Canadian Biotechnology
Advisory Committee

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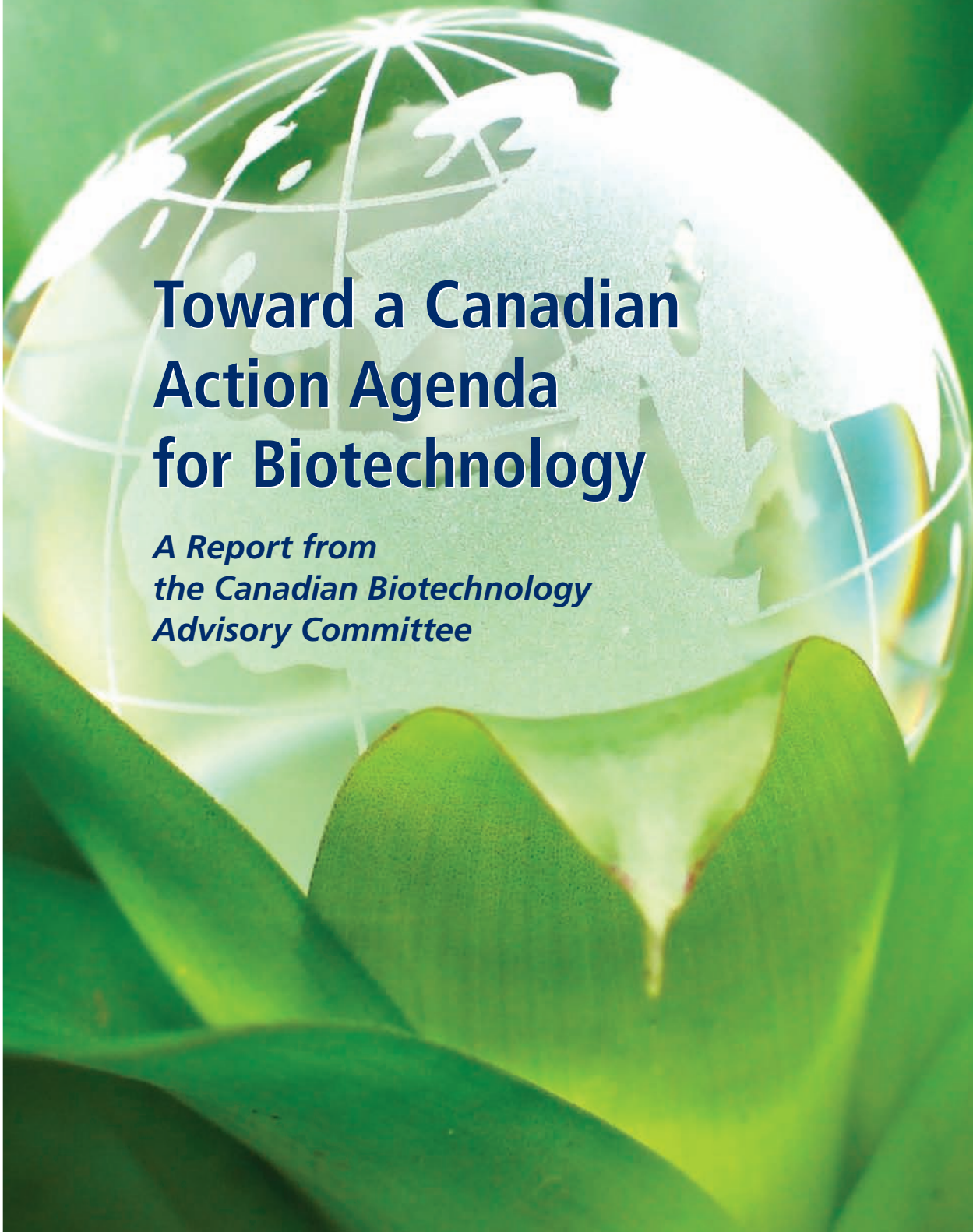

Toward a Canadian Action Agenda for Biotechnology

A Report from the Canadian Biotechnology Advisory Committee

September 2006

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Canadian Biotechnology Advisory Committee

Committee Mandate

The Canadian Biotechnology Advisory Committee (CBAC) is a body of external experts established in September 1999 by the Government of Canada. CBAC provides comprehensive advice on current policy issues associated with the ethical, social, regulatory, economic, scientific, environmental and health aspects of biotechnology. It is also tasked with providing Canadians with easy-to-understand information on biotechnology issues, and opportunities for them to voice their views on these matters.

CBAC provides its advice through the Biotechnology Ministerial Coordinating Committee (BMCC), which is comprised of the federal ministers of Industry, Agriculture and Agri-food, Health, Environment, Fisheries and Oceans, Natural Resources and International Trade. CBAC's reports are available to the general public.

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* CBAC members are appointed by the Biotechnology Ministerial Coordinating Committee on the basis of individual attributes, not as representatives of particular interests. All CBAC members serve on a volunteer basis.

The CBAC Chair receives a per diem (to a maximum number of days of work per year) commensurate with the demands of the position.

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Message from the Chair

This spring, the Canadian Biotechnology Advisory Committee (CBAC) undertook an examination of the Canadian Biotechnology Strategy (CBS), in the context of developments in Canada and globally since the Strategy's inception, as a basis for providing advice to the Government of Canada on a national policy framework going forward.

CBAC developed a background paper on experiences with and related to the CBS and developments in biotechnology generally for use in discussions in expert roundtables and citizen focus groups and conducted a study of biotechnology strategies in other countries. The discussions were forthright, animated, and constructive in illuminating important policy areas and governance considerations that bear upon the responsibilities of governments in guiding the development and adoption of biotechnologies.

We have taken this input, along with the wealth of information gathered by CBAC over the years, into account in preparing this report which outlines the key elements of a national action agenda for biotechnology to replace the current CBS. We view this as a basis for a process of further work and broad consultation necessary to elaborate specific objectives, strategic actions and desired outcomes needed to constitute a fully developed "Canadian Action Agenda for Biotechnology". We acknowledge and thank the contributions of all those who have contributed to the consultations and deliberations upon which this report is based, and hope that they will participate in the further analysis, dialogue and reflection this follow-on process would entail.

Arnold Naimark

Executive Summary

In updating its earlier advice on renewal of the Canadian Biotechnology Strategy (CBS), the Canadian Biotechnology Advisory Committee (CBAC) undertook a round of recent consultations and deliberations from which the following key messages emerged:

- A national policy should be developed that integrates the economic, environmental, ethical, legal, regulatory, scientific and social considerations pertaining to biotechnology and its implications for Canadian society and its long-term interests. Whether designed to stand on its own or complement a general Science & Technology strategy, the policy should recognize the mandates and interests of all relevant government departments and agencies.
- Failure to elaborate and sustain an integrative approach through the implementation of concomitant strategic action plans will compromise Canada's ability to access, apply and harness the power of biotechnology to best serve the public's social and economic interests.
- Canada's current biotechnology strategy is eight years old. While much has happened—in science, commercial development, public acceptance and governance—both domestically and globally over this period of time, Canada must do more to realize the full potential of biotechnology and enhance the country's international standing in this field.
- Canada should replace its current biotechnology strategy with a strategic action agenda that meets current and emerging pressing needs. Canada should move from generalities to specifics and from processes to strategic actions and measurable outcomes.
- A national action agenda requires strong and committed government leadership, meaningful engagement of stakeholders and members of the public, and adequate resources to implement strategic actions and achieve objectives.
- Canadians support biotechnological innovations that significantly—and tangibly—benefit human and animal health, the environment and the economy. However, Canadians also insist that due consideration be given to alternatives that provide equal or greater benefits. The public wants safe, sustainable biotechnological applications and user-friendly, balanced information about biotechnology and the activities of government related to it.

Taking into account these messages and the wealth of knowledge gathered by CBAC over the years, CBAC proposes a national action agenda consisting of the following key elements:

- an overarching goal for federal biotechnology policy;
- the identification of strategic actions in the areas of knowledge generation, development and commercialization, regulation, technology adoption, global outreach, informing and engaging Canadians; and
- a focus on linking strategic actions and directions to outcomes.

Introduction

In the last twenty years, biotechnology has become an increasingly important engine for economic growth and social development. It is now widely held that the transformative power of biotechnology will change forever the way we do things and interact with each other and the natural world, and that it will concomitantly change the culture of societies.

Since the launch of the Canadian Biotechnology Strategy (CBS) in 1998, the pace of biotechnological innovation has accelerated considerably. New biotechnological frontiers have opened up in health, food production,

environment protection, and sustainable industrial development. In the coming years, it is expected that the boundaries of biotechnological innovation will be pushed even further, challenging old categories around which we have constructed our worldview and our institutions—"agriculture vs. medicine", "natural vs. artificial", "animal vs. human", "machine vs. living being", "person vs. object", etc.

Governments around the world are re-energizing their commitment to the use of biotechnology for economic and social objectives through strategic planning, increased investment and policy reforms and/or adjustments. Evidence of accelerating international investments in biotechnology and increased government involvement is compelling and includes the following:

- China has tripled its spending on research and development over the last five years, and India plans to increase the size of its biotechnology sector five-fold over the next five years.
- In 2005, the U.K. government announced it will invest $1.6 billion in biotechnology over three years as part of its $16.3 billion science investment strategy, The British Prime Minister said in 2000 that he intends to make the U.K. the European hub for biotechnology; in 2003, the Biotechnology and Innovation Growth Team (BIGT) was created to guide U.K.'s efforts in realizing this goal.
- Ireland is now a global competitor for biotechnology R&D investment from multinational companies and leading research institutions. This is the result of government policies that have transformed Ireland's academic institutions into world-class science and technology centres by encouraging strong business and academic collaborations. In 2005, the Irish government approved funding for the National Institute for Bioprocessing Research and Training, a state of the art, industry-focused institute aimed at giving Ireland a competitive advantage in serving the global biopharmaceutical industry.
- The number of U.S. states developing biotechnology strategies has increased from 14 to 40 since 2004.

The dynamic nature of biotechnology development requires an equally dynamic, comprehensive, and relevant Canadian agenda for action that takes advantage of opportunities and addresses issues raised by biotechnology in a timely manner. Launched in 1998, the CBS is now eight years old. Much has happened over that period. Important institutional developments have occurred[1] and heightened attention has been directed toward increasing Canada's commercialization performance generally[2] and redressing its weakening international position in biotechnology more specifically.[3]

While progress has been made on several fronts, many of the issues that stimulated the development of the CBS remain as foci for necessary policy development going forward (see Appendix 2). That there is much unfinished business to attend to is not surprising given the pace of techno-scientific development, the rising expectations of the public, the accentuation of the global competitive economic pressure described above, and the differing perspectives of the developed and developing countries on particular applications of biotechnology. All of these elements combine to demonstrate the continuing need for a national focus on biotechnology. The question is not therefore whether to maintain a national policy on

[1] E.g. establishment of the Canadian Institutes of Health Research, Genome Canada, the Networks of Centres of Excellence Program, Canada Research Chairs, and the Canada Foundation for Innovation. Also worth mentioning are the nascent Canadian Academies of Science and the appointment of a National Science Advisor.

[2] Final Report of the Expert Panel on Commercialization: *People and Excellence: The Heart of Successful Commercialization*, 2006.

[3] *Biotechnology in Canada, A Technology Platform for Growth*. The Conference Board of Canada, Ottawa, December 2005; *OECD Biotechnology Statistics 2006*. Organisation for Economic Co-operation and Development, Paris, 2006; National Research Council of Canada. *Looking Forward: S&T for the 21st Century*. Foresight Consolidation Report, NRC Renewal Project. (August 2005). www.nrc-cnrc.gc.ca/aboutUs/ren/nrc-foresight_18_e.html

biotechnology, but what new approaches should be followed to enhance the contribution of biotechnology to Canadian society.

In considering this question, one must keep in mind that, in an overall quantitative sense, Canada is a relatively modest player in the world of biotechnology. Most new biotechnology-based products and processes used in Canada originate elsewhere. These two realities require a policy that embraces both the development of biotechnological products and processes in Canada and the implications of the use of such products and processes for Canadian society whatever their origins.

In December 2004, CBAC[4] called upon the Government of Canada to renew and revise the CBS. CBAC invited government to move forward with the elaboration of a renewed biotechnology strategy that would more fully embrace the economic, environmental, ethical, legal, regulatory, scientific, social and health-related aspects of this technology, and be linked to the programs and responsibilities of all relevant government departments and agencies (see Appendix 2, Document 1). No progress has been made to date toward achieving that goal.

Without clarity of direction and policy coherence, Canada's ability to capture the benefits of biotechnology in a socially responsible fashion will be weakened. What is more, Canada will find itself relegated to a reactive, rather than proactive, role in policy development. CBAC has therefore decided to provide updated advice to government on charting the course forward.

As an integral part of this exercise, CBAC reviewed the biotechnology strategies of other countries and consulted expert stakeholders and informed citizens through roundtable discussions and focus groups held in Montreal, Halifax and Vancouver. This report summarizes CBAC's findings and identifies a new framework for developing a national biotechnology policy.

The Global Landscape of Biotechnology Strategies

Many countries have developed biotechnology strategies in order to stimulate and support the development and commercialization of biotechnology applications to create new high-value employment, generate health and environmental benefits, and provide a strong basis for continued social and economic growth. These strategies range from statements of overarching goals and principles to detailed action plans.[5] Not unexpectedly, biotechnology strategies around the world have many similarities. Typically, they all:

- maintain a strong science base,
- ensure effective regulation of biotechnology research and applications,
- provide balanced information to the public on biotechnology issues, and
- support the growth and competitiveness of the biotechnology industry.

With respect to this last commonality, many strategies focus on creating a supportive business environment for biotechnology firms by addressing the factors that influence innovative capacity; namely: university systems, university-industry technology transfers, intellectual property laws, the pool of scientists and engineers, and availability of venture capital funding.

[4] The Canadian Biotechnology Advisory Committee is the Government of Canada's independent, external advisory committee on biotechnology. Established in 1998 as a cornerstone of the Canadian Biotechnology Strategy, CBAC has advised Ministers on a variety of subjects including the regulatory system for genetically modified foods, patenting of higher life forms, biotechnology and health innovation, the impact of intellectual property protection for human genetic materials on health care, and the role of biotechnology in advancing Canada's sustainable development objectives.

[5] A more detailed description of selected biotechnology strategies is presented in Appendix 1.

An example of a comprehensive strategy is the European Commission's 2002 Strategy on Life Sciences and Biotechnology. It provides a roadmap to 2010 consisting of both policy directions and a 30-point plan for implementation. The Commission reports annually on progress and is scheduled to update the strategy in 2007 in order to keep it as an evergreen policy document. Such precise action plans, however, are the exception rather than the rule. Governments often set out broad objectives and state the mechanisms that they intend to use to achieve them. They rarely go so far as to identify measurable results. While many countries have formulated and adopted national biotechnology strategies, some, such as the U.K. and the U.S., have chosen to address strategic issues through individual departments, notably departments of health and agriculture. In several countries, sub-national jurisdictions (states, provinces) have developed biotechnology strategies.

Almost all countries have external advisory bodies to provide guidance and advice to their respective governments. While some use existing structures (for example, the U.K.'s Nuffield Council on Bioethics advises the government on ethical and social issues in biotechnology), others establish biotechnology-specific bodies such as the U.S. Advisory Committee on Biotechnology and 21st Century Agriculture. Australia is the closest to the Canadian model, with a Commonwealth Biotechnology Ministerial Council and an Australian Biotechnology Advisory Council to provide Ministers with advice on policy issues.

The role of government is most often expressed as that of a facilitator—supporting research, encouraging investment, fostering global linkages, and providing an effective and efficient regulatory regime.

Views from Experts and Involved Citizens

Developments in biotechnology and related technologies are driving a new wave of innovation and creating opportunities for entrepreneurial businesses—large and small—to acquire competitive advantage. At the same time, biotechnology continues to pose important societal questions about benefits and risks, unintended consequences and long-term impacts, the participation of developing countries, social value considerations, global governance and stewardship.

With a view to exploring better ways of addressing this tension, CBAC hosted, from April to June 2006 in Montreal, Halifax and Vancouver, a series of expert roundtables and citizen focus groups under the theme of *"Canada's Biotechnology Strategy: Charting the Path Forward"*. The roundtables were attended by members of the biotechnology community including academia, research centres, industry, financial support agencies, and environmental and other interested organizations. The citizen focus groups were attended by members of the public referred to as "involved" Canadians.[6] The purpose of the roundtables and focus groups was to provide input into the formulation of CBAC's advice to the Government of Canada on revisions required to the existing CBS, taking into account the context of current challenges and opportunities.

Participants in the expert roundtables were provided with a background document (see Appendix 2) that described:

- the origins, vision, principles, goals and themes for action of the current CBS, as well as instruments for its promulgation;
- federal programs and initiatives related to regulation, innovation, public information and engagement, and consideration of the

[6] Involved Canadians are those individuals (27 percent of Canadians) who actively engage in public policy and public affairs issues. From a demographic and geographic perspective, they look a lot like other Canadians. However, their behaviours (e.g. writing letters to the editor, joining community groups, speaking publicly about topics they know) reveal a level of attention to issues that differs markedly from the norm. They tend to be influential in forming the opinions held by the remaining 63 percent of the population. The views they hold can act as a bellwether for public opinion. (Source: Decima Research)

social, legal and ethical aspects of biotechnology applications;

- the challenges in the governance and implementation of the CBS and the unfinished business with respect to Canada's performance in each of the foregoing areas; and
- CBAC's December 2004 Statement on the Canadian Biotechnology Strategy and the evolving role of the CBAC.

