a variety of stakeholders, most notably Indian bands. Concerns focused on the uncertainty of effects of spraying, persistence in the soil, water solubility and the lack of testing of potential effects on amphibians and reptiles to ensure that population declines of certain species are not related to Bt use. Aboriginal peoples' use of lake waters not specifically designated as water reservoirs and, therefore not protected from spraying,

led to a persuasive request for local consultation before spraying to see if there were any local activities which would limit application. Following the hearings, Quebec decided to limit Bt use to instances when it was proven strictly necessary even though the approach seemed natural and environmentally friendly. Other provinces have also provided some opportunities for public input in pesticide use,[37] although the opportunities differ significantly across the country and the capacity for public input on social and cultural aspects at the federal level is quite limited despite the acknowledged value. Some advocacy for public participation seems to focus at least as much on public education to promote acceptance and improve marketing as it does on effective dialogue about social and cultural aspects important to assessment of science and technology.[38]

Indirect risks include the possible contribution of biotechnology through pesticides or other agricultural applications to narrowing of species diversity for a food source and, thus, increasing the risk of blight. Many genetically engineered products are designed for monoculture. Some argue this is a "design [that] may make biopesticides more likely to harm non-target organisms and/or generate selection pressure for resistant pests . . . ."[39] The emergence of Bt resistance, attributed to overuse by farmers, illustrates another risk of biological pesticides, natural or engineered.[40] Since biological alternatives were sought to deal with growing resistance to chemical pesticides, this is a serious concern which colours the rosy picture of environmentally friendly, effective, biological alternatives for pest control. The biological alternative may suffer from the same hazards as the chemical one which it is intended to improve.

Other indirect social and cultural impacts potentially emerging with the use of genetically engineered and other biopesticides include the favouring of one community over another, with agribusiness having better access to new technologies. As well, the introduction of biopesticides to replace chemical ones can cause major upheavals in farming practices and in agricultural industries. As with many of the concerns discussed here, this kind of global issue was raised some time ago — although we seem no closer to a solution or even a forum for considered reflection of these broad, global issues.[41]

An overview of the mechanisms and practices for social and cultural assessment of biological pesticides and of the general regulatory context for biotechnology suggests that:

- While assessment mechanisms are in place, the focus is primarily technical rather than routinely integrating social and cultural factors.
- While specific introduction of a given product may be assessed, there are few mechanisms to deal with general implications and provide a broad overview of the new developments, or to ensure that new approaches are considered in addition to traditional methods in addressing a particular challenge competitively and with minimum risk to health and environment.
- Some steps have been made toward establishment of fora to improve public participation, and there is clear recognition of the need to improve the means. Some of the mechanisms in place are not neutral but subject to real or perceived conflicts of interest as the

principal assessors may be parties with a vested interest in development of the technology.

Examination of this instance and the general area of biotechnology suggests that while mechanisms exist to assess specific applications, there may well be a need for additional neutral bodies to provide key policy advice on science and technology. Such bodies would need a mandate and capability for an integrated and comprehensive assessment of science and technology, including its social and cultural implications. Arguments for and against a continuing national body to address public policy issues related to bioethics in Canada and other countries are well aired[42] and apply as well to an organization with a broad mandate for social and cultural assessment of science and technology.

An issue-based overview of current mechanisms for assessing the social and cultural implications of some applications of biotechnology indicates that we lack structures which would allow the public to help direct the course of technology or to solve complex ethical and social problems associated with new technologies. In a system where potential economic gains and international competitiveness are foremost, where government sees its role as primarily supportive in promoting innovation and development, it is hard to address effectively the complex social and cultural issues of technological choice which arise at least in some problematic applications of biotechnology. Many biotechnological applications are straightforward and provide substantial benefits which clearly outweigh risks. There are also instances of concern and continuing areas of uncertainty which test our approaches to assessing the impact of new technologies and suggest a need to build on our current limited tools for social and cultural assessment and for informed public participation in decision making. While the mandate seems clear and the commitment strong for a variety of federal agencies and departments to promote biotechnological research and development, including regulations to foster its commercialization, the responsibility and authority for concomitant assessment of social and cultural issues related to biotechnology is far less defined. The appropriate venue for an ongoing Canadian forum for stakeholders including the concerned public is not clear. Might it be possible to incorporate such dialogue as a function of the Interdepartmental Committee on Biotechnology which currently co-ordinates biotechnology policy? Might it be based on an expansion of the various biotechnology networks[43] currently designed to keep the inner circle of stakeholders in touch? (If so, this would require provision of additional resources.) Are there effective mechanisms and practices which we could create to meet this need? Some assume that the regulatory departments and agencies have responsibility for assessing these impacts as well. Others argue this is in no way a part of their responsibilities.[44] Should social and cultural assessment be explicitly mandated as a function of regulatory departments who are assessing health and safety impacts?

Chociolko's process-oriented companion study (*see* Appendix II) documents the wide array of structures and mechanisms for assessment and illustrates the complexities of assessment in practice. Some models for new mechanisms can be found in that paper. The need for co-ordination of effort and clarity of responsibilities is also apparent.

There is still an opportunity in the growth of biotechnology to ask in a meaningful way the kinds of questions posed by Sheldon Krimsky, author of *Biotechnics and Society: the Rise of Industrial Genetics* and co-ordinator of the International Network on the Social Impacts of Biotechnology. He asks:

> "What is the responsibility of government in regulating biotechnology? How much effort should be put into evaluating the hypothetical risks of biotechnology? . . . Is there a public role for directing biotechnology toward specific ends or should the market decide which products get developed. . . On the surface [these queries] . . . are about the alteration of biological life forms, but they are also part of a wider dialogue. These debates are an important expression of the prevailing public attitudes toward technology, of scientific-social interactions, and of the means through which our society grapples with scientific uncertainty and social change. Will biotechnology contribute to a more harmonious and sustainable relationship between humans and nature? Will it help to flatten out the vast disparities in wealth on the global scale? Will it make meaningful contributions to improving health . . ?"[45]

Positive responses to these difficult questions require continued and increased commitment to addressing the social and cultural impact of research and development. Without attention to this aspect of biotechnology, illustrated in microcosm for biotechnologically engineered pesticides, only one of the many applications of biotechnology, we would avoid a key part of the new technology, one which may have a significant role to play in shaping its applications and which may also be vital for public acceptance of biotechnology and its products.

NOTES

1. A schema of the Committee Structure of the National Biotechnology Strategy is provided as Annex 1.

2. *See,* for example, *Superpigs and Wondercorn: The Brave New World of Biotechnology and Where it All May Lead*, by Michael W. Fox, New York: Lyons and Burford, Publishers, 1992, and the review of this book by Ann M. Verrinder Gibbins and W. Douglas Morrison, *Journal of Agricultural and Environmental Ethics*, vol. 7, no. 1 (1994), pp. 126-131.

3. Abby Munson, "Better Biosafe than Sorry," *New Scientist*, vol. 142, no. 1931, (June 25, 1994).

4. Bernice Wuethrich, "Will altered plants breed deadlier disease?" *New Scientist*, vol. 142, no. 1919, (April 2, 1994), p. 15.

5. *See* companion articles by Donald N. Duvick, "Our Vision for the Agricultural Sciences Needs to Include Biotechnology" and by Wes Jackson "Our Vision for the Agricultural Sciences Need Not Include Biotechnology," as well as the article by A. David Kline, "We Have Not Yet Identified the Heart of the Moral Issues in Agricultural Biotechnology," in a special issue of the *Journal of Agricultural and Environmental Ethics*, devoted to ethics and agricultural biotechnology, vol. 4, no. 2 (1991), pp. 200-222.

6. Andy Coghlan reports that biotechnologists who are working to transfer genes from beans to peas in order to protect seeds from pests "hope that the gene switch will prove more acceptable ethically to critics of genetic engineering because the transfer is from one edible plant to another, rather than from a bacterium or an animal into a plant."

7. The Canadian Environmental Law Research Foundation, for example, made such a proposal in 1984 following their conference on Regulation of Biotechnology, held in Toronto in October 1984.

8. Les Levidow and Joyce Tait, "Britain's Precautionary Approach to Regulating Releases of Genetically Modified Organisms," *Genewatch*, vol. 8, no. 2, pp. 6, 11.

9. In line with this approach, *see*, for example, Claire A. Franklin, "Modern Biotechnology: A Review of Current Regulatory Status and Identification of Research and Regulatory Needs," *Toxicology and Industrial Health*, vol. 4, no. 1 (1988), pp. 91-105, and C.A. Franklin and N.J. Previsich, "Assuming Human Health Risks of Environmentally Released, Genetically Engineered Microorganisms," in *Safety Assurance for*

Environmental Introductions of Genetically Engineered Organisms, NATO ASI Series, vol. G18 (1988), pp. 555-571.

10 This position was reported, for example, by Jean Hollebone and by Sheila Forsyth of the Pesticides Directorate of Agriculture Canada in the Canbiocon Conference Proceedings of a 1989 meeting published in 1991.

Some argue with this regulatory decision. *See,* for example, "Concerns about Biotechnology: Issues Identified by Environmental Groups," a paper prepared for Environment Canada on behalf of the Canadian Environment Network's Biotechnology Caucus by Buckhard Mausberg and Brewster Kneen, June 1993. The paper identifies a variety of environmental, social and economic issues in biotechnological applications, ranging from disturbance of the natural ecosystem, to insufficient public participation in decision making related to biotechnology despite the public's bearing of the risks, to the impact of biotechnology on biodiversity.

11. Christine Massey in her "Biotechnology and Genetic Engineering Background Paper," prepared for Dr. William Leiss, Centre for Policy Research on Science and Technology (Agriculture and Agri-Food Canada, "Departmental Consultation on Biotechnology Regulation"), June 1994, p. 4, points out:

> "Agriculture Canada's risk assessment model includes the concept of "substantive equivalent" necessary to exempt a product from assessment. Equivalence includes consideration of "an unfamiliar process resulting in unknown risk." If interpreted broadly enough, the notion of substantial equivalence could capture many genetically engineered products. In addition, the focus on products and their characteristics does not restrict regulation to products of genetic engineering but would include products derived from conventional methods but which introduce novel traits."

