1999–2000

Canadian Biotechnology Advisory Committee

Annual Report

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Chair, Canadian Biotechnology Advisory Committee

On behalf of the Canadian Biotechnology Advisory Committee (CBAC), I am pleased to present to you CBAC's first Annual Report *covering the 12-month period beginning with CBAC's first meeting in October 1999.*

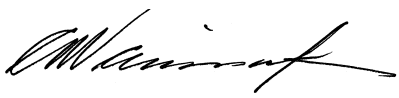
The Report summarizes the initiatives undertaken by CBAC since its inception, and highlights the activities flowing from CBAC's Program Plan 2000 presented to the Biotechnology Ministerial Coordinating Committee (BMCC) in February 2000. These initiatives have been designed to enable CBAC to monitor and assess emerging issues in biotechnology from both domestic and global perspectives, to develop the mechanisms for engaging the public in the process of shaping our advice on major public policy issues, and to provide BMCC with timely input on urgent matters.

The Report provides information on the status of two Special Projects identified in Program Plan 2000 for emphasis in our first year of operation (namely, Regulation of Genetically Modified Foods, and Biotechnological Intellectual Property and the Patenting of Higher Life Forms) and on Advisory Memoranda issued by CBAC on particular emerging issues.

The Report concludes with an overview of key biotechnology trends, developments and breakthroughs over the past year, both in Canada and overseas, which form the context for our ongoing deliberations.

I am deeply grateful to the members of CBAC who have devoted far more time and talent to the Committee's work than could reasonably have been expected of volunteers, and to the staff seconded to CBAC for their tireless efforts in supporting a demanding work schedule. I also wish to acknowledge the cooperation and assistance we have received from federal departments and agencies in the course of our work.

Sincerely,



Dr. Arnold Naimark
Chair, CBAC

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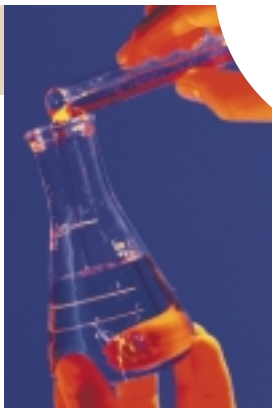

1. CBAC Composition

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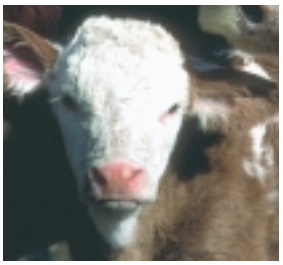
2. Executive Summary



The Canadian Biotechnology Advisory Committee (CBAC) advises the Biotechnology Ministerial Coordinating Committee (BMCC) on the broad policy issues associated with the ethical, social, regulatory, economic, scientific, environmental and health aspects of biotechnology. It is also tasked with making it easier for Canadians to obtain balanced information on biotechnology issues, engaging the public in "national discussions" and providing an ongoing forum for Canadian views. CBAC's members serve on a part-time, volunteer basis for two- or three-year terms, and represent a broad spectrum of society.

During its first year, CBAC invested considerable effort in the general activities that constitute its day-to-day operations. It developed and began implementing a work plan, established operating policies, procedures and principles, and recruited staff and consultants.[1]

Monitoring and tracking systems were put in place so that CBAC can keep up to date on recent developments in biotechnology, including trends in public opinion and the activities and outputs of other advisory bodies in Canada and abroad. It presented advice to BMCC on three matters: the terms of reference for an Expert Scientific Panel on the Future of Food Biotechnology, proposed international initiatives regarding genetically modified (GM) foods and crops under consideration by the G8 countries and OECD, and the deliberations in Canadian courts concerning the patentability of the Harvard Onco-mouse.

CBAC developed and started implementing effective communications channels, viable public awareness strategies and a communications infrastructure. It also set up consultation instruments such as a web site and toll-free telephone number, created and distributed communications materials, initiated contacts with a range of non-governmental organizations, and answered enquiries. CBAC members attended and participated in a variety of regional, national and international conferences, congresses, seminars and workshops dealing with contemporary developments in biotechnology.

Of the five special projects identified in Program Plan 2000, CBAC concentrated on two in 2000: namely, the regulation of GM foods, and the protection and exploitation of biotechnological intellectual property with a special focus on the patenting of higher life forms. Public consultations on these two special projects will take place in 2001, and extensive work was undertaken in 2000 to prepare for them. This included identifying and clarifying key issues to be addressed, gathering information through literature searches, commissioned studies, workshops and other means, developing a

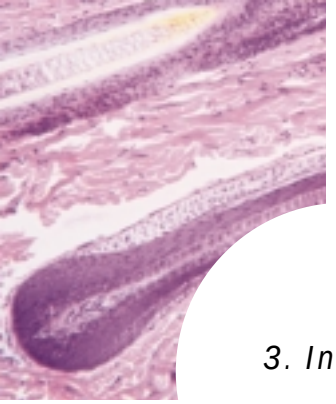
[1] The CBAC work plan, Program Plan 2000, was presented to BMCC in February 2000. It may be accessed through the CBAC web site: http://cbac-cccb.ca

consultation strategy, and creating reference groups of stakeholders to provide advice to CBAC on its consultation materials and plans. Following the consultations, CBAC will produce final reports containing specific recommendations and options for Canadian public policy development.

Groundwork also began on the other three special projects: development of a framework for incorporating ethical considerations into public policy formulation, the use of novel, genetically based interventions and genetic privacy. These projects will be addressed in a comprehensive manner in subsequent years, although intensive work on certain aspects of them may be accelerated as circumstances warrant.

The context for CBAC's current and future activities is evolving rapidly. The pace of scientific discovery and industrial application in biotechnology is accelerating and it is clear that Canada must stay abreast of these developments in order to reap the benefits of these advances while protecting human and animal health and the environment and respecting shared social values. International developments in biotechnology and its regulation have had significant effects on Canada's ability to export products and its competitive position in innovation and intellectual property generation. The Government of Canada has substantially increased its support for fundamental research in recent years, with much of it going to biotechnology-related research. It has also launched several initiatives to pave the way for industrial advances and to adapt regulatory regimes to meet the challenges of the future. The competitive pressures, however, are unrelenting, with several national governments targeting biotechnology as a priority area for significantly enhanced public support.

Development of GM foods, new reproductive technologies, substantial completion of the map of the human genome, gene therapy and several other biotechnological innovations have captured the attention of the media and sparked interest in biotechnology among the public. While the current level of interest tends to be application-specific and the level of knowledge is spotty, the developments cited in this *Annual Report* are in their early stages and there are many more on the horizon. Their full impact on public opinion and the policy imperatives they generate are yet to unfold. Charting a sound course for public policy on biotechnology in this context is a formidable task. CBAC looks forward to continuing to assist the people and the Government of Canada in addressing this challenge.



3. Introduction

Biotechnology is defined in various ways depending on the context in which the term is used. To avoid confusion, CBAC has adopted a definition that steers clear of implicit value judgments (for example, whether the applications of biotechnology are inherently morally good or bad, ethical or unethical, beneficial or harmful). CBAC defines *biotechnology* as a body of technical knowledge about living organisms or their constituent parts, and *applied biotechnology* as those aspects of biotechnology that are used to make products and drive processes that serve social, scientific or economic purposes.

Biotechnology is important for Canadians. Many applications of biotechnology provide significant economic and social benefits in a variety of areas, and new discoveries hold the promise of more benefits to come. However, some uses of biotechnology may involve risks to health or the environment, raise profound social and ethical questions, or challenge the capacity of current approaches to the protection of health and the environment.

Charting a sound course for public policy on biotechnology is a challenging task because it touches on many areas of public interest. The challenge is made all the more intense by the ever-accelerating pace of scientific discovery and the progressively shortening lag between discovery and application — factors that contribute to increasingly diverse and pervasive uses of biotechnology in contemporary Canadian society.

It was in this context that the CBAC was created as a vehicle to assist the Government of Canada in the formulation of public policy on biotechnology. CBAC is pleased to provide a report on activities and developments during its first year of operation under three headings:

- CBAC Origins, Mandate and Organization
- CBAC Activities
- Recent Developments in Biotechnology.

Much of CBAC's work over the past year has centred on the development and implementation of a work plan, the establishment of operating policies, procedures and principles, and the recruitment of staff and consultants needed to meet the Committee's ambitious targets. In succeeding annual reports the focus will shift to summarizing the outcomes of CBAC's investigations into important aspects of biotechnology and their implications for Canadians.

This report, while addressed to the BMCC, is written with a broader, non-expert readership in mind. It does not delve into detail about the topics on which it touches, as these can be found in the source documents cited in the report or its appendices.

Some Applications of Biotechnology

- determining and modifying the genetic make-up of plants and animals (genomes)
- using fermentation processes in the production of beverages, food, chemicals and enzymes
- using living organisms to eliminate environmental contaminants and industrial waste
- using enzymes to produce cleaner-burning fuels
- identifying genes related to, or responsible for, the expression of particular traits including predisposition to disease
- using naturally occurring micro-organisms to help plants absorb nutrients from the soil
- identifying the source of biological material (for example, tissue DNA matching)
- manipulating whole organisms, tissues, cells or constituents of cells in processes such as tissue grafting, organ transplantation and reproduction
- introducing native or genetically modified micro-organisms into industrial processes (mining, crude-oil recovery, pollution control)

4. CBAC Origins, Mandate and Organization

4A) ORIGINS

The Government of Canada first identified biotechnology as an important economic sector in the late 1970s. In 1983, it introduced the National Biotechnology Strategy. A National Biotechnology Advisory Committee (NBAC) was established to advise the Minister of Industry on the economic and industrial aspects of biotechnology. For the next several years, federal initiatives in this area concentrated on strengthening Canada's capacities in research and development, human resources, regulatory matters and economic advancement. This included the adoption, in 1993, of the Principles of the Federal Regulatory Framework for Biotechnology.

In March 1997, the Government of Canada launched a process to renew the National Biotechnology Strategy. The purpose was to create a road map that better reflects the ever-changing global biotechnology landscape, addresses national strategic priorities, deals with the protection of the health of humans, animals, plants and the environment, and takes into account social and ethical issues. The government also sought to encompass matters such as public awareness, involvement and confidence, and to position Canada as a responsible leader in providing and using biotechnology products and services. Based on a series of intensive, broad-based consultations in spring 1998, the renewed Canadian Biotechnology Strategy (CBS) was announced in August 1998.

A key element of the CBS is the creation of CBAC to succeed NBAC and to endow it with a broader mandate and relationship to several ministries concerned with biotechnology.

4B) MANDATE

In general terms, CBAC's role is to advise Ministers on the broad policy issues associated with the ethical, social, regulatory, economic, scientific, environmental and health aspects of biotechnology. In particular, CBAC advises government on ways to:

- optimize the economic, health, safety and environmental benefits of biotechnology in a sustainable way in Canada through the CBS
- ensure that the science base that supports the government's regulatory role is maintained and is internationally competitive
- incorporate social and ethical considerations into policy making
- enhance public awareness and facilitate an open, transparent national conversation on key issues concerning the development and application of biotechnology in Canada.

The Committee is also tasked with facilitating access by Canadians to balanced, easy-to-understand information on biotechnology issues, engaging the public in "national discussions" on biotechnology matters and providing an ongoing forum for Canadians to voice their views.