A shorter version of the background document, written in more accessible language, was provided to participants in the citizen focus groups (Appendix 3).

The expert roundtables revealed several common viewpoints:[7]

- A renewed and revised strategy should take the form of a national action plan for biotechnology. A national overarching goal and objectives must be accompanied by a clear action plan that assigns accountabilities and measures outcomes.
- We are still in the early phases of biotechnology development. Therefore, strong and sustained leadership by the Government of Canada through a national action plan for biotechnology is required to ensure Canadians benefit from the global surge of new knowledge, products and services in this field. Still, all stakeholders should have a role to play in biotechnology in Canada and should be involved in the pursuit of the action plan.
- Four interrelated priority directions need consideration and action: engaging Canadians in informed dialogue; ensuring ethical frameworks are developed and used to consider all the implications of biotechnology applications in our society; stewardship of biotechnology; and advancing the biotechnology sector.
- The design of public engagement activities, and the language used in both the strategy and further dialogue, must allow the Canadian public to engage in meaningful and considered debate.
- The federal government has a responsibility to provide neutral and balanced information to Canadians so that the public is aware of biotechnology developments and their risks and benefits, and can participate in a well-informed manner in shaping public policy.
- Technology and competitiveness should not be the ultimate drivers of a national action plan for biotechnology. Commercial success must not come at the expense of considering the social and ethical dimensions of biotechnology development. The latter should guide the development and diffusion of biotechnology.
- Proper stewardship of biotechnology requires a strong regulatory environment to ensure the health and safety of Canadians and their environment. A supportive and responsive regulatory system is also part of the foundation of a strong biotechnology sector.
- Better support for the development of the biotechnology sector must be provided. Commercialization is a particular challenge in Canada and must be addressed.
- Engendering trust and credibility in any strategy or national action plan depends on successful implementation and achievement of goals and objectives.

The citizen focus group discussions reinforced the strong statements from the roundtables and emphasized the need for:[8]

- more information about the uses of biotechnologies. Health applications of biotechnology were viewed as critically important both to individuals and an effective health care system;
- government to have a sustained source of independent advice;

[7] For a more detailed account of the discussions that took place during the expert roundtables, see the Summary of What We Heard in Appendix 4.
[8] For a more detailed account of the discussions that took place during the citizen focus groups, see the Summary of What We Heard in Appendix 4.

- studies on the long-term impacts of biotechnologies on health and the environment;
- greater transparency in Canada's regulatory system (although it is generally viewed positively with respect to its risk assessment role for new products) and timely assessment of the impact of biotechnologies once they have been in use for a period of time (an element which is seen to be a gap in the current approach);
- informed choice where biotechnologies challenge social or cultural norms; and
- government investment to ensure Canadians benefit from biotechnology.

In both roundtables and citizen focus groups, some participants expressed concern that technology push will overshadow the careful and deliberate assessment of need, alternatives, and who benefits and who decides.

A Canadian Action Agenda for Biotechnology

It has sometimes been suggested that a specific policy focus on biotechnology is not necessary and that any issues related to biotechnology could be addressed as part of a general Science & Technology Strategy. While such a strategy is highly desirable, there are many reasons to maintain a specific biotechnology focus that could, if advantageous, be a complement to a Science & Technology Strategy. Most importantly, only a specific focus on biotechnology will provide the continuous monitoring required for assessing progress on biotechnology developments and their economic, health, environmental and other impacts on Canadian society and the nuanced guidance required in a complex and rapidly evolving field.

Canada's initial biotechnology strategy (1983) was essentially an industrial development strategy under the aegis of the Department of Industry. The objective was to nurture the growth of Canada's biotechnology industry and to facilitate associated human resource development. The 1983 strategy was broadened in 1998 to include the interests and involvement of several other key departments of the federal government and to recognize the social and ethical implications of biotechnology's diffusion in society. The 1998 CBS provided a general framework and set of broad unifying goals around which federal departments and their partners could design programs. It instituted a federal coordinating mechanism and it established an independent external advisory body.

The broad goals in the current national strategy were important guidance setting statements and have served that purpose well. However, moving fully into the biotechnology century, while addressing its challenges, will require something different. Broad goals are no longer sufficient. Precise objectives which are measurable, serve to mobilize partners, assist in defining clear roles and accountabilities, and allow direct evaluation of a renewed strategy's impacts, are required. Moreover, in dealing with biotechnology, governments are faced with issues that cut across departmental lines, sectors, institutions, political jurisdictions and public constituencies. Governments are also required to reconcile competing interests, multiple streams of advice and diverse calls for government action. A Canadian action agenda for biotechnology will have to address these challenges. They are not unique to biotechnology, but are particularly intense in this field because of the public's concerns about the use of technologies that affect health and environment.

CBAC proposes the following outline of the key elements of a Canadian Action Agenda for Biotechnology (CAAB).

Goal

The CAAB should aim to achieve a state in which Canadians realize proven benefits of safe and sustainable applications of biotechnology—in health, the environment and the economy—to an extent that ranks Canada at the forefront of leading industrialized nations. This goal should be pursued within an ethical framework based on shared values, including Canada's commitment to global development.

Areas of Strategic Action

To achieve the aforementioned overarching goal, Canada will have to enhance its capacity to:

- generate knowledge that may lead to the development and use of novel biotechnology-based goods, services, processes and practices (including those that bear upon regulatory functions);
- develop, produce and market new goods, services, processes and practices;
- regulate the introduction of goods and services into the marketplace and monitor their long-term effects;
- adopt the use of biotechnology applications in enhancing and protecting human and animal health, the environment and the economy;
- contribute to and benefit from international linkages; and
- inform and engage Canadians in comprehensive and sustained discussions about the implications of applications of biotechnology.

Desired Outcomes

Objectives should be established under each action area. The objectives should be expressed in terms of desirable quantifiable outcomes and accompanied by specifically targeted action plans. The linkage of strategic action areas to outcomes is illustrated in the grid below.

It is clear that the full development of such a national action agenda, and the filling in of the blank cells in the grid, will require a significant amount of work and broad consultation, both within and outside of government. CBAC does not see the completed grid as static, but as a continuously evolving action agenda.

AREAS OF STRATEGIC ACTION	OBJECTIVES	ACTIONS	SUCCESS MEASURES
New knowledge generation			
Development and commercialization			
Regulation			
Technology adoption			
Global outreach			
Informing and engaging Canadians			

Roles and Responsibilities of the Federal Government

Acting alone or in collaboration with other jurisdictions and sectors, the federal government plays three critical roles related to the stewardship of the national interest in biotechnology:

- fostering social and economic development;
- protecting the health and welfare of the land and its people; and
- representing Canada's interest in international forums.

The federal government should act as an effective catalyst of biotechnology developments and a visible convener of stakeholders — including provinces and territories, business and industry, academia and civil society organizations — by virtue of its pre-eminent role in areas such as regulation, intellectual property protection and international trade relationships. The federal government has the unique responsibility of ensuring Canada is equipped to operate and compete in the global biotechnology arena. In fulfilling this responsibility, its actions must be both strategic and tactical; that is, they should be aimed at both long- and short-term goals.

Effective federal instruments to implement the national action plan will be critical to its success. The 1998 CBS included three mechanisms for implementing the strategy:

- coordinating committees comprised of senior officials from seven departments;
- a CBS secretariat to support and facilitate interdepartmental activities such as educational workshops, symposia and conferences for civil servants; and
- the CBAC, an external body, supported by the secretariat, and composed of experts from various fields, to advise the government, through the ministerial coordinating committee, on all aspects of biotechnology.

The secretariat and CBAC have been active and productive in their respective roles within the limitation of resources. During our consultations, however, we heard considerable concern about the government's lack of responsiveness to reports issued by CBAC, and the relatively modest financial support for the horizontal aspects of the strategy. Comments by the Office of the Auditor General were interpreted as indicating a lack of significant engagement of the ministerial and deputy-ministerial coordinating committees with the biotechnology file, and were taken as representing a lack of commitment to the strategy.

Earlier in this report we indicated that Canada needs both a general Science & Technology Strategy and strategies for specific technological sectors such as biotechnology for attending to their particular societal implications. By the same token, the oversight of biotechnology requires specific mechanisms. Oversight of action plans involving several departments and agencies of government is always a challenge. In our consultations, it was stressed that, in meeting this challenge, the structure of the oversight mechanism is important but not paramount. The most important success factor is the strength of commitment and engagement of ministerial and departmental leadership. While there are a variety of alternative structures that could be designed to provide oversight, the current structure is, in our view, as good as any provided there is appropriate articulation of the mandates, specific responsibilities and *modus operandi* of the senior coordinating committees coupled with a strong and visible commitment to the implementation of the action plan for biotechnology.

Both the roundtables and the citizen focus groups stressed the importance of external advisory mechanisms and, in particular, of bodies such as CBAC that maintain a sustained overview of developments in dynamically evolving fields of technology, whose composition reflect all major sectors of society, that engage the general public and other political jurisdictions, that are independent of government but actively engaged in ongoing

dialogue with various departments and agencies to ensure relevance of their advice to public policy, and that strive to provide balanced and well-founded analyses of important issues.

Conclusion

Our consultations and deliberations indicated a general consensus that the case for maintaining a specific federal policy focus on biotechnology is compelling. Stated briefly, the transformative power of biotechnology requires a specific national policy focus on this dynamic field (either standing on its own or as a complement to a more general Science & Technology Strategy) that integrates the economic, environmental, ethical, legal, regulatory, scientific and social considerations related to biotechnology and that cuts across the mandates and interests of all relevant government departments and agencies.

However, experience to date and emerging developments indicate that a new framework is required to replace the current Canadian Biotechnology Strategy—a framework that reflects the need to move from generalities to specifics and from processes to strategic actions and measurable outcomes. The development of such a framework would help ensure Canada is well-equipped to develop and adopt biotechnological innovations in a socially responsible manner, measure progress and allocate resources effectively, meet its international responsibilities, and provide clarity to the public on the national vision and objectives related to the realization of the social and economic benefits of biotechnology. Accordingly, we recommend that the federal government develop a Canadian Action Agenda for Biotechnology (CAAB) and propose an outline of the key elements upon which the CAAB should be based:

- an overarching goal for federal biotechnology policy;
- identification of areas for strategic action, namely, knowledge generation, development and commercialization, regulation, technology adoption, global outreach, informing and engaging Canadians; and,
- a focus on linking strategic actions and directions to outcomes.

The full development of such a national action agenda will require a significant amount of work and broad consultation. CBAC stands ready to assist in the design and implementation of this process.

Appendix 1

The Global Landscape of Biotechnology Strategies

This table summarizes the characteristics of seven biotechnology strategies (as extracted from websites in 2006) selected to illustrate international approaches. This material is not a distillation of all government policy statements on biotechnology (of which there are many).

AUSTRALIA ***National Biotechnology Strategy (2000; renewed in 2003)*** Source: www.biotechnology.gov.au			
DESCRIPTION	**POLICY GOALS / OBJECTIVES**	**GOVERNANCE**	**ACHIEVEMENTS (EXAMPLES)**
A national strategy to "safeguard human health and protect the environment while capturing the benefits of biotechnology to drive economic and community benefits." Six themes: • Biotechnology in the Community • Ensuring Effective Regulation • Biotechnology in the Economy • Biotechnology in the Global Market • Resources • Momentum and Coordination Australian Biotechnology Strategy for Agriculture, Food and Fibre (2003) is part of the National Strategy.	Safeguard human health and the environment Provide information about biotechnology, potential risks and benefits of applications, ethical issues they raise, and ensure public confidence in way risks are assessed and managed Internationally competitive environment for investment and enterprise development Infrastructure — investments in R&D, world-class education in biotechnology, and conserving genetic resources	Oversight — Commonwealth Biotechnology Ministerial Council Strategy management — Biotechnology Australia Expert advice — Australian Biotechnology Advisory Committee Intergovernmental Relationship — Biotechnology Liaison Committee to provide national government, states and territories with forum for information sharing and policy development	Established Office of the Gene Technology Regulator National Intellectual Property Management Strategy Biotechnology Innovation Fund National Stem Cell Centre AusBiotech established to represent industry Increased public awareness Intergovernmental Agreement on Access to Australian biological resources

CANADA

Canadian Biotechnology Strategy (1998)

Source: www.biotech.gc.ca

DESCRIPTION	POLICY GOALS / OBJECTIVES	GOVERNANCE	ACHIEVEMENTS (EXAMPLES)
A federal strategy 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 in biotechnology." Three themes: • Effective stewardship in the areas of health, safety and the environment • Maximize social, economic and environmental benefits • Engage the public	Access to, confidence in and benefit from safe and effective biotechnology-based products and services Effective scientific base and strategic investments in R&D Position Canada as an ethically and socially responsible world leader Be sensitive to the needs of developing countries Improve public awareness and understanding of biotechnology through open and transparent communications and dialogue Solicit broadly-based advice to the government on biotechnology Promote awareness of, and maintain excellence in, Canada's regulatory system Support the development of a Canadian biotechnology human resources strategy Develop action plans with other stakeholders, including provincial and territorial governments, business, academia, consumer and other advocacy groups	Oversight — Biotechnology Ministerial Coordinating Committee Strategy management — Biotechnology Assistant Deputy Ministers Coordinating Committee Expert advice — Canadian Biotechnology Advisory Committee Coordination Support — Canadian Biotechnology Secretariat	Establishment of Genome Canada Canadian Regulatory Framework for Biotechnology Federal government Genomics Research Initiative Enhanced interdepartmental policy collaboration at federal level BioPortal for public information

CANADA *(continued)* ***Canadian Biotechnology Strategy (1998)*** Source: www.biotech.gc.ca			
DESCRIPTION	**POLICY GOALS / OBJECTIVES**	**GOVERNANCE**	**ACHIEVEMENTS (EXAMPLES)**
	Action themes: • Building public confidence and awareness, and communicating accurate, balanced, easy-to-understand information to Canadians • Further expanding Canada's R&D and science base to support Canadian competitiveness in biotechnology as well as the regulatory system • Regulating to protect health and the environment • Promoting the use of biotechnology for public health and safety • Modernizing Canada's intellectual property laws • Facilitating measures to help accelerate the application and commercialization of new technologies • Demonstrating responsible world leadership to improve market access and acceptance as well as stewardship in developed and developing countries • Developing human resources • Improving policy-relevant data collection and analysis • Building sector strategies and action plans		

EUROPEAN COMMISSION

Life Sciences and Biotechnology – A Strategy for Europe (2002)

Source: www.eurpoa.eu.int/eur-lex/en/com/cnc/2002/com2002_0027en01.pdf

DESCRIPTION	POLICY GOALS / OBJECTIVES	GOVERNANCE	ACHIEVEMENTS (EXAMPLES)
A European policy and 30-point action plan with annual reports on progress Mid-term policy review to be presented by European Commission in September 2006 Four themes: • Harvesting the potential • Governing life sciences and biotechnology • Responding to global challenges • Implementation and coherence	Competitiveness of European biotechnology Intellectual property protection Networking European biotechnology Funding research Confidence in science-based regulatory oversight	Oversight – European Commission according to five action areas: 1. Societal dialogue and scrutiny guiding development 2. Harmony with ethical values and societal goals 3. Informed choice 4. Science-based regulatory oversight 5. International obligations External Advice — European Group on Ethics in Science and New Technologies (renewed mandate 2005) Competitiveness in Biotechnology Advisory Group	Completion of reformed EU regulatory framework for Genetically Modified Organisms (GMOs) 20 percent increase in biotechnology/life sciences research under Framework Programme New financing instrument — "risk-sharing finance facility" Established network of member states on competitiveness — benchmarking European biotechnology policy Implemented Community Pharmaceutical Legislative Framework Biotechnology Patent Directive GMO Directive

INDIA

National Biotechnology Development Strategy (2005)

Source: www.dbtindia.nic.in/biotechstrategy/BiotechStrategy.pdf

DESCRIPTION	POLICY GOALS / OBJECTIVES	GOVERNANCE	ACHIEVEMENTS (EXAMPLES)
"Attaining new heights in biotechnology research, shaping biotechnology into a premier precision tool of the future for creation of wealth and ensuring social justice — especially for the welfare of the poor." Integrated 10-year roadmap for the development of biotechnology in India Provides 11 sectoral roadmaps Six themes: • Human Resource Development • Academic and Industry Needs • Infrastructure Development & Manufacturing • Promotion of Industry & Trade • Biotechnology Parks & Incubators • Regulatory Mechanisms • Public Communication & Participation	Increase scientific and technical human resources Create infrastructure for R&D uptake to scale up technologies Competitive environment for investment and innovation Establish bioparks or incubators in at least 10 states Establish scientifically rigorous, transparent, predictable and consistent regulatory system Build public awareness	Oversight — Department of Biotechnology, Ministry of Science and Technology	Too soon to assess

JAPAN

Biotechnology Strategy Guidelines (2002)

Source: www.jetro.go.jp/en/market/attract/biotechnology/policy.html

DESCRIPTION	POLICY GOALS / OBJECTIVES	GOVERNANCE	ACHIEVEMENTS (EXAMPLES)
"A national strategy including three strategies opening the way to vast improvements in three basic aspects of the human experience: our health, our food, our lifestyles." Overwhelming improvement in R&D Major strengthening of industrialization process Thorough permeation of public understanding	Japan has developed a detailed action plan including 200 specific actions in these areas: • Economic support for R&D • Improvement of application and approval procedures for new drugs and medical devices • Enhancement of research resources • Creating a market open to international companies	Oversight—Biotechnology Strategy Council chaired by Prime Minister and including leading ministers and eminent business and academic leaders	Technology Licensing Organizations established to facilitate transfer of research findings from universities to industry National Bioresource Project to develop one of the world's largest collections of bio-genetic resources by 2010

