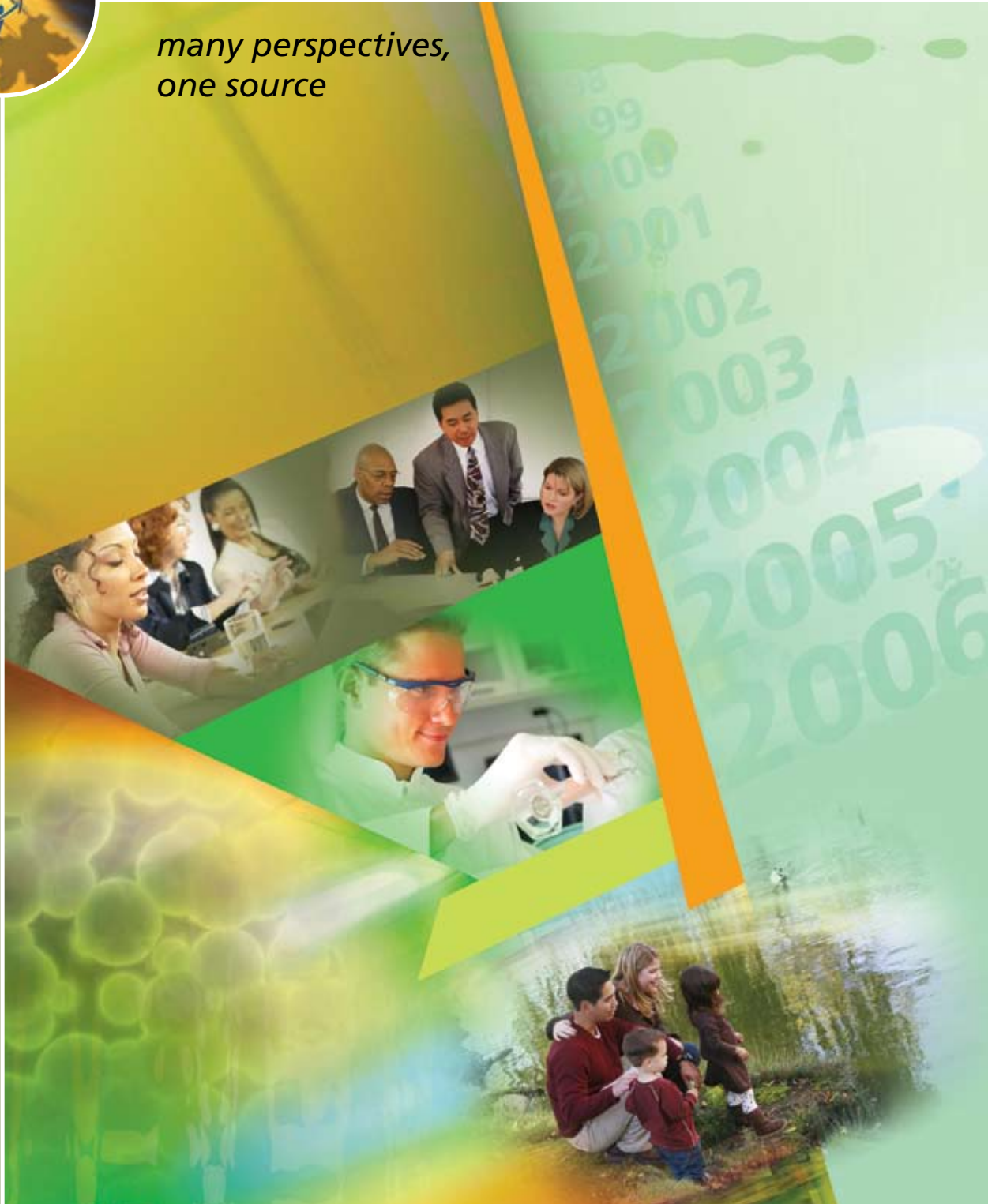




Canadian Biotechnology
Advisory Committee

*many perspectives,
one source*



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CBAC Annual Report 2006

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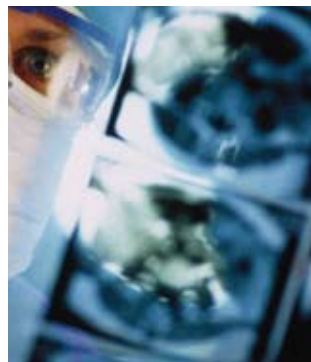


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MESSAGE FROM THE CHAIR

CBAC's activities over the past year, and indeed since our establishment by the Government of Canada in 1999, reflect the increasing complexity of the impact of biotechnology in society. While our early work focused on the adequacy of existing policies and procedures to deal with this impact, our attention has also been focused on the broader societal dimensions of biotechnology. This dual approach is exemplified by two projects completed in 2006: *Human Genetic Materials, Intellectual Property and the Health Sector*; and, *BioPromise? Biotechnology, Sustainable Development and Canada's Future Economy*.