While the federal government or its departments and agencies have other advisory bodies whose role includes specific aspects of biotechnology, CBAC is distinctive in the breadth of its mandate and reporting relationships, its indefinite lifespan and its special responsibility for engaging Canadians in forming policy advice to government. The proliferation of both governmental and non-governmental advisory bodies and task forces can itself contribute to complexity and confusion. CBAC has therefore included in its overall role the task of monitoring the activities and outputs of these bodies and providing an overview and commentary on their observations and recommendations.

4C) ORGANIZATION

CBAC consists of 20 members and a chairperson. The members were chosen from a pool of 175 individuals who either responded personally to a public call for nominations or were nominated by others. CBAC members bring expertise in diverse fields such as science, business, nutrition, law, environment, philosophy, ethics and public advocacy. They serve on a part-time, volunteer basis for two- or three-year terms. Members are appointed on the basis of individual merit, rather than as representatives of particular interests, which helps to ensure that the Committee provides impartial advice representing a broad spectrum of society.

CBAC organized itself into three standing committees reflecting the three main themes of the Canadian Biotechnology Strategy.

- The Stewardship Committee is concerned with the social, legal and ethical dimensions of biotechnology and the fostering of Canada's capacity for innovation.

- The Economic and Social Development Committee is concerned with the applications of biotechnology to economic and social development.

- The Citizen Engagement Committee develops strategies for engaging Canadians in informed discussion of public policy issues in biotechnology.

CBAC reports to the BMCC, which oversees the Canadian Biotechnology Strategy. BMCC comprises the ministers of Industry, Agriculture and Agri-Food, Health, Environment, Fisheries and Oceans, Natural Resources, and Foreign Affairs and International Trade.

CBAC consults with the public and a wide range of stakeholder groups, other relevant advisory boards and government agencies at the provincial and federal levels, as appropriate. As part of its commitment to transparency, openness and building awareness and confidence, CBAC publishes its reports to government and the background papers used in formulating its advice to government.

5. CBAC Activities

CBAC Guiding Principles

- primacy of the public interest
- independence
- knowledge-based deliberation
- integrity
- openness
- responsiveness
- breadth of perspective

CBAC's membership was appointed on September 27, 1999, and on October 13–15, the Committee held its first meeting. Over the following months, members established the Committee's organization, operating procedures, priorities, guiding principles and program of activities.

These elements are embodied in a document titled Program Plan 2000, announced in February 2000. Given the rapid pace of developments in biotechnology, the Plan is intended to be flexible and subject to mid-course adjustments as circumstances warrant.

CBAC's activities divide into two categories: general activities and special projects. General activities are those of a broad, ongoing nature such as monitoring biotechnology developments, providing opportunities to raise public awareness, and maintaining a forum for citizen engagement. Special projects involve the in-depth study of specific subjects as a basis for providing advice to government that is typically informed by public consultation. Each special project is directed by a project steering committee made up of CBAC members.

CBAC's reports to government, through BMCC, fall into three categories:

- occasional reports on emerging or urgent issues identified during CBAC's monitoring of biotechnology developments (these may take the form of advisory memoranda or briefing notes)
- reports arising from special projects
- annual reports summarizing CBAC's activities.

5A) GENERAL ACTIVITIES

CBAC conducts its special projects and other initiatives against a backdrop of general activities that constitute the Committee's day-to-day operations. As this was CBAC's first year, considerable effort was devoted to this aspect of its work.

Monitoring and Reporting Developments

CBAC established mechanisms to monitor emerging developments in biotechnology and public opinion about them. An internal system tracks public comments and enquiries received by CBAC via a toll-free telephone line, e-mail and correspondence. External activities and developments are tracked through linkages with relevant Canadian and overseas bodies and multinational organizations, and through the Canadian Biotechnology Secretariat.

During the year, three specific matters emerged upon which CBAC provided advice to government.

- The ministers of Health, Agriculture and Environment decided to invite the Royal Society of Canada to establish an Expert Scientific Panel on the Future of Food Biotechnology. CBAC provided advice concerning the terms of reference of the Panel and indicated how the Panel's work and its ultimate recommendations would inform CBAC's overall project on genetically modified (GM) foods.

- CBAC submitted an advisory memorandum to BMCC concerning developments on the international front pertaining to GM foods: namely, a proposal emanating from the United Kingdom and submitted for consideration at G8 meetings in June and July 2000 recommending the establishment of an International Panel of Scientists to Assess GM Foods and Crop Safety; and an OECD proposal suggesting that the organization hold an international conference to address the environmental impacts of GM organisms and "continue to undertake analytical work and to play an effective role in international policy dialogue on food safety" (see Appendix D).

CBAC advised BMCC that, given several matters concerning the U.K. proposal requiring clarification,[2] further investigation of the proposal's implications should be undertaken to determine whether the initiative would advance Canada's interests. CBAC observed that it supported in principle the creation of an overarching multilateral mechanism that would serve to clarify and address the full range of scientific and non-scientific issues associated with GM foods, and made suggestions regarding the status, mandate, membership, operation and activities of such a mechanism.

- Canada has historically not granted patents on higher life forms such as multi-celled organisms and transgenic plants and animals. However, on August 3, 2000, this practice was challenged when the Federal Court of Appeal concluded that a patent ought to be granted to Harvard University for the creation of the Onco-mouse.[3] The court ruled that the wording of Canada's *Patent Act*, as it currently stands, permits the patentability of genetically altered non-human mammals for use in carcinogenicity studies.

In September 2000, CBAC issued an advisory memorandum to BMCC (see Appendix D) stating that it concurs with the Federal Court of Appeal's finding that Parliament, not the courts, should determine Canada's policy regarding the patenting of higher life forms (and the distinction between "lower" and "higher" life forms). CBAC observed that Canada's laws ought to reflect social values and that Canadians have not yet had an opportunity to debate the full range of moral, ethical and social issues at stake in this case. The memorandum noted CBAC's intention to facilitate such a debate in the course of its public consultations on the patenting of higher life forms, scheduled to take place in spring 2001.

CBAC encouraged the Government of Canada to take "all reasonable and feasible steps" to facilitate a Parliamentary review of the issue. In this regard, a majority of

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[2] For example, questions about the model on which the panel would be based, how the panel's advice would be reconciled with initiatives emerging from the multilateral trading system, etc.

[3] The United States, Europe and Japan have already granted patents on the Onco-mouse.

CBAC members urged the Government of Canada to prompt Parliament to amend the *Patent Act* so as to explicitly forbid, on an interim basis and pending the completion of a Parliamentary review, the patenting of particular classes of higher life forms such as primates, the human body and certain plant species. Others favoured advising the government to appeal the Federal Court's decision to the Supreme Court of Canada.[4]

Communications

Effective communications and efforts to enhance public awareness are central to CBAC's role. It is hoped that Canadians in due course will come to view the Committee as a ready source of credible, objective information and as a trusted interlocutor for conveying their views to government. In 2000, CBAC concentrated on developing the infrastructure for implementation of its communications strategy.

To learn what Canadians think about biotechnology in general and about its special project subjects in particular, CBAC put in place a variety of consultation instruments, along with plans to implement additional ones next year. One instrument already in place is a web site (http://cbac-cccb.ca) that features an ongoing forum to encourage broad discussion and that will soon host special electronic forums on specific topics. Constructed as an information resource, the site will include relevant research documents that CBAC commissions or receives, summary minutes of CBAC meetings, news items and the Committee's advice to government. The site also offers a glossary of key biotechnology terms and will contain short fact sheets or articles on pertinent issues and links to other information sources.

CBAC's toll-free telephone number — 1 866 748-CBAC (2222) — was activated in September 2000, allowing Canadians to obtain information on biotechnology and to convey their views on particular issues. The toll-free line may also be used, as required, to facilitate registration for consultations.

Outreach Activities

CBAC began work on establishing partnerships with a range of non-governmental organizations that will eventually advance communication efforts via mutual web links and other means such as the provision of CBAC materials (for example, newsletter inserts and feature articles) for distribution, if the partners choose, to their members.

Other outreach activities during the year included distributing Program Plan 2000, news releases and the CBAC brochure and responding to telephone, mail and e-mail enquiries. CBAC's first public appearance took place at the Human Genome Organization (HUGO)[5] international annual meeting in Vancouver in April 2000 where it set up a kiosk to help build awareness of its work. As well, CBAC members participated in several special forums and conferences as speakers. These included, for example, the Canadian Special Crops Association Annual Convention, the 14th World Congress of the International Federation of Home Economics and Food Security Workshop (Ghana), the Third Global Summit of National Bioethics Commissions (London) and the Fifth World Congress of Bioethics (London).

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[4] On October 2, 2000, government lawyers representing the Commissioner of Patents filed an application seeking leave to appeal the decision to the Supreme Court of Canada.

[5] HUGO is an international consortium of researchers from 57 countries. HUGO held its fifth international annual meeting in Vancouver in April 2000. CBAC member Bartha Knoppers chairs the HUGO ethics committee. The international President for 1999/2000 is Canadian Lap-Chee Tsui.

5B) SPECIAL PROJECTS

Special Projects: Overview

Program Plan 2000 identifies five special projects for CBAC consideration. The two on which CBAC chose to focus on in 2000 are the regulation of GM foods, and the protection and exploitation of biotechnological intellectual property, focussing initially on the patenting of higher life forms (see *Priority Special Projects: Public Consultations* below for details regarding these two projects). The remaining three — incorporating social and ethical considerations into biotechnology, policy implications of the use of novel genetically based interventions, and genetic privacy — will be addressed subsequently.

GM Foods: At its inaugural meeting in October 1999, CBAC identified the robustness of Canada's systems for assessing and regulating the application of biotechnological innovations as an issue requiring study and evaluation. It specifically cited GM foods as being of intensifying interest. On the basis of discussions and consultations, the Committee identified three areas of study in this regard: the science base underpinning the regulatory processes, the governance and organization of regulatory systems, and the social, ethical and legal dimensions of GM foods as seen by expert and non-expert sectors of Canadian society. These plans were later refined to focus on the latter two aspects when the government announced in December 1999 the creation of the Royal Society's Expert Scientific Panel on the Future of Food Biotechnology to advise on the scientific capacity of the regulatory system regarding GM foods.[6] CBAC's deliberations will also be informed by the work of the Canadian General Standards Board and the Canadian Council of Grocery Distributors directed at developing voluntary Canadian standards for the labelling of foods with respect to the involvement of genetic modification in their production.

Protection and Exploitation of Biotechnological Intellectual Property/Patenting of Higher Life Forms: This special project encompasses an overall review of Canada's policies on intellectual property as they pertain to biotechnology. Canadian policy and practice will be put into an international context, and the social, ethical and legal dimensions will be examined. CBAC identified the patenting of higher life forms as a topic for special attention in 2000.

Incorporating Social and Ethical Considerations into Policy Making: The objective of this special project is to facilitate the integration of the social and ethical dimensions of biotechnology into the formulation and administration of public policy related to biotechnology. It will involve examining how to identify the values that Canadians wish to see reflected in public policy on biotechnology, identify the procedures and/or structures required to implement these values, and determine ways to monitor and assess the effectiveness of these procedures and/or structures. This examination is being directed, in the first instance, toward policy formulation on GM foods and intellectual property as case studies.