The background study has been an invaluable resource for preparation of this case study.

12. A variety of fora have taken place in a number of settings to foster identification and resolution of issues. One recent example, is documented in *Proceedings of an Interdepartmental Workshop on Ethics and Biotechnology: Moving from Confrontation to Engagement*, Ottawa, March 2-3, 1994. Led by Agriculture and Agri-Food Canada, funded with National Biotechnology Strategy Funding and administered by the Biotechnology Strategy and Coordinating Office, the participants addressed a variety of social and ethical issues, particularly intellectual property, agricultural products and gene therapy.

13. While seeming to provide another venue for consideration of social factors, the perspective is largely economic. For more detail *see* Chociolko's companion paper in Appendix II.

14. The Environmental Assessment and Review Process Guidelines Order calls for:

> "a self-assessment process under which the initiating department shall, as early in the planning process as possible and before irrevocable decisions are taken, ensure that the environmental implications of all proposals for which it is the decision making authority are fully considered and where the implications are significant, refer to the proposal to the Minister for public review by a Panel. . . . An initiating department shall include in its consideration of a proposal . . . (a) the potential environmental effects of the proposal and the social effects directly related to those environmental effects, including any effects that are external to Canadian territory; and (b) the concerns of the public regarding the proposal and its potential environmental effects."

This Act will soon be strengthened in the *Canadian Environmental Assessment Act* as described in detail by Chociolko in Appendix II.

15. "Concerns about Biotechnology: Issues Identified by Environmental Groups," a paper prepared for Environment Canada on behalf of the Canadian Environment Network's Biotechnology Caucus by Buckhard Mausberg and Brewster Kneen, June 1993, p. 3.

16. *See* Decima Research's executive summary of its "Baseline Study of Public Attitudes to Biotechnology," conducted for the Canadian Institute of Biotechnology with a final report issued January 21, 1994.

17. Primary federal acts for regulation of biotechnology in Canada include the *Pest Control Products Act*, the *Canada Seeds Act*, the *Food and Drugs Act*, the *Canadian Environmental Protection Act* (replacing the *Environmental Contaminants Act*). The specific inclusion of biotechnology products in the 1988 *Canadian Environmental Protection Act* is an exception to most federal acts.

18. Supra, note 16.

19. Sheldon Krimsky, *Biotechnics and Society: the Rise of Industrial Genetics*, NY: Praeger Publishers, 1991, p. 97.

20. Initial concerns in biotechnology focused on laboratory-contained research with recombinant DNA. Scientists took the lead in calling for a moratorium at the Asilomar Conference until appropriate safeguards were in place. In Canada, such research is controlled by local biohazard committees applying the *Guidelines for the Handling of Recombinant DNA Molecules and Animal Viruses and Cells* of the Medical Research Council of Canada. Canadian and international standards for such research have gradually become more relaxed as evidence accumulated that the risks were lower than feared. Laboratory

research and small-scale, contained field-testing are generally thought to be relatively safe and well controlled today. Canada, for example, field-tested 489 genetically modified plants in 1993, as reported in Agriculture and Agri-Food Canada, "Summary Information for 1993 Field Testing of Genetically Modified Plants."

21. Thus, for example, Monsanto developed a genetically engineered tomato plant with reputed resistance to insects and Crop Genetics injected corn seedlings with a microbe containing genes toxic to corn pests. Joseph Haggin, "Monsanto Uses Genetic Engineering to Solve Agricultural Problems," *Chemical and Engineering News*, 66 (February 15, 1988), pp. 28-33, cited in Krimsky, *Biotechnics and Society*, supra, note 19, p. 89.

22. Bart Lambert and Marnix Peferoen, "Insecticidal Promise of *Bacillus thuringiensis*," *Bioscience*, vol. 42, no. 2 (1992), pp. 112-122.

23. Ronald Begley, "Biopesticides on the Rise," *Chemical Week*, vol. 153, no. 15 (October 27, 1993), pp. 41-42. *See also* reference supra, note 22, p. 112.

24. Christine Massey reports that biopesticides consist of one to two percent of the total $6 billion market for pesticides.

25. Agriculture Canada, "Guidelines for Registering Pesticides and other Control Products under the *Pest Control Products Act* in Canada," Can 346.0, addendum to the *Pest Control Products Act*, RSC 1985, c. P.9.

26. Interviews with John Frecker and with Geraldine Graham, Pest Management Secretariat, July and August 1994.

27. Canadian Labour Congress, "Statement of Dissent to the Pesticide Registration Review," in *Recommendations for a Revised Federal Pest Management Regulatory System, Final Report December 1990*, Minister of Supply and Services, Canada (ISBN 0-662-57832-5), 1990, p. 53.

28. *See*, for example, Krimsky, *Biotechnics and Society*, supra, note 19, and J. Miller et al, *Biotechnology in Canada: Promises and Concerns*, Science Council of Canada, 1981, especially the paper by D.T. Suzuki, pp. 23-30 and pp. 37-42.

29. F.E. Sharples, "Spread of organisms with novel genotypes: thoughts from an ecological perspective," *Recombinant DNA Technical Bulletin*, vol. 6 no. 2 (June 1983), pp. 43-56, p. 55.

30. Lawton and May, pp. 744-745 in M. Segal, *Hazards from Genetically Engineered Organisms*, Washington, D.C.: Office of Pesticides and Toxic Substances, Environmental Protection Agency, 1983.

31. *See*, for example, R. Brink, R. Kinerson and R. Boethling, "Exposure assessment concerns for genetically engineered organisms," Washington, D.C.: Office of Toxic Substances, Environmental Protection Agency, 1983.

32. For further discussion of the relative safety of releases and diverse views on environmental release, *see* Judith Miller, "Environmental Protection and Uncertainty: the Case of Deliberate Release of Genetically Engineered Organisms," and companion pieces in the same issue of *Politics and the Life Sciences*, vol. 7, no. 2 (February 1989).

33. Agriculture Canada, Food Production and Inspection Branch, Plant Industry Directorate, *Field Testing Genetically Modified Plants in Canada*, Ottawa: Agriculture and Agri-Food Canada, Regulatory Directive 93-08, 1993.

34. Agriculture and Agri-Food Canada, Food Production and Inspection Branch, Plant Industry Directorate, *Proposed Assessment Criteria for Determining Environmental Safety of Genetically Modified Plants.* Ottawa: Agriculture and Agri-Food Canada, 1993.

35. *See*, for example, the author's paper on environmental release, "Biotechnology: Consequences of Deliberate Release," in *The Regulation of Biotechnology*, Toronto: Canadian Environmental Law Research Foundation, 1984.

36. Discussion with Madeline Chagnon, Quebec Bureau d'audience publique en environnement (BAPE), and formerly of the Caucus des Biopesticides, Centre de Valorization des insectes auxilliaires et des biopesticides Inc.

37. Pest Management Alternatives Office, *Pesticide Risk Reduction and Strategic Planning Forum*, Val Morin, Quebec, March 21-23, 1994. See chapter 7, "Issues raised by the Provinces," pp. 16-30.

38. One forum for discussion which addresses some social and cultural aspects of biotechnology is the Food Biotechnology Communications Network (FBCN) which brings together a limited number of consumers, producers, distributors and organizational representatives from North America. This group has hosted a series of four regional meetings to address both scientific potential and social and cultural implications. For example, one meeting addressed innovation in horticultural and microbial biotechnologies and ethical issues. Another will focus on the potential for change in oilseeds production through biotechnology and the implications for staple food products, and yet another on environmental issues associated with food and seafood biotechnologies. The FBCN also offers a speakers' bureau, an information kit and a regular newsletter. While some see the FBCN as a vehicle for assessment of the social and cultural aspects of the introduction of biotechnology, the individual membership fees of $150 may, however, impede widespread participation by the interested public. As well, discussion of implications seems rooted in an appreciation of the need for public education to achieve consumer

acceptance in the marketplace, as stressed, for example, in a lead article of an issue of the *FBCN Forum* concerning the debate of the regulatory evaluation of BST. (*Food Biotechnology Communications Network Forum*, vol. 1, no. 3 (July/August 1994), p. 1, Saskatoon, SK.: Westcross House Publications.)

39. Les Levidow and Joyce Tait, "Britain's Precautionary Approach to Regulating Releases of Genetically Modified Organisms," *Genewatch*, vol 8, no. 2, (11 July 1992) p. 6.