In 2006, we also took the opportunity to reflect systematically on the contemporary scientific, economic and political context for developing public policy related to biotechnology. We concluded that a new approach is required. In our report *Toward a Canadian Action Agenda for Biotechnology*, we recommended the key elements of an approach that would best serve the public interest in harnessing the benefits of biotechnology.

In this year's annual report, we also present an outline of activities undertaken by CBAC since its inception. CBAC is indebted to the many Canadians who have made — and continue to make —



an invaluable contribution to our work. I am deeply grateful to my fellow committee members for their wisdom and dedication, and to the staff of the Canadian Biotechnology Secretariat for their exemplary support. Through their collective efforts, we have capitalized on CBAC's strengths, notably: its diversity and expertise of membership, independence, breadth of mandate and the transparency of its undertakings.

Sincerely,

A handwritten signature in black ink, appearing to read "A. Naimark".

Dr. Arnold Naimark
Chair, CBAC



WHO WE ARE AND WHAT WE DO

Canadian Biotechnology Advisory Committee Membership

CHAIR

Dr. Arnold Naimark
Director
Centre for the Advancement of Medicine
University of Manitoba
Winnipeg, Manitoba

MEMBERS

Ms. Gloria Bishop
Communications Consultant
(specializing in health care)
Toronto, Ontario

Dr. Prabhat D. (Pete) Desai
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Desai and Desai Inc.
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Chief of Gene Medicine Services, and
Director of the Laboratory of Molecular Medicine
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Acadia University
Wolfville, Nova Scotia

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Alton Mackey and Associates
Toronto, Ontario

Ms. Anne Mitchell
Executive Director
Canadian Institute for Environmental Law and Policy
Toronto, Ontario

Dr. Peter W.B. Phillips
Professor, Department of Political Studies,
Associate Member, Departments of Management
and Marketing, and Agricultural Economics
University of Saskatchewan
Saskatoon, Saskatchewan

Dr. David Punter
Professor
Department of Botany
University of Manitoba
Winnipeg, Manitoba

The CBAC Chair receives a *per diem* (to a maximum number of days of work per year) commensurate with the demands of the position. CBAC members are appointed by the Biotechnology Ministerial Coordinating Committee based on their individual attributes rather than as representatives of particular stakeholder interests. All CBAC members serve on a volunteer basis.



What We Do

CBAC provides the Government of Canada with comprehensive advice on policy issues associated with the health, ethical, social, regulatory, economic, scientific and environmental aspects of biotechnology and its applications.

The Committee's work is based on policy gaps and emerging issues identified by members, given their knowledge and expertise in specific fields, and by direct referrals or requests for investigations by federal departments and agencies seeking advice on particular issues.

To prepare its responses, CBAC consults with stakeholders, commissions background studies, conducts research and analysis, convenes roundtables and workshops, and establishes Expert Working Parties on specific topics.

TOWARD A CANADIAN ACTION AGENDA FOR BIOTECHNOLOGY

The goal of the Canadian Biotechnology Strategy (CBS), released in 1998, was to position Canada as a global leader in the burgeoning field of biotechnology. Canada's competitive position in the rapidly growing global market for bio-based products and services, however, is far from guaranteed. According to the Conference Board of Canada's September 2005 report, *Biotechnology in Canada: A Technology Platform for Growth*,¹ "While Canada has the opportunity to capitalize on biotechnology, we face a paradox: we have enjoyed a history of good performance in biotechnology thus far [...] — but we are not well-positioned for the future."



This assessment of Canada's biotechnology performance found that there is still work to be done to realize biotechnology's potential. With the global market for bio-based products and services growing rapidly and governments around the world beefing up their biotechnology efforts, Canada needs to take steps to keep pace.

During 2005, CBAC initiated discussion of the existing CBS with expert roundtables and citizen focus groups to identify Canada's market challenges and opportunities, assess evolving scientific, policy, economic and social contexts in biotechnology in Canada and abroad, and pinpoint the actions Canada must take to stay at the forefront of innovation. In preliminary consultations with CBAC, stakeholders consistently raised the need for a national policy and subsequent action agenda that details specific, measurable outcomes to meet current and emerging requirements.