NEW ZEALAND

Biotechnology Strategy (2003)

Source: www.morst.govt.nz/documents/work/biotech.NZ-Biotech-Strategy.pdf

DESCRIPTION	POLICY GOALS / OBJECTIVES	GOVERNANCE	ACHIEVEMENTS (EXAMPLES)
"A foundation for development with care supporting the vision that New Zealand responsibly develops and applies our world-class biological knowledge, skills, innovation and technologies to benefit the wealth, health and environment of New Zealanders, now and in the future."	Build understanding about biotechnology and constructive engagement between people in the community and the biotechnology sector Grow New Zealand's biotechnology sector to enhance economic and community benefits Manage the development and introduction of new biotechnologies with a regulatory system that provides robust safeguards and allows innovation	Oversight—Government leadership provided by key ministers who oversee and support a balanced and integrated approach to biotechnology. Ministers convened by Minister of Research, Science and Technology	$10 million annually for basic research and proof-of-concept studies $6.8 million in new contracts with the New Economy Research Fund, focused on new and revised biotech research platforms New $4.8 million Pre-Seed Fund, of which a significant proportion is likely to have a biotechnology focus Partnership funds for biotechnology-based research consortia of around $5 million a year New biotech venture capital fund around which will have at least $15 million to invest with private sector partners $12 million for biotechnology development fund to support joint ventures between New Zealand and Australian companies $2.3 million to foster best practices in commercializing biotechnology research

SCOTLAND

Life Sciences Strategy: Achieving a Critical Mass—2020 Vision (2005)

Source: www.scotland.gov.uk/Resource/Doc/37428/0009610.pdf

DESCRIPTION	POLICY GOALS / OBJECTIVES	GOVERNANCE	ACHIEVEMENTS (EXAMPLES)
A national vision with themes and objectives for the next 3–5 years that lays out milestones, lead agencies, and target dates Initiated and driven by industry "A globally focused, sustainable life sciences sector built on a fully connected national strategy that exploits strengths in scientific excellence, financial services and innovative business models and that develops, retains and builds upon Scotland's talents." Themes: • The right people • The right resources • Focus • Collaboration	Increase the contribution by life sciences countries to the Scottish economy Be a more attractive place for life science graduates and experienced senior managers to work Increase the level of investment in life sciences, including attracting lead, expert investors into the country Attract added value foreign direct investment Promote and enhance academic success Demonstrate improved connectivity and collaboration among the stakeholders in the country	Oversight— Strategy is supported by the Scottish Executive and by the Deputy First Minister for Enterprise and Lifelong Learning Advice— Industry Advisory Group	Life Sciences Alliance formed Case studies of "role models" Framework proposals to increase staff exchanges between industry and academia Series of investor brokerage events to connect Scottish life science players to U.K. and international investors

Appendix 2

Canadian Biotechnology Advisory Committee *Roundtable* Background Paper

Canada's Biotechnology Strategy: Charting the Path Forward

June 2006

1.0 Introduction

1.1 The Canadian Biotechnology Strategy is now eight years old. Over that period, there have been important institutional developments (establishment of the Canadian Institutes of Health Research, Genome Canada, Networks of Centres of Excellence Program, Canada Research Chairs, and the Canada Foundation for Innovation, the nascent Canadian Academies of Science, the appointment of a National Science Advisor, etc.) and heightened attention by governments to the mechanisms required to increase Canada's commercialization performance (a report commissioned by the federal government from an expert panel is expected to be released soon). The Prime Minister's Advisory Committee on Science and Technology has completed its work on a national nanotechnology strategy, a genomics review is underway, the National Research Council is completing a comprehensive renewal exercise, and the government's Smart Regulation Initiative is underway. These developments and many more at the provincial and local levels indicate that it is timely to review Canada's current biotechnology strategy with a view to charting the course forward.

1.2 This document provides background for a series of roundtables that will inform CBAC's advice to the Government of Canada on the Canadian Biotechnology Strategy. It provides a high level overview of the current strategy (see Section 2), a summary of identified gaps/unfinished business and continuing challenges (see Section 3) and a summary of developments in other countries (see Section 4). If, in our quest to be concise, we have omitted important matters, we hope you will bring these into the discussion during the roundtable session.

1.3 A recent report by the Conference Board of Canada on the country's performance in biotechnology is being provided as additional background material.[9] We also draw to your attention CBAC's earlier advice to government on the renewal of the Canadian Biotechnology Strategy included in this Background Paper as Document 1. Illustrations of progress made on the Action Themes identified in 1998 are provided as Document 2.

1.4 Three expert roundtable discussions will take place in the April–June 2006 period—one in each of central, eastern and western Canada. Three focus groups of involved Canadians,[10] will be held and representatives from these groups will be included in roundtable discussions whenever possible.[11]

2.0 The Canadian Biotechnology Strategy

Origins

2.1 In 1983, the federal government launched the National Biotechnology Strategy (NBS), which focussed on research and development and human resources development. In the late 1980s, the NBS was broadened to address the regulatory framework for biotechnology. In 1997, the Government of Canada revisited the strategy to review and build on the accomplishments of the NBS, taking into account the views of a broad array of stakeholders and interested citizens. The review resulted in the launch of the Canadian Biotechnology Strategy (CBS) in 1998.

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[9] Conference Board of Canada, *Biotechnology in Canada: A Technology Platform for Growth*, (2005): www.conferenceboard.ca.

[10] Involved Canadians represent about 27 percent of the population as a whole, and they tend to engage in public policy and public affairs issues to a much greater extent than average. While from a demographic and geographic perspective they "look" a lot like other Canadians, their behaviours (writing letters to the editor, joining community groups, speaking publicly about topics they know) reveal a level of attention to issues that differs markedly from the norm. More importantly, they tend to be influential in opinion formation among the rest of the population so views they tend to hold can act as a "bellwether" for where public opinion is likely to go over time.

[11] Due to scheduling challenges, the focus group of involved Canadians in Montreal will take place after the expert roundtable precluding the inclusion of representatives from this focus group in the roundtable.

2.2 The CBS, a multi-departmental strategy involving Industry Canada, Health Canada, Environment Canada, Fisheries and Oceans Canada, Natural Resources Canada, Agriculture and Agri-Food Canada, and International Trade Canada, explicitly recognizes the social and ethical dimensions of biotechnology along with its economic potential.

Vision, Guiding Principles and Goals

2.3 Vision

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 in biotechnology.

2.4 The vision is further elaborated in the strategy's **guiding principles** as follows:

- Reflect Canadian values;
- Engage Canadians in open, ongoing transparent dialogue;
- Promote sustainable development, competitiveness, public health, scientific excellence, and an innovative economy; and
- Ensure responsible action and cooperation domestically and internationally.

2.5 Nine **goals** for Canada's biotechnology strategy emerged from the consultation process that provided input to the formulation of the CBS. These are to:

- Ensure that Canadians have access to, confidence in and benefit from safe and effective biotechnology-based products and services;
- Ensure an effective scientific base and make strategic investments in R&D to support biotechnology innovation, the regulatory framework and economic development;
- Position Canada as an ethically and socially responsible world leader in the development, commercialization, sale and use of biotechnology products and services;
- Be sensitive to the need for developing countries to build indigenous capacity to assess and manage the risks of biotechnology;
- Improve public awareness and understanding of biotechnology through open, transparent communications and dialogue;
- Solicit broadly-based advice to the government on biotechnology;
- Promote awareness of, and maintain excellence in, Canada's regulatory system, based on the Federal Regulatory Framework for Biotechnology (1993), to ensure the country's continued high standards for protecting health, safety and the environment;
- Support the development of a Canadian biotechnology human resources strategy to ensure an adequate supply of highly qualified personnel; and
- Work with the provinces, territories, business, academia, and consumer and other interest groups to develop and implement action plans addressing stewardship issues (for example, health, safety, environment, and social and ethical matters), sectoral opportunities and horizontal challenges (for instance, R&D, regulations, human resources, investment, innovation, technology transfer and market access).

Ten CBS Themes for Action

2.6 The CBS set out ten themes for action to implement the strategy goals as follows:

- Building public confidence and awareness, and communicating accurate, balanced, easy-to-understand information to Canadians;
- Further expanding Canada's R&D and science base to support Canadian competitiveness in biotechnology as well as the regulatory system;
- Regulating to protect health and the environment;

- Promoting the use of biotechnology for public health and safety;
- Modernizing Canada's intellectual property laws;
- Facilitating measures to help accelerate the application and commercialization of new technologies;
- Demonstrating responsible world leadership to improve market access and acceptance as well as stewardship in developed and developing countries;
- Developing human resources;
- Improving policy-relevant data collection and analysis; and
- Building sector strategies and action plans.

2.7 Based on these 10 themes, the CBS is conceived of as resting on three "pillars", which represent the broad areas of interest for the federal government in achieving the vision for the CBS and provide an organizing framework for federal involvement in biotechnology.

Stewardship: ensuring effective stewardship of biotechnology in the areas of health, safety and the environment.

Benefits/Innovation: maximizing the social, economic and environmental benefits associated with biotechnology products and applications.

Citizen Engagement: engaging a wide spectrum of Canadians on biotechnology and its role in society.

Instruments

2.8 The launch of the Canadian Biotechnology Strategy in 1998 included two new instruments to support its implementation—the Canadian Biotechnology Advisory Committee and the Canadian Biotechnology Secretariat. Overseeing the strategy and providing overall leadership is the Biotechnology Ministerial Coordinating Committee.

Canadian Biotechnology Advisory Committee (CBAC)

2.9 CBAC was established as a core component of the CBS to provide government with independent, impartial advice on important policy issues associated with the ethical, social, regulatory, economic, scientific, environmental and health aspects of biotechnology and to provide Canadians with an ongoing forum to voice their views and participate in a "national conversation" on biotechnology issues.

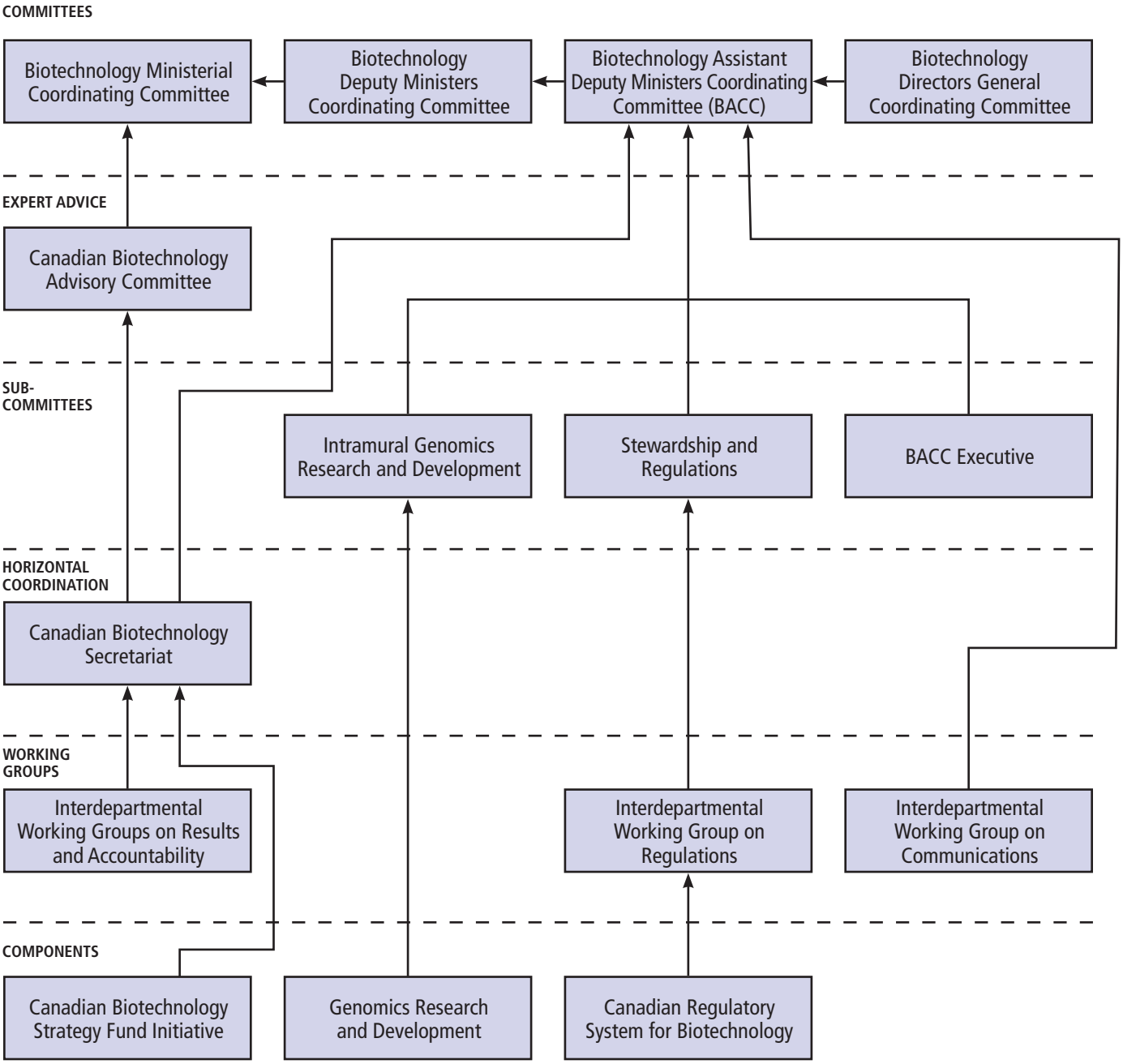
2.10 CBAC reports to the Biotechnology Ministerial Coordinating Committee (BMCC), convened by the Minister of Industry and including Ministers of Health, Environment, Agriculture and Agri-Food, International Trade, Fisheries and Oceans, and Natural Resources.

2.11 In carrying out its program of work, CBAC undertakes environmental scanning, commissions background studies and research, sponsors roundtable discussions, conducts workshops, consults stakeholders and establishes expert panels. Projects are determined by CBAC based on committee members' knowledge of the area or are undertaken in response to referrals from government departments. It tenders its advice in the form of advisory memoranda, major project reports, commentaries on draft policy statements, and through participation in workshops or conferences involving policy makers or program administrators. CBAC's advisory memoranda and project reports are public documents that are disseminated widely.

2.12 CBAC's membership reflects expertise across the range of issues pertinent to biotechnology—scientific, ethical/legal, social, and economic—so that the breadth of perspectives is maintained. Its expertise on specific topics is amplified by convening expert panels where in-depth examination of a complex area is required.

2.13 The role of CBAC has evolved since its inception. Early in its mandate, the focus was on the adequacy of existing policy, instruments and operations (e.g. regulatory systems, patent policy)[12] to deal effectively with biotechnology developments. Latterly, CBAC has also turned its attention to the broader impacts of biotechnology on complex and dynamic systems

Federal Governance Structure for Canadian Biotechnology Strategy



[12] The *Patenting of Higher Life Forms and Related Issues* report provided the Supreme Court of Canada with a reference document for its December 5, 2002 decision in the Harvard Onco-Mouse case. The report on *Improving the Regulation of Genetically Modified (GM) Foods and Other Novel Foods in Canada*, provided the Government of Canada and stakeholders with an in-depth review highlighting the need to improve the management and coordination of the regulatory system for GM foods and to enhance communication with the public.

under the rubric Biotechnology and Canadian Society.[13] CBAC recently completed a study, at the request of the federal departments of Industry and Health, on the impacts of intellectual property protection of human genetic materials on the health sector. CBAC is currently undertaking a major study on Biotechnology, Sustainable Development and Canada's Future Economy.

Canadian Biotechnology Secretariat

2.14 One of the aims of the CBS is to improve the way government coordinates biotechnology policy and program development given its importance in the work of several departments. A governance structure was set up to achieve this coordination and a secretariat was established, housed in the lead department — Industry Canada — and mandated to facilitate the coordination. The secretariat was also mandated to support the work of CBAC.

2.15 The figure on page 26 depicts the organization structure for the CBS. The arrows indicate the reporting relationships but do not convey the dynamic and complex interactions among the various bodies and actors involved in the federal structure. The figure also does not convey the complex set of interactions with organizations outside of central federal departments and agencies involved in research, development, regulation, commercialization and adoption of biotechnology innovations.

Federal Programs and Initiatives

2.16 The annual federal biotechnology investment is about $750 million.[14] Approximately 85 percent of this total amount is spent on research and development (90 percent of this for extramural research); 6 percent on the regulatory system; 5 percent on policy development activities; 3 percent on commercialization; and 1 percent on communications and public awareness. This annual federal biotechnology investment is made through a variety of existing programs summarized below.

Canadian Regulatory System for Biotechnology

2.17 The Canadian Regulatory System for Biotechnology (CRSB) is an interdepartmental initiative that supports departments/agencies in responding to new pressures on the regulatory system. It operates according to the Federal Regulatory Framework for Biotechnology (1993)[15] and has the following objectives:

- Meet technical capacity and human resources needs;
- Improve public awareness of, and confidence in, the regulatory system;
- Increase efficiency, effectiveness and timeliness of the regulatory system; and
- Generate knowledge to support the regulatory system.

[13] CBAC's report *Biotechnology and the Health of Canadians* outlines how the rapid increase in knowledge about the molecular basis of health and disease can be used for prevention, diagnosis and treatment, and describes the policy initiatives needed to ensure these benefits are realized in a socially responsible manner.