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[6] More specifically, the Panel was asked to forecast the types of GM foods expected to be developed and to identify the potential short- and long-term risks to humans, animals and the environment. It is examining current procedures to ensure the safety of GM foods, the future scientific capacities needed to carry out these assessments and any gaps in scientific understanding that may need to be addressed. It is also working to identify what, if any, new policies or regulations may be needed. The Panel's report is scheduled for January 2001.

Use of Novel Genetically Based Interventions: The objective of this special project is to review the social, ethical, legal, economic, regulatory, health and environmental policy implications of new developments in biotechnology related to novel genetically based interventions such as cloning, stem cells, gene therapy and enhancement, and xenotransplantation. In 2000, preliminary work was initiated on the issues raised by recent advances in the isolation and manipulation of embryonic stem cells.

Genetic Privacy: The purpose of this special project is to examine the mechanisms currently in place in Canada that protect the privacy of genetic information. The steering committee will examine Canada's practices compared with those of other countries, assess whether Canada's existing safeguards for medical information are adequate and, if new measures are required, identify what they should be. Background work on aspects of genetic privacy was initiated in 2000.

Priority Special Projects: Public Consultations

Under its mandate to engage the public on important biotechnology issues, CBAC plans to hold public consultations in connection with the five special projects identified. In 2000, preparatory work was undertaken on the public consultations planned for 2001 on GM foods and intellectual property.

Genetically Modified (GM) Foods

Context: Since 1995, Canada and other countries have produced a variety of GM foods and food crops. In addition, research is well advanced on items with new functional, nutraceutical or pharmaceutical attributes. The implications of these new developments for people, animals and the environment are the subject of much debate in Canada and abroad.

The debate focusses primarily on the safety of GM foods, their impact on the environment, their differential effects in the developed and developing worlds, and trade relationships. The controversy has led several governments and international organizations to undertake scientific studies and public consultations on the safety and regulation of GM foods.

Some people contend that biotechnology does not introduce risks different from those already associated with the food supply and that Canada's regulatory capacity for prudent risk management, in terms of both health and environmental safety, is reliable. Others do not share this view and are concerned that the country's regulatory system has insufficient capacity to deal effectively with the health and environmental safety aspects of GM foods, particularly in the long term, as the pace of biotechnological innovation accelerates. Some are also concerned that Canada has not undertaken a sufficiently comprehensive risk assessment effort and that the federal regulatory and policy systems are not mandated or structured to address the broader social and ethical questions inherent in GM foods.

Activities: The steering committee for the special project on the regulation of GM foods began by evaluating the salience of the many topics identified in its research program (see Appendix B) and clarifying the research questions and inherent issues. To this end, the committee reviewed relevant public opinion surveys, conducted literature searches and reviewed related reports, prepared reports describing various aspects of the current situation, produced documents to stimulate thinking regarding the social, ethical and moral parameters of GM foods, and held a workshop with Canadian regulators to learn more about the Canadian regulatory system. On the basis of this information, the committee initiated analyses aimed at identifying and describing lay issues and respective policy options for Canada's policies and legislation regarding GM foods. By the end of the *Annual Report's* reporting period, the research program was about 85 percent completed.

In undertaking its analysis, the steering committee reviewed the documentation, with emphasis on the commissioned studies, and identified issues, conclusions and observations, including best practices and possible policy alternatives. These were studied, grouped and streamlined into an initial set of issues with possible policy options. These elements, along with the work of the Expert Scientific Panel and the Canadian General Standards Board, are expected to form the basis of the consultations.

CBAC, on the recommendation of the steering committee, approved the establishment of a Reference Group composed of representatives of key stakeholder groups. The Reference Group is helping the committee to identify any further studies required to round out its research program, and is providing input regarding the consultation design and document.

Having taken into account the input from the consultations, CBAC will produce for the BMCC advice and specific recommendations for Canada's policies on GM foods.

Intellectual Property/Patenting of Higher Life Forms

Context: Several factors joined forces to prompt Canada to review its *Patent Act* as it relates to biotechnology, particularly in the area of patenting higher life forms. For example, as mentioned, the Canadian courts have been dealing during the past year with the issue of the patentability of the Harvard Onco-mouse. As well, mapping of the human genome was substantially completed in summer 2000. In addition, important international negotiations touching on the patenting of higher life forms, primarily the World Trade Organization (WTO) agreement on Trade-Related Aspects of Intellectual Property (TRIPS), are on the horizon.

As the number of applications for biotechnological innovations multiplies, patents will be increasingly important in realizing biotechnology's benefits. Some concern exists, however, that Canada's patent law may be failing to achieve its objectives of facilitating innovation, commercialization and the dissemination of useful technologies. The National Biotechnology Advisory Committee identified several patenting issues that need to be addressed, some relating to the patenting of higher life forms.[7]

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[7] *Leading in the Next Millennium*, National Biotechnology Advisory Committee, Sixth Report (Ottawa: Industry Canada, 1998).

However, beyond the legal and practical aspects of patenting higher life forms are ethical and social considerations. These issues are broad, sweeping and complex. They include, for example, issues of economics and fairness related to the patenting of agricultural crops, ethical issues related to the patenting of new diagnostic and therapeutic processes and products for humans and animals, and issues related to the impact of a proliferation of patents on the ability of scientists to gain access to materials to conduct research. Some people want such matters addressed in a revised *Patent Act*; others argue that other instruments should be used to address health, safety and environmental issues.

Activities: As with the GM foods consultation preparations, the patenting of higher life forms steering committee concentrated first on clarifying the research questions, identifying the inherent issues and defining the parameters of its work. To this end, the committee commissioned more than 20 reports addressing the research areas in its mandate (see Appendix C).

On September 29, 2000, the committee met with the presidents and chief executive officers of several Canadian biotechnology companies and organizations to brief them on the project and to solicit their views. The objective of the workshop was to examine how Canada's system of intellectual property protection might be improved to better exploit technological innovation and to ensure that citizens are protected. The workshop also provided a contemporary view of the role of the patenting function in stimulating economic growth and the effects of the burgeoning numbers of patents on the ability to conduct research. Other sessions were planned to solicit the views of non-governmental and not-for-profit organizations and the scientific community on biotechnology and intellectual property protection and exploitation.

Public consultation on intellectual property issues is scheduled to take place in spring 2001. Following this process, CBAC will generate a report or series of reports including recommendations concerning the patenting of higher life forms in Canada.

6. Recent Developments in Biotechnology

In the highly dynamic area of biotechnological innovation, each year brings a plethora of new developments. This section touches on the recent developments that are particularly relevant to the themes and topics that comprise CBAC's Program Plan and that may influence the nature or direction of the Committee's activities in the near term.

6A) SCIENCE — THE DRIVING FORCE

Scientific advances are the wellspring of biotechnological innovations used by industry to create new products and services. The pace of both scientific discovery and application is accelerating. It is imperative that Canada stays abreast of these scientific developments for economic reasons and because Canada needs a sound base of scientific expertise to support the regulatory mechanisms required for the protection of human and animal health and the environment.

Human and Animal Health

Genomics[8]: Genomics is a rapidly developing field that is widely recognized as a key driver of the future expansion of biotechnology industries. Genomics embraces the concepts and methods used to decipher and understand the functional implications of the whole of the genetic information content of an organism. This provides the essential science base for a range of applications in areas such as health care, environment, agriculture and forestry.

Genomics is expected to have a major impact on the economy. Fully 25 percent of Canada's gross national product is potentially affected by biotechnology developments, many of which are based on gene science and technology. It is widely believed that the industrial use of biological systems based on genomics research will be a major driver of economic growth in coming decades.

Significant advances occurred in this field in 2000. In Canada, an important development was the formal incorporation of Genome Canada in March 2000. Genome Canada is designed to add value to the efforts of existing organizations and mechanisms that currently support genomics. It was initially created in 1998, operating informally to bring together the Canadian genomics research community. Functioning without a physical presence or location and with a small temporary budget, this early version articulated core mandates for Canadian genomics and developed an operational model to realize those mandates.

Genome Canada's mandate is to:

- set a strategy for Canadian genomics research
- provide leading-edge technology through support for five Genome Centres across Canada
- bring together stakeholders to support large-scale projects currently beyond individual capacities
- encourage investment in genomics
- ensure leadership in social, environmental, ethical and legal issues related to genomics by organizing intellectual resources, communicating genomics to the public, and helping Canadians understand the relative risks and rewards of genomics.

[8] Genomics is the study of how genetic information is structured, stored, expressed and altered. It differs from classical genetic research in terms of its large scale, broad scope, intense reliance on computer-based information technology (bioinformatics) and high throughput screening techniques. Six major technologies and/or approaches are currently essential for research and development in genomics: functional genomics, gene sequencing, genotyping, proteomics, bioinformatics and technology development.

Internationally, the most significant achievement in this field was the substantial completion in July 2000 of the mapping of the human genome.[9] Research in this area progressed rapidly under the Human Genome Project that began in earnest in 1990. The Project's results, as well as those of Celera Genomics, a U.S. company that significantly accelerated the pace of genome mapping, are available on several public genome databases.

In April 1999, 10 large pharmaceutical companies and the U.K.'s Wellcome Trust philanthropy announced a consortium to find and map 300,000 common single-nucleotide polymorphisms (SNPs). The goal is to generate a widely accepted, high-quality, publicly available map using SNPs as markers evenly distributed throughout the human genome. The SNP consortium views its map as a way to make available a precompetitive, high-quality research tool that will spark innovative work throughout the research and industrial communities. While several groups are working to find SNPs, the likelihood of duplication is small because of the estimated 3 million SNPs in the human genome.

The results of gene mapping have the potential to impact human health in many areas, including genetic testing, improved pharmaceuticals and gene therapy.

- Genetic testing has been in use for many years. Genetic tests require only a small amount of blood or cells from the cheek lining to identify gene mutations linked not only with single-gene disorders but also with genetic abnormalities in common multi-factorial conditions.

- Biopharmaceuticals have helped to ameliorate or eradicate many diseases and to improve life expectancy. For example, in Canada, companies have developed vaccines for cancer as well as therapeutic products for infectious agents such as HIV, hepatitis and influenza, and are at the leading edge in the development of diagnostic products for use in detecting life-threatening ailments.

- Research into gene therapy, which involves introducing genetic material into individuals who have genetic defects, has been under way since the 1980s. Although some limited success has been achieved in special circumstances, gene therapy has come under recent critical scrutiny following the September 17, 1999, death of Jesse Gelsinger in the U.S. while participating in a gene therapy trial. Mr. Gelsinger's death has led to calls for more rigorous oversight of clinical trials, increased openness and stricter requirements for data reporting and safety monitoring, and stronger conflict-of-interest guidelines for researchers. Meanwhile, in Canada, some 28 clinical trials in gene therapy are under way. A major one is at Toronto's Princess Margaret Hospital, where 14 patients have undergone gene therapy for aggressive forms of prostate cancer. The trial is into the earliest phase of study.[10] As with many biotechnology applications, gene therapies also introduce concerns. These include the use of genetic engineering for eugenic purposes and the risk of introducing undesirable traits that may be passed on to future generations.

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[9] The announcement came shortly after similar work on rice, the fruit fly and other lower forms of organisms.

[10] Information obtained from the Clinical Research Coordinator, Princess Margaret Hospital.

Stem Cells: In its December 17, 1999 issue, the prestigious journal *Science* declared that the discovery of how to isolate and grow human stem cells outside the body, and how to cause them to develop into a variety of specific tissue cell types, constituted the scientific breakthrough of the year.