Based on input from stakeholders and informed by its own research, CBAC issued *Toward a Canadian Action Agenda for Biotechnology* in September 2006. The report highlights the ways in which other countries are seizing the potential of biotechnology to advance their economies and societies.

¹ To view the Conference Board of Canada's report, visit www.conferenceboard.ca/documents.asp?rnext=1361



Toward a Canadian Action Agenda for Biotechnology further advises that failure to elaborate and sustain an integrated approach to biotechnology implementation will compromise Canada's ability to access, apply and harness biotechnology's power to serve the public's social and economic interests.



In the report, CBAC outlines a six-part framework that calls on the government to:

- generate knowledge that may lead to the development and use of novel biotechnology-based goods, services, processes and practices (including knowledge for affecting 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 biotechnology applications that enhance and protect 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 biotechnology applications.

CBAC endorses the creation of a new framework to ensure Canada is well-equipped to develop and adopt biotechnological innovations in a socially responsible manner; measure progress and allocate resources effectively; fulfill international responsibilities; and inform the public about the government's vision and objectives to realize the social and economic benefits of biotechnology.

To view the full report, visit www.cbac-ccb.ca/epic/site/cbac-ccb.nsf/en/ah00603e.html

BIOPROMISE? BIOTECHNOLOGY'S SUSTAINABLE DEVELOPMENT POTENTIAL

Few Canadians would disagree with the goal of building a Canada that has healthy communities, thriving ecosystems and a robust economy. *BioPromise? Biotechnology, Sustainable Development and Canada's Future Economy* makes the case that biotechnology presents significant opportunity for Canada to harness the benefits of innovation in a manner that facilitates sustainable development.



In 2005, CBAC established an Expert Working Party (EWP) to undertake a comprehensive examination of biotechnology's potential impact on Canada's environment and economy. The EWP concluded in *BioPromise?* that biotechnology innovation could contribute significantly to the country's sustainable development.

In fact, the EWP envisions that, by 2020, biotechnology could supply up to one quarter of Canada's fuel, forming the basis of a flourishing rural economy; meet the need for chemical and synthetic products with renewable sources; reduce the use of environmentally toxic chemicals by up to 50 percent; and help clean up Canada's contaminated industrial sites.

In 2020, Canadians will understand that the application of sustainability principles and the adoption of sustainable practices and new technologies is essential to environmental protection, social progress and continued economic expansion. They will recognize and embrace the potential of biotechnology to advance Canada's sustainability goals.

However, the benefits of biotechnology can only be realized if barriers to innovation are removed and forward-looking, coherent policies are adopted. The EWP points to the importance of increased investments in R&D and environmentally beneficial advanced technologies as part of an integrated national strategy to guide the development and implementation of ground-breaking approaches to sustainable development. Shared values must also play a central role in defining strategic directions, and changing circumstances must be accommodated through an adaptive approach to decision-making.

There is presently no integrated national strategy to guide the development and implementation of innovative technological approaches to sustainable development.

Canada has a potential competitive advantage given its considerable natural resources, including a large supply of biomass from surplus fibre and other forestry and agricultural stock materials. Leveraging this advantage, the EWP cautions, will



not be easy. Canada must: demonstrate an ability to manage the ecological impact of large-scale harvesting; attract new investments; avoid cost-ineffective long-term financial support packages; improve cooperation between federal and provincial governments on innovative-technology regulation; develop cost-effective industrial incentives; and resolve inter-provincial and international trade issues.

Out of consideration for global ecological challenges, the EWP urges Canada to enhance its participation in international knowledge networks on biotechnology and sustainable development, and take greater steps to improve the quality of life of people in developing countries by producing and using new vaccines for humans and livestock, and applying environmental technologies to sanitize water supplies.

BioPromise? was widely disseminated to invite further reaction and commentary while CBAC held discussions with a variety of subject experts. CBAC endorses the report's general conclusions and recommendations. Based on the report's findings, CBAC advises the federal government to:

- Develop an action plan that facilitates initiatives that apply biotechnology to sustainable development as part of the federal government's active engagement with environmental issues.
- Initiate discussions with key stakeholders on the desired components and areas of focus of an action plan. For example, CBAC suggests that biorefineries and ecosystem monitoring be two areas of immediate attention.

- Engage stakeholders and conduct research to identify the contribution of rural biorefineries to the economic sustainability of rural communities.
- Implement an ecosystem-monitoring program, in collaboration with other countries, to ensure environmental performance-measurement targets are met and any unanticipated effects of large-scale activities are spotted promptly and researched meticulously.

