



***Linking In, Linking Out, Linking Up:
Exploring the Governance Challenges of Biotechnology***

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Foreword

In 2000, the Institute On Governance (IOG) launched a program called the *Insurmountable Opportunity*. The name was derived from a speech given by the Clerk of the Privy Council of Canada in which he characterised the development of sound public policy as an “insurmountable opportunity” and a challenge for all public servants. Through this program, the Institute is seeking to explore how governance and public policy development may need to change as a result of contemporary trends. This exploration is being conducted in collaboration with a group of senior public servants from 16 government departments, and it involves seminars, international contacts and research.

Among the themes we are examining is the impact of two major science-based revolutions. The first of these is the information and communications technology (ICT) revolution, now well under way, and the second is the revolution in biotechnology, where new discoveries and advances such as the decoding of the human genome raise seemingly limitless possibilities and questions alike. As we became more aware of the ramifications of this latter revolution, we realised that it might ultimately be more pervasive and significant than the ICT revolution, whose impact has already been enormous. We also realised that its scope was difficult to grasp and that it opened up quite unfamiliar territory for public policy.

As a first step toward developing a better understanding of “biotech”, the Institute organised a symposium in January 2001. The event brought together scientists, journalists, NGOs, ethicists, former politicians and public servants. All participants acknowledged the importance of the issues raised by the science, but they pointed to many gaps in our present practices and knowledge.

As one of several research initiatives associated with the *Insurmountable Opportunity* program, we decided to build on this symposium by launching the present study, in collaboration with two partners, the Law Commission of Canada and the Policy Research Initiative of the federal government.¹ One of its main purposes is simply to examine the scope of the revolution – to present a balanced overview of its different dimensions and possibilities. However, another objective of the study is to take stock of the institutional mechanisms and processes currently in place to deal with this fast-moving science within the federal government. It compares these in a preliminary manner with approaches being adopted in other jurisdictions and asks how the government might be able to strengthen its policy-making and consultative role in the biotech area. The report indicates areas in which future work is warranted and suggests how such work might be carried out.

We hope this study will help to illuminate the potential as well as the risks associated with a fascinating new domain of science. We likewise hope it will serve as a springboard for constructive deliberation both within and outside government with respect to the governance challenges posed by this revolution.

Tim Plumptre,
Managing Director, Institute On Governance,
February, 2002.

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Executive Summary

The pace and scope of recent advances in biotechnology require a different set of tools and strategies by which society and its institutions of governance respond to and anticipate change. Increasingly, government policy makers, regulators, and legislators are required to manage in a climate of uncertainty and experimentation where stakes are high. This uncertainty extends to many sectors of society (including judges, scientists, industry, academics and citizens) that are concerned with the impact of biotechnology on Canada's future. It is useful at this time – *before a crisis erupts* – to examine the degree of governance preparedness to deal with sweeping innovations in the field of biotechnology.

For the purposes of this study, we focus primarily on those aspects of biotechnology where new discoveries are being heralded as enabling and potentially transformative technologies.² Indeed, some of these scientific advances will provide us with the potential to genetically engineer life forms and, ultimately, direct our human evolutionary story. These technologies present both significant potential benefits as well as difficult ethical, social, and legal questions for governments and citizens alike. From a governance point of view, we assert that success can be defined as capturing the potential benefits for Canadians and for the environment, minimizing risks and allowing the economic potential of these new applications to be realised.

The question of how we may need to adapt our governance mechanisms to cope with biotechnology is worth posing because this has been described by some as 'the ultimate horizontal', or cross-cutting, policy issue. Many governments are wrestling with the problem of how to manage broad policy questions that do not conform to conventional departmental boundaries. Typically, their efforts are attended with very limited success: "joined up government", as the British government calls it, is not readily reconciled with some established traditions of Cabinet government or with conventional departmental structures. However, there are more and more of these kinds of issues confronting governments.

Biotechnology, as a case in point, raises policy issues that test the boundaries of government regulation, from the privacy of genetic information to the patenting of higher life forms. It challenges government to connect officials responsible for the development of public policy with scientists working in a burgeoning, highly complex field, with, perhaps, the potential to transform society. This is not a sphere of science that any of us - least of all our elected officials - can afford to ignore. We need to do a good job of handling the issues posed by biotechnology; but how that is to be done is a question for which there are no simple answers

The overarching conclusion of the paper is that government, industry and civil society must link together to ensure that each has sufficient voice, representation, and accountability in policy and decision-making processes on biotechnology. This is essential if the four issue areas flagged – science capacity, stewardship and credibility, leadership, and public engagement – are to be addressed. We advance an expanded definition of 'horizontal' that goes beyond cross-government coordination to include the private sector, universities, and informed segments of civil society. The paper outlines the need for **linking in** (within government departments, within industry, universities and citizens groups); **linking out** (between government departments, joint

² For example, in areas such as genetic engineering, cloning, bioremediation, gene testing and therapy, and biocatalysis.

efforts with other levels of government, industry, universities, other countries, NGOs, and civil society); and **linking up** (making a connection with political leadership and the voting public).

An important issue related to biotechnology arises from the trend in some areas of government to contract-out scientific research and increasingly engage in public-private partnerships for scientific endeavours. While these arrangements can have substantial economic and financial benefits, questions exist about the impact of reduced in-house science capacity and whether these partnerships are always structured in such a way to serve the public interest. Our analysis also revealed concerns regarding a communication gap between science and policy advisors within the federal government, and the impact this is having on the quality and clarity of information and advice received by policy-makers on science-based issues.

An important consideration in dealing with biotechnology is to ensure the credibility of government players involved. We assert that credibility is enhanced through a clear separation of regulatory and promotional roles, openness and transparency in risk assessment and decision-making, and a sound legislative and regulatory framework. A tension within government arises from its dual role as promoter and regulator of biotechnologies. We review the degrees of separation which currently exist in different seats of government, and the role of public input in risk assessment and the decision-making process.

The paper raises questions about deficiencies in patent law, about private-public research partnerships, and with respect to the governance of research on human subjects, but notes that little progress has been made to-date to enhance the legislative and regulatory framework. If it is left unattended, advances in biotechnology will likely burden the courts with questions government has not yet addressed. Ambiguous patent law in Canada is already foisting complex policy questions on the courts which, in turn, are limited by the lack of legislation governing this field.

Linked to these concerns is the question of leadership. Leadership is addressed at both the societal and governmental levels, with emphasis on the notion that no single player in the area of biotechnology and public policy has a monopoly on protecting the public interest. Judges are being asked to render decisions before societal views can be determined and appropriate policy responses developed. Scientists will increasingly be called upon to explain their publicly funded research and engage interested Canadians in a dialogue about their work. Canadians' expectations of government as "public steward" make a compelling case for why government should, in some cases, be leading the way.

In its leadership role, the government must remain abreast of scientific developments, and create and maintain a space where issues of concern to Canadians can be raised and discussed, while at the same time being ready to take the difficult decisions when necessary. Biotech issues (and science issues more generally) in other jurisdictions have led to major public furores – for example, over genetically modified foods. We would argue that biotechnology imposes on government a requirement for heightened vigilance and transparency. The paper notes, however, that at a time when the political leadership in Europe is fully engaged in the debates surrounding new applications of biotechnology, Canadian Members of Parliament and Ministers of Cabinet seem somewhat distant from the issues. Our analysis draws attention to the apparent lack of

senior level inter-departmental discussions on important crosscutting issues in the biotech arena, noting that this is a particularly significant deficiency in our current governance arrangements.

The information deficit among citizens also poses challenges for governments wanting to hear the views ordinary Canadians hold on biotechnology. More must be done to inform and engage the public on biotech questions. There may be lessons to be learned from the European experience, both with respect to biotechnology and science issues more generally. Certainly, recent storms over contaminated blood and BSE (bovine spongiform encephalopathy) have honed the sensitivity of both politicians and officials to the inherent risks of inaction, and driven the point home when it comes to developing biotech policies.

There is a real danger of public debate being driven by misinformation, thus clouding the ability of government to deal with the true issues and to derive full benefit from the remarkable new technologies on our doorstep. Governments both in Canada and elsewhere are gaining experience with a growing number of methods of consulting and engaging citizens in public policy issues, and this experience reminds us that citizen engagement is especially appropriate in cases where basic values are at stake. Biotechnology, with its potential implications for health, longevity, economics and the environment would appear to meet this criterion in spades. We argue that government needs to become both more proactive and more imaginative in its efforts to involve citizens in the biotech 'file'.

Overall, the central message of the report is that two steps must be taken if the biotech challenge is to be met more effectively. First, Ministerial and senior public servant engagement in biotech issues must be increased. Second, stronger incentives and more robust mechanisms for coordination both inside and outside government must be instituted. These measures will not guarantee the avoidance of mistakes. However, they diminish risk and enhance the likelihood that the benefits of biotechnology can be reaped. At the same time, they will help to ensure that any problems that do arise may be handled in a manner that will build, not erode, public trust in our governance institutions.

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A. Introduction

The recent flurry of activity in Canada, the United States, and indeed the world, over stem cell research, genetically modified (transgenic) crops, and genetic testing, to name but a few examples, demonstrates that biotechnology is a recurring and pressing policy priority. The present study constitutes an attempt at scoping the implications of biotechnology for public policy.³

We originally envisaged a study about the 'life sciences' but quickly came to realise that definitions of this term abound. Since the term 'life sciences' signifies different things to different people, a considerable part of our initial discussion was focussed on finding an effective and appropriate way to address the current advances in biological sciences. Karl Ereky defined biotechnology in 1919 as "science and methods that permit products to be produced from raw materials with the aid of living organisms". Although biotechnology per se is not new, it has taken a quantum leap in recent decades, with unprecedented advances in our understanding of the genetic structure and molecular composition of all living things. These modern biotechnologies spur advances in applied fields and technological innovations in areas like genetic engineering, cloning, bioremediation, gene testing and therapy, and biocatalysis, which are collectively known as biotechnology.

Biotechnology is considered by many to be a set of enabling and potentially transformative technologies, and a key driver in the next wave of knowledge-based economies. For the purposes of this study, we use the term biotechnology to encompass those enabling technologies that carry potential benefits for Canadians, combined with significant ethical, social and legal dimensions as to present a real challenge for governments and citizens alike.

Throughout the course of this study we heard several experts speak of Canada's significant potential in the area of biotechnology. The Canadian Biotechnology Strategy⁴ emphasises building on Canada's strengths, with strong bio-health sectors in Quebec, Ontario, Alberta and British Columbia, agriculture-based bio-firms in Saskatchewan, and aquaculture, health and forestry initiatives emerging in Atlantic Canada. Government officials spoke highly of Canada's regulatory structures and stewardship capacity. While upbeat and positive in their assessments, we also sensed a degree of uncertainty (and in some cases frustration) amongst our interlocutors. Questions arose regarding the overall level of government preparedness and its ability to execute its stewardship responsibilities with respect to this dynamic area of science. One of the main purpose of this study is to explore further those aspects of our governance structures and institutions that may not be adequate for the challenges which lie ahead, and to stimulate discussion on what could be done to strengthen their effectiveness in this next era of biotechnology.

Outline

A central premise of this report is that the strength of the inter-linkages between all the players (government, industry, academia and citizens) will be critical to Canada's ability to capture the

³ In preparing this study, we conducted a review of relevant literature and interviewed more than thirty experts in areas relating to biotechnology and public policy. A brief description of the methodology can be found in Annex A.

⁴ Industry Canada, The 1998 Canadian Biotechnology Strategy: An Ongoing Renewal Process, Ottawa, 1998

benefits that biotechnology offers society in a safe and equitable manner. Section B of this report seeks to answer the question: why should we care? It examines the potential inherent in recent biotechnological advances and applications, as well as the challenges these advances pose to good government and sound public policy. It considers the issue of economic and industrial potential and the challenges for industry in the Canadian context. It reviews the pace of scientific discovery and its implications - societal, ethical - and, finally, it examines why these developments should be of interest to policy-makers. In sum, this section establishes a snapshot of the issues and challenges facing society and government.

Section C examines how prepared we are to respond to these challenges by identifying and analysing existing governance capacities. What governance mechanisms exist? What are the roles of government, citizens and others in respect to biotechnology challenges? How has Canada approached governance of the issues, and what might we learn from the treatment of biotechnology in other countries?

Finally, Section D evaluates some of the gaps we have identified in current governance mechanisms and approaches to biotechnology in Canada. We will summarise key governance issues and conclusions identified from our observations, and provide suggestions as to areas which would merit future research.

B. Why Should We Care?

This section seeks to identify the challenges posed by biotechnology. Here, we will examine the pace of scientific discoveries and the implications of a dynamic scientific environment, biotechnology's economic and industrial potential, societal implications, and ethical issues. The section concludes with an overview of why Canadians and their governments should care about these issues.

1. The pace of scientific discoveries and its challenges

Keeping pace

It seems every passing day brings with it more announcements of new discoveries, new products, and new patents. Indeed, the pace of scientific discovery is extremely brisk, and accelerating. Dr. Lap Chee Tsui, the Chief Geneticist at the Toronto Hospital for Sick Children, is uneasy about the frenetic pace: "This particular wave is moving too fast. The technology is leading us."⁵ The convergence of science and the new synergies between disciplines calls for a similar nimbleness in policy capacity.

In conducting this study, we asked about the ability to predict where the science is going, and the nature of the applications coming down the development pipeline. Most respondents said they feel challenged to match the pace of science, but also feel reasonably confident in their ability to foresee what is coming down the pipeline in their respective fields.

Personnel in regulatory agencies were confident of their understanding about what products will enter the regulatory approval process over the next few years. Many departments have engaged in technology foresight exercises with partners from the private sector to acquire intelligence of the research and product pipelines and to start thinking of the economic and social prospects of new developments. One such exercise, the Technology Forecasting and Competitive Intelligence (TFCI), sought to identify departments' forecasting needs, exemplary practices in Canada and abroad, and to establish a methodology for setting up a national TFCI project in the future. Staying on top of technological developments is seen as a priority. Many said that this was not an onerous task as departments are adept at keeping good contacts with stakeholders, clients within the industry, and university communities. Formal and informal networks are used to acquire knowledge.