Stem cells are immature cells that have the potential to develop into a variety of human tissues and organs. Potentially, they could be used to grow many types of replacement tissues from a patient's own cells, sidestepping the increasing scarcity of organs available for transplant and the problems of immune rejection.

Research in this area is controversial because the most useful type of stem cells is obtained from surplus human embryos following *in-vitro* fertilization. Several countries are in the process of examining policy options in the light of recent advances. On August 16, 2000, the U.K. Department of Health released a report that recommended approval of the use of embryos for stem-cell research under certain conditions. The government will introduce regulations for debate in both Houses of Parliament later in 2000, to be followed by a free vote.[11]

On August 25, 2000, the U.S. government released guidelines that outline the criteria that the National Institutes of Health will use to consider applications for federal grant money to study human stem cells. These guidelines are based on the 1999 report of the National Bioethics Advisory Committee, which recommended allowing research on stem cells.[12] The guidelines allow scientists to use only embryonic stem cells taken from frozen embryos left over from *in-vitro* fertilization, and do not permit the creation of embryos solely for research purposes.

Cloning: Cloning involves transplanting nuclei from somatic cells into eggs whose nuclei have been removed. To produce live animal clones, the embryos developed from those cells are implanted in foster mothers who bring the embryos to term and deliver the cloned offspring. In therapeutic cloning, the embryos are allowed to develop only long enough to produce embryonic stem cells, which are then used to generate replacement tissue.

The first animals to be cloned were albino frogs in 1977. Twenty years later, technological advances, particularly in cell biology and recombinant DNA, allowed researchers to produce cloned mice in 1996 and Dolly the cloned sheep in 1997. Since then several kinds of mammals (goats, cattle, pigs) have been successfully cloned. However, cloning efficiency remains at only 2 percent,[13] and many researchers are turning their attention to relevant basic science for answers, while others look to embryo splitting as a means of generating like animals for research.

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[11] See "Stem Cell Research: Medical Progress with Responsibility," Department of Health, United Kingdom, June 2000.

[12] See "Ethical Issues in Stem Cell Research. Volume I: Report and Recommendations of the National Bioethics Advisory Commission," September 1999.

[13] Many introduced embryos do not implant in the surrogate wombs, resulting in miscarriage; a significant fraction of newborn animals die, and some of those that survive have serious developmental abnormalities. A. McLaren, "2000 Cloning: Pathways to a Pluripotent Future," *Science* 288: 1775–80.

Most nations explicitly reject the notion of human cloning. The U.K., Denmark and France, for example, expressly prohibit human cloning, and the United States is in the midst of a five-year moratorium on federal funding for human cloning research. Canada has a voluntary moratorium on human cloning, but no legal prohibition as yet.

However, in August 2000, an expert panel in Britain recommended that the U.K. laws prohibiting human cloning be relaxed, arguing that research into cloned human embryos (up to 14 days) has a reasonable prospect of finding cures for human disease. It also recommended that human reproductive cloning continue to be banned. The British government endorsed the panel's recommendations and called for a free vote on the issue to take place in autumn 2000.

Xenotransplantation[14]: The first recorded case of xenotransplantation dates back to 1682 when a piece of dog skull was successfully used to close a serious human head wound. During the 1950s and 1960s, tissue rejection was a major obstacle in attempts to transplant baboon kidneys and livers into humans, with most patients dying within 100 days. Chimpanzee kidneys were used with moderately more success. In 1984, Baby Fae received a baboon heart and lived for 20 days before her body rejected it. Recent attention has focussed on pigs as a potential source of organs, partly due to the more appropriate size of the organs, and has been intensified since 1993 when the first transgenic pigs were created.[15] Significant concern remains, however, that no matter what animal is used, transplanted organs might allow unknown diseases to jump the species barrier.

Few nations and their advisory bodies have specifically addressed the issue of xenotransplantation. Canada, in this regard, is ahead of other countries in that it is currently developing national standards concerning the safety of tissues and organs for use in transplantation, and several groups are in place with responsibility to monitor the xenotransplantation issue.

Health Canada's Therapeutic Products Program (TPP) plans to develop specific regulations on xenotransplantation, but will first solicit the views of Canadians regarding their concerns and issues on this matter. The Xenotransplantation Expert Working Group provides "expert advice to Health Canada in areas of safety with respect to disease transmission through organs and tissues from transplantation," and the Expert Advisory Committee on Xenograft Regulation advises TPP on "medical, scientific and communications issues related to the regulation of xenografts."

Agricultural Biotechnology

As in the health field, agricultural biotechnology is also experiencing significant scientific advances. For instance, biotechnology can accelerate the rate and reliability of traditional plant breeding techniques. As well, tools such as tissue culture, micropropagation, cloning, marker-assisted breeding, gene splicing and transgenes allow breeders to selectively modify plants and animals at the molecular level. For example, plants have been genetically modified to produce herbicide tolerance, insect and viral resistance,

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[14] The transplantation of cells and organs from one species into another.

[15] Transgenics is the transfer or deletion of a gene in an animal, plant, bacteria or other organism in order to create organisms with specific characteristics. The pigs, in this case, were implanted with human genes to reduce the risk of rejection when organs are transplanted.

increased hardiness in the face of abiotic stresses and new compounds with nutritional or medicinal value, such as rice with increased levels of pro-vitamin A or beta carotene.

Major advances in agricultural biotechnology in 2000 included the completion of a rough draft of the rice genome by Monsanto Company, and the first genetic sequence of a flowering plant, *Arabidopsis thaliana*. Because *Arabidopsis thaliana* is related to canola, the mapping of this wild mustard plant has generated considerable economic interest worldwide. Funds have already been committed for the next phase — determining the function of all 25,000 genes — which is expected to take 10 years and cost US$500 million.

Issues in agricultural biotechnology include possible long-term human health impacts as well as environmental impacts such as the potential for cross-pollination allowing organic and wild species to pick up genes from GM crops, the concern that genes used to modify crops may be able to jump the species barrier and modify bacterial characteristics, and the effects of agricultural biotechnology on biodiversity and long-term sustainability.

Federal Initiatives to Build Scientific Capacity

The seedbed for biotechnological innovations lies in universities and research institutes where advances in fundamental biology are made. Often the technical tools and processes that come to be applied in public and private enterprise are first developed for basic research purposes. In Canada, the federal government has increased its support for fundamental research substantially in recent years with a significant fraction of the new investment going to the support of biotechnologically related research. For example:

- Genome Canada was incorporated in March 2000 with a budget of $160 million over three years. Over the same time period, government departments and agencies will receive $55 million for intramural genomics research.

- The Canadian Institutes of Health Research, announced in the February 1999 federal budget, officially took over as successor to the Medical Research Council in June 2000. The organization has stated that it expects to continue to invest major funds in biotechnology, particularly given the future directions of health research.

- The Canada Foundation for Innovation (CFI), established in 1997, has invested substantially in helping universities and research institutes to build up Canada's research infrastructure. A significant and growing portion of these multimillion-dollar investments is in support of fundamental biological research, the wellspring of biotechnological advances. The original CFI endowment has been augmented twice since the Foundation's beginning.

- The Networks of Centres of Excellence devote much of their funding to networks in the biological sciences. This has led to a variety of technological innovations, several of which have been commercialized.

- The $605-million Canadian Research Chairs Program, announced in autumn 1999, helps Canadian universities attract and keep scientific talent.

6B) BIOTECHNOLOGY INDUSTRY

Industrial application of biotechnology is growing rapidly. The global demand for biotechnology-based products is expected to more than double from $20 billion in 1995 to $50 billion in 2005.[16] Canada is emerging as a significant contributor to this growth.

Biotechnology's greatest impact, both in Canada and worldwide, is in health care. More than 90 percent of the advanced biotechnology products on the world market are health-related. It is expected that about three quarters of global biotechnology demand will continue to be in this area.

The first agricultural biotechnology products entered agri-food markets in the late 1980s. Since then, research has developed a vast array of crops, animals and microbes using new biotechnology methods or which involve input or output attributes involving genetic modification. By mid-2000, more than 40 genetic modifications related to 13 different crops were approved and produced in one of 12 countries, and were available to varying degrees in other nations through international trade.

Several countries have also approved the release of one or more varieties of GM fish, trees, microbes, drugs and animal vaccines. More than 40 other crops and a range of animal species and microbes have been genetically modified and await regulatory approval in various countries involved in the international food trade (OECD 2000). James (1999) estimates that the global production of these crops, scattered across 12 countries, reached about 100 million acres in 1999.[17] The main crops were soybeans (54 percent), corn (28 percent) and cotton and canola (9 percent each).

Canada's Biotechnology Industry[18]

In 1997, Canada's growing biotechnology sector consisted of some 282 core firms in industries such as health, agriculture and agri-food, environment, aquaculture, forestry, mining and energy. It generated $1 billion in sales, with about 40 percent of these sales being exported and with exports almost doubling during 1993–97.

Most of Canada's biotechnology companies are either small or medium-sized firms. Seventy-two percent have fewer than 50 employees, 15 percent have 51–150 employees, and 13 percent have more than 150 workers. Three quarters of these companies are in the health and agri-food sectors.

In 1997, these companies employed almost 10,000 people, with another estimated 2,000 jobs going unfilled. Most of the empty positions were in small firms, where 25 percent of the jobs went unfilled. The health sector accounted for 62 percent of the jobs and 75 percent of the vacant positions. The number of positions in biotechnology is expected to grow by 25 percent by 2001, with most of the growth in small firms, where the number of employees will likely double by 2001. Indicators are that the

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[16] *Leading in the Next Millennium*, National Biotechnology Advisory Committee, Sixth Report (Ottawa: Industry Canada, 1998).

[17] The U.S. accounted for 72 percent of the global area; Argentina 17 percent; Canada 10 percent; China 1 percent; and the remaining eight countries 1 percent.

[18] Data in this section derive from a 1997 survey conducted by Statistics Canada, with Industry Canada and BIOTECanada. Updated Statistics Canada data (1999) are expected in winter 2000.

industry as a whole will continue to face challenges related to growth in the near future, and that finding the necessary highly educated, multi-skilled workers will be one of the main challenges.

Science-based organizations and core biotechnology companies are broadly distributed across the country. Québec, Ontario, Alberta and British Columbia are particularly strong in the health care sector. Saskatchewan is a global leader in agricultural biotechnology. Atlantic Canada excels in aquaculture, forestry and biodiversity.

Federal Initiatives to Facilitate Industrial Development

Compared with other industries, the time frame and costs to move biotechnology products and services from basic research to commercialization are long and expensive. Canada's biotechnology industry, which in the past was mainly focussed on research and development, is expanding its scope to include clinical trials and field testing, manufacturing and marketing. The federal government recently launched several initiatives to facilitate industrial advances in biotechnology.

- Technology Partnerships Canada (TPC) received an additional $150 million in the 1999 federal budget to facilitate growth in high-technology industries. As of May 2000, TPC's investments in biotechnology accounted for $204 million of its total portfolio of $1.2 billion. These investments in eight biotechnology companies will leverage $750 million in new research and development investment.

- The Industrial Research Assistance Program (IRAP) will expand to include research hospitals, providing early-stage funds to small and medium-sized enterprises so that they can participate in the transfer of technology from health-related institutions. IRAP will partner with the Canadian Institutes of Health Research in these activities, and Canada will benefit from the substantial biotechnology-related research undertaken in research hospitals.