While CBAC recognizes there are no quick fixes to the complex challenges highlighted in BioPromise?, it is confident that biotechnology—when applied appropriately — can help Canada achieve its environmental and economic objectives.

To view the full report, visit: www.cbac-cccb.ca/epic/site/cbac-cccb.nsf/en/ah00605e.html



logen Corporation's cellulose ethanol demonstration facility, Ottawa.

PATENTING HUMAN GENETIC MATERIALS, PROTECTING PUBLIC INTEREST

Concerned by genetic-patent holders who exercise their patent rights in ways that stifle the Canadian public's access to important biotechnology innovations, Health Canada and Industry Canada commissioned CBAC to investigate the matter and issue a report.



CBAC struck an EWP, which reported its findings to CBAC in *Human Genetic Materials: Making Canada's Intellectual Property Regime Work for the Health of Canadians*. Using the EWP's document as a foundation, CBAC delivered its report *Human Genetic Materials, Intellectual Property and the Health Sector* in March 2006.

In the report, CBAC calls for several key enhancements to the *Patent Act* that pertain to research, privacy, quality and continuity of care, and access to health information and human genetic material-based health innovations. Specifically, CBAC recommends that the government:

- reword an amendment that exempts research on patented inventions from claims of infringement;
- amend provisions that deal with government use of patented inventions and abuse of rights under patent;
- include a provision to create a Patented Inventions Licensing Review Board, which would assist the Commissioner of Patents in exercising discretionary authority with respect to government use of patented inventions and abuse of rights under patent; and
- identify empirical studies on patenting human genetic material that would help the government with ongoing policy development.

The government must take swift action to encourage innovation and make the benefits of that innovation readily available to Canadians.

Diagnosing Patent Abuse

During the research phase of the project, CBAC was particularly attuned to issues raised by health-services providers, who expressed concerns about perceived abuses of patent rights that limit Canadians' access to genetic diagnostic tests. CBAC proposes two main methods to deal with these challenges:

1. Prevention of abuse

Modify the patenting process to prevent the issue of patents that grant overly broad intellectual-property (IP) rights. Establish guidelines for licensing IP rights under patents that promote behaviour consistent with the public interest and are fair to the patent holder. Provide statutory exemption from claims of patent infringement to select patented inventions.



2. Remediation

Provide statutory remedies to deal with cases of abuse, and meet objectives such as moderating prices of products and services through market regulatory measures and competitive methods that increase bargaining power.

To view the full report, visit:
www.cbac-ccb.ic.gc.ca/epic/site/cbac-ccb.nsf/en/ah00578e.html

CBAC LOOKS BACK

Since its establishment in 1999, CBAC has provided a wealth of guidance to the Government of Canada on many biotechnology-related issues. CBAC's work on major policy topics both anticipated and responded to the government's increasing need, given the escalating rate of scientific discovery, for oversight and strategically sound advice.

MAJOR REPORTS

2006

BioPromise? Biotechnology, Sustainable Development and Canada's Future Economy

Human Genetic Materials, Intellectual Property and the Health Sector

2005

Human Genetic Materials: Making Canada's Intellectual Property Regime Work for the Health of Canadians

2004

Biotechnology and the Health of Canadians

Protecting Privacy in the Age of Genetic Information

2002

Improving the Regulation of Genetically Modified Foods and other Novel Foods in Canada

Patenting of Higher Life Forms and Related Issues

STAKEHOLDER & PUBLIC CONSULTATIONS

2006

Toward a Canadian Action Agenda for Biotechnology

- Halifax / Montreal / Vancouver

2004–2005

Human Genetic Materials, Intellectual Property and the Health Sector

- Researchers and Clinician-Scientists Roundtable
- IP Experts and Economists Roundtable
- Developers, Commercializers and Financers Roundtable
- Health Administrators and Health System Policy Experts Roundtable
- Federal/Provincial/Territorial Officials Roundtable
- Multi-Stakeholders Roundtable