Although many departments are engaged in forecasting and intelligence gathering activities, we found that these initiatives are largely based within individual departments. One could anticipate that more government-wide efforts (along the lines of the TFCI) will be necessary in the future as the volume of work and the speed of scientific change continues to accelerate. One also has to question whether the confidence in internal departmental and agency forecasting abilities might be operational optimism on the part of employees, who may be hesitant to suggest that increased workload and reduced resources have left them struggling to stay abreast of new developments.

⁵ As quoted in Margaret Wentle, "The Human Genome, and Pandora's Box", *The Globe and Mail*, 29 June 2000.

Science Capacity and the Science/Policy Interface

The pace of discovery challenges our policy-making capacity and tests the strength of Canada's science and regulatory apparatus. Science is critical in supporting and contributing to sound policy development. Two important issues surfaced from our interviews: 1) the adequacy of science capacity in government and; 2) the existence of gaps in the science/policy interface.

Does the federal government possess enough science capacity to deal with the opportunities and challenges posed by biotechnology? During program review (mid-1990s), science capacity was cut by approximately 20%. In-house capacity has not recovered from the loss.⁶ Many involved in research and science-based units point to the 'science deficit' as a major potential barrier to the smooth and safe adoption of new scientific applications and products in the future. The question becomes whether enough science is being done in-house. To adequately address this broad question, one must break out the different science functions in government and analyse them independently. For example, one should distinguish between those involved in regulatory science (who do not conduct basic research but need, nonetheless, to stay abreast of recent scientific developments) and those involved in basic R&D performed in government labs. This "unbundling" of the issue would allow for an assessment of the internal/external split of science activities and the degree to which additional resources are required for in-house science.

The increasing prevalence of public-private partnerships in some areas of scientific research draws attention to the importance of clear parameters of accountability. The focus need not be on whether such private-public partnerships ought to exist, but rather on how to extract from these the highest possible standard of conduct and the broadest range of benefits. The perception that government science capacity is too reduced to be effective, and that industry is in a privileged position, could severely damage government's credibility on biotech issues.

The importance of science capacity and the need for a credible public face on science issues led the UK government to strengthen the role of its Chief Science Advisor. This move has received mixed reviews, with some career scientists in the UK arguing this was a political manoeuvre that would allow government to distance itself from the advice of its scientists. Nonetheless, respondents have suggested that Canada might need to reinstate a central locus for science activities in Canada. The call for a national science entity appears to have currency among scientists in Canada. In the year 2000, a working group was charged to study the feasibility of creating the *Canadian Academies*. The *Canadian Academies* would complement existing science organisations, with an eye to providing credible, independent assessments of the sciences on matters of public interest as well as providing a strong voice for science in Canada and abroad.⁷

Charles Scriver, professor of human genetics at the University of McGill, reminds us of the work of the Science Council of Canada which authored a prescient report in 1991, prior to its dissolution by government that same year.⁸ Report no.42 (*Genetics in Canadian Health Care*) foretold many of the biotech issues that practitioners, policy makers, and the public at large are met with today. The report addressed such questions as service delivery, equity of access, and the safety and effectiveness of the new technologies. According to Scriver, the end of the SCC led to the exclusion

⁶ Statistics Canada, "Federal Government Personnel engaged in S&T activities, 1990-91 to 1999-2000", Innovation Analysis Bulletin, II:2, May 2000.

⁷ For more information on the National Science Organisation: <http://www.nrc.ca/indcan/nso/>.

⁸ Charles Scriver, "Genetic Disease: An Orphan in Canadian Health Care", in ISUMA, Vol. 2, no.3, Autumn 2001.

of Report no. 42 from policy circles. Would the reinstatement of a national science organisation prevent such lapses from occurring? It is impossible to answer that question conclusively, but we do find considerable merit in Scriver's argument that sound science recommendations can lie dormant in the absence of an "in-house" advocate to push thinking forward.

The importance of science advice also underscores the need for policy-makers and scientists to interface effectively. One interviewee noted that biotechnology was the first area she had worked in where the pace of change was so rapid that research scientists were needed at the same table as policy advisors to prepare ministerial recommendations. Policy-makers must be able to understand the science advice and its basis, just as scientists, need to understand the policy framework to which they contribute. Herein lies the challenge - the inability to understand each side's advice can lead to frustration amongst policy and science advisors, to inadequate or incomplete recommendations for senior management and Ministers, and, ultimately, can hinder the development of effective public policy.

There are two important dimensions to the science-policy interface. First, there is the communication function which we describe above. Second, there is the accountability question. It is no longer sufficient for scientists to rely on the evaluations of their peers when advancing a position on technology "X". More and more, scientists are being required to share and discuss the results of science with the non-scientific world; in other words, to assume a place at the governance table. Although the government has a framework in place to integrate science-policy advice⁹, we found little evidence that these guidelines are being actively implemented. Ideally, the science-policy dialogue would commence relatively early in the evolution of new scientific research in order to identify potential policy implications of the research plans. One interviewee commented that science and policy are like two different moons in orbit around a Minister. Yet, by separating the two streams of input - science and policy advice - the opportunity for early co-ordination is lost. William Leiss repeats this caveat: "Until governments are able to focus their attention on their inescapable duty to carry out credible risk management, and to staff their professional ranks with the requisite skills for this purpose (which a training in the sciences alone cannot provide), they will not have resolved the real nature of the dilemmas that exist for them at this zone of the science-policy interface."¹⁰

To sum up, the rapid pace of change, combined with reduced in-house science capacity and a communication gap between science and policy advisors, present a considerable policy challenge for government. To understand the science, to effectively communicate the implications of new developments through the management structure of government, and to provide high quality, timely advice to decision makers, assumes a strong science foundation within government. An erosion of this base should be cause for concern.

⁹ A Framework for Science and Technology Advice: Principles and Guidelines for the Effective Use of Science and Technology Advice in Government Decision Making. Industry Canada, 29 June, 2000.

¹⁰ William Leiss, "Between Expertise and Bureaucracy: Risk Management Trapped at the Science-Policy Interface", in G. Bruce Doern & Ted Reed (Eds.), *Risky Business: Canada's Changing Science-Based Policy and Regulatory Regime*, Toronto: University of Toronto Press, 2000, p. 50.

2. Economic and industrial potential

In this section, we take a snapshot of the evolving biotech industry, its economic potential, and the associated challenges for government. In its 1999-2000 annual report, the Canadian Biotechnology Advisory Committee (CBAC) predicted that the world market for biotechnology products would rise from \$20 billion in 1995 to an expected \$50 billion by 2005¹¹. Biopharmaceuticals, which now account for approximately 5% of the world prescription drug market, are forecast to represent 15% of the global market in 2005. In an overview report on the industry in 2000, Ernst & Young went even further, predicting that this century will be the biotechnology century. The commercial prospects of biotechnology spur further research and development (R&D) activities. Health-related and environmental applications will likely remain the principal drivers of biotech R&D.¹²

Advances in this field depend upon successful convergence of technologies to develop hybrid applications, and market strategies to bring new products to market¹³. In a number of fields, biotechnology serves as a catalyst for new research activities. In the chemicals industry, biocatalytic manufacturing processes (using living systems instead of high-temperature or noxious chemicals) could lead to savings and to more environmentally-friendly production processes. Other possible environmental benefits include more efficient production of petroleum, reduction of waste by-products, synthesis of specialty chemicals, pest management, and new mining processes to replace high-energy and high-pollution smelting and roasting, to name but a few. New, more powerful computational capabilities create possibilities for research in molecular modelling (mapping and understanding the relationships between proteins, for instance) and for establishing population-based profiles of genetic functions which, in turn, will help scientists identify new pathways to combat illness. The knowledge of the genome and, in the future, how proteins interact with each other and their environment, opens the door to individualised therapeutic treatment, and potentially safer clinical trials.

The promise of new discoveries leads the biotechnology industry to be a big spender in R&D. Estimates in the United States suggest that a single health-related biotechnology product requires 7-10 years and close to US\$200-300 million in order to pass all the hurdles from research to market.¹⁴ In Canada, 17,000 products are currently at various stages in R&D, half of which at the preliminary stages.

Generally speaking, the outlook for biotechnologies is good. In 2000, the U.S. biotech industry (1,283 companies, public and private) generated US\$22.3 billion in revenues, US\$10.7 billion in research & development expenditures and employed 162,000 people. Biotech companies in the U.S. are generally very reliant on venture capital. Indeed, the market capitalisation of some of the U.S. giants exceeds the capitalisation of the entire European biotechnology industry.¹⁵ In Europe, biotechnology generates US\$7.9 billion in revenues and US\$4.5 billion in R&D expenditures. The sector consists of 1,570 companies and employs close to 61,100 people.

¹¹ Canadian Biotechnology Advisory Committee, CBAC Annual Report-1999-2000, Ottawa: CBAC, 2000.

¹² Ernst & Young, *Convergence: The Biotechnology Industry Report, Millennium Edition*, Palo Alto: Ernst & Young LLP, 2000.

¹³ Ernst & Young, *Op.cit.*, pp. 26-28.

¹⁴ Statistics Canada, *Biotechnology Use and Development - 1999*, Ottawa, 2001

¹⁵ Ernst & Young, *Biotech 99: Bridging the Gap, and Convergence: The Biotechnology Industry Report, Millennium Edition*, Palo Alto: Ernst & Young LLP, 1998.

Canada's place in the biotechnology industry

Although Canada's place in the biotechnology industry is more modest, in 1999 the sector consisted of 358 companies¹⁶, three-quarters of which were concentrated in the health and agrifood sectors. The industry generated approximately \$1.9 billion in revenues in 1999, a figure expected to rise to \$5 billion by 2002. Expenditures in research and development were pegged at \$800 million in 1999 and were forecast to rise to \$1.5 billion by 2002.

Canada is establishing itself as an exporter of biotechnology products. Biotechnology exports were worth \$700 million in 1999, and expected to grow to \$1.7 billion by 2002. The ratio of exports to imports rose from 2:1 in 1998 to 3:1 in 1999, and is forecast to be as much as 5:1 in 2002. The human health and ag-biotech sectors represent practically all exports. Canadian exporters have been fairly proactive in identifying potential markets for their products. While difficulties exist in exporting genetically modified crops or foodstuffs, the outlook for the export of health applications is better.

Biotechnology employed 10,000 people in Canada in 1997. By the end of this year it is expected to employ 16,000. Many industry trackers predict a shortfall of qualified personnel in the Canadian biotechnology industry. To address the anticipated shortfall of graduates, in January 2001 the Université du Québec à Montréal was the first university in the world to start offering an MBA in bio-industrial management. Interestingly, 85% of applicants to the new course of study already held a PhD in science.

Geographical and sectoral breakdown of Canadian industry

Biotech activity in Canada is concentrated in urban centres in British Columbia, Ontario and Quebec. Combined, they account for nearly 80% of all Canadian firms. Canadian biotechnology companies are poised to play a role in four sectors: bio-pharmaceuticals, bio-agriculture, forestry and aquaculture. The human health sector dominates Canadian biotech: 41% of the companies are active in human health, and the sector represents 55% of total biotechnology revenue as well as 86% of R&D spending.

The bulk of the Canadian biotechnology industry - 75% - consists of small and medium enterprises (SMEs). Many of these firms have yet to generate sales and significant revenues. Since the development cycle for new products tends to be ten years or more, it is not surprising to learn that 35% of Canadian companies are engaged in research that does not yet generate revenues. By 2002, SMEs will spend up to \$500 million in R&D, or 75% of their projected revenue from biotech. The 11% of Canadian biotechnology companies classified as large account for 70% of all revenue from biotech, and contribute more than half of the total amount for research & development. Quebec is particularly active with approximately 40% of the R&D expenditures. For a more detailed summary of the Canadian biotechnology industry, refer to Annex B.

¹⁶ Data on the Canadian biotechnology industry is from Statistics Canada, *Op. cit.* They have defined biotechnology companies as companies who are active in R&D in biotechnology and consider it to be a central part of their activities.

Challenges for industry

While the economic potential of biotech is significant, Canadian companies face two related challenges: capturing downstream benefits, and intellectual property protection.

Before investors will commit to a biotech project, initial research and development usually costs between \$100,000 and \$1 million. It is especially difficult to attract private funding for the early proof-of-concept stage.¹⁷ Company incubation has been facilitated by funding by the Canada Foundation for Innovation, the Canadian Medical Discoveries Fund, Network Centres of Excellence, the Canadian Institute for Health Research (CIHR), the National Research Council (NRC), universities, and the newly-created Genome Canada. Quebec has created the *Centre québécois d'innovation en biotechnologie* and Ontario has developed three biotechnology incubation centres to provide start-ups with access to laboratory and office space, as well as proximity to expertise and research institutions. In the last few years, the NRC has spun off more than 20 biotechnology companies, while universities have spun off 90 companies.¹⁸

International research linkages are also becoming more common. For example, in June 2001, Genome Canada signed a memorandum of understanding with the Swedish Karolinska Institute to promote and support exchanges to develop cutting edge genomics research and industry projects. The NRC has signed a letter of intent with the Superior Council of Scientific Research in Spain to identify areas of co-operation and promote bilateral technological and scientific exchanges.

The challenge for Canada is to profit from the downstream benefits of these initial investments. The innovation cycle typically follows this model: government and university-based (or funded) research; company start-up and spin-off; company absorption by a larger, often foreign, enterprise. Large pharmaceuticals seem to have adopted a strategic position to not invest in in-house biotechnology, but instead take over or ally themselves with smaller biotech firms. Since big pharmaceutical companies tend to control the drug delivery system and have the resources and expertise required to navigate the regulatory system, the barriers to entry for Canadian SMEs are considerable. It behooves government to be explicit about its vision for the biotech industry in Canada, and the kind of biotech research it will support. While an analysis of the economic development strategies of the federal government is beyond the scope of this paper, an example from Europe is offered for consideration below.