40. Ann Gibbon, "Moths take the field against Biopesticide," *Science,* vol. 254, no. 5032 (1991), p. 646.

41. Note, for example, this statement in *Biotechnology in Canada: Promises and Concerns*, 1980, p. 41:

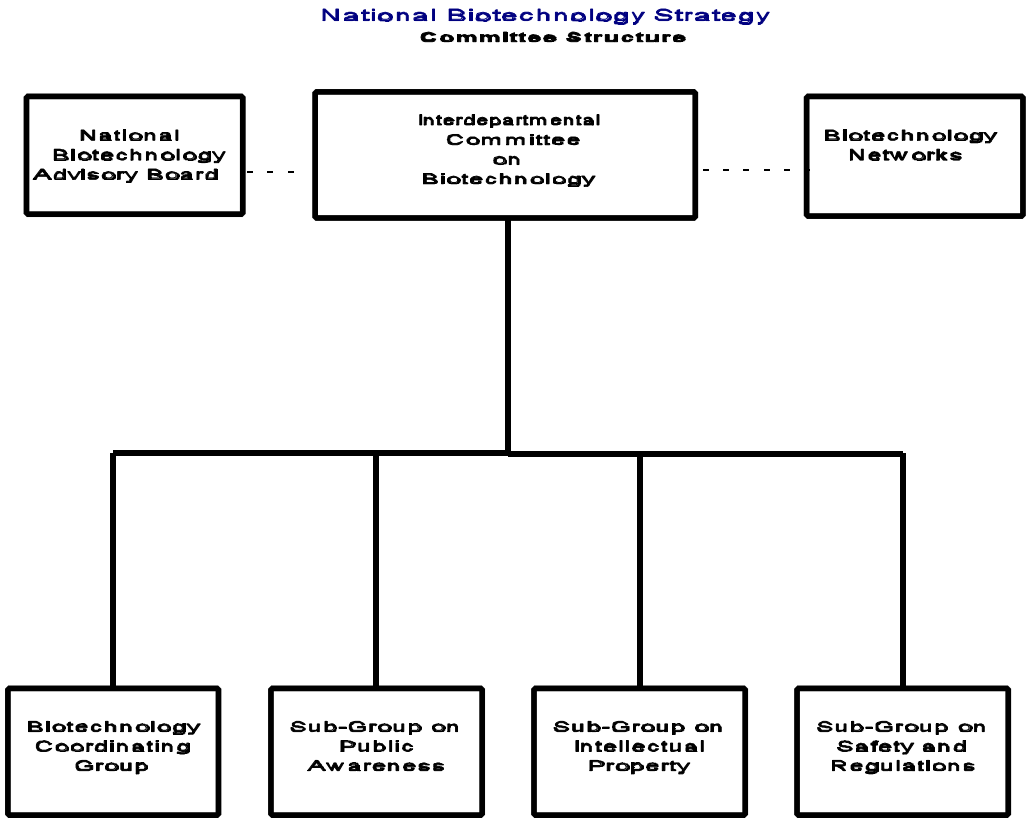
> "One area which has not been talked about at all is the societal impact of biotechnology on the utilization of renewable resources. The simple physical, and philosophical dislocations which will occur in moving towards a more conserver-oriented society are something to be considered...it is something that is perhaps akin to some of the population and the societal dislocations that are occurring in the microelectronics field."

42. *See Biomedical Ethics in U.S. Public Policy - Background Paper, (*Office of Technology Assessment, Congress of the United States, OTA-BP-BBS-105, Washington, D.C.: U.S. Government Printing Office, June 1993), Kathi E. Hanna, Robert M. Cook-Deegan and Robyn Y. Nishimi, "Finding a Forum for Bioethics in U.S. Public Policy," *Politics and the Life Sciences*, vol. 12, no. 2 (August 1993), pp. 205-219 and commentaries on their article, vol. 13 no. 1 (February 1994), pp. 77-105.

43. *See* Annex 2 for a chart of the various Bionets.

44. Comments by a reader in Industry Canada of an earlier draft of this paper note: "It is not . . . within the mandate of the regulatory departments to address social and cultural issues."

45. Krimsky, *Biotechnics and Society*, supra, note 19, p. xiii.


National Biotechnology Strategy
Committee Structure
National Biotechnology Advisory Board
Interdepartmental Committee on Biotechnology
Biotechnology Networks
Biotechnology Coordinating Group
Sub-Group on Public Awareness
Sub-Group on Intellectual Property
Sub-Group on Safety and Regulations

NATIONAL BIOTECHNOLOGY NETWORKS CONTACTS

ISC BIOTECHNOLOGY REGULATIONS INFORMATION

Dr. Terry Walker - (613) 941-0613

IRAP-NRC Technology Assessment and National Coordination

Dr. Denys Cooper - (613) 993-1790

THE NATIONAL BIOTECHNOLOGY NETWORKS

NAME	AREA	DEPARTMENT(S)	COORDINATOR(S)	TELEPHONE
AQUATECH	Fisheries/ Marine Aquaculture	Fisheries & Oceans	Ms. I. Price	613-990-0275
BIOZOOTECH	Animal Development	Agriculture and Agri-Food Canada	Dr. T.R. Batra	613-993-6002
BIOCROP	Plant Strain Development		Dr. J. Singh	613-995-3700
BIOREM	Rhizosphere Enhancing Microorganisms		Dr. L.R. Barran	613-995-3700
BIOFOR	Forestry & Forest Products	Natural Resources Canada	Dr. Wm. Cheliak	705-949-9461
BIOMINET	Mineral Leaching & Metal Recovery	Natural Resources Canada	Dr. A. Oliver	613-996-5619
BIONET	Human & Animal Health Care Products	Health Canada	Ms. S. Hasnain	613-954-0298
		Agriculture and Agri-Food Canada	Dr. A. Fraser	613-998-9320
BIOQUAL	Waste Treatment	Environment Canada	Mr. G. Allard	819-953-3090

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APPENDIX 2
A Case Study of Canadian Mechanisms and Practices for Risk Assessment

By Christina Chociolko

November 1994

Introduction

This case study investigates environmental and human health risk assessment, environmental assessment and technological assessment in a variety of public policy settings, including risk management, environmental planning and management, and technological management. The second part of this paper describes existing mechanisms and practices for assessment. Part three discusses the issues related to the social and cultural implications of science and technology which are encompassed within these assessments. The fourth section evaluates the adequacy of these assessment mechanisms and practices for addressing the social and cultural implications of science and technology.

Ideally, assessment is the scientific process of deciding whether or not a substance, project or policy poses a risk, or adverse impact, to health or environment. Management is the political process of deciding how to deal with an assessed risk or group of risks. Therefore, management involves a wide range of legal, economic, political and sociological considerations in addition to scientific information. Risk assessment typically focuses on risk to human health, usually for purposes of regulation. Environmental assessment focuses on the environmental impact of development projects; environmental assessment of policies and programs is a more recent phenomenon. Life cycle assessment, also a recent phenomenon, focuses on the environmental impact of products and services through research and development, manufacturing and importing, storage, transportation, use and disposal. Technological assessment focuses on social effects of a technology or class of technologies. In contrast to technological assessment, environmental assessment usually focuses on a specific development rather than a class of developments and is usually confined to a single site. This paper focuses on risk to or adverse impact on health or environment (not safety) from technologies (not disease or natural hazards).

Although risk can be broadly defined, the assessment/management processes discussed in this paper generally use the term "risk" to refer to the *likelihood* of adverse impact, with risk expressed as a number. To avoid confusion, the terms specific to each process are used in the second section of this paper. In sections three and four, the term "risk" is defined more broadly (i.e., it can be used interchangeably with adverse impacts) for purposes of discussion.

Mechanisms and Practices

There are a wide variety of mechanisms and practices for risk assessment/management at all levels of government. Tables 1 through 4 show some of the federal mechanisms and practices related to environmental and health policy. Not intended to be comprehensive, the main focus of the tables is on Environment Canada and Health Canada, although a few entries are included for other science-based departments responsible for assessment.

Federal Mechanisms: Statutes

Table 1 shows some of the federal mechanisms for risk assessment.

Federal Practices: Formal Assessment Processes

Assessment processes can range from informal policy dialogues to formal human-health risk assessment. Several formal assessment processes are described below. (Life cycle assessment, under the Environmental Choice Program, environmental assessment of policies, required by a memorandum to Cabinet, and the environmental issue priority setting method, currently being pilot-tested by Environment Canada, are not covered.)

Human Health Risk Assessment: Health Canada

The Health Protection Branch (HPB) is charged with protecting the Canadian public from life- and health-threatening hazards in the food supply, in pharmaceuticals and cosmetics, in medical or radiation-emitting devices, and in the environment. The prime responsibility of the Foods Directorate is to ensure safety, nutritional quality and wholesomeness of the Canadian food supply, e.g., safety of chemicals in foods. The responsibility of the Environmental Health Directorate (EHD) is to protect Canadians from health hazards associated with natural and technological environments. EHD assesses and investigates the health effects of environmental pollutants, pesticides, smoking and tobacco products, technological and sociological environments, radiation sources and hazardous products in occupational and general settings. EHD also controls the use of devices that emit radiation, and, with the Food Directorate, the marketing of medical devices.[1]

Table 1
Federal Mechanisms and Practices According to Statute

STATUTE	DESCRIPTION	AUTHORITY ADVISORS	SIA/PUBLIC INVOLVEMENT
Environmental Assessment Review Process	Under the EARP guidelines order, federal departments are required to conduct initial environmental assessments of federally sponsored, funded, or administered projects and proposals to determine if the project can proceed with or without modification, should be abandoned, or must be referred to the Environment Minister for a public review by an independent panel (see Table 2).	Initiating Minister, e.g., Natural Resources, Transport Environment	"4. (1) An initiating department shall include... (a) the potential environmental effects of the proposal and the social effects directly related to those environmental effects, including any effects that are external to Canadian territory, and (b) the concerns of the public regarding the proposal and its potential environmental effects. (2) Subject to the approval of the Minister and the Minister of the initiating department, consideration... may include... the general socio-economic effects of the proposal and the technology assessment of and need for the proposal..."
Canadian Environmental Assessment Act	Once proclaimed, to replace EARP. Creates CEA Agency to replace FEARO.	Initiating Minister Environment	Environmental effect is defined as "(a) any change that the project may cause in the environment, including any effect of any such change on health and socio-economic conditions, on physical and cultural heritage, on the current use of lands and resources for traditional purposes by aboriginal persons, or on any structure, site or thing that is of historical, archaeological, paleontological or architectural significance."