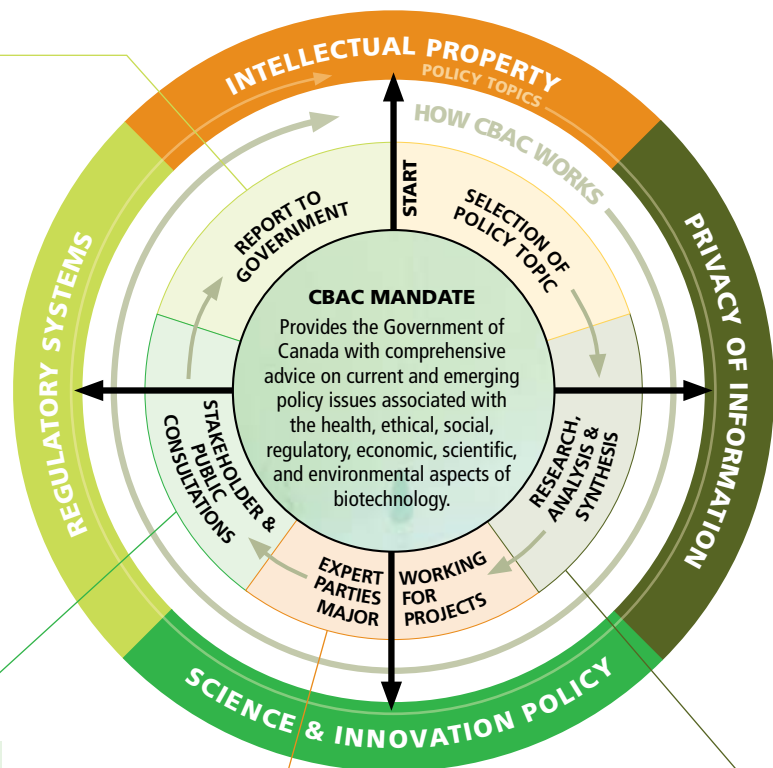
2001

Intellectual Property and Patenting of Higher Life Forms

- Halifax / Montreal / Toronto / Saskatoon / Vancouver

Genetically Modified Foods

- Halifax / Montreal / Toronto / Saskatoon / Vancouver



EXPERT WORKING PARTIES FOR MAJOR PROJECTS

2006

Biotechnology, Sustainable Development and Canada's Future Economy

2004–2005

Human Genetic Materials, Intellectual Property and the Health Sector

2001–2002

GM Food Steering Committee

"Acceptability Spectrum" for GM Foods (Exploratory Committee)

Intellectual Property Project Steering Committee

RESEARCH

CBAC commissioned over 50 research papers, background studies, environmental scans and public opinion research studies to clarify key issues and address knowledge gaps that assisted in the shaping of the committee's advice to government.

BENEFITS TO CANADIANS

- Increased public awareness of biotechnology and its potential to capture the economic, health care, environmental and quality of life benefits from biotechnology.
- Endorsed use of Citizen Focus Groups, Expert Working Parties and Roundtables as a model for an inclusive approach to policy making in science and technology.
- Increased transparency and confidence in regulatory processes.
- All publications and research commissioned are publicly available on CBAC's web site.

ONGOING ACTIVITIES

Undertook a wide variety of activities to sustain CBAC's work and profile in Canada and abroad including:

- Monitoring of national and international developments in biotechnology;
- Appearances before standing committees;
- Briefings of Ministers and Deputy Ministers on CBAC reports and biotechnology developments;
- Liaison with visiting experts from the UK, Australia etc. to share knowledge and experience;
- Representation at key biotechnology conferences (including frequent guest speaking engagements);
- Engaging the media (interviews, news releases and backgrounders) to bring CBAC reports and emerging issues in biotechnology to public attention;
- Publication of an Annual Report to provide an overview of the committee's activities and its recommendations on issues each year.