Ernst & Young's 2001 Report on the European life sciences showed that companies no longer face the same cash crunch as earlier in the 1990s. Hence, mergers and partnerships are born of strategic decisions rather than of desperation. Their research shows that there have been more firm-to-firm alliances and mergers in recent years than take-overs by multinational pharmaceuticals. Biotech companies are attempting to attenuate the challenges of scale by forming alliances with a number of pharmaceutical companies to engage in co-development, co-marketing and co-promotion and sales. Indeed, decisions to create genetic knowledge parks in the UK, and biotech clusters in Germany (their Bio-Regio programme), as well as the five Genome Canada centres, help foster an environment in which synergies between researchers, clinicians and pharmaceutical entrepreneurs can flourish at a sufficiently large scale.

¹⁷ Industry Canada, *Pathways to Growth: Opportunities in Biotechnology*, Ottawa, 2000.

¹⁸ Industry Canada, *Op. cit.*, p. 15.

In addition to the challenge of scale, Canadian firms are confronted with the question of intellectual property. Germane to the debates on biotechnology is the patenting of discoveries. Since biotechnology is a R&D intensive field, the right to patent is sought by firms to recover these investments and commercialise the fruits of their research. At a time where public funding of research has been in decline, biotechnology is increasingly commercially focused, and thus the protection of intellectual property is seen as an important stimulus for further innovation. Yet biotech discoveries and applications are challenging a patent system designed to deal with a quite different brand of innovation.

The German Example

Germany leads Europe in the number of biotech companies (mostly small, private companies). Biotech research in the public sector employs 30,000 people, of which 13,000 are scientists. Three-quarters of the German biotech industry are tied to the pharmaceutical and medical industries. Over the years, the German government has implemented policies that make it a key player on the European biotechnology scene. It has set up effective legal and economic levers, and streamlined its regulatory approval process. It has provided funding for scientific research and technological development: DM1 billion alone to promote R&D in biotechnology and molecular medicine. The BioRegio program provided DM100 million over three years to create three research clusters in different regions. The Federal Ministry for Education and Research (BMBF) has announced DM1.5 billion of financing for promotion of R&D in all sectors of activity (pharmaceutical, medical, agriculture, environment & consumer protection). The German strategy is marked by its comprehensiveness, bringing together all key players and constituents. The role of the BMBF was pivotal as it sought to develop a national strategy and identify appropriate interventions at all points of the innovation chain.

Intellectual property has been the subject of many well-researched studies and reports. While it is beyond the scope of this study to do justice to the broad policy issues surrounding intellectual property, there are two aspects of the debate worth highlighting. First, an important question is whether patents are the best way to foster innovation. Does granting a patent really accomplish what its proponents argue; that is, to protect and stimulate innovation? U.S. Patent 6,200,806 gives control to a University of Wisconsin foundation over the method of isolating embryonic stem cells and over the cells themselves. Many scientists in the U.S. have expressed fears that this patent could be used to hinder further research on cells, or drive it overseas. Firms from other countries who distribute cells in the U.S. could be charged with patent infringement.

Besides the issue of stimulating innovation, there are also concerns over equity and accessibility. These are key issues, especially for products and processes that could yield enormous benefits in the developing world. As an example, scientists in Costa Rica engineered rice to provide resistance to a disease prevalent in tropical climates. However, before they could commercialise the discovery, they were required to obtain clearance from as many as 34 patent holders. Similarly, golden rice, a crop that could alleviate deficiency in vitamin A, was covered by as many as 70 patents owned by 30 companies and universities around the world. Obtaining permissions - even if they are obtained for free - is a time-consuming affair. These debates are unresolved, but the overarching issue is whether the patenting of biotechnological innovations strikes an adequate balance between providing incentives to innovation or hindering it, and at what cost to humanity.

This brief overview of the biotechnology industry in Canada highlights several issues. First, while Canada's industrial presence in this area is modest relative to that of some European countries or to the United States, it is forecast to grow significantly over the next few years. Second, with the world market for biotech products expected to reach \$50 billion by 2005, and predictions that we

have entered the "biotech century", Canada can not afford to forego the opportunities and benefits to flow from knowledge and applications in this area. This study did not attempt to assess the current level of industrial support available for biotech firms in Canada, but we have identified two key challenges for industry relating to capturing downstream benefits and the need for appropriate and equitable rules around intellectual property protection. Neither of these challenges is unique to biotechnology, and both have been the subjects of considerable research. However, there are issues relating to biotechnology, such as the patenting of higher life forms, which do present unique challenges to policy-makers and will therefore require careful, yet timely, consideration by government. We return to the issues of science and patenting in the following section when we review implications of biotechnology for the legal sector.

TRIPS (Trade-related Aspects of Intellectual Property Rights)

Recent discussions on the World Trade Organisation's TRIPS Agreement profile how the rules surrounding intellectual property rights can affect the safety and welfare of citizens. The TRIPS Agreement has become the focal point for discussion about the equity of regulatory regimes that govern medical developments. The HIV/AIDS pandemic in South Africa, for example, has forced the international community to examine these rules more closely.

Two declarations were prepared to address this pressing question at the WTO Members' meeting in Qatar (November 2001). Going into the meeting, Canada was one of five WTO countries to adopt a position¹⁹ which seeks to reinforce the importance of patent protection under the current structure of WTO rules.

The second declaration, prepared by the African Group along with 19 other WTO developing country nations, affirms the right of sovereign nations to take measures to protect public health.²⁰

The nub of the issue rests with the right of a Member country to establish its own policies and rules regarding the exhaustion of intellectual property rights, and the manufacture of affordable medicines. It rests on the Member country's right to decide whether a drug patent ought to be rewarded for five, ten, or twenty years, and under which conditions a patent might be temporarily relaxed to cope with a public health crisis.

This question is not far from home. The recent quagmire over the federal government's decision to purchase the drug Cipro (a broad-spectrum antibiotic used to treat inhalation anthrax) from the generic drug manufacturer, Apotex, touches on very similar questions. The patent holder, Bayer, argued that under international patent law the Canadian government had to purchase the drug from it. Questions later surfaced about the availability of the drug requested from Bayer and the legitimacy of the patent claim (Apotex is taking Bayer to court). The federal government, however, agreed to fill the order with Bayer.

Member nations of the WTO are legally bound by the protection afforded to patent holders under WTO rules. These extend patent protection for a period of 20 years. Countries like South Africa who buck against the rules to respond to wide-scale public health crises – such as the HIV/AIDS pandemic - are met with harsh WTO challenges.

Does the TRIPS Agreement in its current form strike an adequate balance between the need to protect intellectual property and the public interest?

¹⁹ TRIPS: Draft Ministerial Declaration. Proposal from a group of developed countries. October 4, 2001. http://www.wto.org/english/tratop_e/trips/mindecdraft_w312_e.htm

²⁰ TRIPS: Draft Ministerial Declaration. Proposal from a group of developing countries. October 4, 2001. http://www.wto.org/english/tratop_e/trips/mindecdraft_w312_e.htm

3. Societal implications

This section looks at how the transformative and enabling effects of biotechnologies are likely to affect families, professions, and public perceptions in general. For families, the possible implications are numerous. For instance, the possibility that a genetic scan could reveal a person's susceptibility to disease begs the question of whether family members should have a right to know such information. An individual's genetic predisposition to disease may have important lifestyle consequences. At the same time, many of these new tests provide individuals with very imperfect information; they suggest the possibility of future disease but cannot provide definitive answers. Reproductive choices, and gene mapping for the purpose of prognosis (leading to scenarios like whether children should be told they have inherited a disease), are just some of the dilemmas that society and individuals will face.

Scenarios once confined to the pages of science fiction books are now coming to life. At time of writing, the U.K.'s human fertilization and embryology authority was wrestling with whether to grant permission to a British couple who wants to give birth to a "designer child".²¹ The couple wished to save the life of their 2-year old son, who was diagnosed with the blood disorder thalassaemia beta. The perfect match is needed for the bone marrow transplant that will save the boy's life. Should the couple be allowed to contract a U.S. clinic to perform the genetic tests on their embryos? Questions such as these are of a very personal and practical nature, which is why biotech applications are all the more immediate to ordinary Canadians.

Implications for the health sector

Modern biotechnology is expected to transform ways in which society approaches health issues. Dr. Alan Bernstein, President of CIHR, wrote that he believed the sequencing of the human genome and the potential applications which will be derived from it are likely to have a "transformative" effect on health and the health care system". He called this discovery a "profound revolution in health research."²² Today, our health care system is primarily palliative; people are treated on the basis of symptoms they exhibit. With the knowledge gleaned from the human genome, it is reasonable to believe that diagnoses will be more anticipatory; looking to disease prevention based on a person's genetic profile.

These changes are likely to be felt significantly by health care practitioners: "Many primary care physicians will become practitioners of genomic medicine, having to explain complex statistical risk information to healthy individuals who are seeking to enhance their chances of staying well."²³ This will require that physicians close the gap between science and clinical applications. The difference lies in the emphasis placed on genetics as a determinant of disease. It creates the need for more public health research, especially in epidemiology, policy, communication and health services. The possibilities created by individualised medicine raise questions regarding safety and effectiveness: how will genetic tests and preventive services be offered and funded? Is it cost-effective to tailor interventions based on genetic information? The teaching of medicine will need to adapt to these changes. Similarly, keeping track of new treatments will require healthcare professionals to remain on the cutting edge of research.

²¹ Sarah Boseley, "Fertility authority faces 'designer child' decision", *The Guardian*, 2 Oct. 2001.

²² Alan Bernstein, "Balancing Act: Science and Society", *Globe and Mail*, 14 Feb. 2001.

²³ F.S. Collins & V.A. McKusick, "Implications of the Human Genome Project for Medical Science", *JAMA*, 285:540-4, 2001.

As one of our interviewees noted, it is not at all clear how much “health” we will find in genomic medicine. The collective implications of these scientific advances on the individual, community and society will need to be assessed. The benefits which may result will take time to materialise. Yet, genomics provokes a reflection on the very notion of health. Once a genetic profile is established, what does it mean to be 'healthy'? How does one's genetic profile weigh against factors such as lifestyle, diet, upbringing, social status, and environment in determining health?

Implications for the legal sector

In the field of law, the courts are increasingly drawn into the debates surrounding biotechnology. The National Judicial Institute organised a conference in June 2001 for Canadian justices and has subsequently developed a series of learning events regarding advances in biotechnology and its implications for the law. It is an attempt at generating knowledge and awareness of the issues raised by biotechnology, and a good forum to discuss ways in which to apprehend these changes.

Earlier we raised the question of intellectual property, where Canada is seen as lagging behind the U.S. and Europe on the issue of patenting of higher life forms. Thus far, Canada has relied on a more reactive (judicial) process rather than an anticipatory, legislated approach. Canadian courts have rendered interesting verdicts with respect to the patenting of the so-called Harvard Mouse. This "oncomouse" has been genetically altered to make it susceptible to cancer, rendering it both a product of human ingenuity and the laws of nature. In 1998, the Federal Court rejected a patent request on the basis that the law contained no specific provisions relative to biotechnological inventions. The decision was appealed, and in a landmark judgment handed down in August 2000, the Federal Court of Appeals ordered the Commissioner of Patents to deliver a patent for the Harvard Mouse.

Since, the Supreme Court of Canada has given leave to appeal the decision. What is interesting is the treatment the Appeals Court gave to moral, ethical and social questions contained within the patent request - they referred them to the legislator. "S'il est vrai que le présent appel soulève des questions de principe, c'est au législateur fédéral, et non aux tribunaux, qu'il appartient de les examiner."²⁴ The Court's judgments expose the lack of legislative preparedness with respect to biotechnological innovations. It is likely that the courts will increasingly be asked to wade into complex cases, where dilemmas regarding privacy, discrimination and equality will feature prominently.

The draft legislation on assisted human reproduction, currently before the House of Commons Standing Committee on Health, has been criticised for not being flexible enough. The proposed law's reliance on criminal prohibition and the associated enforcement system is seen as too rigid to keep up with the challenges posed by biotechnology. "Criminal laws," write Bartha Knoppers and Timothy Caulfield, "are blunt, inflexible and require a good deal of time and political energy to change." Assisted human reproductive technology is a field that is in constant and rapid evolution, thus provoking accompanying changes in social attitudes to science and technology. Rigid prohibitions would not provide the flexibility required to respond to changes in science and

²⁴ As quoted in Alexandria Obadia, *Xénotransplantation: Le brevet sur l'animal*, Québec: Presses de l'Université du Québec, 2001, p. 65.

society.²⁵ At the same time, there is also a view that a legal, as opposed to a regulatory approach, could constitute a built-in defence against developments that politicians could not otherwise keep up with. It is possible to conceive of a well designed, balanced law that is robust enough to serve the public interest, while not impeding scientific advances. The fact remains that the pace of change in the biotech area will require flexible governance mechanisms to guide industry conduct, likely requiring a combination of legislation, regulation and voluntary compliance mechanisms. The challenge is knowing which instruments will yield the desired outcomes.

Implications for the insurance sector

Another example of biotechnology's societal implications features third party use of genetic information by insurance companies. Under the code of conduct of the Association of British Insurers (ABI), insurance companies can ask applicants for the results of genetic tests that have received approval from the UK government's Genetics and Insurance Committee - the test for Huntington's disease being one of these. Out of fear that this might lead to the emergence of a genetic underclass, MPs and the UK Human Genetics Commission called for a legally-binding moratorium on the use of genetic information. As a result, the ABI has extended its voluntary agreement not to use information for insurance policies worth up to £300,000 for the next two years. The UK House of Lords Committee on Science & Technology published a report in March 2001, castigating the insurance industry for failing to establish a clear policy on the use of genetic information and explaining the policy to British citizens.²⁶ The political leadership in Britain is still considering legislation to prohibit or restrict use of genetic information.