[14] Based on a 2004 Expenditure and Management Review conducted by the Treasury Board Secretariat (unpublished report).

[15] Federal Regulatory Framework (1993):
- Maintaining Canada's high standards for protecting the health of Canadians and the environment;
- Using existing laws and regulatory departments to avoid duplication;
- Developing clear guidelines for evaluating biotechnology products that are in harmony with national priorities and international standards;
- Providing a sound, scientific knowledge base on which to assess risk and evaluate products;
- Ensuring the development and enforcement of Canadian biotechnology regulations are open and include consultation; and
- Contributing to the prosperity and well-being of Canadians by fostering a favourable climate for investment, development, innovation and the adoption of sustainable Canadian biotechnology products and processes.

As the Framework indicates, existing legislation and regulatory departments/agencies implement regulatory responsibilities as follows:

- **Health Canada** regulates biotechnology-derived products that are subject to the *Food and Drugs Act*, that is, genetically modified and other novel foods, biologics, assisted human reproduction technologies and therapeutics. The department also regulates pest control products as they relate to human health and the environment under the *Pest Control Products Act*.
- **The Canadian Food Inspection Agency** (CFIA) regulates biotechnology-derived products including plants, animal feeds and animal feed ingredients, fertilizers and veterinary biologics, and conducts all federal inspection and enforcement services related to food—including those stemming from the *Food and Drugs Act*.
- **Environment Canada** regulates biotechnology-derived products through the *Canadian Environmental Protection Act (CEPA)*,1999, which provides the federal benchmark for notification and assessment of environmental and human health risk from new biotechnology products. Where other acts/regulations meet this benchmark, they are deemed to fulfill CEPA requirements. Environment Canada and Health Canada regulate all other new biotechnology products, and hence provide a safety net to ensure health and environmental assessments are completed.
- **Fisheries and Oceans Canada** is responsible for regulating potential environmental release of transgenic aquatic organisms.

Collaboration among these departments/agencies in regulation of products of biotechnology occurs in all aspects of the regulatory system. A Committee of Assistant Deputy Ministers, the Biotechnology Subcommittee on Stewardship and Regulation, chaired by Health Canada, provides oversight for horizontal issues arising in the regulatory process.

Innovation

(a) Research and Development

2.18 The federal research granting councils (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council, and the Social Sciences and Humanities Research Council), in addition to two arms-length federally funded research organizations (Genome Canada and the Canada Foundation for Innovation) are the main instruments for building research excellence, talent and infrastructure in Canada through extramural funding.

2.19 Federal departments and agencies are also engaged in intramural biotechnology R&D in support of their mandates. The Intramural Genomics Research and Development Program provides interdepartmental coordination and support for federal priorities in this area.

This intramural program plays a key role in building and participating in local, national and international genomics R&D initiatives; supports the development and application of the scientific knowledge base; advances the principles of sustainable development and ethical uses of genomics; evaluates potential new and modified products to protect human health, safety and the environment; and facilitates Canadians' access to accurate and understandable information concerning genome sciences. Programs funded under the Intramural Genomics R&D Program have increased human resources and helped create partnerships among government-based science organizations, universities and other research institutes through the sharing of technology platforms and by collaborating in research areas that cut across traditional departmental sectors.

(b) Commercialization

2.20 There is neither a biotechnology-specific commercialization policy nor a general commercialization plan in Canada. About three percent of annual federal biotechnology expenditures are invested in financing and

pre-commercialization initiatives, which provide support for new technologies, including biotechnology. The main instruments and their specific investments in biotechnology are:

- **Industrial Research Assistance Program (IRAP)**[16] — invested $60M[17] (since 1998)
- **Technology Partnerships Canada (TPC)**[18] — invested $293M (since 2001)
- **Canadian Institutes of Health Research (CIHR)** — invested $13.8M (since 2001)
- **Scientific Research and Experimental Development (SR&ED) Tax Incentive Program**[19] — provided $212M in tax credits and refunds (in 2003)
- **Business Development Bank of Canada (BDC)**: Since October 1, 2002, BDC authorized 52 investments for $92M in the life sciences sector. BDC's life sciences portfolio is comprised of 55 clients with $154M outstanding and committed. Over the fiscal 2006–2010 planning period, BDC plans to invest a total of $191M in life sciences.

(c) Biotechnology Human Resources

2.21 Funded in part by the federal government, the Biotechnology Human Resources Council (BHRC) designs, distributes and promotes programs and services of value to Canada's biotechnology industry for attracting, developing and retaining a highly-skilled Canadian workforce essential for its sustainable growth and international competitiveness. In 2004 BHRC released their analysis of current and future human resource requirements[20] and concluded that measures were urgently required to bolster corporate governance, increase networking and learning opportunities for executives and helping students acquire the job-ready skills required by industry. Other initiatives designed to address the biotechnology skills gap in Canada are described in the 2005 Conference Board report.[21]

Public Information and Engagement

2.22 Since 1999, the federal government, through the CBS, has maintained a large-scale tracking program of public opinion research. During that time, it has commissioned 13 public opinion surveys and more than 100 focus groups in what is North America's largest and most comprehensive investigation into attitudes about biotechnology and the public policy that surrounds it.

2.23 In 2004, the federal government launched the BioPortal (www.biotech.gc.ca), an Internet-based one-window access to comprehensive information on biotechnology and its applications for consumers, industry, scientists and educators. The BioPortal brings together resources from all federal departments and agencies, including government policy and research activity; business support programs and market intelligence; a virtual library of educational resources; and regulations on biotechnology research and applications.

2.24 An operating principle of the Canadian Biotechnology Advisory Committee is that it provides its analyses and advice to government concurrently with public release via the Committee's website. This approach maintains CBAC's independence and its credibility in the eyes of the public. In addition, CBAC posts its documents on the website for public commentary.

2.25 CBAC sponsored the development of a "Dialogue Tool" in 2003 designed to provide a structured methodology for discussions of contentious issues. This tool was developed in the context of genetically modified food but has been revised for broader applicability.

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[16] IRAP provides non-repayable contributions to Canadian small- and medium-sized enterprises (SMEs) interested in growing by using technology to commercialize services, products and processes in Canadian and international markets. IRAP also provides mentoring support and invests in a cost-shared basis for research and pre-competitive development technical projects.

[17] Includes IRAP-TPC Program investments, a joint program of IRAP and TPC which supports innovative SMEs by investing in projects at the pre-commercialization stage.

[18] TPC invests in projects in three technology areas: aerospace and defence, environment and enabling technologies, including biotechnology, information and communications technologies, and advance materials and advance manufacturing. One-third of TPC's budget is expended on environmental and enabling technologies.

[19] SR&ED Program provides financial assistance through investment tax credits to companies conducting R&D in Canada.

[20] Biotechnology Human Resources Council, *Converging Science and Leadership: The Key to the Future*, (2004): www.bhrc.ca.

[21] Conference Board of Canada, *Biotechnology in Canada: A Technology Platform for Growth*, (2005): www.conferenceboard.ca.

Social, Ethical and Legal Aspects of Biotechnology

2.26 The social and ethical dimensions of biotechnology have received significantly more attention since the early 1990s than previously. Social and ethical issues have been addressed by a variety of means, for example, by including them in the terms of reference of all studies conducted by CBAC, as a major topic for framework development by inter-departmental working groups, in major public consultations (e.g. on xenotransplantation), in major conferences and background studies (e.g. privacy, biobanks). Outside of the federal government, the social and ethical dimensions of biotechnology have also constituted a major program focus of Genome Canada (GE3LS). In order to facilitate constructive dialogue on socially or ethically controversial issues CBAC sponsored the development of a Dialogue Tool. Pressing policy issues related to access to biotechnological advances that turn mainly on social and ethical considerations include, for example, the question of supplying expensive drugs for rare diseases.

Important legislation involving biotechnology was enacted (*Assisted Human Reproduction Act*), and major judicial decisions rendered (Supreme Court on the Harvard OncoMouse and Schmeiser cases) in recent years.

3.0 Canada's Biotechnology Performance — Unfinished Business

3.1 Various aspects of Canada's performance in biotechnology have been assessed in recent years. Canada has significantly improved its performance in basic research (notably in genomics and proteomics). However, the Conference Board of Canada states that "the government's performance in creating an enabling environment for biotechnology has been moderate".

3.2 While progress has been made on several fronts, many of the issues that stimulated the development of earlier biotechnology strategies remain as foci for necessary policy development going forward. That there is much unfinished business to be attended to in this field is not surprising given the pace of scientific and technological development, global competitive pressure and the rising needs and expectations of the public.

Regulation

3.3 In an advisory memorandum on regulatory reform,[22] CBAC has observed:

"The lack of a comprehensive regulatory system for products of biotechnology is impeding the development of niche industries in Canada and consequently the potential for consumer and economic benefits. Regulators are justifiably concerned about being able to apply the appropriate risk analysis to new applications of biotechnology. At the same time, Canadian firms need to know what the rules are so they can decide whether to invest in Canada or elsewhere. With respect to some of these emerging industries, such as plant molecular farming, Canada may already have missed the opportunity.

Canada is the leading developer of many of these new products. We should also be leading the way in developing appropriate regulation. Our scientific community has the greatest potential to manage the safe introduction of these products. Yet our apparent inability to act disenfranchises us from the international management of our developments. Canada's standing in and contribution to the international debate about regulation could be jeopardized while our production and export of high-knowledge products could be threatened.

Ultimately, these delays in filling the gaps in the regulatory system threaten the research, development and commercialization in Canada of socially beneficial biotechnology."

[22] Canadian Biotechnology Advisory Committee, *Advisory Memorandum: Completing Canada's Regulatory Regime*, (2004): www.cbac-cccb.ca.

3.4 In its 2004 report, the External Advisory Committee on Smart Regulation (EACSR)[23] built upon previous recommendations by the Royal Society of Canada[24] and by CBAC.[25] It urged the federal government to pay particular attention to the regulatory system for biotechnology and specifically recommended that:

The government should make it a priority to develop and implement a comprehensive, government-wide biotechnology regulatory strategy which would:

- Identify and address legislative gaps, implement systematic international cooperation, and provide accessible and comprehensive information about regulatory developments (EACSR, as a first step, called for acceleration of health protection legislation renewal and that legislation be monitored via regularly scheduled reviews that are provided for in legislation or in departmental mandates, including independent scientific advice and public input where appropriate).
- Identify ways to access and draw from the expertise of the domestic and international scientific communities (EACSR encouraged active and strategic involvement in international regulatory cooperation, including participation by international and domestic experts in peer reviews of studies, risk assessments and regulatory analysis).
- Give due consideration to ethical issues (EACSR highlights the importance of addressing, not only scientific considerations, but also ethical issues in a transparent and inclusive manner to maintain public trust).
- Provide opportunities for input from all stakeholders and for citizen engagement (The U.K.'s Biotechnology Atlas was highlighted as an effective tool in this regard; the need for a sophisticated approach to engage citizens and other stakeholders on public policy issues involving biotechnology, including sharing information on current scientific evidence and risk management analysis, was emphasized).
- Be translated into a detailed work plan that measures and reports on progress.
- Be reviewed regularly and modified to account for progress in implementation and the rapid changes that characterize biotechnology.
- Assign clear and effective accountability for its strategic leadership and management.

Innovation

Research and Development

3.5 After ramping up its investment in research in the biosciences, through the mechanisms described earlier, governments face the challenge of renewing infrastructure and of investing in continued growth and depth of research programs. These provide the seed bed for the development of new technologies and for the training of the highly qualified personnel needed by industry and academia.

Building a Strong Biotechnology Sector

3.6 According to the Conference Board of Canada, Canada's biotechnology sector is struggling. Of the 500 or so biotechnology companies in Canada, 10 companies account for 70 percent of total biotechnology market capitalization. The majority are SMEs, with no major products on the market, fewer than 50 employees and less than two years operating cash on hand. The major challenges for Canadian biotechnology companies remain access to capital to sustain them during the long period between proof of concept to actual revenues and the lack of larger Canadian firms that can act as lodestars for the juniors. Investor confidence is weak, with a focus on short-term returns. In addition, Canadian firms have difficulty recruiting the scientific talent and the marketing, management, and sales expertise required to succeed internationally.

[23] External Advisory Committee on Smart Regulation, *Smart Regulation: A Regulatory Strategy for Canada* (2004): www.smartregulation.gc.ca.
[24] Royal Society of Canada, *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada*, (2001): www.rsc.ca/foodbiotechnology/GmreportEN.pdf.
[25] Canadian Biotechnology Advisory Committee, *The Regulation of Genetically Modified Foods*, (August 2002): www.cbac-cccb.ca.

3.7 Many of the issues and challenges in the biotechnology sector are representative of those found in the innovation "ecosystem" generally. These have been addressed in the National Research Council of Canada's Foresight Consolidation Report[26] which states:

"There is good evidence that Canada's science and technology expertise is world-class and productive. We also have effective and generous tax-credit regimes that support innovation. Canada's R&D community is busy, complex but unfocused as we do not have a clear, explicit strategy for science and technology. In addition, Canada does not have innovation practices that enable increased private sector R&D investment, and support the flow of venture capital. Therefore, Canada's Science and Technology (S&T) strongly favours public and social outcomes of innovation investments. This situation may not be appropriate, given the long-term outlook of the Canadian economy and Canada's declining competitiveness.

Canada has poor coordination among the players in innovation policy, both provincially and federally. There is a lack of focus in innovation policy, strategy and execution – too many players working with different and sometimes opposing plans and policies. In the fast-growing innovation economies (e.g. Finland, Japan), integration, convergence and focus are keywords representing action. They need to be made real in Canada, and some limited progress is now slowly being made.

The Canadian innovation system is also challenged by shortages of highly qualified people in all stages of the innovation process, affecting economic progress. Canada ranks 14th in OECD countries in management (company operations and strategy geared toward improving entrepreneurship and productivity), has fewer S&T workers than many other advanced economies and lacks experienced venture capital fund managers. Other difficulties include securing angel funding, costs of securing access to markets, intellectual property, the business climate and culture, and regulation.

The aging workforce, expected high retirement rates, and the fact that Canada continues to lag behind leading OECD countries in science and engineering degrees and in graduation rates at the PhD level (less than 1 percent of university graduates received a doctoral degree in 2000), means that Canada will become increasingly dependent on immigration to fill needs for specialized skills and sustain labour force growth in the long term.

Consequently, attracting and retaining scientific, engineering and technical workers will be especially challenging as labour market alternatives for graduates in science and engineering are neither extensive nor varied, largely due to the low level of research and innovative capacity in the Canadian private sector. Canada will need to rely on foreign talent likely to come from China, India, Pakistan, the Philippines and other transitional economies (India and China are currently producing a fifth of the world's supply of PhD graduates in science and engineering). Although foreign talent can bridge supply gaps in OECD countries, including Canada, it may not be a permanent and acceptable replacement for national investment in the science and technology workforce."

3.8 In previous consultations on health applications of biotechnology, CBAC heard the following concerns:

- Canada lacks a commercialization strategy that supports its entrepreneurs in developing their products;
- Shortage of bio-manufacturing capacity in Canada is a major impediment to commercialization;
- Insufficient development of shared platforms for commercialization is a problem, and we are underutilizing public institutions (notably major hospitals) for product testing, clinical trials, and technical innovation;
- The federal government's main vehicles for providing financial assistance are not well-aligned with the needs of biotechnology companies. We need a program like the U.S. Small Business Innovation Research Program, which is attached to all federal organizations with extramural research budgets in excess of US$100 million;

[26] National Research Council of Canada, *Looking Forward: S&T for the 21st Century*. Foresight Consolidation Report, NRC Renewal Project, (August 2005): www.nrc-cnrc.gc.ca/aboutUs/ren/nrc-foresight_18_e.html.

- Lack of alignment of Canada's patent system with our major trading partners and lack of clarity on the scope of patent protection are disincentives to investments.

3.9 A more positive assessment has been provided as the following extract from a recent report from an international scan indicates:[27]

"The biotechnology sector in Canada enjoys many of the key ingredients necessary for sustainable growth and a world-class reputation. The country, home to the largest number of biotech companies outside of the U.S., has targeted and well-funded government initiatives in place to support the academic, research and infrastructure requirements of demanded by the biotech sector. Canadian universities are well-versed in collaborative research efforts and various biotech networks exist to foster virtual partnering as well. Early stage capital is available from Canadian, U.S. and European investors and venture capitalists. Given this strong framework, Canadian firms are involved across the entire spectrum of biotechnology research, platforms and products.

Several challenges remain if the country's lofty ambitions in the biotech area are to be realized. There is concern that the current universe of mostly very small, unprofitable firms cannot be sustained. This suggests that consolidation activities will increase. Inevitably, investments and acquisitions will be undertaken by foreign players with the risk that key intellectual property and value creating assets will go abroad, depriving the Canadian biotech sector of critically needed experience. Recent government initiatives aimed at making Canada one of the top nations for innovative R&D and the country becoming home to globally-recognized biotech clusters suggests that Canada is well prepared to face these challenges and build on its strong track record of success to date."

Public Information and Engagement

3.10 Without exception, the critical role of public engagement in policy development concerning biotechnology is emphasized in all countries. Also recognized is the need to invest significant resources in this area in order to meaningfully and systematically reach and engage the public. Initiatives such as the U.K.'s GM Nation have been criticized for failing to engage the uncommitted public and for being insufficiently resourced in terms of time, money and expertise.

3.11 In the context of Canada's regulatory system, the need to provide the public, with information on risk management analysis has been highlighted consistently, as has been the importance of opportunities for the public to engage in dialogue with industry and governments in order to increase understanding of various perspectives.