Canadian Environmental Protection Act	Evaluates the human and environmental risks of substances or mixtures of substances, including products of biotechnology, suspected of being toxic. Health based exposure guidelines and codes of practice will also be developed.	Environment, Health (HPB)	Duties of the Government of Canada include: "(b) take the necessity of protecting the environment into account in making social and economic decisions;" and "(d) encourage the participation of the people of Canada in the making of decisions that affect the environment."
Radiation Emitting Devices Act	Prohibits the sale, lease and importation of radiation emitting devices which do not comply with prescribed standards.	Health (HPB)	
Food and Drugs Act and Regulations	Imposes restrictions on the manufacture, sale and advertising of foods, cosmetics, drugs and therapeutic devices to ensure safety and prevent deception.	Health (HPB) evaluates safety of chemicals accidentally present or added directly or indirectly to foods (agricultural chemicals, components of packaging, chemical contaminants).	
Pest Control Products Act	Establishes a system for yearly registration of pesticide products. Export from Canada and movement between provinces are prohibited unless the manufacturing establishment is licensed and complies with prescribed conditions. There is a general prohibition against manufacture, storage, display, distribution or use of pest control products under unsafe conditions. Includes biotechnology.	Agriculture Health advises on the potential human health hazards to applicators and bystanders associated with the use or misuse of pest control products. Also assesses potential hazards to consumers from residues in treated foods and establishes pesticide residue limits under the Food and Drugs Act and Regulations. Environment evaluates pesticides to determine their environmental impact.	Requires assessment of safety, merit and value of proposed product for registration.

Feeds Act	Includes biotechnology.	Agriculture Health advises on the potential human health hazards associated with additives of contaminants in animal feeds.	
Canada Labour Code		Labour Health advises on the potential occupational health and safety concerns related to chemicals and other substances in the workplace and recommends acceptable exposure levels to such substances.	
Atomic Energy Control Act	Provides control and regulation for development, application and use of atomic energy and enables Canada to participate effectively in measures of international control of atomic energy.	Atomic Energy Control Board (Crown Agency, Natural Resources) Health advises on the human health concerns relating to hazards posed by the nuclear fuel cycle. Environment advises as required.	
Transportation of Dangerous Goods Act	Applies to all handling, offering for transport and transporting of dangerous goods including hazardous wastes, by any means of transport.	Transport Health advises on the human health concerns relating to substances or goods subject to the TDG Act.	

Hazardous Products Act	Prohibits or controls the importation, sale or advertising of products, materials and substances which may be hazardous. Sections relate to the scheduling of prohibited products and the establishment and conduct of Boards of Review for products recommended for scheduling as prohibited or controlled.	Industry Health (HPB), Environment	
Hazardous Materials Review Act		Hazardous Materials Information Review Commission (Crown Agency, Industry) Health (HPB) reviews the toxicity, exposure and risk from chemicals used in the workplace, and prepares information sheets on this information, and reviews submissions by industry for exclusion from the Act.	
Fisheries Act	Designed to ensure acceptable water quality levels necessary to maintain the health of risk and to preserve fish, fish habitat and human use of fish.	Fisheries and Oceans Environment administers sections of the Act which address pollution control provisions (prohibits deposit of substances deleterious to fish, permits deposits authorized by regulation, describes type of regulation that can be made).	
Canada Shipping Act	Provides for the governor in Council to make regulations with respect to prohibiting the discharge from ships of pollutants and prescribing substances and classes of substances that are pollutants.	Transport Environment	

Navigable Waters Protection Act	Provides that no work shall be built or place in, upon, over, under, through or across navigable waters unless the work and site plans have received prior approval.	Transport Environment reviews licence applications for works that may impede navigation, in order to assess their environmental impact.	
International River Improvement Act			
Arctic Waters Pollution Prevention Act	Prohibits any person or ship, unless authorized by regulations, to deposit or permit the deposit of waste in Arctic waters or on any place on land under conditions where waste may enter the Arctic waters	Transport (shipping), IAND (non-shipping) Environment advises on disposal of wastes at sea in Arctic waters	
Inquiries Act*	Empowers Governor in Council (Cabinet) to "cause inquiry to be made into and concerning any matter connected with the good government of Canada or the conduct of any part of the public business thereof." Allows departmental minister to appoint a commissioner(s) for purposes of departmental investigation. Empowers Governor in Council to allow an international commission to carry on a portion of its work in Canada.	Prime Minister, or Minister	

* Provincial governments have similar legislation that provides for establishment of these kind of bodies.

Sources: (1) Health and Welfare Canada, 1990.
(2) Environment Canada, 1993c.
(3) Kernaghan, 1991.

EHD provides advice to other federal government departments and to other levels of government regarding acts they administer, e.g., to Agriculture Canada about the *Pest Control Products Act*. The Directorate administers the *Tobacco Products Act* and various medical device regulations, and co-administers the *Canadian Environmental Protection Act* with Environment Canada.

The risk determination model is the basic approach to all risk assessment/management decisions made by HPB. The model has two phases: risk assessment and risk management. During the risk assessment phase, hazards are identified, their risks estimated (risk analysis) and various strategies for dealing with risk are developed and analyzed (option evaluation). During the risk management phase, one or more options to control the risk are chosen and implemented. The decision is then monitored and evaluated, and may be changed if a review of current information indicates a need.

Evaluation or analysis of the options takes various forms and may:

- Weigh risks against health benefits (using cost-benefit analysis, cost-effectiveness analysis, cost-utility analysis, risk-benefit analysis), scrutinize the uncertainties in the risk estimate or apply principles such as "As Low As Reasonably Achievable" (ALARA) or de minimus (zero-risk principle, risk-risk analysis, comparative risk analysis, best available technology, best practical technology).
- Look at the issue from an individual or a societal perspective; take into account the public's perception of the risk.
- Consider the feasibility of the proposed options, their economic and environmental impact.
- Study the social, political and cultural implications of each option.

Methods of public involvement in the risk determination process include:

- documents (information letter, medical devices alert and surveillance or regulatory impact analysis statements published in the *Canada Gazette*, the annual *Federal Regulatory Plan* or *HPB Issues*);
- public membership on advisory committees;
- public meetings about specific risks;
- public opinion surveys;
- opinion and advice requested from consumer consultants; and
- permanent or ad hoc advisory committees.[2]

Environmental Risk Assessment, Priority Setting: Environment Canada: CEPA

The *Canadian Environmental Protection Act* (CEPA) was created to ensure Canadians have the right to an equal level of protection from the risks associated with the use of chemicals and from exposure to toxic substances. CEPA authorizes the ministers of Environment and Health to request the testing and gathering of information on substances, whether they are new or already in use. (Industry has not been asked to provide new information. Assessment of new substances begins in 1995.) This includes identifying substances that may be toxic and assessing them to establish the degree of toxicity. When substances are found to be toxic, CEPA provides for establishing and applying controls throughout their life cycle.

Under CEPA, substances are defined as discrete chemical compounds, classes of chemicals, emissions and effluents, and products of biotechnology, including micro-organisms. A substance is defined as toxic if it enters, or may enter, the environment in quantities, concentrations or under conditions that do (or may) result in harmful effects to the environment or to human health.

CEPA requires that the Environment and Health ministers publish and amend a list of priority substances (the Priority Substances List, or PSL), respond to public nominations for additions to the list within 90 days and conduct an assessment to ascertain whether or not each listed substance is "toxic." If the assessment report is not published within five years of a substance being added to the list, this could lead to the establishment of a board of review. The ministers must also publish a summary of the assessment report in the *Canada Gazette*, along with an indication of whether they intend to recommend the development of regulations to control the substance.[3]

Environment Canada is responsible for assessing the environmental impact of priority substances, for creating and enforcing CEPA regulations and for developing environmental quality guidelines. Health Canada is charged with developing guidelines related to human health and with assessing the implications of priority substances for human health.

Assessment by Priority

The Priority Substances List (PSL) sets priorities for assessment, not for control. It is a screening process, and priority substances are selected from the over 22,000 substances on the Domestic Substances List.

To compile the first PSL, the ministers chose to use an advisory panel made up of representatives from various stakeholder groups, including industry, environmental groups, other levels of government and academia. The federal government appointed Dr. Hall as chair, and panel members were selected from a list of nominees suggested by the departments of Environment and Health. PSL1, a list of 44 substances, was published in 1989. The Green Plan committed the government to publish a revised PSL in 1994 and on a continuing basis every three years thereafter. The goal is to assess 100 priority substances by the year 2000.

Process for Assessment

The priority substances assessment work is shared by the departments of Health and Environment. Government scientists and evaluators review the data requested and received from industry, examine available chemical, biological, medical and environmental literature, and supplement this information with testing and research following recommendations expressed in the assessment report. The process of assessment includes the following steps:

- identify substance on PSL;
- assess environmental and health impact;
- conclude if the substance is toxic under CEPA, is not toxic under CEPA, or if there is insufficient information to conclude (recommend further studies);
- if toxic, develop *strategic options* for keeping toxic substances out of the environment (voluntary actions, codes, guidelines, regulation); and
- finalize and publicize the decision, monitor the effect of the decision and evaluate it.

The government may order controls to be applied immediately or to be phased in over time. Such measures may involve provincial and territorial governments.

The (risk) assessment process under CEPA, a partnership between the departments of Environment and Health and those of Fisheries and Oceans and Agriculture and Agri-Food, and is conducted by interdepartmental teams. Environment, after determining that the substance enters or may enter the Canadian environment, establishes a departmental evaluation team that determines the extent of exposure and whether or not the substance is a hazard. In addition to industry, environmental groups and universities are contacted for both published and unpublished information.

Other departments may be invited to advise on specific topics. Consultants may be contracted to conduct certain steps, e.g., literature search, expert assessment, modeling or peer review. A revised version of assessment guidelines is currently being reviewed. (Health's general approach to risk assessment was described earlier under Human Health Risk Assessment: Health Canada.)

To compile the second PSL, Environment and Health analyzed the Hall Panel's recommendations and sought the views of key individuals from government, industry and environmental groups on elements related to developing PSL1. Consultations are currently under way. The federal government has proposed a ministers' expert advisory panel to serve as focal point for consultations, with panel members and the chair appointed by the ministers. The panel would consist of about 20 representatives from groups with a "vital" interest, who may be directly affected by the outcome or who may make an important contribution to the proceedings, e.g., environmental and labour groups, industry producers and users, and federal, provincial/territorial and municipal governments. Panel members would be expected to evaluate technical criteria and information dossiers on each substance; therefore, they would require an appropriate scientific background. They would also be expected to provide consensus recommendations for the composition of PSL2 to the ministers.