In Canada, these issues have already arisen: Canada's insurance industry has expressed interest in gaining access to individual genetic information as it becomes available.²⁷ Will knowing one's genetic profile affect the information we must provide insurers? Will coverage be denied on the basis of genetic predispositions? Does such denial raise Charter issues? Although the Personal Information Protection and Electronic Documents Act limits the collection, use and disclosure of personal health information to what is considered an 'appropriate' use, the definition of 'appropriate use' is likely to become an important issue to the insurance industry. If a person refusing to provide information is denied insurance coverage, a complaint might be made to the Privacy Commissioner, and could eventually end up before the Federal Court, thus engaging the legal system to solve the dilemma.

Other questions will also have big implications for the insurance industry. For example, in due course, might new discoveries in genetics lead to an increase in average life span in developed countries of, say, two or three decades? What impact will this have on life insurance policies? What happens in case of intentional, or inadvertent, disclosure of personal genetic information to third parties - what kinds of lawsuits and other controversies are likely to arise from this, and what might this imply for liability coverage?

²⁵ Bartha Maria Knoppers & Timothy Caulfield, "Don't Make Science a Crime", *The Globe and Mail*, 20 August 2001.

²⁶ United Kingdom, House of Lords Select Committee on Science and Technology, *Science and Society* (Third report of the Committee on Science and Technology), London: The Stationery Office, 2000. Available at: <http://www.parliament.the-stationery-office.co.uk/pa/cm200001/cmselect/cmsctech/174/17402.htm>

²⁷ Laura Landon, "Insurance Giant Wants Your Gene Map", *Ottawa Citizen*, 6 July 2000.

Public preoccupations²⁸

As the impacts of new scientific developments work their way through the various sectors of society, public perceptions about the science become increasingly important. Almost everyone interviewed agreed that public awareness and acceptance of biotechnology are key determinants of "success". In this instance, success can be defined as capturing benefits for Canadians, minimising risks and allowing the economic potential of these new applications to be realised. A crisis in public confidence over the safety of products and applications is seen by many as a threat to the prosperity of the industry. Indeed, several of our respondents cited the potentially enormous benefits that could easily become "losses" if the issues are not communicated properly and a "fear factor" takes hold. For many, the concern about public perception relates primarily to the economic benefits of biotechnological advances. We would like to consider the issue in its broader perspective: it is not only the potential benefits that are at stake, but the integrity of Canada's regulatory system and policy-making capacity.

Public opinion research shows that Canadians see a hierarchy of benefits in biotechnology: health and medical benefits rate highest, followed by environmental, and finally, economic outcomes. The larger the perceived benefits, the wider the margin of risk people are prepared to accept. Although the Canadian public generally remains a casual observer of biotechnology, those surveyed demonstrated a keen awareness of the significance of the issues. Research in the United Kingdom reached similar conclusions. The British public, by and large, is more tolerant of scientific development aimed at achieving improvements in public health. Similarly, when a purpose is expressed as having a purely economic benefit, respondents were overwhelmingly opposed.²⁹

Overall, Canadians surveyed expressed confidence in science: if scientific evidence demonstrates a product is safe, it should be approved. "Science" should be the primary guide to decision-making about biotechnology applications. The public would be more likely to accept a scientific development to the extent they are familiar with it and believe it is beneficial and useful. They do not see a *prima facie* conflict of interest in government assuming the dual role of promoter and regulator of the technology. At the same time, as the most recent polling data shows, it is the regulatory rather than the promotional role that is a higher priority for Canadians.³⁰

Surveys have also revealed that Canadians lack knowledge in the field of biotechnology. Although levels of professed knowledge have been rising, it remains that Canadians find the field too complex and technical to follow. The lack of knowledge leads to resignation. People see risk as inevitable, but acceptable to the extent they know that someone else - government in most cases - is taking the lead in evaluating and mitigating risk. Media coverage of biotechnology is largely responsible for rising knowledge levels. Nevertheless, these findings suggest that Canadians have only a "surface level" trust in the government's ability to manage biotech issues on their behalf, based on limited understanding of the issues involved.

²⁸ Unless cited otherwise, the data on Canadian public opinion is taken from the Pollara Research & Earncliffe Research and Communication's Public Opinion Research into Biotechnology Issues, first, second, third and fourth waves. Environics Research Group's 2001 study for CBAC, Secondary Analysis of Public Opinion Research Regarding Genetically Modified Food and Related Biotechnology Issues was also useful.

²⁹ Robert M. Worcester, *Science and Democracy: Public Attitudes to Science and Scientists*, London: MORI (World Conference on Science), 1999

³⁰ Environics Research Group, *Secondary Analysis of Public Opinion Research Regarding Genetically Modified Food and Related Biotechnology Issues*, Ottawa: CBAC, 2001.

Public opinion research reveals some worrisome trends which are reaffirmed with each new poll. The public demonstrates significant deficiencies in knowledge about how government works, and the procedures and mechanisms in place to oversee biotechnology approvals. Nor do those polled place greater trust in the actions of stakeholders, NGOs and environmental organisations, whom they perceive to be influenced by corporate funding or motivated by a more limited agenda.

The low levels of understanding of government's roles and policies in the field of biotechnology, should, however, not be interpreted as indifference. Polling data show that Canadians want transparency, and a clear sign of transparency is the availability of impartial information. Consultations are seen as a demonstration that the government is open to citizens' thoughts on the issues, even though most Canadians polled had no personal interest in participating. The dominant view is that the public considers it has neither the knowledge nor the ability to make effective decisions, and are willing to defer to public health experts (scientists, university researchers, government researchers, policy makers) who are seen as better placed to make those decisions. From this data a rather worrying portrait emerges; respondents do not necessarily want to be engaged in the issues, though they have little or no understanding of biotechnology and of the mechanisms that govern it. They have little trust in government or stakeholders, yet will defer to experts when it comes to making decisions on the issues.

This summary of potential societal implications represents just the tip of the iceberg as to how biotechnology developments may affect the day-to-day lives of Canadians. Health practitioners and their patients, judges, lawyers, legislators and insurance companies will be just some of those implicated in the evolution of biotech applications. Canadians more broadly reveal only a limited understanding of (or interest in) what may lie ahead. These are the challenges to which we will return in the later section on informing and engaging citizens.

4. Ethical framework

The seemingly limitless technological possibilities of biotech raise a host of ethical questions. There are the issues surrounding human and animal research subjects, the desirability of being able to synthesize life, privacy and accessibility. The questions are pervasive.

Why "ethics"?

Ethics involves the systematic study of norms and values in particular actions (whether an action is right or wrong), consequences (whether it is good or bad) and character (virtue or vice).³¹ Ethics can be descriptive (reconstructing social schemes of reference and bases for judgement), theoretical (examining concepts central to ethics) or normative (inquiring into values people ought to have, identifying moral standards).

"An issue does not become "ethical" simply in virtue of its popularity, but because deep and systematic differences in values and interpretations open up the possibility for incompatible prescriptions for action."³² The strong public expression of ethical concerns around some aspects of biotechnology is a clear sign that a social consensus on many issues is lacking.

³¹ Michael McDonald, *Biotechnology, Ethics and Government: A Synthesis*, Ottawa: CBAC, 2000.

³² Paul Thompson, *Food and Agricultural Biotechnology: Incorporating Ethical Considerations*. Ottawa: CBAC, 2000, p. 35.

The ethical issues surrounding biotechnology lead to questions of democratic decision-making and policy adjudication. Indeed, policy interventions are expected to weigh such questions as equity, accessibility, and the public interest. But as the debates become more politicised, there is a real risk that public discourse on biotech will reflect the strategic interests of industry and activists. Government finds itself having to justify why its decisions fall closer to one camp or the other.³³

GELS research

The ethical and social dimensions of research in biotechnology also warrant special attention. In its first round of funding, Genome Canada required each of its five centres to include a component on 'Genomic Ethical, Environmental, Legal and Social Issues' (GELS). Genome Canada is a collaborative initiative with multiple partners who fund large-scale genomic research. Funded projects included research on privacy issues and intellectual property, and on how developments in genomics may affect developing countries. The Canadian Biotechnology Advisory Committee is also conducting research into ethical questions as part of its mandate to incorporate social and ethical insights into policy-making. The increase in funding of such work in Canada led one of our respondents to add that the ethicists, sociologists and environmentalists active in GELS research feel that they have "arrived in heaven".

Clearly, the return on these investments will depend upon the quality of the results and the ability to disseminate the findings broadly among all the players. It is commendable that organisations are increasingly dedicating resources to further research in these areas. Bundling ethics issues and funding them separately, however, may give rise to a problem of perception - ethics research and issues being considered as marginal, or a side issue. It would seem important to ensure that the ethical, environmental, and social implications of biotechnology be taken into account at every stage from research through to market applications.

The concern that ethics may be treated as a marginal side issue has arisen in non-genomic contexts. In his study for the Law Commission of Canada, Michael McDonald raises a similar concern in challenging the mechanisms that exist to govern research involving human subjects (RIHS). With RIHS, the system places primary responsibility for oversight on research ethics boards. McDonald found that in many cases, "ethics" has simply become a question of successfully navigating the ethics approval stage of research. The main purpose of the research ethics board is to efficiently process research protocols that may - or may not - bear much resemblance to the actual conduct of research or its results. This results in what he calls an "ethical tunnel vision", where more bureaucratic concerns (such as the processing of project proposals) supersede the provision of effective oversight of the ethical dimensions of research proposals.³⁴

It is important to ensure that GELS research does not fall into a similar trap. By setting ethics issues apart from primary research and development, there is a danger that the two paths will never really converge. Ethics committees, as one respondent told us, are seen as a sort of priesthood - farming out values to advisory bodies and expert committees rather than seeing the

³³ Paul Thompson, *Op. cit.*

³⁴ Michael McDonald, *The Governance of Health Research Involving Human Subjects (HRIHS)*, Ottawa: Law Commission of Canada, 2000. We were advised that the Province of Québec recently created an ethics commission under the aegis of its Conseil de la science et de la technologie. It may serve as a test case for dealing with these kinds of concerns.

bundle of issues as integral components of research. Carl Elliott, a bioethicist at the University of Minnesota, goes even further, fearing that ethicists be used as corporate window dressing: "Bioethics boards look like watchdogs, but they are used like show dogs."³⁵ There is a need to guard against the assumption that ethics alone is an antidote to socially or environmentally harmful uses of biotechnology.

Professional standards

Another challenge in the incorporation of ethical concerns in biotech research is the lack of explicit professional standards for ethicists and the potential for conflicts of interests. Without licensing or accreditation, it is difficult to determine whether an ethics 'expert' is really an expert. Increasingly, bioethicists are coming under scrutiny - as well as the kinds of arrangements and bargains they strike with scientists and researchers. Since bioethics has gained prominence in shaping the tone of public discourse on controversial topics (such as embryonic stem cells), resolving the issue of accreditation is gaining importance. One option has been advanced by the Ethics Practitioners Association of Canada (EPAC). This organisation has established a competency profile for ethics practitioners which could be turned into an accreditation system.³⁶ However, as in the case of scientists, accountability should be enlarged to include other players in the governance of biotechnology. As there are no rules for ethicists who associate themselves with industry, important questions about transparency and independence are raised. In the absence of a code of conduct, whether or not an ethicist accepts corporate money, donations, or fees is a matter of personal rather than professional standards.

Academic integrity faces similar challenges. As more and more of the research and development conducted on university campuses is industry-partnered - with the goal of developing new commercial products - the integrity of the institutions is coming under fire. Tufts University and the University of California completed a comprehensive analysis of disclosure policies in science and medical journals in the U.S. A review of 181 academic journals and 61,134 articles found that in just one half of one percent of all articles, personal financial interests (including honoraria, consulting arrangements, expert witness fees, equity and stock and patents) had been disclosed. Further, all the disclosures appeared in only one third of the 181 journals surveyed.³⁷ The editors of leading medical journals have only recently joined together and have agreed not to publish articles in which scientific objectivity is in question. They want to see findings critical of drug performance published.³⁸ This is an important first move in the right direction to protecting credibility and reassuring their readers and society that medical research is a public good.

Partnership agreements and sponsorships of universities or research projects raise the question of whether biotech research serves the interest of corporations at the expense of free inquiry and unfettered research. Is this appropriate? According to one source, at the University of California (Berkeley), corporate sponsorship typically provides the corporation with the right to license discoveries, and even to have representation on departmental research committees.³⁹

³⁵ Sheryl Gay Stolberg, "Bioethicists Fall Under Familiar Scrutiny", New York Times, 2 August 2001.

³⁶ EPAC: www.epac-apec.ca.

³⁷ Sheryl Gay Stolberg, "Scientists Often Mum About Ties to Industry", New York Times, 25 April 2001.

³⁸ André Picard, "Medical Journals Set Stricter Rules for Studies", Globe and Mail, 10 September 2001.

³⁹ Ibrahim Warde, "For Sale: US Academic Integrity", Le Monde Diplomatique, March 2001.

In Canada, there is little cause for complacency. Pharmaceutical and biotechnology companies fund between 16 and 30 percent of research at big medical schools (McGill, Queen's, Toronto, British Columbia). Even where government funding has been involved, that funding is increasingly tied to matching private sector funds.⁴⁰ Research ethics boards are currently considering the consequences of such arrangements. There is an informal consensus that universities must be open and transparent about commercial relationships, and that such relationships should not undermine academic freedom. Yet, how many universities have implemented official codes of conduct? And how standardised is the practice?

A number of separate controversies at Canadian universities show that the line between corporate interest and academic freedom is increasingly blurred. World-renowned scientists, Drs. Olivieri and Healy each paid a high professional cost for going public with their research findings. In Dr. Olivieri's case, her disclosures threatened to interfere with the approval of a new drug. She was thus removed as director of a blood research program at the Hospital for Sick Children. Dr. Healy advanced the view that a widely prescribed anti-depressant was responsible for suicidal tendencies in some patients. Thereafter, the University of Toronto rescinded a prestigious job offer. A letter signed by 27 of the world's leading scientists condemned the treatment of Dr. Healy by the University.⁴¹ Both cases illustrate the fragility of the border between academic freedom and financial gain.