PRIVACY OF INFORMATION

ISSUE	CBAC RECOMMENDATION(S)
<p>How can Canada realize the potential health advances from the collection of genetic information for health research while protecting Canadians' rights to privacy and confidentiality?</p> <p>By 2000, Population Biobanks — collections of large amounts of genetic data used by researchers to improve their understanding of genetic influences on health — were either established or planned in a number of countries. Canada considered several proposals to set up similar research databanks. Between 2000 and 2004, CBAC advised legislators and policymakers on how to grapple with the social, ethical and legal implications involved with the establishment and use of Biobanks. In 2004, CBAC released <i>Protecting Privacy in the Age of Genetic Information</i>, a collection of three studies on genetic information.</p>	<p>CBAC recommends that specific issues be addressed before any Population Biobanks are established in Canada. From the very beginning, Population Biobanks must be designed with public confidence and acceptance, and the dividends of genetic research must be shared appropriately. Any genetic information collected from Canadians must be handled, stored and used with appropriate safeguards, data encryptions and security systems to ensure privacy and confidentiality are protected. Also, individuals who consent to provide their genetic information must fully understand all possible outcomes of their participation.</p>
<h3>RELEVANT DEVELOPMENTS</h3>	
<ul style="list-style-type: none"> • CBAC commissioned the paper <i>Biobanking in Canada — Ethical, Legal and Social Issues</i> to summarize and synthesize the salient ethical, legal and social issues pertaining to biobanking in Canada. The report was delivered to CBAC in July 2002. • In March 2003, the Canadian Biotechnology Secretariat released <i>Public Opinion Research into Genetic Privacy Issues</i>, a report that probes issues related to biobanking. • Since 2001, the Canadian Institutes of Health Research (CIHR) have been developing the Canadian Lifelong Health Initiative (CLHI) to facilitate a research program to conduct large multi-centred longitudinal cohort studies of Canadians. CLHI will help create a common research platform that will give Canadian scientists a unique advantage in conducting original population studies, and place Canada at the forefront of modern health research. In 2004, study protocols were in the approval process. Upon approval, a piloting and development phase would begin, with the launch of the program expected in 2008 (www.cihr-irsc.gc.ca/e/18542.html). 	

SCIENCE & INNOVATION POLICY

ISSUE	CBAC RECOMMENDATION(S)
<p>How can Canada reap the benefits of transformative technologies such as biotechnology while managing their risks?</p> <p>CBAC recognizes that complex transformative technologies such as biotechnology have the potential to provide Canadians with significant economic, social, health, environmental and quality of life benefits; but there are also potential challenges, risks, hazards, tensions and tradeoffs that must be addressed and managed.</p>	<p>Biotechnology should be a central element of Canada's Innovation Strategy.</p>
<p>Does Canada need a renewed strategy for biotechnology?</p> <p>In 2004, CBAC advised that the rapidly changing nature of biotechnology and its use in society necessitates a dynamic biotechnology strategy. CBAC highlighted the need to renew the Canadian Biotechnology Strategy, established in 1998, to build on its strengths, address new opportunities and anticipate future challenges.</p> <p>In 2005–2006, CBAC undertook a series of expert roundtables and citizen focus groups to advise the federal government on its ongoing work to chart a national action agenda for biotechnology. CBAC released its report, <i>Toward a Canadian Action Agenda for Biotechnology</i>, in Spring 2006.</p>	<p>The federal government should develop a Canadian Action Agenda for Biotechnology — complete with an overarching goal for federal biotechnology policy, identified areas for strategic action, and a focus on linking strategic actions and directions to outcomes.</p>
<p>How can rapid advances in biological science be used to benefit Canadians?</p> <p>In its 2004 report, <i>Biotechnology and the Health of Canadians</i>, CBAC described how the increase in knowledge about the molecular basis of health and disease can be used to prevent, diagnose and treat illness, and advised the government on the policy initiatives that are needed to ensure that benefits are realized in a socially responsible manner.</p>	<p>The federal government should build scientific and management capacity to generate innovations, create a supportive economic and regulatory environment, optimize access to health innovations, manage risk and ensure ethical use of biotechnology. Furthermore, the federal, provincial and territorial governments must play a pivotal role in creating policies and mechanisms that guide the use of biotechnology and produce system-wide analysis and coherent decision-making.</p>
<p>How can Canadians engage in constructive dialogue on highly contentious issues?</p> <p>Biotechnology has social, economic and ethical impacts that may result in people adopting polarized views on the use of the technology. In consultations with stakeholders on Canada's approach to GM food and feeds in 2001, CBAC identified the need for a mechanism to foster dialogue among stakeholders with divergent views.</p>	<p>In 2004, CBAC launched <i>The Dialogue Tool</i>, a facilitation guide and compendium of scenarios that uses an interactive process to deconstruct complex issues in a structured discussion session.</p>
<p>How can biotechnology help Canada achieve its environmental and economic objectives?</p> <p>In response to increasing public concern about the environment and a growing sense that Canada needs to make tangible progress on sustainable development for the benefit of future generations, CBAC commissioned an Expert Working Party (EWP) to undertake Canada's first comprehensive examination of biotechnology's potential in relation to sustainable development. The EWP report, <i>BioPromise? Biotechnology, Sustainable Development and Canada's Future Economy</i>, was released in Fall 2006. CBAC provided its commentary on the report to the federal government in Spring 2007.</p>	<p>CBAC concurs with the general thrust of <i>BioPromise?</i> and endorses its recommendation that the federal government develop a strategic approach to biotechnology and sustainable development that:</p> <ul style="list-style-type: none"> • focuses on implementation of advanced technologies; • recognizes the interlocked nature of the environment and economy; • engages citizens and stakeholders in deliberative dialogue; • emphasizes international cooperation; and • strengthens governance to facilitate adaptive management.
<p>RELEVANT DEVELOPMENTS</p>	
<ul style="list-style-type: none"> • CBAC regularly alerted the federal government to issues of immediate importance, and assisted decision-makers to develop effective courses of action by: <ul style="list-style-type: none"> • reporting on the impact of government policy on biotechnology development in Canada; • identifying areas and issues requiring policy development or clarification; • raising awareness of gaps in public policy and offering multiple options to remedy the situation; and • publishing a comprehensive body of work that includes reports, advice and research papers on important biotechnology issues. • CBAC developed <i>The Dialogue Tool</i>, which is available to policymakers, industry leaders, not-for-profit organizations and academics. It can be used both to inform policy-making and as an educational tool to examine an issue collectively. • In Budget 2007, the federal government signalled that it will preserve the environment through a balanced action plan. 	