The EACSR states, "In light of its significant ethical, social, environmental and economic implications, biotechnology is an area where government should be particularly active in engaging citizens and stakeholders and in encouraging public debate".

Social, Ethical and Legal Aspects of Biotechnology

3.12 Much work remains in this emerging area of biotechnology and includes efforts to connect research to policy development, develop new frameworks or modify existing ones to ensure that methodologies incorporate social and ethical considerations systematically. This is an area where a public engagement strategy that is inclusive and sustained is critical.

Governance

3.13 In its 2005 report on the functioning of "horizontal programs" the Office of the Auditor General noted that "inadequate implementation of governance structure" and "lack of top-level leadership" have resulted in CBS "not functioning as planned". The Report states:

"The Canadian Biotechnology Advisory Committee provides biotechnology ministers with independent advice on emerging biotechnology policy issues from senior experts. We expected that ministers

[27] New Economy Strategies LLC and *Global Bioeconomy Consulting LLC, Global Hubs and Nodes of Biotechnology: An International Scan of Biotechnology Strategies*, Initiatives and Institutional Capacity, (2005).

would receive and consider advice in a timely way, given that rapid changes in biotechnology can affect health, safety, the environment, and the economy.

We found a lack of top-level leadership for the strategy. The ministerial co-ordinating committee has met only once in six years, and the deputy minister co-ordinating committee has not met since 2002. We found that some of the advisory committee's recommendations had been considered by the working groups. However, we found that the mechanism for addressing external advice did not function as planned. By April 2005, the ministerial co-ordinating committee had not officially responded to a number of advisory committee reports that required prompt action."

4.0 Developments in Other Countries

4.1 Recognizing the transformative nature of biotechnology, its powerful contribution to economic growth and to progress in solving long-standing global challenges, governments around the world are taking decisive steps to advance their competitive advantage in biotechnology and to address areas of weakness.

4.2 Among developed countries, the European Union, Japan, New Zealand and Australia all have specific national biotechnology strategies. In the U.S., although there is no national strategy, most states have biotechnology programs as part of their economic agendas. Among developing and middle power countries, India and Chile have placed a special focus on biotechnology, along with other countries such as Singapore, Cuba and South Korea.

4.3 Not surprisingly, the U.S. is the dominant global biotechnology player in a number of areas including revenue, R&D expenditure, number of employees and market value of public companies.[28]

4.4 Europe is leading in the number of biotechnology companies and has the lowest revenue per company and per employee, indicating, according to the Conference Board of Canada, that these firms are at relatively early stages in terms of taking products to market. The U.K. is the European leader in the bioscience industry, and number two in the world after the U.S. The U.K. biotech sub-sector (as defined by Ernst & Young) includes over 400 companies with over 25,000 employees and with £3 billion in revenues. The majority of these companies are small, privately held, and without profit. The broader bioscience/health care sector (which also encompasses diagnostic, device, service and supply companies, but excludes major pharmaceutical companies) includes over 1,100 companies, employs 100,000 people, and generates revenues of £11 billion.

4.5 Australia is also a key biotechnology player. With an R&D budget a tenth of the size of Canada's and a biotechnology workforce of less than half the size, Australia's average revenue per company is three-quarters that of Canadian companies. The efficiency of their spending is very high, resulting in a substantially higher level of revenue per annual R&D expenditure—about five times greater than Canada's and four times that of the U.S. However, while its performance is strong today, the Conference Board suggests that Australia may face serious challenges over the longer term unless its R&D investments begin to grow.[29]

Strategic Research Priorities

4.6 Many of Canada's competitors are prioritizing their research funding in areas of strategic or national importance, with biotechnology as a key element. In India, for example, the health sector accounts for two-thirds of all biotechnology investment. In the U.S., the government is investing heavily in the National Institute for Allergy and Infectious Diseases as part of the BioShield Initiative, through which US$5.6 billion will be spent over the next 10 years to improve medical countermeasures (e.g., vaccines) against bioweapons.[30]

[28] Conference Board of Canada, *Biotechnology in Canada: A Technology Platform for Growth*, (2005): www.conferenceboard.ca
[29] Ibid
[30] U.S. Department of Health and Human Services Fact Sheet—Project Bioshield, July 21, 2004.

4.7 The majority of funding in the United Kingdom goes to the Medical Research Council, supporting its dedicated strategy for maintaining its leadership in genomics. The United Kingdom is moving from a primary emphasis on basic research to an approach that includes more support for applied research. Seven research councils have been established to support this shift.[31]

4.8 Priority areas for the Australia Research Council include nano-materials and bio-materials, genome/phenome research, photon science and technology, and complex and intelligent systems. The Australian Research Council (ARC), one of the main funding agencies in Australia for basic research, administers a range of competitive granting schemes that provide funding to Australian researchers and universities for a variety of research endeavours (excluding clinical medicine and dentistry). The ARC identifies investment strategies in six key areas: industry linkages, research training and development, research infrastructure, priority setting, community awareness and governance.[32]

R&D Tax Incentives

4.9 Some countries offer R&D tax incentives or other tax relief to encourage basic research. These incentives are relevant, although not specific, to biotechnology.[32] Japan and Canada give tax credits for basic research conducted by the private sector. Japan also offers direct tax relief for companies performing or financing basic research.

4.10 Another common tactic is to stimulate more collaborative research between industry and public research institutions and universities through the design of R&D tax incentives. Japan and the United Kingdom, for instance, provide tax incentives for industry R&D projects contracted to universities and public research institutes. Japan has made substantial progress since 2001, with its government investing in incentives that will help attract foreign companies into the biotech market. For example, 12 percent of overall R&D spending is now tax-deductible.[32]

4.11 The tax credit established in the United Kingdom is provided to companies conducting rather than financing R&D, unless carried out in collaboration with universities or research organizations. In March 2002, the United Kingdom announced a new research and development tax credit for larger companies to match a similar program already in place for smaller firms. The new tax credit is designed to encourage collaborative research with universities, and allows companies to claim research and development as a write-off against their taxes.[32]

4.12 Australia has a broad-based, market-driven tax concession allowing companies to deduct up to 125 percent of qualifying expenditure incurred on R&D activities when lodging their corporate tax return. A 175 percent Premium (Incremental) R&D Tax Concession and R&D Tax Offset are also available in certain circumstances.[32]

Commercialization

4.13 The U.S. holds the lead with respect to the commercialization of biotechnology products and applications. This lead is considered to be as a result, in part, from its early beginning in this field (e.g. commercialization of biotechnology products and services in the U.S. began in the mid-1970s, while Japan, the United Kingdom, France and Canada didn't really enter the market until the early 1980s). Further, according to the Conference Board, it is generally agreed that the U.S. has an efficient technology transfer system that links basic research with companies and investors, that there is sufficient venture capital, and that there exist many clusters of biotechnology activity. For example, the U.S. has 51 bio-clusters; by comparison, the United Kingdom has nine, and Canada, France and Japan each claim to have eight.

[31] Organisation for Economic Co-operation and Development, Governance of Public Research: Toward Better Practices, (2003).
[32] Organisation for Economic Co-operation and Development, Science, Technology and Industry Outlook, (2004).

4.14 Unlike Canada, a number of its competitors have implemented specific biocluster policies (e.g. U.K., France, and Japan). In the U.K., fostering clusters in the health/pharmaceutical sector is considered a key mechanism for supporting biotechnology commercialization. Other efforts include a reduction in drug approval times, more efficient clinical processes, and the creation of the National Clinical Trials Agency to support clinical research and trials, and facilitate a more rapid connection between researchers and patients. In France, government investment is shifting to support biotechnology clusters and networks. National legislation has been enacted that facilitates researcher-industry partnerships, allows universities to set up incubators, lightens tax burdens and, in general, promotes a more supportive environment for technology transfer and commercialization operations. In Japan, the fostering of bioclusters is seen by government as a key tool in the achievement of national development in biotechnology.[33]

4.15 In China, government efforts toward biocommercialization began in the late 1990s with the establishment of the China National Center for Biotechnology Development (CNCBD), which plays a key role in supporting innovation in biotechnology.

Regulation

4.16 The regulation of biotechnology food products in the U.S. does not differ fundamentally from the regulation of conventional food products. Existing food safety and environmental protection laws and regulations are applied to biotechnology products. For example, the Animal and Plant Health Inspection Service (APHIS) regulates based on the process (e.g. genetic engineering) by which products are developed rather than on the characteristics, traits or novelty of the end product.

4.17 Japan uses existing legislation to regulate genetically modified organisms. It lacks one coordinating body to oversee the involvement of different ministries in biotechnology. This has led to overlapping policies launched by competing agencies that serve to protect ministerial jurisdiction rather than respond to safety requirements.

4.18 In the U.K., in 2001, the Department of Trade and Industry developed an online regulatory map, *The Biotechnology Regulatory Atlas*, to serve as a guide to the main technical regulation affecting biotech companies—particularly for businesses without access to dedicated regulatory staff. The European Union has adapted the "precautionary principle" based on their social and political situation and history of food safety scares. The precautionary principle is fundamentally a risk management approach. It comes into effect when potentially dangerous effects deriving from a phenomenon, product or process have been identified, and when scientific evaluation does not allow the risk to be determined with sufficient precision.

4.19 While some commentators argue that India's regulatory policies are compliance-friendly, open and transparent, it is generally considered that there may be too many agencies involved in providing regulatory clearances related to biotechnology. To address the concerns of both the general public and business, efforts are underway to establish a single point of contact for India's regulatory mechanisms to promote the speedy commercialization of biotechnology products and processes.

Public Information and Engagement

4.20 Without exception, the critical role of public engagement in policy development concerning biotechnology is emphasized in all countries. Also recognized is the need to invest significant resources in this area in order to meaningfully and systematically reach and engage the public. Initiatives such as the U.K.'s GM Nation have been criticized for failing to engage the uncommitted public and for being insufficiently resourced in terms of time, money and expertise.

[33] Conference Board of Canada, *Biotechnology in Canada: A Technology Platform for Growth*, (2005): www.conferenceboard.ca

Biotechnology Human Resources

4.21 A problem faced by governments around the world is the attraction, retention and development of the top biotechnology talent required to compete successfully in the global marketplace. A shortage of highly qualified personnel exists, particularly those who possess business skills and scientific knowledge, as well as managerial, marketing, regulatory and governance capabilities.[34]

4.22 The U.S. shows a substantial lead among major competitor nations with more than 160,000 biotechnology employees in 1999. Governments are striving to amass the labour force required to compete with the U.S. For example, India has taken steps to establish institutional infrastructure for human resource development (e.g. through the efforts of the Department of Biotechnology, more than 62 universities and institutions are engaged in biotechnology training and education-related programs and there are 55 centres for bioinformatics which are linked with databases and networks around the world). The Australian government has identified human resource development as a critical success factor and is working to address this issue through its National Biotechnology Strategy (e.g. focusing on those fields where Australia has strong capacities to commercialize biotechnology research outcomes).[35]

4.23 To exacerbate matters, competitive wages offshore are driving outsourcing and global pricing differentials are giving some countries a competitive edge (e.g. India's less costly labour wages enable competitive pricing while the skills and capabilities of its workforce continue to improve). It has been noted that "early drug development work can be done in countries like Taiwan, Singapore and China for as little as 10 percent to 40 percent of the U.S. cost".[36] In addition, countries such as Singapore and India are establishing new research centres designed to attract the best scientists and companies in the field of biotechnology such as Singapore's Biopolis, a state-of-the-art research facility, and India's Genome Valley, the first of its kind biotechnology cluster in India for life science research, training and manufacturing activities.

[34] Conference Board of Canada, Biotechnology in Canada: A Technology Platform for Growth, (2005): www.conferenceboard.ca.

[35] Ibid

[36] San Francisco Chronicle *Are Biotech Jobs Next to Go? Stronghold of Bay Area Economy Not Immune to Trend*, (April 2004): www.sfgate.com/cgi-bin/article.cgi?f=/c/a/2004/04/18/MNGBM672L01.DTL.

Document 1

Statement on Renewal of the Canadian Biotechnology Strategy and the Evolving Role of CBAC

December 2004

The Canadian Biotechnology Advisory Committee (CBAC) strongly advises the Government of Canada to renew and build on the Canadian Biotechnology Strategy established in 1998 and, as part of that renewal and enhancement, continue and reinforce the mandate of and support for CBAC.

The reason for this advice is simple. There is a continuing need for a strategy that focuses on biotechnology per se; that embraces the economic, scientific, ethical, legal, social, regulatory, environmental, and health aspects of this transformative technology; and that is linked to the programs and responsibilities of several federal ministries. This need is greater now than ever before. It is worth reiterating briefly the basis for this assertion.

The Case for a Renewed Biotechnology Strategy

Why Biotechnology per se?

- Because biotechnology (a body of technical knowledge and a set of powerful tools) is the aspect of the life sciences that is most directly applicable to human and animal health, the environment, food, international trade and the economy.
- Because the vast majority of the economic, social, ethical and legal issues of primary concern to the public and to policy makers related to life sciences involve applications of biotechnology.
- Because biotechnology is an increasingly important engine for economic growth (the global market for biotechnology products is expected to reach $50 billion in 2005). Our country is well placed to capitalize on its strengths in biotechnology (our revenue-generating performance increased by 83 percent between 1999 and 2001, reaching $3.6 billion), provided Canada maintains a focused approach to development of this sector.

Why a Comprehensive "Horizontal" Strategy?

- Because governments are faced with having to deal with issues that cut across departmental lines, sectors, institutions, political jurisdictions, and public constituencies. Governments are also required to reconcile competing interests, multiple streams of advice and diverse calls for government action.

Why Now?

- Because the pace of biotechnological innovation is accelerating. The next decade will see an increasing economic impact from biotechnology and its applications. Just think of what has happened in the few short years since the current strategy was instituted. In that brief interval, we have seen the mapping of the genomes of humans, plants, animals and microbes and the emergence or rapid expansion of new fields of biotechnology (genomics, pharmacogenomics, proteomics, stem cell biology, bioinformatics etc.).
- Because we cannot take our current favourable international standing for granted. Canada ranks second to the U.S. in number of biotechnology firms, third behind the U.S. and U.K. in revenues and first in

R&D per employee. However, the competition is intensifying and we must redouble our efforts to keep pace—to stand still is to lose.

At a time when new biotechnological frontiers have opened up in health, food production, the environment and sustainable industrial development, and when governments around the world are re-energizing their commitment to the use of biotechnology for economic and social objectives through increased investment, the question is not whether to renew the CBS, but how to enhance it to make biotechnology work for Canada.

The Elements of a Renewed Canadian Biotechnology Strategy (CBS)

The current CBS is predicated in large part on the fact that issues related to biotechnology permeate several key departments and programs of government. Its pervasiveness demands cross-departmental ("horizontal") attention to its implications. The importance of this fundamental principle remains paramount. Without clarity of direction and policy coherence, Canada's ability to capture the benefits of biotechnology in a socially responsible fashion will be weakened, and it will find itself relegated to a reactive rather than proactive role in policy development.

What Modifications Should be Made to the Canadian Biotechnology Strategy?

The three pillars of the current CBS are: **innovation, stewardship** and **citizen engagement**. This conceptual base remains valid as far as it goes, but should be reformulated and enhanced. Innovation and stewardship determine how biotechnology is developed and used in our society and are the main foci of government policy. By contrast, citizen engagement is a facilitating process; it is the means by which the views and interests of the public can inform policy development and strategies related to innovation and stewardship.

It should be noted that citizen engagement is not the only modality for facilitating policy-making and strategic action. The multidimensional nature of the objectives of a national biotechnology strategy should be more fully expressed in a renewed Canadian Biotechnology Strategy. The following framework illustrates the multidimensionality of the strategic challenges. It consists of:

Key Strategic Themes:

Innovation

- Scientific, technical and social innovation
- New products, processes, practices and organizational features

Stewardship

- Conservation and protection
- Nurturing human, social and economic capital

Facilitators and enablers

- Citizen engagement
- Capacity development
- Collaboration (inter-departmental; inter-sectoral; inter-jurisdictional)
- Education
- Decision support mechanisms

Elements of the technology "life-cycle"

- Research and development
- Regulation and commercialization
- Technology assessment
- Technology diffusion and uptake

The core value dimension

Supporting a Renewed Canadian Biotechnology Strategy: The Canadian Biotechnology Secretariat and the Canadian Biotechnology Advisory Committee

The current CBS is supported by a secretariat (the "CBSec"). The CBSec supports a variety of interdepartmental activities related to biotechnology and provides the staffing and operating support required by CBAC.

It is obvious that any renewed strategy will require a resource such as the CBSec. While a good deal of important and useful work has been undertaken, the overall level of support is inadequate to allow the CBSec to be as useful as it could be. The matter of support for CBAC is touched on below.

The Evolving Role of CBAC

CBAC was established in 1998 as a core component of the CBS with a mandate to provide comprehensive advice on current policy issues associated with biotechnology. It is also tasked with providing Canadians with easy-to-understand information on biotechnology issues, and providing opportunities for Canadians to voice their views on the matters on which CBAC is offering advice to the Government. The importance of external advice to the government is even more compelling now than when CBAC was first established. One thing is clear—independence is critical to the credibility of our advice and to the value-added we bring as an advisory body to government. The issues that biotechnology raises are becoming more complex and require many perspectives and greater depth of analysis.

The totality of its mandate, structure and constellation of functions and activities make CBAC unique among advisory bodies both in Canada and abroad. It is a body of experts drawn from diverse fields; it is supported by government, yet operates independently and reports publicly; it acts as a convenor of the many groups with a stake in biotechnology and facilitates productive dialogue among them; it acts as a medium of linkage and exchange between experts in the government and those in the private sector and/or in public institutions outside of government; it is free to pursue any topic it deems to be appropriate and important while also responding to requests for advice on special topics by government; and its mandate is long enough to allow it not only to address current topics but also to maintain a watching brief over emerging trends.