The conflict of interest policy at Harvard University is considered to be one of the more stringent in North America today. Harvard bars scientists from doing clinical research in the following instances: (i) for a company in which they own stock, a commercial interest, or more than 5% of the company; (ii) where funding is derived from a single corporate sponsor; (iii) where the researcher holds an executive position in a for-profit business engaged in biomedical research or sales.⁴² While these measures guard against an individual scientist's misuse of authority, do they serve to protect scientists from the punitive actions of their employers (the University) when research findings place the commercial interests of industry partners in jeopardy? There is not sufficient evidence to-date to judge whether Harvard's conflict of interest policy is itself sufficient, but it does set a standard in this area. Recent initiatives worth noting include the proposed rules by the Canadian Medical Association Journal restricting which papers it will publish depending upon the degree of industry support for the academic research. More steps in this direction will be very important since conflicts of interest and secrecy undermine science's reputation, as well as the trustworthiness of university-based researchers, and of biotech research in general.

We have reviewed the prevalence of ethical questions with regard to biotech developments, and discussed the need for active consideration of "GELS" issues from the initial research and development phase through to market applications. Juxtaposed against the importance of these issues is the lack of professional standards for "ethics experts" and the challenges to academic integrity in research. These are issues which are not easily solved, but some of the developments described above represent steps in the right direction. From our observations, it is clear that our systems of governance will increasingly be called upon to grapple with difficult ethical issues. The harvesting of embryonic stem cells, the accessibility of new technology in developing

⁴⁰ Statistics Canada, "Commercialization of federal government and university research", Innovation Analysis Bulletin, II:3, September 2000, p. 7 and Anne McIlroy, "Drug Research Walks Thin Line", Globe and Mail, January 1, 2001.

⁴¹ Campbell Clark, "Top Scientists Allege U of T Academic Chill", Globe and Mail, 6 September 2001.

⁴² Anne McIlroy, "A Scientist's Sacrilege: Making Money", Globe and Mail, 3 January 2001.

countries, a court's decision on the actions of front line health practitioners; these are just some of the ethically imbued questions that decision makers will face in the coming years.

5. Why should government care?

This section began with a look at the economic benefits derived from biotechnology, and the potential of new applications in health, environment, and many other sectors of the economy. The potential of the technologies and their application – both in economic and social terms – are compelling drivers. We turned to the challenges imposed by the pace of biotech research and commercialisation, focusing on the issue of science capacity in government. We reviewed the implications of scientific advances for different sectors of our society. The low level of public awareness and knowledge of biotechnology, and Canadians' general disengagement on these issues, present unique challenges to government. In addition, we outlined some of the ethical dimensions of biotechnology as well as the pressures on ethicists and academics to maintain credibility.

Biotechnology is not being a single technology or process but rather a cluster of many different technologies, which carry policy implications that are multiple and diverse. The recurring nature of these issues, and the expectation Canadians have that government will provide high quality stewardship, make a strong case for why government should not only be involved, but in some cases, lead the way.

Government's role in biotechnology in Canada is increasingly complex: policy-making and law making, risk management and regulation, industrial promotion, international co-ordination and communication/consultation activities. As Jarvis indicated, in science-based issues, government is expected to be custodian, partner, and leader.⁴³ Observers of government activities in biotech have tended to classify actions in two ways: regulation or promotion. From the beginning, Canada has attempted to balance both activities. In a study of the federal regulatory regime, the House of Commons Standing Committee on the Environment and Sustainable Development wrote that it hoped regulations on biotechnology would "protect the health of Canadians and the Canadian environment, but at the same time would not produce a regulatory climate that would unfairly hamper the development of industry in Canada."⁴⁴

This is the stance that was adopted by the federal government in its 1998 Canadian Biotechnology Strategy. While one could question whether it is possible to adequately balance these roles, on the whole, our interviewees thought that the Canadian government has been successful in separating its regulatory duties from its promotional role. For example, most respondents seem satisfied that the regulatory functions of the Canadian Food Inspection Agency are sufficiently independent from Agriculture and Agrifood Canada's "promotional" activities. Nevertheless, the separation of roles (including a clear public understanding of where one mandate ends and another begins) remains an important issue. Departments such as Environment Canada and Fisheries and Oceans were at time of writing reviewing their internal organisational structures and accountability frameworks to ensure regulatory and promotional roles with respect to biotechnology are adequately "separated". As one respondent noted, public concern about roles and responsibilities

⁴³ Jarvis, Bill, *A Question of Balance: New Approaches for Science Based Regulations*, Ottawa: Public Policy Forum, 1998.

⁴⁴ Canada, House of Commons Standing Committee on the Environment and Sustainable Development, *Biotechnology Regulation in Canada: A Matter of Public Confidence*, November 1996.

within government is unlikely to develop until some form of food, health, or environmental "crisis" emerges, at which time calls for organisational change will abound.

The fact remains that many different departments or agencies are involved on any given biotech issue. At the same time, departmental mandates do not necessarily reflect the horizontal nature of biotech issues. Biotech challenges a system that was not designed to reward individuals or institutions that oversee horizontal initiatives. In a system where 'my Minister, my mandate, my budget' continues to be the chorus, there is a built-in disincentive to design effective, joint policy responses. A report by the UK Cabinet Office on 'joining up' reaffirms this difficulty, noting that senior management must define crosscutting outcomes which are government-wide priorities. Addressing crosscutting issues presents a problem to policy-makers, for it requires that policy be made around shared goals, rather than around organisational structures, mandates or functions. Joining up is not just about common approaches to crosscutting issues; it also means better co-ordination among policy makers in the same departments, by linking with service deliverers and those who implement policy. Hence, the report argues that effective governance of a horizontal issue such as biotechnology is not so much an end in itself, as a process to be implemented where it adds value to policy and policy-making.⁴⁵

Many respondents raised doubts as to whether the organisational means exist to promote collaborative and horizontal decision-making. The lack of incentives for collaboration, to challenge institutional designs and develop linkages between departmental mandates, is a problem for government that is by no means new. However, the breadth of biotech issues and the speed of new developments are highlighting the lack of flexibility in the machinery of government to come to grips with such multi-faceted and complex issues. There is a need to establish cross-governmental priorities so that departments can better prioritise their work to further these long-term goals. We will return to this point when we discuss the challenge of leadership.

⁴⁵ United Kingdom, Cabinet Office (Strategic Policy Making Team), *Professional Policy Making for the Twenty First Century*, London, 1999.

C. Responding to the Challenges

This section looks at what governance capacity exists to respond to biotech challenges and to ensure democratic and effective management of the issues. There are four themes to explore. First, co-ordination and leadership: who – in or outside government – assumes a leadership role? Second, we will focus on the role of government, giving particular attention to institutional structures and legislative frameworks that are in place to manage biotechnology issues. Third, we will examine how well government is “joining up” with its partners and co-ordinating policy and responses. Finally, we will examine the critical issue of informing and engaging the public in order to ensure that government policies reflect society's values.

1. Co-ordination – the challenge of leadership

When one asks the question "Who is leading with respect to biotechnology?" the answers vary considerably. Some say that the scientific researchers whose discoveries allow for new applications and potential benefits are leading. Others say industry is, as it invests in the R&D and moves biotech applications from the laboratory to the marketplace. Still others refer to the courts, which have been asked to render some defining judgments with respect to patents and intellectual property. From within government, the question tends to elicit a "micro" focus, with the answer being one or another department of government. A debate ensues about whether Industry, Agriculture or Health should be “in the lead”.

We would argue that all of these different actors have a hand in providing leadership on the issues. As one interviewee said, no single player has a monopoly on protecting the public interest with respect to biotechnology and its applications. Industry, civil society, and government (including the legislative and executive branches, as well as the courts) must contribute to the political and social debates surrounding biotechnology.

From our perspective, government has a significant leadership onus when it comes to biotechnology. Its role is to ensure that differing perspectives are given voice and representation, and that an informed and balanced appraisal of new biotech applications occur through open discussion and debate. This entails a capacity to keep abreast of developments and a capacity to react credibly. It means creating and maintaining a space (or spaces) where issues of a broad and perhaps controversial nature can be discussed, while at the same time taking a leadership role when decisions need to be made in the public interest. In essence, it is the role of government to bring together “leaders” and to facilitate that dialogue in order to maximize the benefits and minimize the risks inherent in biotechnology.

There is little evidence that Ministers have engaged in discussions of the issues in a meaningful way. According to our interviews, the Biotechnology Ministerial Co-ordinating Committee has met only once since August 1998, when it was formed. While Parliament has been asked to participate in discussions on the Assisted Human Reproduction draft bill, very little meaningful debate has occurred on these issues over the many years since the publication of the Royal Commission on Reproductive Technologies report in 1993. This is in stark contrast to the European experience, where recent crises over genetically modified foods, contaminated blood and BSE have honed governments' sensitivity to science issues and the risks inherent in inaction.

Hence, while Canadian departments may well be doing an adequate job of keeping abreast of developments, leadership is seen as a major challenge. Indeed, while many individuals across departments were confident with their command of the issues and the challenges biotechnology presents to their sectors of activity, most point to a lack of senior level engagement on biotech issues. Interdepartmental co-ordination is seen as an increasingly heavy burden. Being proactive in contacting other players, from within and outside government, is a time consuming affair for which there is little or no recognition from senior management. Many respondents repeated that senior management needs to be more engaged, particularly at the Deputy Minister level, on policy issues surrounding biotech. Although policy committees of Assistant and Associate Deputies have tackled some of the issues at hand, involvement of Deputies is seen as crucial to advance the file.

In many of our discussions with officials, they noted the difficulty of getting interdepartmental groups to rise above the question: "What's in it for my group, or my department?" Indeed, in government-wide initiatives, when departments are called upon to contribute their own resources, staff and time, they are considered as having a strong tendency to fail. As one respondent noted, at the end of the day, it was still "your minister, your budget, and your agenda." Unless there were new resources to draw upon or definitive direction from Ministers and Deputies, most people did not believe departments would address the issues from the broader perspective of good government.

Many respondents questioned whether one department should have a mandate to lead government's activities in biotechnology. The choice of a lead is clearly the key issue, with little agreement on who that should be. Although many admit that having a champion raises the likelihood that an initiative will be carried through, some expressed reservations about the fact that Industry Canada is often in the lead role. Similarly, some argued that the Canadian Biotechnology Secretariat should be relocated to another department or institution. Industry Canada's promotional mandate was seen as problematic when it comes to maintaining credibility with the public. Others felt that Health Canada's preoccupation with safety and the potential costs to the healthcare system could overwhelm other aspects of the file. In contrast, some argued that the health benefits from biotech will be a principal driver for public acceptance of the new technology and that Health Canada should be in the lead.

In terms of facilitating senior discussions on these issues, some raised the possibility of a central agency assuming a lead role. The above raises real questions about the need for a new mechanism to overcome the focus on individual mandates and facilitate government-wide priorities and planning exercise on biotech issues. Should a central agency be mandated to take the lead on policy-making and stewardship of biotech issues? Are the costs of managing the file horizontally outweighed by the benefits? We return to this issue in the next section where we discuss the role of the Canadian Biotechnology Secretariat.

2. Government's Role

Institutional mechanisms

In 1983, the federal government implemented a National Biotechnology Strategy. The strategy was designed to promote industrial development. Industry Canada played a lead role, while the NRC concentrated on fostering research and development activities, and Health Canada and Agriculture and Agri-Food Canada focused on regulatory and promotional aspects. In 1997, a

renewal process was initiated and overseen by Industry Canada. Stakeholder consultations were part of this process. The exercise resulted in the establishment in 1998 of the Canadian Biotechnology Strategy (CBS), in which nine federal departments and agencies are partners: Agriculture & Agri-Food Canada, the Canadian Food Inspection Agency, Environment Canada, Fisheries and Oceans Canada, Foreign Affairs and International Trade, Health Canada, Industry Canada, Natural Resources Canada and the National Research Council.

The Canadian Biotechnology Strategy seeks to promote balance between industry development and social and ethical concerns. The vision outlined in the CBS is to "enhance the quality of life of Canadians in terms of health, safety, the environment, and social and economic development by positioning Canada as a responsible world leader on biotechnology". The document outlines nine goals that emerged from the consultative process, ranging from ensuring an effective science base and making strategic investments in R&D to positioning Canada as an ethical and social world leader in the development, commercialisation, sale and use of biotech products and services. The goals also include improved public awareness and understanding of biotech through open and transparent dialogue. The strategy sets out key themes and possible actions to be considered for implementation. It does not, however, outline a government-wide strategic action plan with well-defined cross-departmental objectives.

One of the strategy's key objectives was realised in 1999, with the creation of an independent expert advisory body, the Canadian Biotechnology Advisory Committee (CBAC). CBAC has a mandate to provide independent advice to government with a special emphasis on engaging Canadians. The strategy also established co-ordination mechanisms within the federal government. For instance, the Biotechnology Ministerial Co-ordinating Committee was put in place to oversee the implementation of the strategy, and to address issues that cut across the mandates of federal departments and agencies. The Ministerial committee also serves to provide direction to, and receive advice from, CBAC. It comprises seven federal ministers whose portfolios most closely touch on biotechnology. The Ministerial Committee's work is supported by an eight-member Co-ordinating Committee of Biotechnology Deputy Ministers and Agency Heads, as well as a nine-member co-ordinating committee of Assistant Deputy Ministers. The Canadian Biotechnology Secretariat, headed by an Executive Director, provides assistance to the Advisory Committee and co-ordinates the work of the aforementioned committees.