- The 2000 federal budget reduced the corporate tax burden on small businesses (most biotechnology companies are small) including reduced corporate tax rates and improvements in the capital gains and capital cost allowance provisions.

- The federal government, provincial governments, the Biotechnology Human Resources Council and others are working together to build on existing educational programs and to establish a one-year, master's-level program geared to the biotechnology industry. Other human resource initiatives are also under way.

- The Canadian Intellectual Property Office recently augmented its staff of patent examiners to deal with the increased number of patent applications in biotechnology. As well, in spring 1999, the government introduced amendments to the *Plant Breeders Rights Act*.

6C) REGULATION

Canada regulates biotechnology-related products to protect health, safety and the environment. Canada's regulatory system uses science-based risk assessments and takes into account the characteristics of the product and any potential risks throughout its life cycle. In recent years, the Government of Canada has instituted several initiatives to upgrade its regulatory regime.[19]

- The 2000 federal budget provided $90 million for biotechnology regulation, targeting four strategic areas: developing government technical and human resource capacity, increasing awareness of the regulatory system, increasing the efficiency, effectiveness and timeliness of the regulatory system, and generating knowledge to support the regulatory system.

- Industry Canada's new Biotechnology Regulatory Assistance Virtual Office, or BRAVO, identifies Canadian federal and provincial acts, regulations and some guidelines that currently or could potentially regulate various aspects of biotechnology (http://bravo.ic.gc.ca). Industry Canada is also developing a "Biotechnology and the Consumer" web site centering on the science, regulation, health and safety, and benefits and risks associated with biotechnology.

- Other initiatives include amendments to the *Health Protection Act* and to the Canadian Food Inspection Agency legislation, and draft legislation on human reproductive technology.

6D) INTERNATIONAL DEVELOPMENTS

CBAC has been particularly interested in developments in other countries. These developments can have important consequences for trade, may be harbingers of phenomena that are likely to emerge in Canada in due course, or may be instructive for Canadian public policy formulation.

International Developments Concerning GM Foods

Biotechnology issues are at the forefront in many international arenas. A prime area of discussion and the subject of several national and international developments has been food and food products derived from genetically modified organisms (GMOs). Concerns about the safety of GM foods and the need for further regulation intensified in 2000.[20]

In January 2000, negotiation of the Biosafety Protocol was completed. The Protocol recognizes the right of countries to restrict the importation of living modified organisms that pose a risk to biodiversity and outlines a precautionary approach recognizing that countries may wish to take action even in the absence of full scientific certainty. Canada has not signed the Protocol.

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[19] Other Government of Canada initiatives concerning biotechnology regulation — notably CBAC's initiatives regarding the regulation of GM foods, the Expert Scientific Panel on the Future of Food Biotechnology, and the work of the Canadian General Standards Board and the Canadian Council of Grocery Distributors to develop a voluntary labelling standard — are noted elsewhere in this report.

[20] In addition to the events listed below, two other international initiatives — the U.K. proposal to G8 nations regarding an international panel of scientists to study GM foods and crop safety, and an OECD proposal to hold an international conference to address environmental impacts and to play an ongoing role in this regard — are addressed in Part 5A).

A January 2000 conference (Biotechnology: The Science and the Impact), sponsored by the U.S. and Dutch governments, showed substantial support among participating nations for medical and agricultural biotechnology. The conference's goal was to find common ground between U.S. and European views.

In January 2000, the U.S. Environmental Protection Agency (EPA) announced new regulations aimed at reducing the risks from corn genetically modified to produce its own insecticide. This brings the U.S. regulations in line with Canada's. The move follows a Cornell University study in May 1999 finding that GM corn's pollen could kill monarch butterfly caterpillars in the laboratory. The EPA said that although the evidence of harm to monarch butterflies is preliminary, it was directing biotechnology seed companies to ask farmers to voluntarily protect butterflies by planting traditional corn around the edges of Bt corn fields. This would create a buffer to prevent toxic pollen from blowing into butterfly habitats. Farmers are also required to plant at least 20 percent of their crops as non-Bt corn.[21] Planting a minimum of non-Bt corn has been a mandatory requirement in Canada since 1996.

The OECD Conference on "GM Foods Safety: Facts, Uncertainties and Assessment" took place February 28 to March 1, 2000, in Edinburgh, Scotland, bringing together 400 representatives of government, industry and non-governmental organizations from more than 40 nations. The meeting was the result of a G8 request in June 1999; results were presented to the G8 nations at their summit in Okinawa, Japan, in July 2000.

In March 2000, the CODEX[22] Task Force on Biotechnology, assigned to develop general principles of risk/safety assessment for GM foods, held its first meeting. It expects to complete its mission by 2003. In May 2000, the CODEX Committee on Food Labelling held its most recent meeting in Ottawa. Canada is a member of both groups, and chairs the Committee on Food Labelling.

On April 12, 2000, the European Parliament rejected biotechnology-specific environmental liability legislation which was introduced as part of the revision of EU Directive 90-220 on the deliberate release of GMOs. The same vote also agreed to move toward a centralized procedure for the safety assessment of GMOs, to evaluate the impact of gene flow on a case-by-case basis, to phase out the use of antibiotic resistance markers in clinical and veterinary use by 2005, and to exempt pharmaceutical products from the Directive.

A U.S. National Academy of Sciences report in April 2000 was generally positive concerning agricultural biotechnology but urged strengthened regulation. Also in 2000, the U.S. Academy joined six others (U.K., Brazil, China, India, Mexico and the Third World Academy of Sciences) in calling for the increased development and use of GM crops to combat hunger and poverty in developing nations. The report also called for regulatory systems to be implemented in every country.

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21 *New York Times*, Jan. 17, 2000.

22 The CODEX Alimentarius is a United Nations Special Organization funded jointly by the FAO and WHO since 1982 for the purpose of elaborating and coordinating food standards, facilitating the trade and movement of food, and protecting consumers.

In a letter to the Convention on Biological Diversity meeting in Nairobi in June 2000, 310 scientists from developed and developing countries asked for a moratorium on GM foods production due to concerns about corporate monopolies and potential dangers to biodiversity, food safety, human and animal health.

In July 2000, G8 countries released a formal communiqué addressing several matters, such as encouraging the CODEX Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology to produce a substantial interim report before completing its mandate in 2003, encouraging the FAO and WHO to organize periodic international meetings of food safety regulators to advance the process of science-based public consultations and, in response to the U.K. proposal to establish an international scientific panel, promising to explore with other relevant bodies how to integrate the best scientific knowledge available into the global process of consensus building.

In July 2000, participants at the International Society for Plant Molecular Biology meeting in Québec City unanimously endorsed the AgBioWorld "Declaration in Support of Agricultural Biotechnology," which was similarly supported by the Society for In-vitro Biology.

Intellectual Property Protection

The fast pace of scientific breakthroughs has a major impact on intellectual property matters. One of the most significant events in this regard in 2000 was the substantial completion of the sequencing of the human genome.[23] Patenting genes raises important public policy issues. Some of these issues concern patent law itself while others, such as those relating to health care policy and the ethical treatment of DNA donors, are broader.

During the past year, the U.S. Patent Office refused to allow patents on gene SNPs, sequences or fragments that are not explicitly linked with one or more genetic functions. Patents proposed for genes will require proof of substantial and specific utility of the gene's biological function, but will not require the full gene function to be articulated in the patent application. More than 1,000 patents have been granted on human genes in the U.S. Some have argued that the U.S. Patent Office has been more reluctant to issue patents covering human tissue material.

The British government issued a patent to the U.S. company Geron Corp. for the cloning method that produced the sheep Dolly. The patent gives the company exclusive rights to "a reconstituted animal embryo prepared by transferring the nucleus of a quiescent diploid donor cell into a suitable recipient cell." In an article in the publication *Science*, a company spokesperson stated that the claim includes human embryos. A U.K. patent office spokesperson said that the patent was allowed because it covered only embryos in the very early stages of development that would not result in a viable birth.[24]

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[23] A significant event in this field in Canada — the ongoing deliberations in the Canadian courts concerning the patentability of the Harvard Onco-mouse — is addressed in the *Human and Animal Health* section at the beginning of this chapter.

[24] *Science* 287: 559.

Some companies are releasing their genetic research data for other users. For example, in September 2000, Celera Genomics announced the launch of its SNP database for the human genome, which is expected to support and accelerate pharmacogenomics research. As well, Cereon Genomics has released 39,000 *Arabidopsis* SNPs, which will allow academic and non-profit users to patent discoveries made with the Cereon SNPs.

Governmental Support for Development of Biotechnology

Around the world, especially in countries such as the United States, England, Germany, China and Japan, national governments are targeting biotechnology as a key enabling technology of the future and a priority area for enhanced public support. For example, in the U.S., total spending on biotechnology research and development is estimated at US$7.9–10 billion. Combined with the research efforts of government agencies, the U.S. conducts more basic research in genetic engineering and molecular biology than any other country. In the U.K., the government recently announced a comprehensive multimillion-pound program to keep it in the vanguard of world science, with much of this funding going to biotechnology-related activities. Some other national governments are also shifting substantial focus to biotechnology and some of these countries are starting to emerge as key biotechnology players.[25]

China, for instance, is focussing on molecular biosciences and biotechnology research as key to increasing food production and improving health care. Having embraced biotechnology for agriculture, this nation is now growing cotton and other biotechnology crops faster than any other Asian nation. Economically, China hopes that biotechnology can improve its farmers' competitiveness by helping to produce lower-cost, high-quality crops before it joins the World Trade Organization.[26] Hong Kong, an excellent centre for raising capital and attracting professionals, is a key determinant in China's emergence as a biotechnology player.

South Korea is committed to long-term economic growth with a heavy investment and focussed development in biotechnology, information technology and image technology. It plans to encourage investment by private institutions to create venture funds of approximately US$100 billion to support this growth. It will also fund knowledge-based research in 103 core technologies including those relating to biotechnology, and the creation of national and local technology centres and parks. The main sectors are biomedical, environmental, agricultural and food.

The Philippines, too, is fuelling its national biotechnology engine. During 2000–04, the Philippine Council for Agriculture, Forestry and Natural Resources and Development, and the National Agriculture and Resources Research and Development Network, will address the technology gap in agriculture, forestry and natural resources. The country is focussing on research and development programs, including those involving biotechnology, that have an intended ultimate use or purpose.

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[25] The information (unpublished) on emerging players was prepared for CBAC by Global Trade Solutions, a research and analysis company specializing in competitive intelligence.

[26] Membership in the WTO will eliminate many import restrictions on foreign agricultural products, causing China's meagre farm incomes to shrink even more than they already have from falling grain prices and rising expenses.

Denmark and Sweden host Medicon Valley, one of the most successful biotechnology regions in Europe. Located in the Oresund region, the centre of medico/human life science research in Scandinavia, Medicon Valley has an estimated 90 biotechnology companies, 71 pharmaceutical firms and numerous industry-related support businesses.[27]

6E) PUBLIC OPINION CONCERNING BIOTECHNOLOGY

Public policies in respect of biotechnology are influenced by public opinion. Concerns about biotechnology have gained increasing media attention recently, fuelled by specific high-profile events. Several polls have been conducted in recent years, both in Canada and elsewhere, to assess the breadth and depth of these concerns on a more comprehensive basis.