The role of CBAC has evolved in the five years since its inception. Early in our mandate, the focus was on the adequacy of existing policy, instruments and operations (e.g. regulatory systems, patent policy) to deal effectively with biotechnology developments. Latterly, we have also turned our attention to the broader impacts of biotechnology on complex and dynamic systems under the rubric *Biotechnology and Canadian Society*. We have completed and are in the process of publishing our study on *Biotechnology and the Health of Canadians* and are about to launch a major study on *Biotechnology, Sustainable Development and Canada's Future Economy*.

We have also developed a suite of products and activities that can be customized to align with the interests and needs of government and with the rapidly changing scientific and social context. The unique nature of CBAC outlined above has proven to be ideal for it to act as a "meta advisory body" (i.e., as a body that synthesizes and reconciles the streams of analysis and advice coming from a variety of other advisory groups in Canada and abroad) and as a body that explores the various perspectives of the Canadian public and diverse stakeholder groups.

Our work on the Regulation of Genetically Modified Food and Feed, for example, was informed by the Royal Society's Expert Panel Report on the scientific aspects of this topic. We related that work to a broader investigation of the social, ethical and economic issues involved and their policy implications—an investigation that involved broad public and stakeholder consultations. The latter activities resulted in the "spin-off" of a process that led to the creation of a "Dialogue Tool" for facilitating debate on controversial topics. One can readily envision CBAC exercising its meta-advisory role in relation to the assessments that might be undertaken, at the request of the government, by the nascent Canadian Academies of Sciences.

What Needs to Change?

It is clearly reasonable to contend that, with respect to CBAC and the CBSec, "the proof of principle" has been demonstrated. However, steps need to be taken along two fronts in order to have these entities reach their full potential; namely, enhanced resources and more effective reporting relationships. Our comments relate primarily to CBAC, since the assessment of CBSec and its future needs in relation to its inter-departmental coordination role are properly the purview of the ministries involved.

Resources

There are two aspects to the need for enhanced resources. First, citizen engagement broadly defined is costly. The current resources available to CBAC are insufficient to support citizen engagement activities that have both the reach and continuity required for optimum impact in respect of providing Canadians with the information and resources they need to make informed decisions. Second, the accelerating pace of developments in biotechnology about which policy makers require advice warrants an increase in CBAC's resources so that we can expand the range and scale of projects we undertake.

Reporting Relationships

Ministers need to collectively consider Canada's biotechnology policy and its impact in achieving national objectives. The technology and its implications for Canada are simply too important to leave to individual departments to deal with in an ad hoc manner. Because biotechnology is not the purview of one Minister, but rather requires the collective consideration of many, we strongly urge the introduction of a revised reporting mechanism that would have CBAC report formally and regularly to a cabinet committee. The new Cabinet Committee on the Environment and Sustainable Economy could provide the appropriate forum for receiving and discussing collectively CBAC's advice, thus facilitating the over-arching policy integration necessary for a complex horizontal file. CBAC's activities would continue to involve regular and frequent engagement with individual Ministers, or sub-groups of Ministers, and their respective staffs on specific issues.

Looking Forward

The dynamic nature of biotechnology and its use in our society requires a dynamic biotechnology strategy — nimble enough to take advantage of new opportunities and forward-looking enough to anticipate new challenges and adjust accordingly. CBAC is well positioned to undertake the ongoing review and wide-ranging consultations necessary to ensure that Canada's biotechnology strategy remains current and relevant in a fast-paced international arena.

Document 2

Action Themes of the Canadian Biotechnology Strategy — Illustrations of Progress Made[37]

ACTION THEMES	EXAMPLES OF PROGRESS MADE AND RELATED DEVELOPMENTS
Building public confidence and awareness, and communicating accurate, balanced, easy-to-understand information to Canadians *Variety of sources of information available, outreach limited.*	*The following examples of public information and outreach illustrate the variety of sources of information available:* • Canadian Biotechnology Advisory Committee (CBAC) — All publications and research commissioned are publicly available on CBAC's website. • *Biotech Watch* — CBAC's newsletter informs readers of committee work and highlights special topics. • Federal BioPortal — launched in 2004; designed to help the public navigate federal information holdings related to biotechnology. • Genome Canada website for General Public — DNA Basics, Ethics, Health, Environment. • Public Outreach — "The GEEE! In GENOME" sponsored by Canadian Museum of Nature, Genome Canada, and the Canadian Institutes of Health Research (also features in-class activities for teachers). • Canadian Biotechnology Education Resource Center "improving the quality of biotechnology education in Canadian schools". • BIOTECanada — Biogen Idec Teaching Excellence Award — a national award program dedicated to promoting and recognizing teaching of biotechnology at the secondary-school level in Canada. • National Biotechnology Week — held annually in September by BIOTECanada to raise awareness.
Further expanding Canada's R&D and science base to support Canadian competitiveness in biotechnology as well as the regulatory system *World-class science; Large government investments in R&D generally have supported development of biotechnology; specific genomics focus put Canada on map internationally.*	• Large investments in R&D and the creation of new institutions that fund research, build international partnerships, and train researchers; Support to higher education R&D increased 238 percent since 1999; Canada second in OECD countries for higher education R&D investment; Canada tops world in biotechnology crop research and development. • National Research Council of Canada investments in biotechnology. • Canadian Light Source Inc., Saskatoon — a tool for biotechnology research.

[37] Please note that the examples listed are not limited to those directly attributable to the Canadian Biotechnology Strategy. They are meant to illustrate the types of initiatives in Canada that contribute to achieving the broad strategy goals. Further, this is not an exhaustive list, but meant to be illustrative only.

ACTION THEMES	EXAMPLES OF PROGRESS MADE AND RELATED DEVELOPMENTS
	• Canadian Institutes of Health Research and its Institute of Genetics e.g. research initiative Facing Our Future: Human Genetics, Ethics, Law and Society. • Natural Sciences and Engineering Research Council (NSERC) — federal granting council funds genomics and biotechnology research. • Genome Canada and six Genome centres across Canada — large-scale research projects in key selected areas such as agriculture, environment, fisheries, forestry, health and new technology development; international partnerships with Sweden, the Netherlands, Denmark, Spain, U.K., United States, Australia and New Zealand; GE3LS (Genomics ethical, environmental, economic, legal and social) research initiative. • BIOCAP Canada Foundation — mandate to establish, encourage and capitalize on research partnerships to enable the transformation to a sustainable bioeconomy in Canada.
Regulating to protect health and the environment *Focus on biotechnology regulation under Canadian Biotechnology Strategy; more to be done on coordination, transparency, etc as recommended by CBAC.*	• Canadian Regulatory System for Biotechnology — Established in 2000 to enhance regulatory capacity and to ensure that Canadians have an efficient, credible and well-respected biotechnology regulatory system that safeguards health and the environment, and permits safe and effective products. • CBAC — advice to government on improving the regulation of GM Foods (2002). • Federal government's Smart Regulation Initiative (2004) highlights biotechnology as a key sector and one where a comprehensive federal strategy is required. • Increasing transparency of regulatory system — Canadian Food Inspection Agency and Health Canada Notices of Submission Project. • Ecosystem Effects of Novel Living Organisms — a proposed research strategy to study long-term effects of GM organisms.
Promoting the use of biotechnology for public health and safety *Good progress.*	• Biotechnology widely used as a tool for public health measures — e.g. a Canadian team was the first to sequence the genome of a SARS viral strain. • Facilities such as National Microbiology Laboratory in Public Health Agency of Canada using biotechnology to advance research and development. • Canadian Institute of Health Research's Institute of Population and Public Health — advancing global health research and leading the development of Canada's public health research agenda.

ACTION THEMES	EXAMPLES OF PROGRESS MADE AND RELATED DEVELOPMENTS
Modernizing Canada's intellectual property laws *No policy changes yet.*	• CBAC has provided analysis and guidance to government on the issues of (1) patenting higher life forms and (2) on the impact of patenting human genetic material on the health sector.
Facilitating measures to help accelerate the application and commercialization of new technologies *Remains a challenge. Concern re: commercialization performance of Canadian companies.*	• Many federal programs contribute to this theme, for example, Industrial Research Assistance Program, Technology Partnerships Canada, Business Development Canada. Issues of coherence and gaps in addressing unique needs of biotechnology companies have been raised as shortcomings. • Federal research funding agencies, e.g., Canadian Institute of Health Research's Proof of Principle Program, contribute to this theme. Issues around adequacy of funding have been raised.
Demonstrating responsible world leadership to improve market access and acceptance as well as stewardship in developed and developing countries *Canada playing prominent role on international stage.*	• Convention on Biological Diversity Canada co-chairs the effort to arrive at an International Regime on Access and Benefit-Sharing of Genetic Resources, to be delivered by 2010. • Federal government programs promote Canadian capability in biotechnology in the global marketplace in order to improve market access for Canadian biotechnology products, manage trade relationships and support Canadian business. • Canada is playing a leading role in setting international standards for biotech foods and their labelling through the Codex Alimentarius Commission, established jointly by the Food and Agriculture Organization and the World Health Organization. • Canada chairs and participates in the Codex Committee on Food Labelling—developing guidance on the labelling of foods derived through biotechnology, and has chaired an international drafting group to provide further technical input on guidelines for the labelling of these foods. • Officers based in Canada and posted abroad are trained to effectively troubleshoot on behalf of Canadian biotechnology interests, particularly in areas of prospective strategic alliances, intellectual property rights and the regulatory environment as it affects commercial and research institute relationships. • Canada Bioscience Group has created a marketing strategy and information kit for trade commissioners to use in the U.S. marketplace to promote Canada's bioscience capabilities in the U.S. market. • Canadian International Development Agency (CIDA)—a major sponsor of Biosciences—eastern and central Africa which is mobilizing biosciences for Africa's development.

ACTION THEMES	EXAMPLES OF PROGRESS MADE AND RELATED DEVELOPMENTS
Developing human resources *Gaps exist but programs underway.*	• The Canadian biotech industry employs approximately 12,000 highly skilled employees. Several initiatives aim to support the development of human resources in research and business and to generate interest among young Canadians in this area of science. • Biotechnology Human Resources Council (BHRC) — national source of human resource information and biotechnology skills development (e.g. BioCareers — a resource for biotech employees offered by BHRC). • Federal granting councils and Genome Canada fund the training and development of researchers. • Dual biotechnology/MBA programs e.g. Simon Fraser University, Ivey MBA Biotechnology Stream, University of Saskatchewan biotechnology management program, University of Calgary MBA/MBT (Master of Biotechnology) Combined Degree Program. • Sanofi-Aventis Biotech Challenge — a series of annual science competitions intended to raise awareness among students, educators and the public about the emerging science of biotechnology.
Improving policy-relevant data collection and analysis *Ongoing requirement; work underway.*	• Statistics Canada — world leader in developing statistical information on biotechnology. World first biotechnology survey was conducted by Statistics Canada in 1996. Canada leads the biotechnology statistical work at the OECD. An international biotechnology definition and model survey based on Canadian proposal was adopted in 2002. An OECD Framework for Biotechnology Statistics was published in 2005. • Public Opinion Research Program — under the Canadian Biotechnology Strategy, Canada has developed one of the world's most comprehensive data sets on pubic opinion about biotechnology and its applications. • CBAC commissions research and analysis on biotechnology policy issues and conducts consultations with stakeholders in order to ensure its advice to government is evidence-based and informed by many perspectives. All analyses are publicly available on CBAC's website. • Since its inception, CBAC has published close to 100 reports and research papers which contribute to the knowledge base and advance analysis on important issues.

ACTION THEMES	EXAMPLES OF PROGRESS MADE AND RELATED DEVELOPMENTS
Building sector strategies and action plans *Nature of sector strategies varies; biotechnology becoming more integrated.*	• CBAC's analysis of Biotechnology and Health Innovation (2004) provides strategies for the health sector in research and development, regulation and commercialization, technology assessment and appraisal, and health system adoption. • Federal/Provincial/Territorial Agricultural Policy Framework. • BioSeas Partnership (Atlantic Canada)—to increase export activity in the marine biotechnology sector.

Appendix 3

Citizen Focus Groups Background Paper: A Biotechnology Strategy for Canada: Issues and Considerations

Prepared by: Decima Research Inc.

May 2006

This Project

As we all can observe in newspapers and on television, biotechnology is not only an economic sector undergoing rapid evolution, but also a sector in which Canadians are playing a significant role in its advancement. That is why the Canadian Biotechnology Advisory Committee[38] (CBAC) is seeking your views on public support, acceptance, and concern towards biotechnology and on the issues that you believe are important to consider so that Canada can take advantage of the promise of biotechnology while effectively managing its risks.

To achieve this dialogue, CBAC is convening a series of discussions that will take place between April and June 2006. During this period, three public opinion focus groups and three expert groups will meet in Montreal, Halifax, and Vancouver. The results of these engagements will inform CBAC's advice to the Government of Canada on the Canadian Biotechnology Strategy (CBS).

You are one of the participants in these focus groups.

What is Biotechnology, and Why are People Talking about it?

Biotechnology is one of the central elements of the new knowledge economy. Like information technology and other emerging fields (e.g. nanotechnology), it represents one of the fields of scientific advance that many say has the potential to improve quality of life and create significant economic opportunity, in North America, and worldwide.

Biotechnology is a body of technical knowledge about living organisms or their constituent parts.

Applied biotechnology is the use of this knowledge to make products and drive processes that serve social, scientific or economic purposes.

In Canada, and the rest of the industrialized world, governments, industries, as well as the public at large are being challenged by the scope of change that new technologies such as biotechnology present, and the implications they will have on our long-term economic development and social well-being.

Research suggests that one of the key reasons why there has been debate about biotechnology is because of its basis in the very nature of life (genetic material), in particular our understanding of genetics and biological development. Biotechnology advances build on recent scientific achievements like the Human Genome Project as well as research in areas of embryo development and tissue regeneration, which have engaged both the expertise and interest of Canadians.

Today, biotechnology affects many scientific disciplines and technology sectors, but historically biotechnology can be traced along two pathways. One pathway, referred to as traditional biotechnology dates back thousands of years, to early agrarian societies in which people collected seeds of plants with the most desirable traits for planting in subsequent years. Today these practices have evolved into sophisticated methods of *selective breeding* and *biodiversity prospecting*. They use DNA and cell manipulation tools that have provided the foundation for modern, molecular biotechnology introduced in the late 1970s. This second pathway of biotechnology development enables the manipulation of genes from any living organism, in

[38] CBAC is an independent, expert committee charged with providing the federal government with impartial advice on important policy issues associated with the ethical, social, regulatory, economic, scientific, environmental and health aspects of biotechnology.

more precise and controlled ways than earlier traditional biotechnology. Such manipulations include refining the expression triggers of specific genes within an organism to produce a certain trait, and also transferring certain genetic traits from one species to another.

Currently, molecular biotechnology techniques are being used to upgrade traditional technologies that address areas such as food, agriculture, health care, forestry, as well as the environment. The latter includes renewable energy, and the recovery of minerals, oil and gas. Summarized below are some of the ways that modern biotechnology techniques have been applied in these areas.

Food and Agriculture

One of the most extensive applications of biotechnology has been in agriculture. Biotechnology techniques have been used to develop plants and animals with enhanced or novel traits. Novel plant traits include herbicide tolerance and pest, insect and virus resistance as introduced into crops like corn, soy, and canola. New applications in food and agriculture promise to provide foods with enhanced nutritional benefits. Some people are concerned about the potential impact of genetically modified (GM) crops on biodiversity, environment and health.

Health Care

To date, applications of biotechnology in health care have focused on fighting diseases using the human body's own 'weapons'. Biotechnology-based medicines and therapies involve or target trigger proteins, enzymes, antibodies and other substances that occur naturally in the human body, to fight infections and diseases. However, biotechnology also uses other living organisms (i.e. plants and animals) and their cells, and viruses as well as bacteria and yeasts to help produce human medicines.

There are several areas in the health care sector where biotechnology is currently being used. They include the following: treatments for diabetes and immunologic disorders; vaccines and antibiotics to prevent disease (e.g. hepatitis B, HIV); and diagnostic tests to identify disease (e.g. chlamydia, gonorrhea, and herpes). Health researchers are studying the use of gene therapy, a technique to correct defective genes responsible for disease development, as a potential cure for common illnesses such as cystic fibrosis and more complex diseases such as arthritis, psoriasis and coronary heart disease. While the promise of biotechnology benefits are apparent, concerns have been raised about ethical issues such as protecting the privacy of genetic information, and the long-term health impacts of biotechnology applications.

Environment

Biotechnology applications in the environment focus on using living organisms to treat waste and prevent pollution. Examples of these applications include bio-filtration and bio-remediation. Bio-filtration refers to the use of micro-organisms to remove pollutants from air emissions and waste water discharges related to various human activities including manufacturing processes. Bio-remediation refers to a number of processes that use living micro-organisms to turn toxic waste into harmless byproducts such as water, carbon dioxide and other materials. One example of a bio-remediation process is bio-stimulation, a technique that involves introducing nutrients to stimulate the growth of "waste-eating" micro-organisms already present in the environment at a waste site. With these kinds of applications, the main concerns that people raise revolve around potential impacts of biotechnology applications on surrounding eco-systems.