REGULATORY SYSTEMS

ISSUE	CBAC RECOMMENDATION(S)
<p>What are the public-policy implications of recent discoveries in stem-cell research?</p> <p>In 2001, CBAC released <i>Stem Cells: Opportunities and Challenges</i>, an Advisory Memorandum that details the policy implications and international trends related to two major advances in stem-cell biology: the successful isolation and culture of stem cells from embryonic and fetal tissue; and the potential development of stem cells from adult tissues into cells with a wider variety of specific characteristics than previously believed.</p>	<p>Canada should establish a broad framework of regulation pertaining to assisted reproductive technologies. The framework should:</p> <ul style="list-style-type: none"> • address the scientific, ethical and social issues raised by primordial stem-cell research; • adapt readily to new discoveries and experience gained in the application of new technologies; and • review and revise (as necessary) current guidelines to take into account recent and projected scientific and technological advances related to primordial cells.
<p>How can Canada manage and coordinate its food regulatory system and facilitate informed consumer choice in the area of genetically modified (GM) foods?</p> <p>Public concern about the consumption of GM foods has emerged as a dominant and highly contentious issue in Canada and abroad. In 2002, CBAC completed a rigorous exploration of the issues surrounding GM foods that was guided by research and consultations with key stakeholder groups and the public. CBAC's report, <i>Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada</i>, identifies opportunities to improve the management and coordination of Canada's food regulatory system and help consumers make informed choices.</p>	<p>Canada should improve the management and coordination of its food regulatory system to help consumers use voluntary labelling and "single window" access to information on genetically modified foods to make informed choices.</p>
<p>What changes are required to Canada's regulatory systems to manage the safe introduction of food products that result from new applications of biotechnology?</p> <p>Since its inception, CBAC has identified gaps in Canada's regulatory system that threaten the research, development and commercialization of socially beneficial biotechnology products. Its advice has focused on the need to develop and implement a comprehensive and functional regulatory system that ensures Canada remains a leading developer of biotechnology products.</p>	<p>Canada should lead the way in developing appropriate regulation and extending its biotechnology regulatory framework to products such as transgenic animals and fish, cloned animals, functional foods and nutraceuticals, and novel protein-production systems.</p>

RELEVANT DEVELOPMENTS

- The Canadian Regulatory System for Biotechnology was established in 2000 to enhance regulatory capacity and ensure Canadians have an efficient, credible and well-respected biotechnology regulatory system that safeguards health and the environment, while permitting safe and effective products.
- In 2000, the Royal Society of Canada convened an Expert Panel on the future of food biotechnology; its report, *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada*, was delivered to the Government of Canada in February 2001 (www.rsc.ca/index.php?page_id=119).
- In April 2004, the federal government adopted an official standard for voluntary labelling of genetically engineered foods.
- An interdepartmental committee, led by Environment Canada, is developing a research strategy to generate knowledge on the long term ecosystem effects of novel living organisms.
- Since 2002, Health Canada and the Canadian Food Inspection Agency have undertaken several initiatives to increase transparency and confidence in the food regulatory system:
 - publication of final guidelines for foods and feeds;
 - adoption of harmonized approval policy to minimize the potential for entry of unapproved products into the food or feed supply or the Canadian environment;
 - launch of a pilot project to post industry "Notice of Submission" documents for public comment;
 - posting of decision documents on each plant with novel trait authorization.
- Informed by CBAC's work, the federal government's Smart Regulation Initiative (2004) highlighted biotechnology as a key sector in which a comprehensive federal strategy is required.
- Launched in 2004, the BioPortal (www.biotech.gc.ca) is hailed as one of the most comprehensive and vital biotechnology web-based resources in the world. It features a BioRegulations section that provides information on how Canada regulates biotechnology applications (ranging from cosmetics to drugs to medical devices), and facilitates searches for relevant legislation, guidelines, forms and industry contacts.
- Assisted Human Reproduction Canada (AHRC) was established in Vancouver in January 2006 to administer and enforce the *Assisted Human Reproduction Act*, which became law in March 2004 (www.hc-sc.gc.ca/hl-vs/reprod/index_e.html).
- Health Canada's involvement in the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology has ensured that the federal government's requirements for determining the safety and nutritional quality of these food products remains consistent with guidance adopted at the international level.