The proposed process for selection of candidate substances for PSL2 includes:

- nomination of substances by stakeholders and the panel;
- application of screening criteria by Environment and Health;
- preparation of dossiers for substances;
- sorting into substances that do/do not meet screening criteria; and
- sorting by the ministers' expert advisory panel (based on review of dossiers) into set-aside substances, substances for consideration for future PSLs (lower priority), or nominations for PSL2 substances.[4]

Strategic Options

If a substance is deemed toxic, strategic options are developed for preventing or reducing the release of toxic substances into the environment, e.g., voluntary controls or federal regulations. Toward this, Environment Canada has recently released a guidance document on the strategic options process. In the document, Environment Canada, Health Canada and key

stakeholders (industry, Aboriginal groups and non-governmental organizations) propose a multi-stakeholder approach for the development of options. Principles of the options evaluation include:

- public participation;
- openness and transparency in the decision-making process;
- exploration of instruments beyond command and control regulations;
- cost-effectiveness;
- flexibility;
- cross-sectoral equity; and
- harmonization of environmental management of CEPA toxics among federal and provincial governments.

Stakeholders will be given the opportunity to participate in each phase of this consultative process and make recommendations to the accountable federal and provincial ministers. Federal departments, provincial governments and key stakeholders will be involved early in the decision-making process, and consideration of pollution prevention and a wide range of instruments to achieve environmental and health objectives will be encouraged.[5]

CEPA Regulations

If regulations are the preferred course of action, draft versions are developed and sent to the Cabinet Committee following public consultation. The proposed regulations appear in the *Canada Gazette*, Part I, with a Regulatory Impact Analysis Statement (RIAS) which includes a description of the proposal, alternatives to regulation considered, reasons for rejection, assessment of anticipated costs and benefits, information on the resultant paper burden to industry, consultations that have taken place and a description of enforcement mechanisms to ensure compliance. (Treasury Board policy directs that government decisions to pursue regulatory initiatives should be based on positive net benefits, and formal cost benefit analysis is required for regulatory proposals for which compliance costs are more than $100 million.) Following a 60-day period set aside for public comment, the government finalizes the proposed regulations. After regulations are registered, they are in force and published in the *Canada Gazette*, Part II.

For hazards that require immediate action, the government may issue interim orders and temporarily bypass the public consultation system.[6]

See the companion paper (Appendix II) to this report for specific application of CEPA in the area of biotechnology.

Environmental Risk Assessment: Canadian Wildlife Service

Although there is no legal requirement, risk assessments are also conducted by the Canadian Wildlife Service. Such information is useful to a variety of departments with responsibilities in areas such as waste management, pesticides and accidents. The Service has its own assessment guidelines.

Environmental Assessment: EARP

Created by Cabinet in 1973, the Environmental Assessment Review Process (EARP) Guidelines Order introduced environmental impact assessment at the federal level in Canada. The Federal Environmental Assessment Review Office (FEARO), which reports to the Minister of Environment, was established to administer the process. EARP's major objective is to ensure that any potential environmental (biophysical) and directly related socio-economic impact (e.g., economic losses resulting from environmental degradation) is considered early in the planning stages so that decisions can be made to avoid or mitigate these impacts. The Environmental Assessment Review Process applies to projects either implemented or funded by the federal government and those carried out on federal lands.

The process has two separate, sequential phases for the assessment of the environmental impact of proposals: initial assessment phase and public review phase. A third phase, implementation, provides for monitoring and follow-up.

Initial Assessment

Each department is responsible for screening the proposal which it initiates or sponsors.

The first step is *screening*. The department with decision-making authority for the proposal examines the potential environmental impact and public concerns. Public consultation can be an important factor at this stage. Based on the screening results, the initiating department then determines whether to:

- proceed as planned (automatic exclusion from EARP);
- proceed with mitigation;
- investigate unknowns further within the department;
- modify the project;
- abandon the project; or
- refer the project to the Environment Minister for a public review because of "perceived or real significant effects."

The second step, *initial environmental evaluation*, is carried out only if a need for further study is identified.

Each department has its own guidelines for initial assessment and may also refer to the FEARO screening guide. (There are no guidelines for assessing socio-economic impact.) The following factors may be considered in the initial assessment:

- the characteristics of the proposal itself (physical design, construction plans, timing and operating procedures);
- the physical, biological, social and economic characteristics of the environment; and
- the interaction between the proposal and the environment.

Factors that may be considered in determining the significance of impact include magnitude, prevalence, duration and frequency, risk, socio-economic importance, public concern, impact on land use and precedent.

Public Review

If the initiating department refers the proposal for public review, an environmental assessment panel is established, and members are appointed by the Minister of Environment. If it is a joint public review, it is done in co-operation with the other jurisdiction. Procedures are established for the review in accordance with the terms of reference issued by the Environment Minister.

The four steps of public review include these.

- Scoping: the panel is composed of persons knowledgeable in the subject matter likely to be raised. With the assistance of participants in the review, the panel analyzes existing information and determines which issues must be studied further. (Intervenor funding is available.) It then makes information about the proposal available to the public and convenes public meetings for review participants to indicate the major issues to be studied and discussed.
- Environmental Impact Statement (EIS) guidelines: the panel then prepares EIS guidelines to be used by the proponent (or initiating) department and to be made public. (The EIS describes the project proposed and its potential environmental impact.)
- Public review of the EIS: the panel makes the EIS available to the public. The panel must now decide whether the EIS meets the requirements set out in the guidelines and determine whether the statement contains all the necessary information. After this, a public information meeting may be convened to provide clarification to the

panel, the public and government agencies with clarification about the quality of information and methods used to prepare the EIS. A period of about 45 to 60 days is provided for public review of the EIS prior to announcement of public hearings.

- Public hearing: if the panel is satisfied that the EIS complies with the guidelines, a public hearing is announced. If it is not satisfied, the panel issues a request for additional information and makes this available to the public. In this latter case, the public hearing will not be held until the panel has received a satisfactory response and that response has been made public. A period of at least 30 days after the distribution of the response is allowed. After these steps are completed, the panel proceeds with public hearings. Hearings are non-judicial, informal (although structured) and conducted in a non-confrontational way.

The panel then reports to both the Environment Minister and the minister of the initiating department. The initiating minister decides to what extent the panel recommendations become requirements for proceeding with the proposal, and makes the decision public.[7]

Only a small fraction of projects screened within initiating departments ever reach public review. Of 1000 projects screened, 100 receive further study and of these, only one may be referred to formal review stage.[8] Table 2 shows current panel reviews.

Table 2
Current Environmental Assessment Panel Reviews

PROJECT	PROPONENT INITIATING DEPARTMENT	ASSESSMENT ISSUES	REFERRAL DATE TARGET COMPLETION DATE	AUTHORITY	CURRENT STATUS
Low Level Military Flying, Quebec & Labrador	¥ National Defence ¥ National Defence	Environmental & socio-economic issues associated with low-level flights; public health effects; land use by natives	¥ February 1986 ¥ November 1994	Federal	Revised EIS could be submitted to panel by early 1994
Grande-Baleine Hydro-electric Development* Project assessed globally as a single project	¥ Hydro-Quebec ¥ Fisheries and Oceans; Transport	Potential effects on physical and social environment; cumulative effects; impacts on areas of federal jurisdiction	¥ February 1991 ¥ October 1995	Federal & Quebec	EIS provided August 1993. Public consultation on EIS to begin in December after summary translated into Cree and Inuktitut
Lachine Canal Decontamination	¥ Parks (now with Heritage) and Old Port of Montreal Corporation (Public Works, now with Government Services) ¥ Environment Canada; Public Works	Environmental and social impacts of various methods of decontaminating, treating & disposing of toxic sediments	¥ June 1989 ¥ February 1995	Federal & Quebec	EIS could be submitted to panel by early November 1993

Elliot Lake Uranium Mines Decommissioning	¥ Rio Algom Ltd. and Denison Mines Ltd. ¥ Atomic Energy Control Board; Energy Mines and Resources (now with Natural Resources)	Health safety issues of public concern; impacts downstream on Serpent River Indian Reserve; viability of preferred alternative for decommissioning	¥ February 1993 ¥ Fall 1995	Federal	Panel issued draft EIS guidelines for public comment in October 1993. Scoping meetings to begin December 1993 and written comments on Rio Algom's EIS will be accepted until then
Nuclear Fuel Waste Management and Disposal	¥ Atomic Energy Control Board ¥ Energy, Mines and Resources	Safety/ acceptability of disposal concept; related nuclear fuel waste management issues; social, economic and environmental implications of nuclear fuel waste management facility	¥ September 1988 ¥ March 1996	Federal	Proponent to submit EIS by May 1994
North Central Transmission Line	¥ Manitoba Hydro ¥ Indian Affairs and Northern Development	Level of service provided to Indian communities; socio-economic benefits	¥ March 1990 ¥ November 1993	Federal & Manitoba	Public hearings held by August 1993.
Rabbit Lake Uranium Mine	¥ Cameco Corp. ¥ Energy, Mines and Resources	Public concern regarding effects of radioactivity; socio-economic benefits	¥ April 1991 ¥ November 1993	Federal	Public hearings concluded July 1993

Uranium Mining Developments	¥ Cogema Resources Ltd., Cameco Corp., and Cigar Lake Mining Corp. ¥ Energy, Mines and Resources	Effects of radioactivity on humans/ environment; socio-economic benefits, cumulative impacts, health, history of uranium mining in Sask.	¥ April 1991 ¥ Early 1996	Federal & Sask.	Governments release joint report on three proposals on October 1993. Federal response to panel recommendations regarding one proposal issued August 1993.