Some studies have indicated that people actually have little knowledge, understanding and awareness of biotechnology. This was borne out in a Pollara survey in Canada in autumn 1999, which found that public opinion concerning biotechnology was largely unformed and tentative.[28] A focus group study in March 2000 by the Consumer's Association of Canada and the Office of Consumer Affairs found that consumers have limited understanding of biotechnology or its direct-to-consumer benefits (with regard to food) and how it is regulated.[29] As well, internationally, the results of *The Environmental Monitor: Global Public Opinion on the Environment 1999 International Report*, conducted and published by Environics International, indicated that one in five respondents has little awareness of biotechnology.[30]

The CBC reported on January 27, 2000, that the Canadian Health Food Association had presented 31,000 signatures on a petition asking the federal government for mandatory labelling of GM foods, citing concerns regarding unknown long-term health consequences. On April 3, CBC reported on an Environics poll commissioned by the Council of Canadians, which found that 75 percent of Canadians worry about the safety of GM foods. In September 1999, Greenpeace surveyed individuals in Vancouver, Montréal and Toronto and found that GM foods ranked eighth among eight priority environmental issues (such as toxic dumping in oceans, chemicals in food, nuclear

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[27] In addition to its collaboration with Denmark in the Oresund region, Sweden possesses a well-organized infrastructure to support biotechnology growth.

[28] It also found that Canadians group biotechnology with other advanced technologies as having potential benefits, not only primarily for the economy, but also in health and the environment; that Canadians see risk management as a technical problem to be handled by experts; and that they are confident in government stewardship with regard to food safety, although they do support labelling.

[29] The study found that dominating concerns are the apparent lack of independent, long-term testing and regulatory transparency; that people get most of their consumer information from the media despite scepticism about editorial bias; that consumers want unbiased, balanced information from identified sources; and that, with regard to labelling, they want supplementary information through means such as a 1-800 number.

[30] This report was based on telephone or in-person surveys with about 1,000 randomly selected people in each of 27 countries, representing 65 percent of the world's population. The study also found that majorities in all countries except Germany and Great Britain support biotechnology applications for new medicines and treatments for human disease. In more than half of the countries, again excluding Germany and Great Britain, majorities favoured using biotechnology to grow pest-resistant crops and more nutritious foods. Except in developing countries, people resist using biotechnology to enhance the productivity of farm animals.

energy). An Angus Reid World Poll conducted in eight countries[31] in 1999 found that the public is largely aware of GM foods, and perceives the benefits to accrue mainly to producers. It also found that perceived risks include food safety or health concerns and uncertainty surrounding the potential impact of these foods. The findings also reveal that the knowledge that a food product contains GM ingredients has a potentially negative impact on purchase behaviours.

The foregoing summary of significant developments in biotechnology in recent months and years, while focussing on just a few of particular interest to CBAC, is nonetheless sufficient to convey the dynamism of this field.

[31] Australia, Brazil, Canada, France, Germany, Japan, United Kingdom and United States.

7. Looking Ahead

Having invested considerable effort in its first year to laying the foundation for fulfilling its mandate, CBAC looks forward to the second year of its program.

Two central activities for the upcoming year are the consultations on GM foods and intellectual property, and the CBAC reports that will flow from them. At the same time, preparations will proceed for the subsequent consultations to be held on incorporating social and ethical considerations into policy making, the use of novel genetically based interventions and genetic privacy. CBAC will continue to monitor and report on biotechnology developments, to advise Ministers on emerging issues as necessary and to foster citizen engagement in the process of developing public policies.

Recent developments amply convey the dynamism of biotechnology and clearly suggest that the momentum of biotechnological innovation will continue to build. Next year and in subsequent years, we will see more scientific breakthroughs, which, in turn, will mean more industrial applications, ever-increasing numbers of products and services in the marketplace, and unrelenting pressure for continued public policy development that is sensitive to both economic and social imperatives.

The Government of Canada has undertaken an array of initiatives in recent years (several of them in response to NBAC recommendations) to build the scientific base that supports and drives biotechnology, to develop and commercialize industrial applications and to address other pertinent areas such as intellectual property and regulation.[32] However, although significant progress has been made, the horizon continues to expand and to present Canadians with both new challenges and new opportunities.

[32] Several provinces have also increased their investment in biotechnology.

Appendix A — Glossary

Bioinformatics: The large-scale computational techniques used to organize, analyse and interpret the enormous amounts of data generated by the study of genes and the functions they perform.

Biotechnology: A body of technical knowledge about living organisms or their constituent parts. The term "applied biotechnology" refers to those aspects of biotechnology used to make products and drive processes that serve social, scientific or economic purposes. Much of modern biotechnology is concerned with techniques involving the manipulation of tissues, cells and their internal structures, and biological molecules (including DNA).

Chromosome: A structure in the nucleus of each cell containing most or all of the DNA or RNA comprising the genes of the individual.

Clone: A group of genes, cells or organisms derived from a common ancestor. Because there is no combining of genetic material (as in sexual reproduction), the clone is genetically identical to the parent. (Cloning involves transplanting nuclei from somatic cells into eggs whose nuclei have been removed.)

Functional genomics: The field of study that identifies the function of specific genes and groups of genes in both normal and disease states.

Gene: A segment of the DNA molecule, made up of linear sequences of four molecules (bases), that carries the structural information for the assembly of a protein. Proteins make up the cell's structure, mediate its metabolism and control all cellular functions. The human genome contains more than three billion such bases.

Gene therapy: Gene therapy is an experimental form of treatment that involves substituting healthy genes for abnormal or missing genes. The genetic insertion can be performed either inside the living body or in extracted cells that are then returned to the body. Two categories of genetic therapy exist: somatic-cell gene therapy, which concerns body cells (blood, organs) and affects only the individual; and germ line therapy, which is performed on reproductive cells affecting both the individuals and their offspring.

Genome: The entire set of genes of an organism. The word genome is derived from the words GENe and chromosOME.

Genome map: A description of the order of genes and the spacing between them in all chromosomes of an organism.

Genome sequencing: The determination and description of the linear sequence of bases comprising the entire DNA complement of an organism's genome. This descriptive knowledge must be augmented by functional genomic research to characterize the role of particular segments of the complete DNA sequence.

Genomics: The study of how genetic information is structured, stored, expressed and altered.

Genotyping: Determining, in cases where there are variants of particular genes in a family or a population, which variant a particular individual has.

Harvard Onco-mouse: An animal that has been genetically modified to exhibit highly increased susceptibility to the development of cancer and that is, therefore, of great value for cancer research.

Higher life form: The term "higher life form" has no technical meaning in Canadian law. It generally includes plants and animals and their parts, cells and genetic information. While the term "higher life form" covers a broad range of materials, the common link is that they derive from living organisms, whether plants or animals. As the word "higher" implies, "higher life forms" do not include micro-organisms. They also do not include humans, since humans are not subject to ownership. Between these extremes, however, lies a wide variety of biological material ranging from strands of DNA to cells, tissues and organs to entire plants and animals.

Human Genome Project: A public consortium of international researchers established in the 1990s to map the human genome.

Proteomics: The field of study concerned with the structural and functional relationships between proteins and the genes governing their synthesis and the application of this knowledge to identifying potential target sites for the design of novel therapeutic agents.

Single-nucleotide polymorphism: The DNA in genes is made up of subunits called nucleotides. The circumstance in which there are variations among individuals in the structure of a nucleotide at a specific location, in a particular strand of DNA, is called single-nucleotide polymorphism.

Somatic cells: Cells of the body that compose the tissues and organs other than the germ cells (sperm cell or egg or their antecedent cells) involved in reproduction.

Stem cells: Cells found in animal and human tissues that are themselves non-specific (in the sense that a nerve cell, bone cell or muscle cell has specific structural and functional characteristics) but are nonetheless capable of developing into such specific ("differentiated") cell types. While the undifferentiated cells of the early embryo are the most commonly recognized examples of stem cells, such cells also exist in adult tissues and some differentiated adult cells can be made to behave like stem cells.

Transgenics: The transfer or deletion of a gene in an animal, plant, bacterium or other organism in order to create organisms with specific characteristics.

Vector: An organism that carries a gene from one host to another.

Xenotransplantation: The transplantation of cells and organs from one species into another.

Appendix B — Research Program: GM Foods

Objectives

- identify the issues that require examination in the public debate on GM foods in the broader context of agriculture and food production in general
- examine issues related to the governance and organization of the food regulatory system for GM foods not examined by the Expert Scientific Panel on the Future of Food Biotechnology
- examine other issues related to GM foods including social, ethical, legal, economic and environmental issues
- make recommendations concerning policy options for Canada
- maintain liaison with the Expert Scientific Panel and to relate its findings to the outcome of the work of CBAC on governance and organization and on social, ethical, legal, economic and environmental issues
- raise public awareness and engage Canadians in an unbiased manner.

Research Topics

1. Examination of the governance and regulation of the food regulatory system.

What is the rationale for a state-operated regulatory system for food? Do GM foods alter that rationale?

How does the Canadian regulatory system for GM foods (as it relates to human and animal health and the environment) compare with the systems in other leading industrial countries with respect to governance and organization, including:

- structures of accountability to the government and the public?
- performance standards and measurements for effectiveness and efficiency?
- the openness and transparency of the current system?
- the separation between the regulators and the promoters of GM foods within the government?
- public input into the development of regulatory policy and individual regulatory decisions?
- pre- and post-release monitoring systems?
- the approval process for GM foods?
- the monitoring of food consumption by Canadians?
- the mechanism for regulatory enforcement?
- roles for the regulator vis-à-vis the various stakeholders (for example, scientists, suppliers, farmers, the general public)?

What is the appropriate position for Canada with respect to international harmonization and specialization of various elements of the regulatory system?

What changes in the regulatory system are needed to increase effectiveness and public confidence?

2. Examination of the social, ethical, legal, economic and environmental aspects of GM foods.

What are the current and anticipated benefits of GM foods (economic, health, legal, environmental, etc.)? Do these differ according to gender, race, ethnicity, social class, region, etc.? In what way?

What ethical and justice issues (including distributive, social and global justice) are raised by GM foods? Are they different for different aspects of GM foods (food consumption, industrial development, pharmaceuticals/nutraceuticals)?

Do GM foods present unique concerns in the area of research ethics?

How, when and by whom are non-science issues identified and addressed in the current regulatory and policy system? Should this change?

What are the rationales and methods used (including labelling) to make information available to the public and consumers to support citizens and consumers decisions? What are the alternatives? What is the likely effectiveness, cost and benefit of each method?

Studies Commissioned

Food and Agricultural Biotechnology: Incorporating Social and Ethical Considerations, by Dr. Paul Thompson, Distinguished Professor of Philosophy, Joyce and Edward E. Brewer Chair of Applied Ethics, Purdue University, West Lafayette, IN, U.S.

Meeting the Public's Need for Information on Biotechnology, by Edna F. Einsiedel, PhD, Professor of Communication Studies, Faculty of Communication and Culture, University of Calgary; Karen Finlay, PhD, Associate Professor, Department of Consumer Studies, University of Guelph; and Jennifer Arko, Research Assistant, University of Calgary.

Labelling of GMO Products: Strategic Trade Policy Considerations for Canada, by Ramesh Chaitoo, Senior Trade Policy Analyst, Centre for Trade Policy and Law, Carleton University, and Professor Michael Hart, Simon Reisman Chair in Trade Policy, Norman Paterson School of International Affairs, Carleton University.