As noted, an important element of CBAC's mandate is to raise public awareness and engage Canadians in a dialogue concerning issues raised by the development and use of biotechnology. CBAC is still in early days. It has held two major cross-country consultations. Its first major product was the interim report published in August 2001: *Improving the Regulation of GM Foods and Other Novel Foods in Canada*. This is the first real test of the Committee, whose consultations met with considerable controversy as several stakeholders boycotted the discussions, citing concerns about the legitimacy of the process. Nevertheless, the Committee is accepting comments from the public until January 2002. The CBAC's final recommendations on the regulation and labelling of transgenic food will be a good litmus test of the advisory committee's ability to combine what they hear from the public with their own scientific expertise and insights and translate this into advice for government. Indeed, the government's response to the report on GM food will be an important test of the effectiveness and legitimacy of the young advisory body.

Other countries' experience with expert advisory committees demonstrates this point. The real test for an advisory body is the incorporation of its advice into government policy. Many countries have established bodies that are issue-specific, with a mandate to provide independent advice to the political leadership. France has a formal advisory framework in place: the National Advisory Committee on Ethics in Health Sciences is an independent and interdisciplinary body. In the United Kingdom, the Human Genetics Commission was created to provide Ministers with advice on developments in genetics, and how these will affect people and the delivery of health care. The European Union recently struck a Temporary Committee on human genetics and other new medical technologies, to provide it with political direction. The Norwegian Biotechnology Advisory Board helps review applications for the release of genetically modified organisms.

In the aftermath of the BSE (bovine spongiform encephalopathy) crisis in the UK, an inquiry was struck that drew firm conclusions about the use of scientific advisory committees. The report concluded that advisory bodies should be given a specific mandate, with clearly defined roles and expectations. The report also said that the work of issue-specific committees should be supported by the related departments, to ensure multi-way channels of communication.⁴⁶ This raises some interesting questions about the breadth of the current mandate of the CBAC, and whether issue-specific advisory committees such as those in place in Europe would constitute a more effective means of gathering independent advice. In our view, the most obvious drawback to the Inquiry's recommendation is that it risks a compartmentalised approach to the issues and analysis, reinforcing the very stovepipes within government that we have identified as damaging to the management of biotech issues.

Another important "institutional mechanism" with respect to biotechnology is the Canadian Biotechnology Secretariat. The Secretariat's role is to promote the integration of advice and strategies over a range of biotech issues and sectors. This group is responsible for co-ordinating the development and implementation of the Canadian Biotechnology Strategy, as well as providing advice on policy, communications and other issues. As we stated earlier, no single department has assumed a broad co-ordinating function when it comes to biotech. Instead, we found that much hope was placed in the Secretariat to do so. Many felt this is a natural fit for the Secretariat, given its mandate to support CBAC and the various other co-ordinating committees on biotech.

Many of the people we interviewed spoke of the Secretariat's unrealised potential with respect to the government-wide co-ordination function. There is a perception that the Secretariat has shifted its focus towards supporting the Advisory Committee and away from its co-ordinating responsibilities. Some respondents suggested this was due to the government focus on the "innovation agenda", which until recently dominated many interdepartmental discussions. This, they argued, left little time for Assistant Deputy Minister (ADM) level (and above) discussions regarding priority setting with respect to biotechnology. We are not in a position to judge this shift in focus, but would note that the ministerial committee has met only once in three years. Regardless of the cause, the lack of senior-level engagement (Deputy Ministers and Ministers) has created an apparent policy vacuum where important crosscutting issues in the biotech arena are not receiving top level consideration.

⁴⁶ United Kingdom, House of Commons, The BSE Inquiry Report, Volume 1, "Lessons to be Learned", 2000.

Engaging senior level management and Ministers is never an easy task, given the competing demands for their time. Several interlocutors spoke of the importance of a “champion” in moving an issue forward in government, noting that the strong personal determination of a Minister (and/or Deputy) can be critical in developing the required momentum. Since the Biotechnology Ministerial Co-ordinating Committee has not engaged, one idea raised was a theme day at Cabinet were a series of briefings on key biotech issues might spark the beginning of serious Ministerial dialogue.

Legislative framework

From a legislative perspective, Canada has only poorly developed 'rules of the game' on several key biotech issues. It is a well understood fact that every major piece of Canadian legislation that pertains to biotech needs to be updated, including the Food & Drug Act, the Fisheries Act, and the Patent Act. In April 2001 a draft bill on Assisted Human Reproductive Technology was referred to the House of Commons Standing Committee on Health. An earlier attempt at legislation in this area failed, having languished on the Order Paper prior to the 1997 election.

As mentioned earlier, the Royal Commission on Assisted Human Reproduction issued its report (and its 293 recommendations) in 1993. In 1995, a working group on embryonic research reported to Health Canada. A voluntary moratorium on (certain) reproductive techniques and genetics was introduced in 1995, but many now recognise that it is openly flouted. One expert we interviewed stated that the only significant guidelines governing research on stem cells are those which regulate research on human subjects. There are no guidelines specific to embryonic stem cells or genetics. Is it fair to suggest, as some have, that Canada is the 'Far West' of biotech research? Are current laws and regulations adequate to govern research and genetic manipulation?⁴⁷

Outdated and non-existent legislation creates a questionable environment for business investment in Canada. Uncertainty is often a significant deterrent to new investment, and opportunities may well be lost to other countries with clear and up-to-date legislative and regulatory frameworks. Furthermore, the absence of clear guidelines in challenging areas such as stem cell research and genetics will increasingly result in reference to the courts for resolution where the legislator has not fulfilled its responsibility to society.

3. Co-operation

Throughout the study, we have stressed the importance of organisations linking out and sharing knowledge with partners: private sector companies, universities, governments. Cuts in public funding have affected the science capacity of universities and government departments, creating a need for partnerships with other organisations to maintain their research programs. In some cases, this had led to departments linking with universities and non-governmental organisations (NGOs), with the Canadian Foundation for Innovation, Natural Sciences and Engineering Research Council of Canada (NSERC), and other granting agencies. Third parties are increasingly involved with government in joint priority setting. These activities present new opportunities and promote synergies. But, as many respondents pointed out, such arrangements, if not properly managed, are fraught with risk. As we discussed in the earlier section concerning the pace of

⁴⁷ Judith Lachapelle, "Le Canada, Far West des biotechs?", *Le Devoir*, 21 December 2001.

change and scientific capacity in government, a careful balance must be struck between the benefits of outreach and co-operative work arrangements and the risk of a real (or perceived) loss of independence in the government's stewardship role.

Genome Canada is an interesting model of co-operation. As stated earlier, its creation was led by the co-ordinated efforts of several departments and individuals. It relies on a governance model that is flexible enough to bring together the federal and provincial governments, universities and other institutions to facilitate broad partnerships and embrace a myriad of partners. Interestingly, Dr. Henry Friesen, Chairman of Genome Canada, suggests that "horizontality" in this case worked to the benefit of this initiative because seven different departments attached sufficient priority to Genome Canada to co-sign the Memorandum to Cabinet requesting the funds to translate the vision into a reality.

Lessons could be learned from this high level of inter-organisational collaboration. Critical to the success of this initiative was the early recognition that no one entity or organisation would achieve success by working in isolation in the area of genomic research. "The Genome Canada vision focused on building on existing excellence...Its innovation was its inclusiveness."⁴⁸

International co-operation is another important element of the government's biotechnology strategy. The Science and Technology Division (STD) within the Department of Foreign Affairs and International Trade (DFAIT) provides insights on how to enhance linkages between Canada and international counterparts. The directorate seeks to exploit interactions between Canadian firms, and foreign firms and researchers. Similarly, an interdepartmental working group composed of science & technology representatives from Canada's science-based departments and agencies was struck to focus STD's program and the role of Canada's science counsellors located abroad. While the emphasis is on R&D collaboration and technology financing, these activities facilitate interdepartmental and international co-ordination on science and technology issues.

4. An informed and engaged public: the missing link

Throughout this study, we heard the argument that good governance of biotechnology requires the integration of sound policy analysis, clear communication efforts, and an informed public voice. This section will consider the challenge of informing and involving Canadians on biotechnology issues. We will argue that public perceptions can be overwhelming, and constitute a powerful motivator to establish effective communication strategies.

Public awareness and education

The ability of government, industry and scientists to generate, share and disseminate information has direct consequences for the degree of public awareness and the nature of ensuing discussions with citizens. During our interviews, a level of dissatisfaction emerged with respect to how government has informed Canadians on biotechnology issues so far. As one individual stated, Canadians have not been well served by the information they have received to-date from government. In many cases, the information does not present a balanced assessment of the

⁴⁸ Christine Nymark, *A Model for Governance in the 21st Century: Establishing Genome Canada*, Industry Canada, March 2001

benefits and risks; biotechnology is more often than not portrayed in a positive light, with the emphasis on presumed benefits.⁴⁹

As noted earlier, public opinion data demonstrates that there is an information divide: citizens have little grasp of the science behind biotechnology, or of the institutions and mechanisms that exist to manage biotechnologies. Some interviewees argued that the main focus of a public information program should be government's stewardship role. However, if citizens are not better equipped to deal with the basic science issues behind the regulation and management of biotech, clarifying the question of stewardship will do little to improve the public's confidence and trust. Indeed, raising public awareness is much more than assuring Canadians that the government is doing a good job "protecting them". It is about providing ordinary Canadians with the means to actively and confidently debate some of these important topics.

Several of our interlocutors argued for more science education at every level, starting in elementary schools. Others expressed pessimism about the government's ability to take on such a task. As Powell and Leiss write, "Carrying the refrain that 'knowing more about science is good for you' is a bit like trying to convince children to eat the vegetables they dislike".⁵⁰ This is an issue which should interest provincial governments, and which invites federal-provincial collaboration.

A very useful reference in this regard is the UK Report by the House of Lords Committee on Science & Technology.⁵¹ The report questions public awareness of science issues, citing the role of education and the media. They caution against the use of the phrase 'public understanding of science', as it sets up a line of division whereby society is presumed to be at a natural disadvantage over science and, therefore, always the more ignorant. Notably, the report stresses that promotion of science literacy is not a task that belongs exclusively to government. Scientists too have a professional responsibility to promote public understanding of science. They suggest linking a portion of grants to the dissemination of findings as a way to enhance dialogue and information exchange. Hence, civic-minded scientists would help to make science more accessible, and to cultivate a science literate citizenry. At the same time, it would secure scientists' 'license to practice'. The best way to ensure that the public and the experts understand one another is to explain the scientific issues, and to allow people to make their views known.⁵²

While the media could play an important role in educating the public on science developments, this will depend on the quality and independence of science journalism in Canada. The danger of misinformation is significant. On stem cell research, extensive media coverage has been devoted to embryo-related breakthroughs (the political issue) while the silence has been striking with respect to non-embryo developments. A major breakthrough for diabetes using adult stem cells has received virtually no press coverage.⁵³ There is also a very real issue regarding the level of understanding among journalists of biotechnology developments and their implications. The

⁴⁹ Many participants at the IOG symposium on the Life Sciences (January, 2001) outlined their concerns over the tenor of information which is conveyed to citizens on biotechnology. The furor caused by an insert produced by the Canadian Food Inspection Agency in *Canadian Living Magazine* in 2000 serves to illustrate the tenuous balancing act between providing information and promoting biotechnology.

⁵⁰ Douglas Powell & William Leiss, *Mad Cows and Mother's Milk: The Perils of Poor Risk Communication*, Montreal & Kingston: McGill-Queen's University Press, 1997, p. 222.

⁵¹ United Kingdom, House of Lords Select Committee on Science and Technology, *Op. cit.*

⁵² The BSE Inquiry Report, *Op. cit.*, Volume 15, "Government and Public Administration", p. 44.

⁵³ Kathryn Jean Lopez, "Truth and Stem Cells", *National Review*, 12 June 2001.

initiative underway at the National Judicial Institute to organise learning events for Canadian justices makes immense sense from our perspective, and could well be a model for educating journalists and the media more generally.

Public consultation

Some of our respondents are troubled by the government's approach to public consultation on biotechnology. Many suggest the federal government needs to be more proactive in its consultation exercises and less reliant on polling data. As mentioned earlier, CBAC's stakeholder consultation on GM foods was boycotted by a number of NGOs, who contended that the exercise did not provide sufficient time to consult with their members and report back to the Committee. Several interlocutors argued that the government has not yet shown real commitment to the application of sound consultative practices. There is genuine concern that the resources allocated to consult with the public are insufficient. In addition, there is a sense that the Canadian Biotechnology Secretariat should make better use of the consultative expertise that already exists within the government, and of interdepartmental advice on these issues.

There is no doubt that raising public awareness and engaging Canadians in a meaningful dialogue on these issues is a real challenge. Having said that, we would argue that public engagement in biotech issues is no more challenging than engagement on many other public policy issues. The caveats are the same: engagement is most meaningful when those sitting at the table are committed to it and can demonstrate that people's views count (link to outcomes). Yet the reality of public consultation is that it often happens in an *ad hoc* manner and is disconnected from institutional and decision-making contexts. There is little assurance that feedback will be acted upon in a demonstrable way. Similarly, an exercise that is framed to neutralise the issues is likely to invite hostility. On this point, the House of Lords reported that "Policy makers will find it hard to win public support on any issue with a science component, unless the public's attitudes and values are recognised, respected and weighed along with the scientific and other factors."⁵⁴

There exists a wide range of techniques designed to ensure successful citizen engagement, and we make no attempt to review them all in this study. Norway has experimented successfully with an approach called "consensus conferences." In Canada, the University of Calgary's citizens' conferences were largely imported from the European model.⁵⁵ The lessons drawn from these conferences, which are designed to enhance a group of citizens' knowledge of complex societal and scientific issues, are positive. These conferences also provide public access to scientists and decision-makers. A study for the OECD concerning the use of consensus conferences on GM foods reminds us that these citizens' forums should be used to supplement democratic decision-making processes, not in lieu of.⁵⁶ Although such conferences are expensive, the expanded use of information technologies creates new possibilities.

⁵⁴ United Kingdom, House of Lords Select Committee on Science and Technology, Op. cit., §5.