* includes application of James Bay and Northern Quebec Agreement

Source: Environment Canada, 1993b, p. 44-6.

Canadian Environmental Assessment Act

The EARP Guidelines Order allows the minister responsible for proposed projects to decide on the need for public review. It does not provide clear procedures for environmental assessment nor clarify the responsibilities of certain agencies and federal bodies, e.g., Crown corporations. Neither does it establish mechanisms for full public participation in the initial assessment part of the environmental assessment process.[9]

Intended to address these shortcomings, the CEAA, once proclaimed law, will replace EARP. (It received royal assent in 1992 and was to be proclaimed in early 1993.) CEAA prescribes a "clear and legally precise" process for projects requiring a decision by the federal government, including federal projects and projects involving federal funding or regulation. The Act will create the Canadian Environmental Assessment Agency (replacing FEARO) to administer an expanded and streamlined environmental assessment process.

New features include the following:

- The process is administered before a federal decision can be taken to proceed with a project.
- Project proposals are streamlined into categories to facilitate decisions on projects posing the greatest environmental risk.
- Joint review panels reduce duplication and promote co-operation between different levels of government.
- Mediation is an alternative or complement to a review by a public panel.
- Significant provision for public involvement is included because concern for the environment and responsibility for its protection are shared by governments, business and the public.
- Proponents are required to prepare follow-up and monitoring plans to ensure that any provisions to limit or eliminate potential environmental harm are effective.[10]

However, CEAA does not include projects within the area of federal responsibility that have "negligible" environmental effects or minimal responsibility. It includes just projects, not government programs or policies, and public review is by recommendation.[11]

Technology Assessment:
Royal Commission on New Reproductive Technologies

The Royal Commission on New Reproductive Technologies (NRTs), which had a mandate to evaluate the social, legal, ethical, economic, research, and health implications of NRTs, designed a research program. The program included in-house and contract research by academics and non-governmental organizations and by Burson Marsteller on the social and cultural implications. The Commission also established mechanisms for public consultation, such as holding hearings and accepting written or recorded submissions from groups and individuals. Special meetings with various groups were organized around specific issues, private meetings were held with individuals to recount personal experiences, and a toll-free line was provided for recorded messages.[12]

> Massey concludes that:
> the public participation program provided none of the resources, feedback, level of accessibility or education necessary to allow the public the space and the tools necessary to engage in the process in a meaningful way. The limited opportunities for public involvement ... denied the value of the public perception of science and contained participation ... preventing significant public input into questions of research priorities and management.[13]

Federal Practices: Policy Advisory Groups

This sub-section draws heavily on *Public Policy Analysis* by Leslie Pal.[14]

Tables 3 and 4 show some of the federal practices for risk assessment. The tables focus on "professional" policy advisory groups, i.e., groups that present themselves as neutral and non-partisan, such as line departments, advisory agencies and private groups. Such advisory groups as interest groups and political parties are not included; they are openly biased and expected to be so — not that advice from openly partisan groups doesn't influence the policy process and, occasionally, contribute valuable ideas.

As reflected in the tables, Canada's policy advisory groups can be divided into two sectors: state and private.

Table 3
Main Advisory Bodies in the Federal Environmental Policy Domain

STATE SECTOR: GOVERNMENT

Advisory Body	**Description**	**Type** **Duration**	**Authority**	**Membership** **Selection**	**Advice** **Confidentiality**
Cabinet Committee on Economic Development Policy	Body formed to discuss and debate economic development issues at level of Cabinet	¥ General ¥ Permanent	Prime Minister	¥ Cabinet Ministers ¥ Appointed	¥ Optional ¥ Private
Interdept.al Committee on Biotechnology	Established 1985, at ADM/Director level to coordinate federal activities Includes Sub-Groups on: ¥ Public Awareness ¥ Safety and Regulations ¥ Intellectual Property	¥ Inter-governmental ¥ Permanent		¥ ADMs from various federal departments ¥ Appointed	¥ Optional ¥ Private
Science Advisor		¥ General ¥ Permanent	Director General, Ecosystem Sciences and Conservation	¥ Expert, Civil Servant ¥ By position	¥ Optional ¥ Private

STATE SECTOR: QUASI-GOVERNMENT					
Advisory Body	**Description**	**Type** **Duration**	**Authority**	**Membership** **Selection**	**Advice** **Confidentiality**
Standing Committee on Environment & Sustainable Development	A committee of the House of Commons	¥ General ¥ Permanent	¥ House of Commons	¥ Members of Parliament ¥ Appointed	¥ Optional ¥ Public
National Round Table on Environment and Economy*	Forum created for discussions between senior government decision-makers, industry, academics, and non-governmental groups on sustainable development	¥ General ¥ Ad hoc	¥ Prime Minister	¥ Government, Lay Industry, NGOs, Experts ¥ Appointed	¥ Optional ¥ Public
Canadian Environmental Advisory Council	An independent advisory group to the Environment Minister Terminated in 1992 Budget as of May 1992.	¥ General ¥ Permanent	¥ Environment Minister	¥ Experts ¥ Appointed	¥ Optional ¥ Private/Public

Environmental Assessment Panels	Can be formed to study the environmental impacts of federally sponsored, funded, or administered projects through the Federal Environmental Assessment Review Office. FEARO provides the secretariats for these panels. See Table 2.	¥ Specific task ¥ Ad hoc	¥ Environment Minister	¥ Experts ¥ Appointed	¥ Optional ¥ Public
Canadian Environmental Assessment Research Council	An advisory group to the chair of FEARO on environmental assessment research and implementation Terminated by Ministerial order as of April 1993.	¥ Research ¥ Permanent	¥ Environment Minister	¥ Experts ¥ Appointed	¥ Optional ¥ Public
Environmental Choice Panel	A group advising the Environment Minister on environmentally acceptable consumer and industrial products	¥ Specific task ¥ Permanent	¥ Environment Minister	¥ Experts, Lay ¥ Appointed	¥ Optional ¥ Public
Canadian Council of Ministers of the Environment	An interjurisdictional body of federal and provincial Environment Ministers Formed to co-ordinate policies of the two levels of government	¥ Inter-governmental ¥ Permanent	¥ N/A	¥ Environment Ministers ¥ By Position	¥ Optional ¥ Private/Public

Federal Inquiry on Water Policy	Charged with investigating water policy from 1984-85.	¥ Specific task ¥ Ad hoc	¥ Environment Minister	¥ Experts ¥ Appointed	¥ Optional ¥ Public
Economic Council of Canada	To advise and recommend the best means by which Canada can achieve the highest possible levels of employment and efficient production in order that the country may enjoy a high and consistent rate of economic growth Scheduled to be dissolved as of June 1992.	¥ General ¥ Permanent	¥ Prime Minister	¥ Experts ¥ Appointed	¥ Optional ¥ Public
Science Council of Canada	Eliminated in federal Budget of February 1992 as of June 1992.	¥General ¥ Permanent	¥ Industry, Science and Technology Minister	¥ Experts ¥ Appointed	¥ Optional ¥ Public
Law Reform Commission of Canada		¥ General ¥ Permanent	¥ Justice Minister	¥ Experts ¥ Appointed	¥ Optional ¥ Public
Advisory Committee on Environmental Protection	Provides strategic advice on pollution prevention and sustainable development	¥ General ¥ Permanent	¥ Environment and Industry ADMs	¥ Industry and Environment ADMs, industry, environmental groups, labour, academia, industry associations.	¥ Optional ¥ Private

PRIVATE SECTOR: PROFIT					
Advisory Body	**Description**	**Type** **Duration**	**Authority**	**Membership** **Selection**	**Advice** **Confidentiality**
CanTox Inc.		Specific Task Ad hoc	Minister	Experts By position	Optional Private
Decima Research		Specific Task Ad hoc	Minister	Experts By position	Optional Private

PRIVATE SECTOR: NON-PROFIT: NON-UNIVERSITY BASED					
Advisory Body	**Description**	**Type** **Duration**	**Authority**	**Membership** **Selection**	**Advice** **Confidentiality**
Resource Futures International		Specific Task Ad hoc	Minister	Experts By position	Optional Public?
Rawson Academy		Specific Task Ad hoc	Minister	Experts By position	Optional Public?
CD Howe Institute		Specific Task Ad hoc	Minister	Experts By position	Optional Public?
IRPP		Specific Task Ad hoc	Minister	Experts By position	Optional Public?

PRIVATE SECTOR: NON-PROFIT: UNIVERSITY BASED					
Advisory Body	**Description**	**Type** **Duration**	**Authority**	**Membership** **Selection**	**Advice** **Confidentiality**
SDRI		Research Ad hoc	Minister	Experts By position	Optional Public?
IRR		Research Ad hoc	Minister	Experts By position	Optional Public?

* There are also Roundtables in New Brunswick, Nova Scotia, Ontario, Manitoba, Prince Edward Island, Yukon, Newfoundland and Labrador. Manitoba has about 52 community roundtables, while B.C. has about 30 local roundtables. The B.C. and Alberta Roundtables were recently disbanded due to provincial budget cuts (National Round Table Review , 1994).

Sources: 1. Filyk and Cote, 1993.
2. Environment Canada, 1993b.
3. CCH, 1994.