Inside the Canadian Biotechnology Regulatory System: A Closer Exploratory Look, by Professor Bruce Doern, School of Public Administration, Carleton University, and Politics Department, University of Exeter.

Taking Stock: The Benefits and Costs of Genetically Modified Crops, by Richard Gray et al., Professor, Department of Agricultural Economics, University of Saskatchewan.

International Comparison of Regulatory Frameworks for Food Products of Biotechnology, by Dr. Donald J. MacKenzie, Executive Vice-President, Agriculture and Biotechnology Strategies (AGBIOS) Inc.

Regulators and Promoters of Genetically Modified Foods in the Government of Canada: An Organizational and Policy Analysis, by Michael Prince, Lansdowne Professor of Social Policy and Associate Dean, Faculty of Human and Social Development, University of Victoria, British Columbia.

Status Report and Commentary on the International Debate over the Precautionary Principle, by Dr. Marc Saner, Managing Director, Ethics and Policy Issues Centre (EPIC), Department of Philosophy, Carleton University.

International Approaches to Non-Science Issues in Regulating the Products of Biotechnology, by Ozzie Silverman, Consulting Partner, Secor Conseil Inc.

Analysis of Relevant Canadian Legislation, by Dr. Donald J. MacKenzie, Executive Vice-President, Agriculture and Biotechnology Strategies (AGBIOS) Inc.

Appendix C — Research Program: Protection and Exploitation of Biotechnological Intellectual Property and the Patenting of Higher Life Forms

Objective 1. To advise government on policy initiatives that will enhance the ability of Canadians to protect and exploit intellectual property developed through biotechnology.

Research Topics

How does the Canadian system of intellectual property protection compare with the systems in other leading industrial nations (that is, G8 countries)?

If the parameters of Canada's intellectual property system are markedly different from those of other countries, what implications will this have for Canada?

How does the current Canadian system of intellectual property protection affect the development and exploitation of biotechnological innovations?

What changes in the system are desirable from a scientific and economic perspective?

What social and ethical considerations should be integrated into the design and implementation of a Canadian system of intellectual property protection?

Objective 2. To advise government on whether or not the patenting of higher life forms should be permitted in Canada.

Research Topics

What should be included in the term "higher life forms"? (It could include animals, plants, transgenic entities and/or the human body and human organs and body elements.)

Which biological entities should be included or excluded as patentable subject matter in the *Patent Act*?

Should the *Patent Act* include a "public policy" exception such as the "ordre public" or "morality" provision found in the European Patent Convention Article 53(a)? If so, what should be the scope of this exception?

Should the *Patent Act* contain specific exemptions such as "methods of medical treatment" or "research/experimental use" affirming the common law developed to date?

Should an opposition procedure to a particular patent be created? If so, what should the form and grounds for opposition be? Who should be responsible for the operation of the procedure?

Studies Commissioned

Patenting of Biotechnological Innovations Concerning Animals and Human Beings, by Ted Schrecker, Social Scientist, Montréal, Québec, and Alex Wellington, Professor of Philosophy, Ryerson Polytechnic University and York University.

Patenting of Higher Life Forms and Human Biological Materials, by Ted Schrecker, Social Scientist, Montréal, Québec, and Alex Wellington, Professor of Philosophy, Ryerson Polytechnic University and York University.

Institutional Animal Use in Scientific Research and as Vessels for Productions of Genetic Production, by Dr. Clément Gauthier and Dr. Gilly Griffin, Canadian Council on Animal Care.

Alternatives to the Use of Animals for Research and as Potential Production Vessels, by Dr. Clément Gauthier and Dr. Gilly Griffin, Canadian Council on Animal Care.

Human Rights Issues Related to the Patenting of Human Biological Materials, by Barbara von Tigerstrom, Professor, University of Alberta, Health Law Institute.

Patents in Genes, by Dr. E. Richard Gold, Assistant Professor, Faculty of Law, University of Western Ontario; Senior Fellow, Einstein Institute for Science, Health and the Courts.

Patenting Life Forms: An International Comparison, by Dr. E. Richard Gold, Assistant Professor, Faculty of Law, University of Western Ontario; Senior Fellow, Einstein Institute for Science, Health and the Courts.

Economic Profile of the Biotechnology Sector, by Kenneth White, Acton White and Associates.

Intellectual Property Protection for Biotechnological Innovations, by Mona Frendo, Legal Analyst, Intellectual Property Protection, Industry Canada.

Socio-economic Considerations Related to Patenting (Human Rights), by Barbara von Tigerstrom, Professor, University of Alberta, Health Law Institute.

EU Directive on the Legal Protection of Biotechnological Inventions, by Dr. E. Richard Gold, Assistant Professor, Faculty of Law, University of Western Ontario; Senior Fellow, Einstein Institute for Science, Health and the Courts.

History of Patents in Canada, by Vic Duy, BSc, Mechanical Engineering.

Innovation in the Livestock Industry, by Dr. Robert Kemp, RAK Genetic Consulting Ltd.

Survey of Practices, Attitudes and Opinions of Canadian Biotechnology Researchers and Research End Users/Managers with Respect to the Research Exception and Methods of Medical Treatment Exemption in Canadian Patent Law, by Chris Baker and Jeff O'Neill, Environics.

The Policy Maker and the Economics of Intellectual Property Rights, by Jock Langford, Senior Policy Analyst, Intellectual Property Protection, Industry Canada.

*Socio-economic Considerations Related to Patenting (*Competition Act*, etc.)*, by Warren Grover, Senior Partner, Barrister and Solicitor, Blake, Cassels and Graydon, Toronto, Ontario.

1. International Initiatives Respecting Scientific Assessment of Safety of Genetically Modified Crops and Foods (July 12, 2000)

In May of this year, Sir Robert May (Chief Scientific Adviser and Head of Office of Science and Technology, U.K.), in discussion with the Chair of the Canadian Biotechnology Advisory Committee (CBAC), noted that a proposal to establish an "International Panel of Scientists to Assess GM Foods and Crop Safety" was contained in a background paper intended for submission to the Carnegie Meeting of G8 Science Ministers in Bordeaux, June 23–25, 2000.

The proposal was discussed at CBAC's June 22, 2000, meeting in the context of CBAC's major project: *Regulation of GM Foods in Canada*. The project includes a review of multilateral efforts relating to GM foods regulation, the identification of relevant international "best practices" and standards, and the provision of advice to the Biotechnology Ministerial Coordinating Committee (BMCC) in relation to Canada's position in multilateral initiatives involving GM foods. A representative from the Department of Foreign Affairs and International Trade (DFAIT) provided a detailed briefing in regard to the aforementioned United Kingdom proposal as well as other related multilateral initiatives.

At its June 26–27 meeting, the OECD Council of Ministers invited the OECD to consider holding an international conference to address the environmental impacts of genetically modified organisms. The meeting's final communiqué also indicated that the OECD would ". . . continue to undertake analytical work and to play an effective role in international policy dialogue on food safety, maintaining its engagement with civil society and to share its work in this area with countries outside the Organization's membership."

Although international initiatives in relation to safety of GM foods is among the topics to receive further examination by CBAC, the following observations are offered as preliminary advice to BMCC in view of the forthcoming multilateral intergovernmental discussions to take place in the next few weeks.

The U.K. Proposal

Sir Robert May's background paper notes that the Chair of the OECD Edinburgh Conference, Sir John Krebs, put the proposal for an international panel forward. It is conceived as bringing scientists together "to discuss and evaluate the best available scientific evidence. It should clarify areas of scientific fact or certainty and, where it exists, the lack of certainty on the key issues. In doing this, it should reflect the majority scientific view but, crucially, also include the views of dissenters. This, together with independence from government, would help demonstrate to the public the full and open discussion of the risks and benefits of GM products by an authoritative but all inclusive group, in a rigorous and transparent way." The proposed panel is conceived of as being analogous to the Intergovernmental Panel on Climate Change (IPCC). However, the context of the GM foods debate is different from that which existed when discussion of the IPCC was first enjoined. This relates both to the level of consensus on science issues and the fact that numerous intergovernmental bodies already exist to examine issues related to GM foods and crops. It is therefore desirable to evaluate the applicability and acceptability of the IPCC model in depth before adopting it in the case of GM foods and crops.

The driving force behind the U.K. proposal is the fact that public confidence in the integrity and efficacy of the food regulatory system in the U.K. and in several other European countries has been seriously eroded. The same situation does not currently exist in Canada: a majority of Canadians continue to express confidence in our domestic regulatory instruments. Given the many social and ethical issues to which GM foods give rise and the role of these concerns in contributing to the corrosiveness of the debate over GM foods in some countries, it is not clear what added value the creation of a new expert scientific panel would provide in reconciling entrenched positions arising from these non-scientific issues.

Canada is at the forefront of research into food biotechnology and is an important exporter of GMOs. Accordingly, Canada has a compelling interest in ensuring that the regime governing multilateral trade provides clear rules, consistently applied and enforced, that enable potential disputes to be resolved quickly and effectively. It is not clear how the advice or recommendations emanating from the proposed panel might be reconciled with initiatives emerging through the multilateral trading system, or what legal or moral status may eventually be ascribed to its recommendations.

Given the several matters requiring clarification with respect to the U.K. proposal for a standing international panel of scientists to assess GM foods and crop safety, CBAC's advice is to seek such clarification before considering whether or not Canada's interests would be advanced through support for, or participation in, such an initiative.

The OECD and Related Initiatives

In regard to the OECD proposal and related multilateral initiatives, CBAC notes that there are several multilateral agencies and advisory mechanisms tasked with monitoring, examining or regulating one or another discrete aspect of GM foods (e.g. the CODEX Alimentarius Commission, the FAO and the WHO). We are therefore heartened that the OECD proposal states, ". . . the work of the OECD will effectively complement, without duplication, the activities of other international organizations, in particular the Food and Agriculture Organization and the World Health Organization."

CBAC notes that while there is a need to clarify the mandates of some multilateral agencies in relation to GM foods, and to strengthen the capacities of others, there is currently no acknowledged focal point within the multilateral system to facilitate policy exchanges or to address (and to the extent possible reconcile) the full range of issues to which food biotechnology gives rise.

> *Accordingly, CBAC is supportive in principle of the establishment of an over-arching multilateral mechanism that will serve to clarify and address the full range of scientific and non-scientific issues associated with GM foods.*

It is desirable that the following attributes be incorporated in such a mechanism.

Status

- It should be under the aegis of a body representative of both developed and developing countries. For example, under the UN system, it could be part of an existing UN agency or forum, or a new UN entity.

- It should complement the activities of existing multilateral mechanisms and forums (including any international scientific panel(s) that may be established) and, to the extent possible, promote harmonization of their activities in relation to GM foods.

Mandate

- It should operate in an exclusively advisory capacity.

- It should seek to address the full range of issues — both scientific and non-scientific — associated with GM foods simultaneously, rather than discretely, and should focus on clarifying issues and identifying areas of consensus and disagreement.

- It should establish a research agenda to bridge knowledge gaps in relation to the science of GM foods, their safety and potential long-term and cumulative health and environmental effects.

Membership

- Its membership should be inclusive in terms of developed and developing countries.
- Its members should be selected from lists provided by member countries developed pursuant to an open, domestic public nomination process.
- Its members should be autonomous and should be appointed for fixed, non-renewable terms, solely on the basis of their technical knowledge or expertise.