In recent years, it has become clear that biotechnology is one of the most intensely competitive sectors of the economy, with many small start-up companies working to compete with (and sometimes to sell to) large multinational companies, and governments working actively to compete for biotechnology investment and the high, value-added jobs that go with it. Recent experience shows that government policies can have a profound influence on the location of R&D expenditure by biotechnology companies, for example in

areas where governments have made significant investments in basic research at the university level.

Today, the Canadian biotechnology sector is primarily comprised of many small companies with innovative ideas but not much capital, and this circumstance has important implications for the current and future potential of this industry in Canada.

Canadian Biotechnology Strategy

In 1998, the Government of Canada introduced a strategy for biotechnology, with a view to fostering the responsible development of biotechnology to improve quality of life for Canadians while protecting health, safety and the environment.

Since then, there have been many important developments in a number of areas:

World-class Biotechnology Research

The establishment of research institutes and scientific funding agencies like the Canadian Institutes of Health Research, Genome Canada, Canada Research Chairs, and the Canada Foundation for Innovation.

The Establishment of CBAC

CBAC is an expert committee charged with providing government with independent, impartial advice on important policy issues associated with the ethical, social, regulatory, economic, scientific, environmental and health aspects of biotechnology.

Major Advances in Key Fields

Canadian scientists and biotechnology companies have made important advances in key areas:

- A team from the Faculty of Medicine at Centre hospitalier universitaire de Québec at Université Laval recently discovered a natural defense mechanism the body deploys to combat nerve cell degeneration observed in people with Alzheimer's disease. The discovery could lead to a new therapeutic approach to Alzheimer's disease.
- University of Toronto biomedical scientists have pioneered the genetic mechanisms for several diseases, and more recently bioengineers discovered a way to increase the yield of stem cells from umbilical cord blood by removing unwanted cells that inhibit stem cell growth. If the team can grow blood stem cells from umbilical cord blood (usually only containing enough blood stem cells to treat children), they could treat adult diseases with this method, rather than the current method, which requires bone marrow transplants.
- Scientists at McGill University recently discovered a gene that controls the speed at which patients develop tuberculosis, providing a new view of the mechanisms underlying the development of tuberculosis and possibly leading to public health efforts aimed at containing the disease. The gene, NRAMP1, is involved in many other illnesses, including leprosy and rheumatoid arthritis. Variants (alleles) of NRAMP1 are now known to control the speed at which tuberculosis develops. This is a breakthrough in understanding how a gene can control the time frame between initial infection and the disease.
- A BC neuroscientist developed the world's first diagnostic blood test to detect diseases such as Alzheimer's, Parkinson's, Lou Gehrig's, and mad cow disease. This test could be available in as few as two years.
- University of Toronto researchers have designed a chemical screening tool that lights up when dangerous pathogens and disease-causing agents in air, water and bodily fluids are present. The technique using DNA to detect target DNA, could one day be used in clinical care situations to quickly detect diseases such as AIDS and hepatitis, and it could act to constantly monitor the environment and sound an alarm if harmful agents were to appear.

- In the area of environmental bio-remediation, an international team led by three University of British Columbia microbiologists recently completed the mapping (or sequencing) of the genetic makeup of a soil bacterium called Rhodococcus sp. RHA1. It is the first organism of its kind to be completely sequenced. This work contributes to our understanding of how this soil organism breaks down PCBs and other toxic wastes and adapts to the environment around it.

A Brief Overview of the Canadian Biotechnology Strategy

Origins

In 1983, the federal government launched a National Biotechnology Strategy (NBS) which focused on scientific research and development, and human resources development. The NBS was broadened to address regulatory, social and ethical issues which underpinned the launch of the CBS in 1998.

The CBS, a multi-departmental strategy involving Industry Canada, Health Canada, Environment Canada, Fisheries and Oceans Canada, Natural Resources Canada, Agriculture and Agri-Food Canada, and International Trade Canada, explicitly recognizes the social and ethical dimensions of biotechnology along with its economic potential.

Vision of the CBS

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 in biotechnology.

Ten CBS Themes for Action:

- Building public confidence and awareness, and communicating accurate, balanced, easy-to-understand information to Canadians;
- Further expanding Canada's R&D and science base to support Canadian competitiveness in biotechnology as well as the regulatory system;
- Regulating to protect health and the environment;
- Promoting the use of biotechnology for public health and safety;
- Modernizing Canada's intellectual property laws;
- Facilitating measures to help accelerate the application and commercialization of new technologies;
- Demonstrating responsible world leadership to improve market access and acceptance as well as stewardship in developed and developing countries;
- Developing human resources;
- Improving policy-relevant data collection and analysis; and
- Building sector strategies and action plans.

The Three "Pillars" of Biotechnology:

Based on these 10 themes, the CBS rests on three "pillars", which represent the broad areas of interest for the federal government in achieving the vision for the CBS and provide an organizing framework for federal involvement in biotechnology.

- **Stewardship:** ensuring effective stewardship of biotechnology in the areas of health, safety and the environment.
- **Benefits/Innovation:** maximizing the social, economic and environmental benefits associated with biotechnology products and applications.
- **Citizen Engagement:** engaging a wide spectrum of Canadians on biotechnology and its role in society.

Federal Programs and Spending on Biotechnology Today

The annual federal biotechnology investment is about $750 million.[39]

- Approximately 85 percent of this total amount is spent on research and development (90 percent of this for research outside government);
- 6 percent on the regulatory system;
- 5 percent on policy development activities;
- 1 percent on commercialization; and
- 1 percent on communications and public awareness.

Canada's Biotechnology Performance

Various aspects of Canada's performance in biotechnology have been assessed in recent years. Canada has significantly improved its performance in basic research (notably in genomics[40] and proteomics[41]).

I. Innovation

Research and Development

Research and development and the innovation it spurs are at the heart of the future impact of biotechnology, not just in Canada, but worldwide. Scientific discovery and innovative research and development are what drives this industry.

The federal research granting councils (Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council and the Social Sciences and Humanities Research Council), in addition to two arms-length federally funded research organizations (Genome Canada and the Canada Foundation for Innovation) are the main instruments for building research excellence, talent and infrastructure in Canada through our universities. Federal departments and agencies conduct biotechnology research in support of their own programs, and, in particular, the science that underpins regulation of biotechnology products.

The Conference Board of Canada states, "the government's performance in creating an enabling environment for biotechnology has been moderate".

"While the government's overall performance has been assessed as moderate, the specific performance of underlying factors varies. The Canadian public's confidence in the regulatory process is high—just behind confidence levels in Australia and the United States. Canadians are increasingly receptive to the development and use of aspects of biotechnology, a factor that may prove to be advantageous for companies deciding where to locate operations.

While the regulatory approval process in Canada is longer than in comparator countries, and is not considered to be sufficiently harmonized with those of other key nations, the system regulates based on the novelty of the technology and is well respected by Canadian residents.

The federal government has more than doubled its spending commitments to academic research in life sciences (biotechnology) over the past five years, indicating a positive trend. However, this is considered by many to be insufficient, as the investments made by other nations are much more aggressive.

Government research institutes are also major players in the performance of basic research in biotechnology. The challenge is to connect this

[39] Based on a 2004 Expenditure and Management Review conducted by the Treasury Board Secretariat (unpublished report).

[40] Genomics is defined as the study of the entire genome (including chromosomes, genes and DNA) and how different genes interact with each other. Genomics and molecular biology form the basis for modern biotechnology and, more specifically, pharmacogenomics, or the application of genetic analysis to identify potential targets for therapeutic products (drugs, vaccines).

[41] Proteometics is defined as the study of the protein products of genes, protein-protein interactions and protein sub-cellular localization. Examples could include engineering of new systems to sequence proteins or study protein interactions with other proteins or DNA, developing faster and cheaper detectors, such as high-density capillaries or high throughput mass spectrometers, and developing centres with expertise and accountability for protein analysis, such as 2D protein databases.

research to the business community in order to help Canadian companies survive and grow in this increasingly competitive field. Canada also has a favourable tax treatment for R&D expenditures, but this advantage is waning as other nations respond with their own models." [42]

Many of the issues and challenges in the biotechnology sector are representative of those found in the science and innovation sphere generally. These have been summarized in the National Research Council of Canada's Foresight Consolidation Report[43] that states:

"There is good evidence that Canada's science and technology expertise is world-class and productive. We also have effective and generous tax-credit regimes that support innovation. Canada's R&D community is busy, complex but unfocused as we do not have a clear, explicit strategy for science and technology. In addition, Canada does not have innovation practices that enable increased private sector R&D investment, and support the flow of venture capital.

Canada has weak coordination among the players in innovation policy, both provincially and federally. There is a lack of focus in innovation policy, strategy and execution — too many players working with different and sometimes opposing plans and policies. In the fast-growing innovation economies (e.g. Finland, Japan), integration, convergence and focus are keywords representing action. They need to be made real in Canada, and some limited progress is now slowly being made."

Building a Strong Biotechnology Sector

According to the Conference Board of Canada, Canada's biotechnology sector is struggling financially. Of the 500 or so biotechnology companies in Canada, 10 companies account for 70 percent of total biotechnology market capitalization. The majority are small- to medium-sized enterprises, with no major products on the market, fewer than 50 employees and less than two years operating cash on hand. The major challenges for Canadian biotechnology companies remain access to capital to sustain them during the long period between proof of concept to actual revenues and the lack of larger Canadian firms that can act as lodestars for the juniors. Investor confidence is weak, with a focus on short-term returns. In addition, Canadian firms have difficulty recruiting the scientific talent and the marketing, management, and sales expertise required to succeed internationally.

Commercialization

(Activities specifically oriented to developing new biotechnology products for sale in global markets.)

There is neither a biotechnology-specific commercialization policy nor a general commercialization plan in Canada. About one percent of annual federal biotechnology expenditures are invested in financing and pre-commercialization initiatives, which provide support for new technologies, including biotechnology. Many experts are concerned about what they observe to be poor performance in developing products in Canada.

Biotechnology Human Resources

Funded in part by the federal government, the Biotechnology Human Resources Council designs, distributes and promotes programs and services of value to Canada's biotechnology industry for attracting, developing and retaining a highly-skilled Canadian workforce essential for its sustainable growth and international competitiveness.

The Canadian innovation system is challenged by shortages of highly qualified people in all stages of the innovation process, affecting economic progress. Canada ranks 14th in Organisation for Economic Co-operation and Development countries in management (company operations and strategy geared toward improving entrepreneurship and productivity), has fewer science and technology workers than many other advanced economies and lacks experienced venture capital fund managers.

[42] National Research Council of Canada, *Looking Forward: S&T for the 21st Century*. Foresight Consolidation Report, NRC Renewal Project, (August 2005): www.nrc-cnrc.gc.ca/aboutUs/ren/nrc-foresight_18_e.html.

[43] Conference Board of Canada, *Biotechnology in Canada: A Technology Platform for Growth*, (2005): www.conferenceboard.ca.

Consequently, attracting and retaining scientific, engineering and technical workers will be especially challenging as labour market alternatives for graduates in science and engineering are neither extensive nor varied, largely due to the low level of research and innovative capacity in the Canadian private sector.

II. Regulation

Regulation is a tool government uses to protect the health, safety and well-being of Canadians as well as Canada's natural environment. Biotechnology regulation involves the supervision of safety issues associated with biotechnology, and the approval processes associated with bringing a new biotechnology product to market. Regulatory agencies are the agencies or government departments that have responsibility over the legislation (acts and regulations) for a given sector of the industry. Below you will find more details.

Regulation is of international importance. As scientific advances increase the complexity of products being developed using biotechnology, time and effort is required to improve international cooperation, coordination, and development of new regulatory tools and processes. For example, the consideration of ethical issues has been raised as an important element of the process.

The Federal Regulatory Framework for Biotechnology (1993) provides guidance for regulating products of biotechnology as follows:

- Maintains Canada's high standards for protecting the health of Canadians and the environment;
- Uses existing laws and regulatory departments to avoid duplication;
- Develops clear guidelines for evaluating biotechnology products that are in harmony with national priorities and international standards;
- Provides a sound, scientific knowledge base on which to assess risk and evaluate products;
- Ensures the development and enforcement of Canadian biotechnology regulations are open and include consultation; and
- Contributes to the prosperity and well-being of Canadians by fostering a favourable climate for investment, development, innovation and the adoption of sustainable Canadian biotechnology products and processes.

Regulatory departments/agencies implement regulatory responsibilities as follows:

- Health Canada regulates biotechnology-derived products that are subject to the *Food and Drugs Act*. Health Canada and Environment Canada share the responsibility for regulating bioproducts relevant to *Canadian Environmental Protection Act*, 1999 (CEPA);
- Environment Canada regulates biotechnology-derived products subject to the CEPA which provides the federal benchmark for notification and assessment of environmental and human health risk (conducted by Health Canada) from new (as well as existing) biotechnology products;
- The CFIA regulates biotechnology-derived products including novel plants, animal feeds and animal feed ingredients, fertilizers and veterinary biologics, and conducts all federal inspection and enforcement services related to food; and
- Fisheries and Oceans Canada is responsible for regulating potential environmental release of transgenic aquatic organisms.

Experts have commented on the regulatory system indicating that there has been progress in this area, but that outstanding issues remain.

In a 2004 report, the External Advisory Committee on Smart Regulation (EACSR)[44] built upon previous recommendations by the Royal Society of Canada[45] and by CBAC.[46] It urged the federal government to pay particular attention to the regulatory system for biotechnology and specifically recommended that the government should make it a priority to develop and implement a comprehensive, government-wide biotechnology regulatory strategy.

In a recent advisory memorandum on regulatory reform, CBAC has further observed:

"The lack of a comprehensive regulatory system for products of biotechnology is impeding the development of niche industries in Canada and consequently the potential for consumer and economic benefits. Regulators are justifiably concerned about being able to apply the appropriate risk analysis to new applications of biotechnology… At the same time, Canadian firms need to know what the rules are so they can decide whether to invest in Canada or elsewhere. With respect to some of these emerging industries, such as plant molecular farming, Canada may already have missed the opportunity.

Canada is the leading developer of many of these new products. We should also be leading the way in developing appropriate regulation. Our scientific community has the greatest potential to manage the safe introduction of these products. Yet our apparent inability to act disenfranchises us from the international management of our developments. Canada's standing in and contribution to the international debate about regulation could be jeopardized while our production and export of high-knowledge products could be threatened.

Ultimately, delays in filling the gaps in the regulatory system threaten the research, development and commercialization in Canada of socially beneficial biotechnology."[47]

III. Public Information and Engagement

Public information is the provision of information to the population at large. There is no single definition of public engagement, but the one most appropriate for these purposes encompasses "individual and collective actions designed to identify and address issues of public concern". It can include efforts to understand and address public concerns about certain issues, or it can include efforts to directly address an issue, work with others in a community to solve a problem or interact with the institutions of representative democracy.

The federal government tracks public opinion on biotechnology and its applications. The results are made publicly available on the BioPortal (www.biotech.gc.ca).

The BioPortal is an Internet-based, one-window access to comprehensive information on biotechnology and its applications for consumers, industry, scientists and educators. The BioPortal brings together resources from all federal departments and agencies, including government policy and research activities; business support programs and market intelligence; a virtual library of educational resources; and regulations on biotechnology research and applications.

CBAC has sponsored the development of a "Dialogue Tool" designed to provide a structured methodology for the discussion of contentious issues. This tool was developed in the context of GM food but has been revised for broader applicability. It is available at (www.cbac-cccb.ca/epic/internet/incbac-cccb.nsf/en/h_ah00350e.html)

[44] External Advisory Committee on Smart Regulation, *Smart Regulation: A Regulatory Strategy for Canada*, (2004): www.smartregulation.gc.ca.
[45] Royal Society of Canada, *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada*, (2001): www.rsc.ca/foodbiotechnology/GmreportEN.pdf.
[46] Canadian Biotechnology Advisory Committee, *The Regulation of Genetically Modified Foods*, (August 2002): www.cbac-cccb.ca.
[47] Canadian Biotechnology Advisory Committee, *The Regulation of Genetically Modified Foods*, (August 2002): www.cbac-cccb.ca.

Without exception, the critical role of public engagement in policy development concerning biotechnology is emphasized in all countries. Also recognized is the need to invest significant resources in this area in order to meaningfully and systematically reach and engage the public. Initiatives such as the U.K.'s GM Nation have been, on the one hand, lauded for innovation at seeking to engage thoughtful engagement of the public, but have also been criticized for being insufficiently resourced in terms of time, money and expertise.

In the context of Canada's regulatory system, the need to provide the public, with information on risk management analysis has been highlighted consistently, as has been the importance of opportunities for the public to engage in dialogue with industry and governments in order to increase understanding of various perspectives.

The EACSR states, "In light of its significant ethical, social, environmental and economic implications, biotechnology is an area where government should be particularly active in engaging citizens and stakeholders and in encouraging public debate".[48]

IV. Social, Ethical and Legal Aspects of Biotechnology

Social, ethical and legal aspects of biotechnology involve the investigation of the complex issues that society must consider as applications of biotechnology evolve. Issues like cloning, privacy of our genetic information, gene patenting, and certain forms of stem cell research are examples.

The social and ethical dimensions of biotechnology have received significantly more attention since the early 1990s. They have been addressed by a variety of means, for example, by including them in the terms of reference of all studies conducted by CBAC, as a topic for framework development by interdepartmental working groups, in public dialogue, in major conferences and background studies (e.g. privacy, biobanks). Federal government funding for initiatives to explore the social and ethical dimensions of biotechnology have also been provided to Genome Canada.

Much work remains in this emerging area of biotechnology and includes efforts to connect research to policy development, develop new frameworks or modify existing ones to ensure that methodologies incorporate social and ethical considerations systematically. Some call for a public engagement strategy that is inclusive and sustained so that the public is informed and meaningfully connected to the policy development process.