Table 4
Some State Advisory Bodies in the Federal Health Policy Domain

STATE SECTOR: GOVERNMENT					
ADVISORY BODY	**DESCRIPTION**	**TYPE** **DURATION**	**AUTHORITY**	**MEMBERSHIP** **SELECTION**	**ADVICE** **CONFIDEN-TIALITY**
Cabinet Committee on Social Development Policy	Body formed to discuss and debate social development issues at level of Cabinet	¥ General ¥ Permanent	Prime Minister	¥ Cabinet Ministers ¥ Appointed	¥ Optional ¥ Private
Interdept.al Committee on Biotechnology	(See Table 3)				
Branch Biotechnology Committee	Drugs, coordinates biotechnology research and regulatory activities in HPB, and acts as liaison with other government departments	¥ Inter-governmental ¥ Permanent	ADM, HPB	¥ Experts, Civil Servants ¥ By position	¥ Optional ¥ Private

STATE SECTOR: GOVERNMENT					
ADVISORY BODY	**DESCRIPTION**	**TYPE** **DURATION**	**AUTHORITY**	**MEMBERSHIP** **SELECTION**	**ADVICE** **CONFIDEN-TIALITY**
Standing Committee on Health	A committee of the House of Commons	¥ General ¥ Permanent	House of Commons	¥ Members of Parliament ¥ Appointed	¥ Optional ¥ Public
Royal Commission on New Reproductive Technologies	Mandated to evaluate the social, legal, ethical, economic, research, and health implications of NRTs	¥ Specific task ¥ Ad hoc	Prime Minister	¥ Academic Experts, Lay Citizen ¥ Appointed	¥ Optional ¥ Public
Federal/ Provincial Advisory Committee on Environmental and Occupational Health	Sub-committees include radiation surveillance, drinking water Health, EHD, advises on national issues relating to occupational and environmental health	¥ Inter-governmental ¥ Permanent	Conference of Health Deputy Ministers	¥ Experts, Civil Servants ¥ By position	¥ Optional ¥ Private
Joint Consultative Committee of Senior Health and Environment Officials	Health, EHD, provides a forum for liaison and coordination between the ACEOH and the Canadian Council of Ministers of the Environment	¥ Inter-governmental ¥ Permanent	Conference of Health and Environment Deputy Ministers	¥ Experts, Civil Servants ¥ By position	¥ Optional ¥ Private

Multimedia Guidelines Advisory Committee	EHD, develops health-based exposure guidelines for chemical contaminants to which persons are exposed via more than one route of exposure	¥ Inter-governmental ¥ Permanent	Conference of Deputy Ministers	¥ Experts, Civil Servants ¥ By position	¥ Optional ¥ Private

Sources: (1) Health and Welfare Canada, 1990.
(2) Massey, 1994.

State Sector

In the state sector, two broad categories can be identified: government and quasi-government.

- *Government*: these bodies are directly responsible to, and may be directed by, Cabinet or ministers. They include: ministerial research staffs, central agencies (Privy Council Office, Prime Minister's Office) and departmental policy advisory groups. They also include:
  - Cabinet committees (bodies formed to discuss and debate certain issues at level of Cabinet);
  - interdepartmental committees (groups operating at the senior bureaucratic level, dealing with specific issues, such as water, toxic substances, oceans and biotechnology); and
  - sectoral or special advisors (individual advisors to senior management and services within Environment Canada, e.g., the Office of the Science Advisor).
- *Quasi-government*: autonomous advisory councils and regulatory agencies and boards have been established by Canadian governments to provide more independent advice. While the government appoints the agency's director, determines its mandate and supplies its budget, the agency sets its own agenda. Governments may also occasionally appoint royal commissions and task forces to investigate specific questions. Finally, parliamentary committees, while appointed by the government and from the legislature, have begun to exercise greater independence in undertaking investigations; their autonomy extends to the tenure of appointments (people can only be dismissed for "just cause"), an independent research agenda, research publications and hiring.

  This organizational form is adopted because:

  - a government may need advice based on a wider perspective than its internal analysts can provide;
  - a policy area may cut across departmental boundaries and, thus, may be fragmented rather than addressed coherently; and
  - it can help build consensus on public opinion or among interested groups.

Advisory councils (e.g., the now-defunct Economic Council of Canada) and regulatory boards and agencies (e.g., Atomic Energy Control Board) are permanent bodies with stable mandates. Royal commissions (e.g., on new reproductive technologies) or task forces (e.g., EARP review

panels) are appointed for specific investigations and operate for limited periods. Parliamentary committees include special committees of the legislature (and Senate) to investigate selected policy issues, parliamentary standing committees that review legislative proposals and legislative committees that now have an important role in the public hearings process. (There are currently Standing Committees on Health, Environment and Sustainable Development, Agriculture and Agri-Food, Fisheries and Oceans, and Natural Resources, as well as a House of Commons Subcommittee on Environmental Awareness for Sustainability.)

Advisory councils linked to the executive are multiplied at both the federal and provincial level. There are relatively few at the municipal level. Councils normally oversee a specific area and report to a designated minister, but function at arm's length from government. Their purpose is to provide advice, by conducting research or acting as sounding boards for policy proposal. They differ in the degree to which they explicitly incorporate interested parties. For example, the Economic Council of Canada brought business and labour together to discuss economic issues and its reports were consensual documents. It was also mandated to provide government with expert advice on long-term economic issues concerning employment, productivity and other issues ranging from international trade to competition policy. The Science Council of Canada had a less explicit consensus-building role, focusing more directly on policy research and advice. It was mandated to provide advice on broader societal and economic consequences, and its advice sometimes conflicted with that of the Economic Council.

Regulatory agencies oversee and implement legislation in a given policy field. They usually issue licences, hold hearings, and develop procedures to implement legislation. While their advice may be proffered informally, some agencies have a formal advisory function, e.g., the CRTC. Regulatory agencies are in constant contact with policy fields and actors, and are uniquely placed to offer advice to their respective governments.

Governments on an occasional basis may appoint royal commissions or task forces allowing for expert analysis of a single policy issue without having to establish a permanent agency. Commissions usually conduct hearings, and then develop research programs and issue studies in support of findings. Many royal commissions have been established to deflect public criticism; few have had any immediate impact on public policy, but reports and research findings frequently define relevant issues and the scope of the policy debate. Commissions will depart from their mandate if necessary, and sometime submit advice at odds with prevailing government

policy, e.g., the 1977 Mackenzie Valley Pipeline Inquiry. Royal commissions established by other levels of government include the Royal Commission on the Future of Toronto's Waterfront, and British Columbia's Royal Commission on Health.

Private Sector

The private (or non-governmental) policy research and advice industry can be classified based on profit orientation and institutional affiliation.

- *Profit*: there is a large for-profit consulting industry which bids on government and some private contracts for policy research (and advice). The dimensions of the Canadian consulting industry are unknown because there are no licensing requirements. Millions of dollars are spent each year by municipal, provincial and federal departments and agencies on outside consultants, who work on a contract basis, for profit.

The industry responds to demands from both the public and private sectors. The rationale for the public sector, including all three levels of government and the voluntary sector, is to contract out certain research that calls for specific personnel or equipment which the client need not retain on an ongoing basis. The private sector is interested in monitoring policy because it affects economic livelihoods directly.

The core of the private consulting industry is in the Toronto-Ottawa-Montreal triangle near major government offices. Consultants in the environmental policy domain include: Hickling Corporation, CanTox Inc., SENES Consultants Ltd., ESSA, EVS Consultants, Peat Marwick Stevenson & Kellogg, and Concord.

- *Non-profit, university-based*: if little is known of the profit-based policy-advice industry, the university-based sector is almost completely unexplored. Canadian universities recently created numerous institutes, centres and units devoted to policy-oriented research and advice. Their funding comes mainly from university, government and private endowments, with some revenue generated through contract research and publication sales.

Academic research meets a different standard from the majority of work produced elsewhere. Researchers frequently situate advice in terms of important questions within their own disciplines, referring to bodies of theory and debate not usually found in the more applied studies conducted by government. Academic advice appeals to the researcher's audience of peers, university courses and key decision makers.

Each of the 66 universities in Canada has several institutes and centres that produce policy-relevant research and advice, e.g., the Sustainable Development Research Institute (University of British Columbia), the Institute for Research on Environment and Economy (University of Ottawa) and the Institute for Risk Research (University of Waterloo). The institutes are usually small, with about five to 25 associated researchers and a handful of staff. Researchers are usually full-time university academic staff. Funding may have come from an initial endowment or ongoing sponsorship by government and private-sector associations, but most rely on contract and sponsored research, as well as on the sale of publications. Most try to produce a quarterly or annual publication as a vehicle for research results and as a means of establishing credentials. They may also hold conferences.

- *Non-profit, non-university-based:* this sector includes organizations such as the Institute for Research on Public Policy (IRPP), the Fraser Institute, the C.D. Howe Research Institute and the Conference Board of Canada. Their financing may come from endowments or from contract research, initiated by, and reflecting the needs of, a client. Some undertake "sponsored" research, stemming from the group's own agenda, conducted independently but with financial support from a "sponsor." Most organizations in this sector are established to present a particular viewpoint on public policy, with the possible exception of IRPP.

Research and advice from an organization in this sector is distinct from that sponsored by, for example, the Tri-Council Eco-Research Program, because researchers are employed directly to work in selected areas and publish results under the organization's own name.

These organizations operate on a non-profit basis, but are entrepreneurial in bringing research before the public. For example, the Fraser Institute has a vigorous public education campaign.

The barriers between the non-governmental sectors (including policy institutes, government councils and commissions, consultants and interest

groups) or what Lindquist[15] has termed the "third community" are quite permeable, and social scientists often move from sub-sector to sub-sector. Not only do they move, but they can co-exist in more than one sub-sector: for example, an academic might also have a consulting business.

Provincial Mechanisms and Practices

Under the *Constitution Act*, provinces are assigned authority over provincially owned lands and resources, and exclusive jurisdiction over the development, conservation and management of non-renewable resources in the province, including forestry and hydro-electric facilities.

Ontario

Ontario was the first Canadian jurisdiction to enact legislation providing for environmental assessment. The *Ontario Environmental Assessment Act* requires preparation and internal review of environmental assessments for all provincial government undertakings before they proceed, unless they are exempted by Cabinet. (Sections extending application to the private sector have not been proclaimed.) The Act created the Environmental Assessment Board which holds public hearings on the adequacy of such assessments in certain cases and also on certain kinds of approvals under regulatory legislation. The Board operates as a quasi-judicial tribunal: rulings are authoritative with respect to undertakings considered under EAA, and its powers extend to imposition of terms and conditions on project proponents.[16]

However, Cabinet can exempt any undertaking from the Act "in the public interest," or reject or vary a Board decision under the Act. Holding of public hearings is at the discretion of the Environment Minister.[17]

Nova Scotia

The main advisory bodies in the environmental domain counsel the Environment Minister on new policies and legislation and on their implementation. The more or less permanent ones include:

- Environmental Control Council;

- Provincial Round Table on Environment and Economy;

- Pest Control Products Advisory Committee; and

- Environmental Trust Fund Committee.