Operation and Activities

- It should be funded entirely by developed countries to a level sufficient to fulfil its mandate.
- It should convene an annual meeting of the heads of existing national and international advisory bodies on GM foods.
- It should work collaboratively, on an as-requested basis, with domestic government departments or agencies in supporting broad citizen awareness and engagement activities in relation to the development, use and regulation of GM foods.

2. The Federal Court of Appeal's Decision Against the Commissioner of Patents on the Harvard Onco-mouse Case (September 8, 2000)

On June 21, 1985, Harvard filed a patent application for an invention titled "Transgenic Animals." This application sought patents on both (a) the process of producing transgenic (i.e. genetically modified) mice that were susceptible to cancer and (b) the products of that process: the Harvard Onco-mouse and its transgenic offspring. The Patent Examiner granted Harvard patents on its method of genetic modification, but refused to allow patents on its transgenic mice. The Commissioner affirmed this decision. Harvard appealed to the FTD (Federal Court Trial Division).

The FTD upheld the decisions of both the Examiner and the Commissioner. The FTD judge ruled that although the definition of "invention" in the *Patent Act* had been previously extended to include lower life forms (e.g. yeast), it was inappropriate to stretch it even further to include higher life forms (e.g. transgenic animals) because of the level of control over the inventive subject matter. As such, the FTD judge held that the Harvard Onco-mouse and other similar transgenic, non-human mammals were not patentable subject matter in Canada.

The case was then directed to the Federal Court of Appeal (FCA) whose decision is an appeal from the FTD. On August 3, 2000, the Canadian Federal Court of Appeal delivered its judgment. By a majority ruling, the court found in favour of the appellant and awarded costs to Harvard for the proceedings before the FCA and the FTD.

Non-human higher life forms are considered patentable by both the United States Patent and Trademark Office and the European Patent Office. Canada would be better able to contribute to forthcoming multilateral negotiations on biological intellectual property if a domestic policy were established prior to the commencement of these negotiations.

Federal Court of Appeal Finding

In this case, the Federal Court of Appeal ruled that the wording of Canada's *Patent Act*, as it currently stands, permits the patentability of genetically altered non-human mammals for use in carcinogenicity studies.

The Harvard Onco-mouse patent application is specifically directed to a transgenic animal, particularly a mouse. The Commissioner of Patents and the Federal Court of Appeal (Trial Division) previously refused this application on the grounds that they did not consider a genetically modified animal to be an invention within the definition of the *Patent Act*. The Federal Court of Appeal's decision overturns these rulings. The majority judgment states that the Harvard Onco-mouse qualifies as a new, useful and non-obvious composition of matter within the definition of the *Patent Act*, and therefore is patentable subject matter in Canada. It also refers the matter back to the Commissioner of Patents with the direction to grant a patent on the Harvard Onco-mouse.

The majority's rationale for overturning the lower court's decision and determining that the Harvard Onco-mouse was, in fact, patentable subject matter in Canada was based upon, among other things, seven critical findings.

The first finding, and the one with the most public significance, was that it was inappropriate for the courts to take into account public policy arguments when deciding this case. The Honourable Justice Rothstein, writing for the majority, stated that the proper forum for addressing public policy issues on the patentability of complex life forms was Parliament, and not the appeal courts.

The second finding was that the Supreme Court of Canada's (SCC) past analysis of the patentability of complex life forms indicated that it had accepted that living things were not necessarily excluded from patent protection in Canada. Hence, the majority found that it had a duty to be cautious, but not necessarily restrictive when determining whether the Harvard Onco-mouse was patentable under the current parameters of the *Patent Act*.

The third finding was that Parliament's intentions regarding the interpretation of Canada's *Patent Act* were similar to that of Congress because our Act was modelled on the U.S. statute and used the same broad language. As such, the majority held that the U.S. Supreme Court's (USSC) conclusion that their *Patent Act* was intended to include higher life forms within the definition of "invention" was relevant and had persuasive value for Canadian courts. On the basis of this finding, the majority found that the Harvard Onco-mouse and its transgenic offspring qualified as non-naturally occurring "compositions of matter" under our *Patent Act*.

The fourth finding was that the FCA was obliged to allow Harvard's appeal in this case if it found the legal reasoning of the FTD judge and the Commissioner to be incorrect. The rationale for applying such a high level of judicial review to the lower court's and the Commissioner's decisions was that this case involved the interpretation of a fundamental clause of the *Patent Act*, the definition of "invention" and would likely have significant precedential value.

The fifth finding was that the Commissioner and the FTD judge had erred in law in deciding that the Harvard Onco-mouse and its transgenic offspring were not "useful inventions" because all of their physical characteristics were not under the *full* control of their inventors. In the majority's opinion, the correct test for usefulness was much narrower. It was whether or not an inventor had control over the elements of an invention that made it useful (i.e. in this case, the fact that the mice were susceptible to cancer). The majority found the Harvard Onco-mouse and its transgenic offspring met this much narrower test for usefulness.

The sixth finding was that the Commissioner had erred in law in splitting the invention of the Onco-mouse into two phases: phase one, which involved inventive ingenuity and was considered patentable; and phase two, which involved the laws of nature and was considered unpatentable. According to the majority, this distinction was illogical. The Commissioner incorrectly denied Harvard a patent on its Onco-mouse on the grounds that these transgenic animals were only the products of phase two, the unpatentable phase, when in reality they were the products of both phases.

The seventh, and final critical finding, was that the *Patent Act*'s definition of "invention" could not be extended to include human beings. The majority's reasoning for this assertion was that patenting is a form of ownership, and ownership concepts cannot be extended to human beings under the common law and the *Canadian Charter of Rights and Freedoms*.

The Honourable Justice Issac dissented from the majority on the ground that the majority should have accorded a more deferential standard of review to the Commissioner's decision. Justice Issac considered the question of patentability of inventions to fall squarely within the expertise of the Commissioner. Consequently, he considered the proper standard of review for the Commissioner's decision to be reasonableness and not correctness. In addition, Justice Issac concluded that the Commissioner's rationale for denying a patent on the Harvard Onco-mouse was properly informed by public interest considerations. These considerations justified a very deferential standard of review, especially in light of the morally divisive nature of this case.

It must be noted that the Honourable Justices Linden and Rothstein state in the majority reasoning for their decision that "it is Parliament and not the court that defines the limits of patentability." This is significant to CBAC, as a portion of our mandate is to seek out the views of Canadians and provide policy advice to the Canadian government on how it should proceed with the issue of patenting of higher life forms.

The Federal Court of Appeal has given the Government of Canada the right to seek leave to appeal this matter to the Supreme Court of Canada within 60 days following the August 3, 2000, judgment.

Summation of Relevant Concerns

CBAC notes that the Commissioner of Patents can apply to the Federal Court of Appeal for an order staying execution of its own judgment, prior to appealing to the Supreme Court. If the judgment is not appealed, then the Commissioner is required to comply with the judgment and to grant a patent for the contested claims. The Commissioner would also be bound by the judgment to allow patents for life forms which are within the scope of the judgment.

It is also important to note that in the appeal judgment it is stated that the issue on appeal is directed to the interpretation of the *Patent Act* and whether or not the subject matter (pertaining to a higher life form) is patentable subject matter. There is no consideration of whether or not the subject matter is a non-human higher life form, for example, a primate or a plant. There is also no stated limit that section 2 applies only to non-human higher life forms, since this requirement can also be satisfied by other higher life forms that are new and useful.

It is also important to note that on enquiry with the Patent Office, our legal counsel was advised that if the judgment is not appealed, any life form "below" an animal may also be considered patentable, for example, plants. However, there has been no official policy set on this matter by the Canadian Patent Office at the present time. In addition, it is stated in [127] that the *Patent Act* cannot extend to cover human beings in part due to section 7 of the *Canadian Charter of Rights and Freedoms*. Furthermore, there is no analysis in the judgment of whether or not elements of a human body, including human genes, products or processes at the genetic level, are patentable subject matter. Rather, in [128] it is stated that this matter requires determination by the courts or Parliament.

We also observe that although no comment is made in the judgment on the patentability of primates, as primates are non-human animals, any invention that pertains to a primate and that is new, useful, non-obvious, a composition of matter and involves inventiveness or ingenuity (and not just laws of nature) would, arguably, also be patentable subject matter.

From a global perspective, biotechnology patenting issues will be considered in international negotiating fora. The next round of multilateral trade negotiations is expected to commence this year. The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) addresses the question of patentability of higher life forms in Article 27.3(b). The operation of this section allows WTO members to exclude from patentability plants and animals and essentially biological processes for the production of plants and animals. Some members are advocating for the article's expansion, while other members (e.g. the United States) are advocating for a narrowing of the article and possibly its elimination. Canada would be better able to contribute to this debate if a domestic policy were developed prior to the commencement of these negotiations.

Conclusions

On the basis of the foregoing observations CBAC advises as follows:

First, CBAC concurs with the Federal Court of Appeal's finding that Parliament, not the courts, should determine Canada's policy with respect to the patenting of higher life forms (and the distinction between "lower" and "higher" life forms).

Second, CBAC believes that to date, Canadians have not had an opportunity to debate the full range of moral, ethical and social issues that are at stake in this case. CBAC believes that Canada's laws must reflect the values Canadians share.

Third, a decision on whether or not to appeal the court's ruling is, for CBAC, a moot consideration. If the decision stands, the courts will have *de facto* decided on a policy issue that CBAC believes to be the proper prerogative of Parliament. Moreover, until Parliament deals with these issues, the current public concerns as to what biological products or processes are patentable will remain. Even if the court's finding is appealed, it will not obviate the need for Parliament to address what is, ultimately, a policy issue.

Fourth, CBAC encourages the Government of Canada to take all reasonable and feasible steps to facilitate Parliamentary review of the issue of patenting of biological products and processes. In doing so, it would be desirable to use an appropriate mechanism to "stop the clock" while the policy review process is undertaken. In that regard, two options were considered by CBAC:

OPTION 1

CBAC encourages the Government of Canada to *immediately begin the Parliamentary process to consider an amendment to the Patent Act*, to explicitly forbid patenting, if required, particular classes of higher life forms such as primates, the human body and certain plant species. Parliament may also want to consider the addition of a policy provision (e.g. the ordre public and morality clause found in The European Patent Convention) within the current patent regime, which would allow the explicit consideration of policy issues with each patent application. Upon initiation of this interim process the Government of Canada would advise Parliament if necessary to amend the relevant provisions of the *Patent Act*. CBAC would assist in this process by consulting Canadians on the issues at stake in this debate and reporting on their views.

OPTION 2

CBAC encourages the Government of Canada to *file an application for leave to appeal the Federal Court of Appeal's judgment on the Harvard Onco-mouse case to the Supreme Court of Canada*. While this application is being considered, the Government of Canada would advise Parliament if necessary to amend the relevant provisions of the *Patent Act*. CBAC would assist in this process by consulting Canadians on the issues at stake in this debate and reporting on their views.

A majority of CBAC members favoured Option 1. There was minority support for Option 2 based on the argument that this highly important issue of public policy should not be determined by the courts but by Parliament, and that a full public debate on the issue of the patenting of higher life forms should inform Parliament's deliberations. An appeal accompanied by a stay of the judgment of the Federal Court of Appeal could provide an opportunity for such a process to be implemented. Those supporting Option 1 acknowledged this point, but believed an appeal could result in a lengthy court process and that Parliament would await the Supreme Court of Canada's decision prior to beginning the desired review.