Developments in Other Countries

Recognizing the transformative nature of biotechnology, its powerful contribution to economic growth and to progress in solving long-standing global challenges, governments around the world are taking decisive steps to advance their competitive advantage in biotechnology and to address areas of weakness.

The U.S. holds the lead with respect to the commercialization of biotechnology products and applications. This lead is considered to be as a result, in part, from its early beginning in this field (e.g., commercialization of biotechnology products and services in the U.S. began in the mid-1970s, while Japan, the United Kingdom, France and Canada didn't really enter the market until the early 1980s).

The U.K. is the European leader in the bioscience industry, and number two in the world after the U.S. The U.K. biotech sub-sector (as defined by Ernst & Young) includes over 400 companies with over 25,000 employees and with £3 billion in revenues.

Among developed countries, the European Union, Japan, New Zealand and Australia all have specific national biotechnology

[48] Conference Board of Canada, *Biotechnology in Canada: A Technology Platform for Growth*, (2005): www.conferenceboard.ca.

strategies. In the U.S., although there is no national strategy, most states have biotechnology programs as part of their economic agendas. Among developing and middle power countries, India and Chile have placed a special focus on biotechnology, along with other countries such as Singapore, Cuba and South Korea.

Many of Canada's competitors in the U.S., Europe, and the developing world are prioritizing their research funding in areas of strategic or national importance, with biotechnology as a key element.

Economic Tools: R&D Tax Incentives

Some countries offer R&D tax incentives or other tax relief to encourage basic research. These incentives are relevant, although not specific, to biotechnology. Japan and Canada give tax credits for basic research conducted by the private sector. Japan also offers direct tax relief for companies performing or financing basic research.

Another common tactic is to stimulate more collaborative research between industry and public research institutions and universities through the design of R&D tax incentives. Japan and the United Kingdom, for instance, provide tax incentives for industry R&D projects contracted to universities and public research institutes. Japan has made substantial progress since 2001, with its government investing in incentives that will help attract foreign companies into the biotech market. For example, 12 percent of overall R&D spending is now tax deductible.

Economic Tools: Bioclusters

Unlike Canada, a number of its competitors have implemented specific biocluster policies (e.g. U.K., France, and Japan). In the U.K., fostering clusters in the health/pharmaceutical sector is considered a key mechanism for supporting biotechnology commercialization. In France, government investment is shifting to support biotechnology clusters and networks. In Japan, the fostering of bioclusters is seen by government as a key tool in the achievement of national development in biotechnology.[49]

In China, government efforts toward biocommercialization began in the late 1990s with the establishment of the China National Center for Biotechnology Development, which plays a key role in supporting innovation in biotechnology.

According to the Conference Board of Canada, it is generally agreed that the U.S. has an efficient technology transfer system that links basic research with companies and investors, that there is sufficient venture capital, and that there exist many clusters of biotechnology activity. For example, the U.S. indicates that it has 51 bioclusters; by comparison, the United Kingdom has nine, and Canada, France and Japan each claim to have eight.

[49] Conference Board of Canada, *Biotechnology in Canada: A Technology Platform for Growth*, (2005): www.conferenceboard.ca.

Appendix 4

Summary of Input from Expert Roundtables and Citizen Focus Groups[50]

[50] Complete reports of each expert roundtable and citizen focus group as well as more detailed summary reports can be accessed on the CBAC website (www.cbac-cccb.ca).

I. Introduction

A series of expert roundtables and citizen focus groups, sponsored by the Canadian Biotechnology Advisory Committee (CBAC) under the theme of "*Canada's Biotechnology Strategy: Charting the Path Forward,*" were held from April to June 2006 in Montreal, Halifax and Vancouver. The roundtables were attended by members of the biotechnology community including academia, research centres, industry, financial support agencies, and environmental and other interested organizations. The citizen focus groups were attended by members of the public referred to as "involved" Canadians.[51]

The purpose of the roundtables and focus groups was to provide input into the formulation of CBAC's advice to the Government of Canada on revisions required to the existing Canadian Biotechnology Strategy, now eight years old, in the context of current challenges and opportunities.

II. Canadian Biotechnology Strategy

The starting point for the discussion was the existing Canadian Biotechnology Strategy (CBS), launched by the federal government in 1998. The CBS provides overall guidance for the development of biotechnology in Canada. As a broad statement of the Government of Canada's commitment to the responsible development of the technology, it sets out a vision for Canada:

> 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 in biotechnology.

The strategy provides guidance to the federal government although its goals and principles also suggest action for biotechnology stakeholders more broadly. It identifies areas of development but is not prescriptive. The strategy is not specifically or centrally funded as a federal program. Consequently, each department with biotechnology-related activities is responsible for defining their role under the strategy, undertaking actions relating to their department's mandate, and defining and measuring successful implementation using their own performance measures. Mechanisms for interdepartmental coordination are in place through a governance structure that includes a ministerial coordinating committee along with deputy ministerial and assistant deputy ministerial coordinating functions. These are supported by a secretariat, which also provides support to the government's independent external advisory committee, CBAC.

III. Expert Roundtable Results

Overall, participants supported the development of a renewed strategy with certain conditions; the strategy should be focused and action-oriented with strong federal government leadership and measurable results. It should provide a holistic and balanced/neutral view of biotechnology and biotechnology issues. This view should be supported by strong risk-benefit analysis as well as consideration of moral and ethical questions. Many participants indicated that if the renewed strategy lacked these qualities, it would not add value and should not be developed.

The renewed strategy should take the form f a "national action plan for biotechnology" and should have a broad Canadian scope. The action plan should outline responsibilities for government and for its partners, and include measurable outcomes. A range of stakeholders federal and provincial governments,

[51] Involved Canadians represent about 27 percent of the population as a whole, and they tend to engage in public policy and public affairs issues to a much greater extent than average. While from a demographic and geographic perspective they "look" a lot like other Canadians, their behaviours (writing letters to the editor, joining community groups, speaking publicly about topics they know) reveal a level of attention to issues that differs markedly from the norm. More importantly, they tend to be influential in opinion formation among the rest of the population so views they tend to hold can act as a "bellwether" for where public opinion is likely to go over time.

academia, industry, representatives of civil society, the public all have a role to play in biotechnology in Canada and should be involved in the strategy. Partnerships between governments and with industry and other stakeholders will be important for successful governance and implementation of a renewed strategy.

Many participants noted the importance and usefulness of appointing a federal "champion" to provide leadership for biotechnology. Improving coordination across federal departments, between governments and with industry and other stakeholders (both domestic and international) was identified as another critical issue for success. Having expressed the desire for a multi-stakeholder governance model, participants also recognized the challenges associated with such a model in terms of effective decision-making leading to real results.

Advancing the biotechnology sector was an important element of a renewed strategy to many participants. Some felt that there would be merit in building excellence in specific areas of strength. They noted that provinces and regions have different strengths which could be capitalized on successfully. However, they cautioned against developing a strategy that is too prescriptive in order to avoid marginalizing activities outside the immediate scope of the strategy; the strategy should enhance, not limit, activity.

In each session, many participants highlighted the commercialization challenge faced by Canadian companies. They pointed to the following areas that would enhance the biotechnology industry:

- clear government priorities and targeted policies;
- necessary human capital (especially skilled and experienced senior managers) to build successful companies;
- support for small- and medium-sized companies;
- venture capital investment in Canadian companies;
- long-term investment in Canadian companies; and
- support for the full range of activity in the biotechnology sector (e.g. from research to product development and commercialization).

Public awareness activities must provide balanced and unbiased information about the risks and benefits of biotechnology, and how and where biotechnology contributes and can contribute to societal needs. The objective of these activities should be to support informed decision-making by Canadians. Opportunities for the public to engage in dialogue around the moral, ethical, social and cultural dimensions of biotechnology are required.

A renewed strategy needs to build new ethical frameworks to properly equip us to discuss and deal with the complex and value-laden aspects of current, emerging and still unheard of areas of biotechnology. Participants pointed out that the strategy should elicit trust and credibility. Consideration of the language used in the strategy, the way that issues are presented and an overall willingness to analyze risks and benefits fairly and accurately would help build support for a strategy.

Some participants expressed concern that Canada's biotechnology strategy is, and will be, seen as biotechnology promotion alone without balanced attention to stewardship. They noted a built-in contradiction in creating a government strategy on biotechnology. This contradiction is rooted in the tension between the government's responsibility to both regulate and promote biotechnology. We do not yet have the answers to this dilemma, but we have noted the problem exists. The next strategy should provide a more holistic and balanced/neutral view of biotechnology and biotechnology issues, and its implementation mechanisms should include transparent risk-benefit analysis as well as consideration of moral and ethical questions.

Four main challenges emerged as **priority directions for further consideration and action in a renewed strategy**. These interrelated directions are: engaging Canadians in

informed dialogue; ensuring ethical frameworks are developed and used to consider all the implications of biotechnology applications in our society; stewardship of biotechnology; and advancing the biotechnology; sector.

1. Engaging Canadians

In addition to acquiring a better understanding of how and where biotechnology contributes and can contribute to societal needs, Canadians would benefit from dialogue around the moral, ethical, social and cultural dimensions of biotechnology. The design of public engagement activities, and the language used in both the strategy and in dialogue, must recognize the desire of Canadians to engage in meaningful and considered debate.

Public awareness activities, including the provision of information about biotechnology, must be balanced and unbiased to support informed decision-making by Canadians. Information to inform the public should provide an accurate assessment of risks and benefits. Needs, alternatives, ethics and social values must become consistent aspects of the biotechnology discussion.

2. New Ethical Frameworks

A renewed strategy needs to provide new ethical frameworks and possibly new vocabulary to properly equip us to discuss and deal with the complex and value-laden aspects of current, emerging and still unheard of areas of biotechnology. At a fundamental level, we need to consider carefully how we analyze and discuss biotechnology. To date, some felt that views have been narrowly defined around constructs that were more economically focused. Risk assessment is a fundamental part of this; we may even need to change the way we talk about risks and benefits.

Participants pointed out that the strategy should elicit trust and credibility. Consideration of the language used in the strategy, the way that issues are presented and an overall willingness to analyze risks and benefits fairly and accurately would help build support for a strategy.

3. Stewardship of Biotechnology

Participants agreed that the federal government, with stakeholders and civil society among others, must conscientiously steward biotechnology by enabling dialogue and informing Canadians, identifying and brokering related social and ethical issues, providing transparent risk assessment, and advocating responsible development and use.

Some participants cautioned against immediate action to advance the biotechnology sector calling instead for more dialogue with Canadians about biotechnology issues. They noted a need to question the assumption that it is important and necessary to increase research and development in biotechnology and to quickly develop the Canadian biotechnology sector. We have to be clear about why biotechnology is needed and why we need to move quickly. Technology and competitiveness should not be the ultimate drivers of this strategy.

As well, participants in each session pointed out a need to better understand and communicate the risks associated with biotechnology and the liability issues that arise. New risk assessment models may be needed to make sure that issues such as assessing risk over time (e.g. risk over decades) and potential consequences on other sectors/environments (e.g. aquatic environment) are explicitly and adequately addressed.

Proper stewardship of biotechnology also means making certain that we have a strong regulatory system to ensure the health and safety of Canadians and their environment. Many participants pointed to our regulatory system as a Canadian success that could be marketed and shared with other countries. However, they also called attention to regulatory deficiencies that should be addressed in a renewed strategy. Participants observed that government staff may lack the resources required to stay abreast of emerging biotechnologies. In addition, the nature of the

Canadian process makes it difficult for it to remain flexible enough to keep up with the fast pace of the biotechnology sector.

4. Advancing the Biotechnology Sector

In each session, many participants stressed the need for a renewed strategy to support development of the biotechnology sector. They particularly highlighted the following challenges:

- There is a lack of clear government priorities and targeted government policies to support biotechnology development in Canada.
- Government funding programs also need to be better targeted to support the full range of activity in the biotechnology sector (e.g. from research to product development and commercialization).
- Canada lacks the necessary human capital (especially skilled and experienced senior managers) to build successful companies. It was suggested that education systems place greater emphasis on developing entrepreneurial skills required to build successful companies and thus a successful biotechnology sector.
- We do not support small companies adequately. Tools required for success in biotechnology (e.g. patent protection advice) are often inaccessible and/or unavailable to small- and medium-sized enterprises due to issues such as cost or lack of expertise/knowledge.
- There is a lack of venture capital investment in Canadian companies, and investments are often short-term.

Some participants noted that Canada has a great environment for developing "ideas" but a poor business-oriented environment. Improving the business environment would attract talent and investment to Canada. Focusing on achieving world-class processes and structures to support biotechnology thus creating a biotechnology-friendly environment in Canada was suggested.

It was pointed out that success in other countries has been supported by targeted government policy. Thus, many participants suggested that the Canadian government identify priorities for biotechnology and develop and implement strategic policies to support them. Investment in biotechnology could be targeted to those areas where Canada is well positioned to grow and/or be effective (e.g. health biotechnology). Some participants pointed out that strategic investments in areas of Canadian strength/competitive advantage will create the conditions needed for innovation in other areas both within and outside biotechnology (e.g. investment in defence led to the development of the Internet). Participants generally supported this approach but noted that the idea of strategic biotechnology clusters should not be embraced at the expense of continued broad based activity in other areas.

Investment in R&D is necessary but not sufficient to support the biotechnology sector. Specific initiatives to advance commercialization objectives are required and these must be grounded in the relationship between "technology push" and "market pull." Market considerations should be addressed earlier in the research and development cycle in order to evaluate the potential competitiveness of a product before too much investment is made. It was noted that innovative companies are skilled at connecting technologies to markets early.

A well-functioning regulatory system is needed to advance and support the biotechnology sector. However, several participants in all three sessions stated that Canada's regulatory system is not responsive enough. Many felt that our regulatory environment is too slow and does not respond easily to changing technology thus creating an unpredictable environment that is not conducive to helping safe and effective biotechnology products reach the market. It was also pointed out that the regulatory system is complicated and involves many players (e.g. Canadian Food Inspection Agency, Health Canada, Environment Canada, Fisheries and Oceans Canada). Consequently, the specific requirements, timelines, processes and

players are often not well understood by the Canadian public and in some cases by government and industry.

Overall, it was recommended that the federal government improve its role in: strategy leadership, federal coordination, stewardship, and regulatory efficiency (without compromising quality).

Some participants suggested that Canada should aim to harmonize its regulatory processes with other similar countries, while maintaining Canadian standards for quality, to better support innovation and competitiveness in a global market. They pointed out that our processes are significantly longer than most other countries and that delays in decision-making (and in some cases, an absence of key decisions) can have a negative impact on innovation. In the area of intellectual property protection (including data protection) some participants emphasized the importance of moving to harmonize with global trading partners in order to create the climate for commercial success.

Discussion of the form of the strategy whether a federal government strategy or a national strategy led participants to underscore the importance of action, accountability and leadership regardless of the form.

IV. Citizen Focus Groups:

Qualitative research was conducted through citizen focus groups of involved Canadians in three sessions held in Halifax, Montreal and Vancouver. The research findings suggest the following:

1. There is a lack of public understanding about the applications and the issues that biotechnology touches. There was a clear and pervasive view that Canadians lack the appropriate level of knowledge and understanding of this field, given its broad scope and its implications for society. Some felt that this lack of public understanding could be a limiting factor to public willingness to allow these technologies to evolve. Others felt that it was a challenge in that they feared that some issues were being purposely kept from the public, and several cited the lack of labeling of genetically modified food as an example of information being kept from Canadians.

2. The groups expressed the view that biotechnology should be a priority for Canada and that the federal government needs to have a stronger role in biotechnology. Several reasons were advanced to elaborate this viewpoint:

- There is perception that important and positive impacts on the health of Canadians would result from biotechnology research.
- Some participants expressed a sense of greater comfort that appropriate measures would be taken to deal with regulatory and ethical considerations in Canada than would likely be the case in other countries. Participants generally indicated a belief that biotechnology is evolving globally and, in that context, there is a strong and widely held view that Canada should be involved and be a leader.
- It was pointed out that Canada may likely possess natural abilities in certain areas that should bode well for success, whether in terms of scientific capacity or in terms of natural resources, or both (e.g. crop experts).
- Biotechnology is perceived by many as a leading edge technology that will bring with it high-value employment and economic benefits.

3. Priorities for the Federal Government. Fundamental to the discussion of the federal government role and priorities was the view that the development of biotechnology presents risks and that Canada's regulatory systems for safety, health, and environmental protection are of utmost importance to public confidence in this technology and its applications. This core function of government must be implemented within a credible system of ethical governance that is clear to Canadians so that the benefits of biotechnology are achieved without compromising social values.

- **Public education and outreach.** Canadians require more information about biotechnology and all of its areas of inquiry, as well as information about systems of regulatory and ethical governance, their main elements, and measures undertaken to consider long-term potential impacts of these technologies. Many say that their level of comfort with these technologies going forward is going to be predicated on knowing more about how they work, and what measures are in place to address safety and ethical issues. Most importantly, people are looking for information from government, not promotion of any viewpoint.

- **Regulatory supervision/long-term research.** Participants expressed a strong interest in more investment made into this sphere, in scientific capability, with a long-term testing/research focus, and with clear insulation from politics and industry interests.

- **Larger strategic investments in research, focusing mostly on health applications of the technology.** There is a continuing need for government to play a role in funding research in this sphere, through its funding agencies and research institutions, to support basic and applied research that can lead to further commercial activity. Some participants expressed hope that this funding would be allocated based on pursuing specific areas of pre-existing strength, so as to avoid diluting the available funding.