Ad hoc bodies include:

- Environmental Assessment panels;

- Minister's Task Force on Hazardous Waste Management;

- Minister's Task Force on Clean Air; and

- Minister's Task Force on Clean Water.

The Environment Minister was Chair of the Canadian Council of Ministers of the Environment (CCME) from 1990 to 1991.[18]

Issues

This section discusses the key issues related to the social and cultural implications of science and technology which are encompassed within risk assessment. (The term "risk" is defined broadly to include adverse impact.)

It is generally accepted in risk assessment/management that it is difficult to separate values from science; the separation of risk assessment and risk management is for practical purposes. However, the degree to which that separation can be practically achieved is not a matter of explicit debate. In other words, it is generally accepted that social and cultural values should be considered in risk management for reasons such as fairness. How that is done, and by whom, remains a matter of great debate. However, it is not generally accepted that social and cultural values should be (explicitly) considered in risk assessment. Here, the question of how that is done, and by whom, is seldom raised.

Yet studies of expert disagreement have found that experts (like lay people) are prone to a number of biases when making risk judgments, including unstated assumptions and mindset, and structural, motivational and cognitive biases.[19] Further, studies have found that when experts judge risk, their responses correlate highly with technical estimates of annual fatalities. Lay people can assess annual fatalities if they are asked to (and produce estimates somewhat like the technical estimates) but their

judgments of risk are sensitive to other factors such as equity, catastrophic potential, controllability and threat to future generations.[20]

The findings from these studies lend support to the conclusion that social and cultural values cannot be separated from science in risk assessment. This conclusion is also consistent with a growing body of literature.[21]

The inability to separate values from science has two important implications for risk assessment. One is that the role of experts in risk assessment should be modified. Experts still have an important role to play in risk assessment. Society depends on experts; there are certain technical issues relevant to risk that the average lay person is not capable of understanding in depth. Furthermore, the experts' judgments are needed now. For many environmental problems, society cannot afford to wait for more and better science. Experts may be prone to biases but they don't always make errors in judgment. To improve the quality of expert judgment, risk estimates should be conducted by a panel of experts from different disciplines (including the social sciences and humanities) and representing a broad range of opinion in a semi-formal consensual process, with some opportunity for lay observation or participation.[22]

The second important implication is that the role of lay people, especially the lay public, in risk assessment should be strengthened. Lay people are typically excluded from risk assessment. Yet, the risk judgments of interested and informed lay people are not necessarily wrong. Rather their view of risk is richer and more complex than the expert's narrow, technical view. (Also, an expert is simply a lay person outside of his or her narrow range of expertise.) The role of the lay public should go beyond provision of information and selection of expert panel-members to actual participation on panels, helping assess the adequacy (quality and quantity) of the information.[23] Lay people may lack theoretical knowledge and be biased by self-interests, but it can also be argued that experts lack practical knowledge and have their own forms of bias.

Especially problematic is the determination of "acceptable" risk or "significant" adverse impact, falling somewhere between the already unclear dividing line between technical assessment and political management of risk. What criteria should be used to determine acceptability? Acceptable to whom? Who decides? Here, the role of lay people is critical in identifying criteria, that is, explicit statements of the values which should be used to determine whether or not a risk is acceptable. These might include legal and policy criteria, functional criteria,

normative criteria (general principles, community environmental goals, publicly valued environmental components) and controversy.[24]

With both experts and lay people participating in the risk assessment/management process, decisions that are made will be more publicly, and more scientifically, defensible. The fundamental issue is how to design an effective, efficient and fair process that integrates expert judgment with societal values, including social and cultural, while at the same time avoiding other forms of elitism and undue influence from special interests.[25]

(This section has discussed social and cultural implications associated with risk assessment mechanisms and practices. See the companion paper, "A Case Study of Canadian Approaches to Social and Cultural Implications of Biotechnology," in Appendix I, for discussion of social and cultural implications specific to the issue of biotechnology.)

Adequacy

This section evaluates the adequacy of risk assessment mechanisms and practices for addressing the social and cultural implications of science and technology. (The term "risk" is defined broadly to include adverse impact.)

As discussed in the previous section on issues, social and cultural factors have implications throughout the risk assessment/management process. Therefore, an evaluation of the adequacy of mechanisms and practices must consider both assessment and management.

Generally, the mechanisms and practices reviewed conduct risk assessment and management as two separate, often sequential steps. Typically, risk assessment criteria do not explicitly include social and cultural (or societal) values. In risk management, explicit economic values or implicit political and legal values are factored in, usually at the expense of social and cultural values. Environmental and technological assessment processes appear to be somewhat less rigid than risk assessment processes in drawing the line. For example, the public may be involved in setting terms of reference. Still, assessments are typically conducted by experts, with their deliberations closed to public purview. Furthermore, the majority of assessments are conducted in-house by a limited number of government scientists.

The experts who conduct risk assessment are usually trained in scientific and technical fields. Risk management is typically conducted by engineering, economic and legal experts. Other social scientists are seldom involved. Characteristically, lay people are excluded from risk assessment, particularly the determination of acceptable risk. (Some environmental groups have proposed splitting risk assessment into two distinct steps: risk estimation, followed by risk acceptability.) Opportunities for public involvement in risk management have increased over recent years. But public involvement is not the only method for identifying social and cultural issues, and it does not guarantee addressing of those issues.

One of the simplest ways of involving lay people in risk assessment (and management) has been neglected — that of lay people providing information to experts. Aboriginal environmental knowledge has only recently been recognized as valuable; recognition of local knowledge is required.

This whole area of experts providing information to lay people has also been neglected. For example, risk messages and supporting materials typically minimize the existence of uncertainty, and do not disclose data gaps or areas of significant disagreement among experts, nor indicate the level of confidence of estimates or the significance of scientific uncertainty.[26] Value judgments are not clearly identified and made explicit for the scrutiny of the decision maker and the public, nor is information presented from several perspectives including those of the concerned public and scientists.[27]

Formal social impact assessment (SIA) is one potentially useful tool for channeling information provided by, and to, lay people. Assessing the nature and extent of the present and anticipated social impact associated with a project is difficult because of the lack of relevant data and limited resources. Certain social values may clearly exist but are difficult to measure, such as, spiritual, cultural and aesthetic values and social concerns of a community affected by environmental problems; concern with the fairness of any impact on specific populations or future generations; and the value of one's sense of community. Integrating SIA into risk assessment and management is even more difficult due to a lack of fully developed (predictive) tools for integrated environmental assessment and a lack of evaluative tools.[28]

Yet, even with these limitations, the potential of social impact assessment has not been tapped. Used for a long time in the context of EARP and major federal regulatory developments, it is seldom used in risk

management, let alone in risk assessment. In risk management, economic assessment often serves as surrogate for SIA, which even if used may be conducted by an economist. There is a lack of professionally trained environmental social scientists; monitoring of predictions is seldom undertaken, and the current source of SIA predictions is unverified predictions made in previous SIAs.[29]

Several other factors also affect the adequacy of risk assessment for addressing social and cultural implications. Risk assessment is often conducted at the discretion of the proponent, as under EARP. Administratively, there may be little incentive for the initiating agency to conduct an impartial assessment. Unless the assessment — risk, environmental or technical — is required, it is unlikely that social and cultural implications will be addressed. Even if an assessment is required, it will be more likely that social and cultural implications are addressed if SIA and public involvement are also required. Finally, the responsible decision maker is most likely not legally obligated to act on any assessment/management advice. This is further complicated by the overwhelming likelihood that multiple sources of advice, often conflicting, will be offered, even from within the same government. Conversely, there may be too little advice because of lack of interest in a particular policy field and its issues. For example, Aboriginal rights, environment, northern development, agriculture, transport, fisheries and culture have no permanent, institutional monitoring of the calibre devoted to economic and business issues. Issues are addressed only on an ad hoc basis by university-based researchers or by advocacy organizations in the field.[30]

Some classes of mechanisms and practices described in this report (for example, a particular policy advisory group) may more adequately address the social and cultural implications of assessment than others. A detailed comparative evaluation is beyond the scope of this paper. A few initial observations can, however, be made. EARP panel reviews, no matter how "successful" they may appear, are the exception and not the rule to assessment practices. Also, such review processes (including royal commissions and task forces) are very resource intensive, and it is impossible to refer every issue. Less resource-intensive practices, e.g., private consultants, have other problems. Because professional policy analysis is usually conducted for clients who have specific interests and values, advice often reflects the client's value position. There is no national professional association, nor code of conduct for policy analysts in North America.[31]

The fundamental issue in risk assessment/management remains to be answered — how to design an effective, efficient and fair process that integrates expert judgment with societal values while at the same time avoiding other forms of elitism and undue influence from special interests. There may be more than one process that is adequate, with the mechanism and practice dependent on the issue. But one thing is certain, without a clear understanding of the complex relationship between social and cultural values and the assessment of science and technology, the "success" of such processes will be limited. More research needs to be conducted in this area, a possibility reduced by the demise of the Canadian Environmental Research Council (CEARC) and the Science Council of Canada.

(This paper has examined the adequacy of "risk" assessment mechanisms and practices for addressing the social and cultural implications of science and technology. The focus has therefore been on process, i.e., risk assessment. See the companion paper in Appendix I, "A Case Study of Canadian Approaches to Social and Cultural Implications of Biotechnology," for an evaluation with respect to an issue/substance.)

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