⁵⁵ Sponsored by the University of Calgary, the National Institute of Nutrition, and the Food Biotechnology Communications Network, this conference was the first of its kind in Canada to be held (1999). The purpose of the conference was to bring together different and opposing views on biotechnology, combining education with dialogue and discussion between a citizen's panel and an expert scientific panel.

⁵⁶ Alf J. Mørkrid, *Strengthening Government-Citizen Connections: Using Consensus Conferences on GM Food in Norway*, Paris: OECD (PUMA), 2001.

Another recent example of effective public consultation comes from Quebec. In June 2001, a project was launched to establish a database of Quebecers' genetic information. Baptised "Cart@gène", the program seeks to establish a baseline of information to track the prevalence of certain diseases and link these with socio-economic circumstances, habits, etc. Réseau de médecine génétique appliquée organised a public workshop to present the project's methodology and to respond to concerns. The project raises a number of controversial questions, such as the confidentiality of the data, and the potential for its use or misuse by pharmaceutical firms. Building on lessons drawn from similar projects (in Iceland, Estonia, Newfoundland), the workshop touched on issues of privacy, accessibility and the benefits of the research. The workshop also generated considerable press coverage in Quebec, which helped to disseminate knowledge of the study and understanding of its limitations and uses.

Other possible techniques include deliberative polling, citizen juries and electronic town meetings. From our interviews, it was not apparent that government has considered the full range of available options and techniques. Furthermore, it was not clear that a "master plan" exists to act upon one of the guiding principles of the Canadian Biotechnology Strategy, which commits the government to "engaging Canadians in open, ongoing, transparent dialogue"⁵⁷ We will return to this issue in Section D - Conclusions and Next Steps.

The importance of perception – Crises waiting to happen?

Powell and Leiss⁵⁸ have demonstrated the challenges posed by crises in confidence. Inconsistent messaging on government's part can serve to further devalue trust in government activities. And if a crisis becomes "mediatised", the coverage can fill the risk perception gap. There are useful lessons to be drawn here from the BSE crises in France and Europe. In both cases, public perceptions were in conflict with scientific assessment and government statements. The report by the French Senate's inquiry into food safety concluded that the crisis had been "over-mediatised" (sur-médiatisée). This, in turn, led to sensationalism and the broadcast of wrong or unclear information. The commission concluded that ineffective risk communication was at the root of the problem: "La Commission estime [...] que l'impact de cette médiatisation parfois excessive n'aurait jamais atteint cette ampleur si une crise de confiance ne s'était pas instaurée entre les consommateurs et les pouvoirs publics."⁵⁹ A mass of contradictory information on the BSE epidemic contributed to weaken the government's credibility in the eyes of the public. Similarly, the BSE Inquiry concluded that the Government, by attempting to appear to have all the answers in a situation of uncertainty, and where the public did not possess sufficient knowledge to fully grasp the issues, only exacerbated the crisis in confidence.

We need only think about the crisis that erupted in the UK over genetically modified crops to realise the potential pitfalls of a cavalier approach to a government's stewardship role in biotechnology. At the beginning of this year, two large supermarket chains in Britain said they would no longer sell the meat or milk of any animal fed with genetically modified (GM) soya or maize.⁶⁰ Later in June, a series of citizen-led campaigns destroyed six GM oil seed rape fields. This

⁵⁷ Industry Canada, *The 1998 Canadian Biotechnology Strategy: An Ongoing Renewal Process*, Ottawa, 1998, p.8

⁵⁸ As quoted in Douglas Powell & William Leiss, *Op. cit.*, p. 21.

⁵⁹ Gérard Deriot & Jean Bizet, *Farines: l'alimentation animale au coeur de la sécurité sanitaire*, Rapport de la commission d'enquête sur les farines animales, France: Sénat., (rapport no 312), 2001.
<http://www.senat.fr/commission/enquete/Farinesanimales/Index.html>.

⁶⁰ John Vidal, "Supermarket giants pave the way for 'GM-Free Britain,'" *The Guardian*, 27 January, 2001

action will likely delay approval for commercialisation of the GM crop for another year. The graphic image of seven protesters dressed as grim reapers became a symbol of the popular anti-GM voice in the UK. One protester in Scotland summed up these events as "an inevitable consequence of the government ignoring local democracy."⁶¹

There are lessons to be learned here for Canada. It is our view that the current status of public awareness of government's stewardship roles and of basic science issues may well be a crisis waiting to happen. It is an extremely demanding risk management scenario. As Leiss argues, good risk management lies somewhere between scientific assessment and public perception of risk. And perceptions, misconstrued or not, can take the day. "People are not reasoning machines, they are fearing machines and, when there's a scare, politicians and scientists better tremble."⁶² Citizens who do not understand the basis for risk assessment and management decisions will fill the risk perception vacuum from other sources. If a public scare flares up on some issue related to biotech in Canada, fanned by advocacy groups and fed by misinformation, it is not difficult to imagine the confusion that could result under present circumstances. Who would lead the communications initiative on behalf of government? How would issues related to departmental 'turf' be handled? What department or agency would be perceived as objective and credible on scientific issues in the face of media controversy?

Risk management & communication

Risk management literature underlines the importance of integrating policy, science and communication functions. Managing risk has three components:

- Risk assessment: involves scientific analysis of probable severity of consequences.
- Risk management: involves analysis and actions to reduce, avoid, hedge, and insure against risks, or against a decision not to act.
- Risk communication: a purposeful exchange of information about risks, also communication that seeks to change public attitudes and knowledge.⁶³

These tasks (assessment, management, and communication) require a proper dialogue between scientists and policy-makers. The dangers inherent in failures in linking up become more worrisome when we add the communication component into the equation. Effective communication on a policy issue presumes there is a pre-existing consensus on the scope of the issues, their consequences, and available options. When the processes are disjointed, communication becomes reactive; that is, a reaction to events, or to media and other third-party accounts. Leiss and Powell give many examples of this sort of communication intervention.⁶⁴

Throughout our interviews, most participants agreed that government is not sufficiently proactive in its communications efforts, nor is it properly equipped to carry out the "crisis management" communications function. In sum, many people felt that policy and communications have failed to keep up with each other. This disconnect opens the door to the possibility that, should a crisis arise, even a good policy would be misunderstood by the public. Furthermore, new policies could

⁶¹ John Vidal, "GM trials face delay as crops destroyed," *The Guardian*, 9 June, 2001

⁶² Stephen Strauss, cited in Powell & Leiss, *Op. cit.*, p. 21.

⁶³ G. Bruce Doern & Ted Reed (Eds.), *Op. cit.* p. 12.

⁶⁴ Douglas Powell & William Leiss, *Op. cit.*

be dictated by a communications strategy established on the fly, rather than from good analysis, with anticipated outcomes and communications options. Such a distinction is important, as reactive policy formulation and communications does not necessarily allay public concerns or fears. Instead, it may lead to greater instability and mistrust. (We need only think of the caricaturised scene of British Cabinet ministers eating beef burgers at the height of the BSE crisis – in a desperate move to affirm the safety of British beef – to realise that ill-conceived communications responses to events have a lingering impact on a government's credibility.) These are the main conclusions drawn by French and British commissions examining the fall-out from the BSE crises: an absence of anticipation, information that was contained within departments rather than acted upon government-wide, and inconsistent messaging by government officials and spokespersons.

It is a fact that adoption of new biotechnology products and services creates new risks. It is therefore highly likely that there will ultimately be some sort of crisis, whether it is in the areas of food safety, health or the environment. Since there is no such thing as zero risk, sufficient thinking must go into the answer to the inevitable question "Yes or no, Minister: is it safe?" The lessons as to what constitutes an effective answer are well established: a government must resist any temptation to appear to have all the answers. Sir Robert May, former Chief Science Advisor to the UK government, clearly stated that a government must overcome the temptation to control information so that a single position may be articulated. Instead, if a situation is fraught with uncertainty and risk, these should be openly and clearly disclosed.⁶⁵ The public must be trusted to respond rationally to openness, which as a cornerstone of democratic governance, is necessarily key to the governance of biotechnology.

⁶⁵ The BSE Inquiry Report, Op. cit., Volume 1, p. 265.

D. Conclusions & Next Steps

1. Linking in, linking out, linking up

The sequencing of the human genome, announced with great fanfare in February 2001, represents a virtual information revolution in genetics. Dr. Eric Lander, from the Whitehead Institute at MIT, compares this discovery to the organisation in 1869 by Dmitri Mendeleev of the elements into the periodic table. Establishing the human periodic table opens new possibilities to explain fascinating things about the human species, including the tremendous diversity of the human race and its susceptibilities to disease. The potential in biotechnology for progress in the fields of health and environmental protection (to name but two) is enormous, yet at the same time worrying. Recent scientific discoveries, which could substantially improve the quality of life of citizens around the world, may also transform the ways in which society conceives the notions of health, life and family.

The challenge posed by new technologies and new applications concerns society's response to them, and by implication the government's stewardship role in protecting the public interest – herein lie the questions of public policy and our interest. The governance of biotechnology in Canada constitutes a fascinating case study of our capacity to manage broad, horizontal files. As we have attempted to highlight in this study, it is the characteristics of biotechnology that pose a new challenge to government and society. We have touched upon the speed of change and developments, the transformative potential of some of the changes and the controversial nature of many discoveries and applications. Recent debates on embryonic stem cell research – benefits, risks, meaning, consequence – clearly show that the issues are far from resolved. The challenge for government is to give Canadians the tools, following Michèle S. Jean's words, to "avoid the worst and benefit from the best".⁶⁶

There is increasing cross-fertilisation between disciplines and markets involved with biotechnology and its applications. We have argued in this paper that no one player can afford to go it alone in this field. All of our interviewees were adamant on this point – successful research and development, commercialisation, regulation and governance of biotechnology depend on all players linking together to capture the benefits for Canadians. The ability to do this depends on public support, which in turn relies on trust and credibility. Credibility is fostered by open and transparent processes of discovery and decision-making. A rift in this continuum will lead to different – and less than optimal – outcomes. Such a rift would prejudice consumers' trust of scientists and government, impede industry's success and profitability, and ultimately result in lost opportunity for Canadians.

We have argued that government, citizens, industry and civil society must link together to ensure that each participant has sufficient voice, representation and accountability in policy-making and decision-making processes on biotechnology. By linking together, we create the mechanisms and regimes whereby all players can be confident that everyone plays by similar rules, and that these rules privilege openness and the public interest. Effective regulatory oversight, successful public information campaigns, public trust in the science, applications and regulatory systems rely on co-operative and integrated approaches. Hence the need for:

⁶⁶ Comments made to the Institute on Governance Life Sciences Symposium, January 2001.

Linking in: within government departments, within industry, universities and citizen groups.

Linking out: between government departments, collaborative joint efforts with all levels of governments, industry, universities, other countries, NGOs and civil society.

Linking up: to ensure connection of this policy file with the political leadership and the voting public.

Our overarching conclusion, which pervades all of the main findings summarised below, is that joining up, or linking in, out and up, is essential to Canada's ability to benefit from all that biotechnology will offer us in the years ahead. This is in fact the essence of the "horizontality" challenge that faces government in many key policy files on its current economic and social agenda. While recognizing the complexity of the issue, outlined below are our main observations and conclusions from this study which we put forward in the hope of advancing the thinking on these important issues.

2. The hierarchy of policy challenges

Throughout this study, we heard examples of government reaching out to the private sector, other governments and universities – Genome Canada being a good case in point. We learned of international agreements to co-operate and share research findings. We heard of an innovative approach to the introduction of draft legislation on assisted human reproductive technology (which was referred to Committee before first reading) which should allow for greater Parliamentary input in the government's final bill. However, our study has also identified fairly significant shortcomings in our governance capacity with respect to biotechnology. We have grouped our conclusions and concerns into four clusters of issues: 1) science in government; 2) stewardship and credibility; 3) leadership; 4) informing and engaging the public. Where appropriate, we identify areas where future action and/or research may be warranted.

On the issue of science in government, two main concerns emerge from our analysis. First, there are doubts as to the sufficiency of government science capacity. Program Review cutbacks in the 1990s reduced science capacity, and the latter has not recovered. Considering the increasing prevalence of science issues in policy processes, and the myriad of science issues raised by biotechnology, science capacity is considered a key question. To adequately address this broad question, one must separate the pure science function from the policy science function in government. Insufficient capacity casts doubt on the government's ability to fully acquit itself of its responsibilities. University-based research faces similar challenges: the prevalence of this type of working arrangement with the private sector, in view of the absence of clear guidelines on how to ensure science and academic freedom are not breached, is a source of concern.

Second, we encountered many persons who believe there is a communication gap between science and policy advisors within the federal government. We repeatedly heard that scientists and policy analysts do not speak the same language and engage each other only when necessary. The inability of scientists and policy advisors to engage at early stages on any given issue, particularly given the rapid pace of change, is an obstacle to implementing co-ordinated (and timely) approaches to new developments in biotechnology. The effectiveness of the science-policy interface is of fundamental importance, as it will impact the quality and clarity of information and

advice received by policy-makers on science-based issues. This interface issue will become increasingly problematic for Deputy Ministers (who need integrated strategic advice for Ministers) as the pace of scientific change quickens.

On government science, there are several areas in which future work is possible. First, we suggest that more analysis is warranted with respect to the adequacy of resources dedicated to science in government, focusing on international comparisons with other G-8 countries. Further analysis on the merits of a national science organisation would also be warranted in light of the United Kingdom's efforts to bolster the legitimacy of its National Science Advisor, as well as the influence the position carries in respect to fostering and protecting science capacity within the British government.

Difficulties in the policy and science to interface lead us to conclude that some sort of professional development activities may be warranted to give science and policy advisors the tools required to communicate effectively. The objective would be to ensure that scientists could communicate complex ideas in a language that their non-scientific counterparts can grasp, and can also accept the constraints and limitations of the policy processes to which they contribute advice. Overall, new tools are required to better integrate science into policy advice.