INTELLECTUAL PROPERTY (IP)

ISSUE	CBAC RECOMMENDATION(S)
<p>Should seeds, plants and non-human animals be patentable in Canada? If so, under what conditions?</p> <p>CBAC provided comprehensive analysis and guidance to government on the issues of biotechnological intellectual property and the patenting of higher life forms. Its recommendations were guided by original research, and consultations with and feedback from key stakeholder groups and members of the public.</p> <p>For detailed information, refer to the following documents: <i>Harvard Onco-mouse Case</i> (Advice 1999); <i>Patenting of Higher Life Forms and Related Issues</i> (Project Report 2002); <i>Higher Life Forms and The Patent Act</i> (Advice 2003); and <i>Rationalizing Patent Law in the Age of Biotechnology</i> (Advice 2004).</p>	<p>CBAC recommends that higher life forms (i.e., seeds, plants and non-human animals) be patentable, but that patents not be issued for human bodies at any stage of development. If higher life forms are to be patentable, it must be under the clear and unequivocal direction of Parliament and not the courts. Government needs to examine and address the potential impacts of patenting of genetic-based inventions on the health care system.</p>
<p>How can Canada enhance its IP regime to encourage health innovation and make the benefits accessible to Canadians?</p> <p>From 2004 to 2006, CBAC studied the issues surrounding the patenting of genetic diagnostic tests involving human genetic materials (HGMs) at the joint request of the ministers of Health and Industry. CBAC struck a Working Party comprised of experts in various fields to analyze how Canada's IP regime could be improved to stimulate the development and introduction of innovations.</p> <p>CBAC's final report, <i>Human Genetic Materials, Intellectual Property and the Health Sector</i>, was delivered in 2006.</p>	<p>CBAC recommends that the <i>Patent Act</i> be amended to enhance the IP regime's capacity to address unduly restrictive licensing practices, and better protect the public interest in relation to the patenting of the rapidly expanding array of HGM-based health innovations. Specifically, the Act should be modified to:</p> <ul style="list-style-type: none"> • exempt research on patented inventions from claims of infringement; • strengthen existing provisions regarding abuse of rights under patent and government use of patented inventions; and • create a Patented Inventions Licensing Review Board to help the Commissioner of Patents exercise his or her discretionary authority with respect to government use of patented inventions and abuse of rights under patent.
<p>RELEVANT DEVELOPMENTS</p>	
<ul style="list-style-type: none"> • In two cases, the Supreme Court of Canada used CBAC's report <i>Patenting of Higher Life Forms and Related Issues</i> as a resource on patent issues: <ul style="list-style-type: none"> • In <i>Harvard College v. Canada</i> (2002), the court ruled in the "Harvard Onco-mouse" that animals do not fall within the definition of invention in the <i>Patent Act</i>, and are therefore not patentable in Canada. • In <i>Monsanto Canada Inc. v. Schmeiser</i> (2004), the court ruled that, even though plants are not patentable in Canada, a patent on a plant cell or a modified gene in a cell gives the patent holder the right to control what others do with the plants because each individual cell in the plant contains the modified gene. • In 2002, the Organisation for Economic Co-operation and Development (OECD) began developing guidelines for the licensing of genetic inventions. The OECD Council adopted the Recommendation on the Licensing of Genetic Inventions in February 2006 (www.oecd.org/sti/biotechnology/licensing). • Established in 2001, the Stem Cell Network brings together more than 70 leading scientists, clinicians, bio-engineers and ethicists to investigate the immense therapeutic potential of stem cells for the treatment of diseases currently incurable by conventional approaches (www.stemcellnetwork.ca). 	

All CBAC reports, advice and research are available at www.cbac-cccb.ca