The adequacy of science in government underlies all other policy questions that might arise. If the assessment or understanding of the fundamental science issues is incorrect, debates concerning credibility, leadership and choice of policy instruments will be of little relevance. It may be helpful to borrow Maslow's hierarchy of needs, and think in terms of a hierarchy of challenges, where science capacity is the foundation of the pyramid (see Figure 1).

Building upon this foundation, we see a second cluster of issues surrounding the stewardship of biotechnology and the credibility of all players involved. Our analysis suggests that credibility is derived from a clear separation of roles, openness and transparency in risk assessment and decision-making, and sound legislative and regulatory frameworks. In terms of the first two issues, questions persist about the nature of the balance within government between promotion and regulation of biotechnology and the ability of government to maintain a strong stewardship role in protecting the public interest. Issues of credibility also exist for ethicists, universities and academics who need to ensure their independence is not compromised by their associations with, or reliance on funding from, the private sector.

As for the adequacy of our legislative and regulatory frameworks, we noted that Canada is considered in some circles as the Far West of biotechnology due to its limited progress with respect to new legislation. Although attention has been brought to the deficiencies in patent law, in private-public partnerships in research, and with respect to the governance of research on human subjects, little progress has been visible. The fact that many such mechanisms are ineffective or simply absent in Canada is cause for concern. Inadequate legislative frameworks put at risk the economic potential of biotech development as firms gravitate towards countries with the best intellectual property protection and the most developed (least uncertain) regulatory framework.

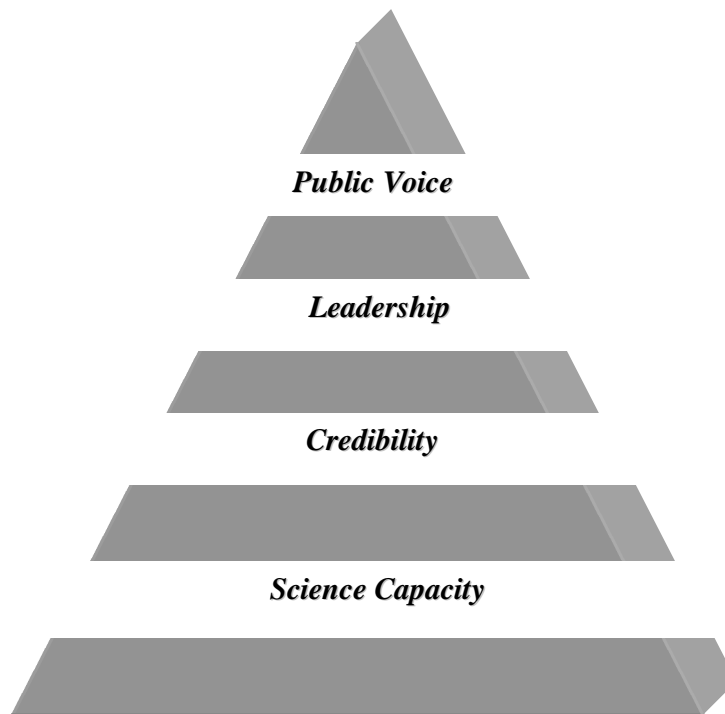


Figure 1: Hierarchy of Policy Challenges

In addition to these economic considerations, our study raised concerns about the slow pace of progress on difficult ethical issues such as those surrounding assisted human reproduction technology and the implications the legislative void has for our judicial system. We believe progress on all of these fronts is of paramount importance and would argue that increased public participation in the discussions (which we raise below) would stimulate more legislative action on the part of government.

The next "layer" of issues relates to governance and the challenge of leadership. It has been argued that all players in the field of biotechnology – R&D companies, clinicians, academics, government, and the informed public – have a role in leadership. As one interviewee stated, no single player in the area of biotechnology and public policy has a monopoly on protecting the public interest. Judges are being asked to render decisions before societal views can be determined and appropriate policy responses developed. Scientists will increasingly be called upon to explain their publicly funded research, and engage interested Canadians in a dialogue about their work. Government has a significant burden with respect to leadership in this area. It must remain abreast of scientific developments, create and maintain a space where issues of concern to Canadians can be raised and discussed, while at the same time being ready to take the difficult decisions when necessary.

At a time when the political leadership in Europe is fully engaged in the debates surrounding new applications of biotechnology, Canadian Members of Parliament and Ministers of Cabinet seem somewhat distant from the issues. Mechanisms, such as the Biotechnology Ministerial Coordinating Committee, can facilitate dialogue among Ministers, but they are not well used. Some of our interlocutors suggest this is due to "calm waters"; to date, Canada has been spared any major food, health, or environmental crisis tied to biotechnology. They suggest that steady Ministerial engagement will likely not occur until the issues become magnified and of sufficient

public concern. We also heard similar concerns expressed with regard to the involvement of Deputy Ministers in shaping the overall direction of the government's policy stance in the area of biotechnology.

In order to set joint priorities, and to establish shared goals, our interlocutors were unified in their assessment of the need for greater senior management/Ministerial involvement. This observation is not unique to biotechnology; for significant progress to occur on any policy file in government, strong political leadership is required. Since the Biotechnology Ministerial Co-ordinating Committee has not engaged, alternative venues for Ministerial discussion, such as a biotech theme day at Cabinet, warrant further consideration. This might allow the government to further develop the Canadian Biotechnology Strategy, which currently sets out main themes and possible actions but stops short of outlining a government-wide action plan with defined cross-departmental objectives.

On the governance of biotechnology, it is clear to us that the horizontal nature of the challenges stands in stark contrast to the institutions that exist to deal with them. The incredible scope of biotechnology puts pressure on conventional government institutions and practices. We have noted an apparent shift in the role of the Canadian Biotechnology Secretariat away from its co-ordinating role towards supporting the Advisory Committee, and highlighted the lack of senior level engagement on important crosscutting issues in the biotech arena. The lack of incentives for collaboration is a real obstacle to Canada's development potential. Some have suggested that the Privy Council Office might play a facilitating role in bringing together the key players and developing the kind of action plan referenced above for Ministerial consideration. Others, however, are doubtful that PCO would be able to discharge this role effectively and do not think that such a move, particularly if unaccompanied by other measures, would be an adequate response to biotech challenges.

Perhaps we need to think "outside the box". It may be necessary to step back from our more traditional responses to the challenges of horizontality, and to contemplate more imaginative ways of collaborating.

Finally, this report has raised questions about the role of advisory bodies in assisting government to understand the more complex aspects of biotechnology. We have noted that several European countries have chosen to establish issue-specific advisory bodies, such as the Advisory Committee on Ethics in Health (France) and the Human Genetics Commission (UK). There is clearly a trade-off between the benefits of a broad based mandate (such as CBAC) which encourages a more holistic assessment of biotech issues, and the risks that such a broad based mandate will cause a committee to lose focus and momentum. Our study suggests that a review of the mandate of the Canadian Biotechnology Advisory Committee would be useful at this point, to assess whether its capacity to contribute to policy can be enhanced, and whether issue-specific advisory committees would be a helpful complement to its work.

In terms of further research in this area, a sustained examination of biotech federalism in Canada, the roles and responsibilities of the federal and provincial governments, could identify areas in which co-ordination could be improved and those where conflicts are possible. Research into how the co-ordination of biotechnology within government has been dealt with in other countries

could be useful. New Zealand and Australia have implemented a joint regulatory regime to oversee food safety, which could reveal helpful lessons for Canada.

The fourth and final cluster of issues involves informing and engaging citizens, thereby ensuring adequate "public voice" in the decision-making process. Government's success in promoting a balance between securing the benefits of biotechnology and protecting citizens from risks depends in large part on how successful we are in educating citizens (on benefits, risks, costs) and providing ordinary Canadians with the means to actively and confidently debate some of these important topics.

There are important lessons to be learned from the European experience with the BSE epidemic and GM foods. The fact that citizens in Canada have little knowledge about biotechnology and its processes, as well as the regimes that currently exist to regulate and govern these discoveries, is in our view a crisis waiting to happen. Gaps in public knowledge can easily become gaps in perception and withdrawal of citizens' support for adoption of new biotech applications. If citizens are to reject certain applications of biotech, let it be on the basis of informed judgment. This "missing link" is an extremely demanding risk management scenario.

We must ensure that the tools exist to head off such crises in a responsible and legitimate way. Clearly, education and awareness of the issues is needed. Information – detailing the benefits as well as the risks associated with new biotech applications – must be freely and openly available. Many of our interlocutors questioned the adequacy of the government's communication effort to-date, noting that the level of resources available for communications has been on the decline while the magnitude of the task is on the increase. We would argue that more efforts are required to build effective inter-departmental communication teams on these issues, combining resources and expertise wherever possible.

We note that the education challenge extends not only out to citizens but up to senior management and Ministers within government. We have discussed the importance of ensuring that Ministers and Deputies are kept abreast of new developments in this dynamic area of science, where change is so rapid and often accompanied by significant societal implications. We believe that lessons could be learned from the UK in this regard, where the UK Cabinet Office suggested a "senior government network" in which Ministers and other senior policy makers meet for focused seminars on cross-cutting and top-level management issues.

We have also argued that the education challenge extends out to the media, and suggested that learning initiatives such as those offered by the National Judicial Institute (for Canadian judges) would be worth replicating in this context. Given the scope of public education, an informed media will be a key ingredient in any sustained public outreach campaign. Government, scientists, and industry representatives will need to reach citizens through every possible medium – Internet, radio, television, and the print media. We have also raised concerns about the adequacy of science education in schools, and questioned whether consideration should be given to a joint federal-provincial initiative to increase the science literacy of the next generation of Canadians.

With adequate information available to them, Canadians will be in a position to engage government in a constructive dialogue on the policy options under consideration. While polling reveals a certain lack of interest in being personally involved in the discussions at this point in

time, we would argue that this perspective could change very easily in the face of a food, health or environmental crisis.

We have noted that raising public awareness and engaging Canadians in a meaningful dialogue on these issues is a real challenge, but we have also argued that public engagement in biotech issues is no more challenging than engagement on many other public policy issues. The caveats are the same: engagement is most meaningful when those sitting at the table are committed to it, and can demonstrate that citizens' views count (link to outcomes). We believe that a more thorough examination of the full range of options and techniques for successful citizen engagement is warranted. To be successful in this area will require a creative and open-minded approach, since true engagement is achieved not simply through the organisation of a single event, but through a conscious policy decision to find ways to bring a stronger public voice to bear on decision-making on an ongoing basis.

The final question we pose for consideration is whether or not a crisis in the area of biotechnology and its applications is inevitable. To those who believe Canada will continue on its current path, and remain free of any serious kind of crisis surrounding a biotech issue, our current governance mechanisms may appear sufficient. We would argue that some form of "crisis" is inevitable given the rapid pace of change and the stress that speed places on the institutions of government. As a result, we have highlighted four areas where attention will need to be focused to ensure Canada is ready for whatever the future in biotechnology might bring: strengthening science capacity in government, stewardship and credibility, leadership, and citizen education and engagement.

Annex A: Methodology

In preparing this study, we conducted a thorough review of relevant literature (see bibliography) and interviewed 32 people; some two-thirds of the interviewees were federal managers in the areas of policy and science, hailing from the following departments and agencies: Life Sciences Branch, Industry Canada; Privy Council Office; Science and Policy Planning Division, Agriculture and Agri-Food Canada; Biodiversity and Genetic Resources, Agriculture and Agri-Food Canada; Health Policy and Communications Branch, Health Canada; Environmental Biotechnology Applications; Environment Canada; Economic and Policy Analysis, Fisheries and Oceans Canada; Science and Technology Branch, National Defence; Office of Biotechnology, Canadian Food Inspection Agency; Science and Technology Division, Department of Foreign Affairs and International Trade; Office of Biotechnology and Science, Food Directorate, Health Canada. We also interviewed managers directly involved in the Canadian Biotechnology Strategy.

The remaining one-third of interviewees were leading academics or industry experts in the life sciences field: University of Ottawa; Centre for Advancement of Medicine; Ethics and Policy Issues Centre, Carleton University; Canadian Centre for Management Development; Université de Montréal; Genome Canada; Department of Premier and Cabinet, Australia.

This scoping study was also submitted to review by a cross-section of senior government officials, and external peers with scientific standing. We would like, in particular, to acknowledge the high degree of co-operation we enjoyed from public servants across government, whose willingness to share their insights and time with us revealed a deep-seated interest in their own work and how it might relate to this broader study.

Our discussions focussed on the following issues: 1. the potential inherent in biotechnologies; 2. the pace of scientific and industrial developments and the associated challenges posed to government and industry; 3. an assessment of government's proactivity on the issues; 4. mechanisms used to ensure effective co-ordination; 5. the state of public communication and involvement. We also discussed exemplary practices and lessons from other governments and countries. Interviewees were asked to reveal the most significant challenge they face in dealing with these scientific advances and to identify areas in which they require more expertise or knowledge.

Annex B: Canadian Biotechnology Industry

British Columbia, Ontario and Quebec are the major hubs of Canadian biotech. Within these provinces, the cities of Montreal, Toronto, Ottawa, Kitchener-Waterloo and Vancouver support significant university research and hospital networks. Manitoba and Saskatchewan, although investing less than the three main provinces, play a strong role in ag-biotech. Tables A and B provide additional information on the Canadian biotechnology industry.⁶⁷

Table A: Canadian Biotechnology Industry at a Glance (1999 figures)

Province	No. of firms (% of total)	Biotechnology revenues (\$ 000, 000) (% of total)
British Columbia	71 (20)	138 (7)
Ontario	111 (31)	635 (33)
Quebec	107 (30)	554 (28)
Other provinces	69 (19)	621 (32)

Table B: Canadian Biotechnology R&D Expenditures

Province	R&D in 1999 (\$000,000) (% of total)	R&D in 2002 (forecast) (\$000,000) (% of total)
British Columbia	131 (16)	251 (17)
Ontario	223 (27)	378 (25)
Quebec	337 (40)	641 (43)
Other provinces	136 (17)	211 (14)

⁶⁷ Statistics Canada, Biotechnology Use and Development - 1999, Ottawa, 2001.

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