Annual Report 2003

CANADIAN
BIOTECHNOLOGY
ADVISORY
COMMITTEE

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Message from the Chair, Canadian Biotechnology Advisory Committee

On behalf of the Canadian Biotechnology Advisory Committee (CBAC), I am pleased to present CBAC's fourth Annual Report, covering the year 2003.

In doing so, I wish to acknowledge the generous contribution of the time and talent of members of the Committee to its various undertakings and their dedication to fulfilling CBAC's mandate. I also wish to acknowledge the efforts of the staff of the Canadian Biotechnology Secretariat, who have provided invaluable support to the Committee; the excellent cooperation of officials in departments and agencies of government; and the input and advice received from stakeholder groups and the public at large.

CBAC now enters its fifth year. Its activities and accomplishments to date have established a sound base of experience upon which to build its future contribution to assisting the Government of Canada in responding to the opportunities and challenges posed by developments in biotechnology.

Sincerely,

Dr. Arnold Naimark
Chair, CBAC

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Executive Summary

In 2003, advances in biotechnology continued to emerge at an accelerating pace. Research in genomics and proteomics, stem cell biology, transplantation and reproductive biology produced powerful new tools for application in several sectors, particularly human and animal health, agriculture and the environment.

However, while technology moved ahead rapidly, policy-making and regulatory systems struggled to keep pace. Individual nations and international organizations grappled with issues such as human therapeutic cloning, privacy and genetic information, the impact of gene patents on health care, the acceptability or non-acceptability of genetically modified (GM) crops and foods, and the growing technology gap between developed and developing nations.

This, the fourth Annual Report of the Canadian Biotechnology Advisory Committee (CBAC), describes some of the foregoing developments after outlining the Committee's own activities in 2003.

CBAC Activities

General Activities: CBAC continued to take an active interest in matters pertaining to the two major reports it released in 2002, namely, *The Regulation of Genetically Modified Foods* and *Patenting of Higher Life Forms*. CBAC met with interested parties including government officials, tracked pertinent developments, monitored public opinion, and sponsored further research and background studies. CBAC looks forward to receiving the government's response to these reports.

In February 2003, CBAC submitted an Advisory Memorandum to the Biotechnology Ministerial Coordinating Committee (BMCC) concerning the Supreme Court of Canada's ruling in December 2002 that the Harvard onco-mouse is not patentable in Canada. The memorandum concluded: "If the Government of Canada wishes higher life forms to be patentable, it must propose amendments to the *Patent Act* and gain Parliament's agreement." It also encouraged the government to act on other recommendations contained in CBAC's report *Patenting of Higher Life Forms* and to address other specified biotechnology issues.

CBAC also continued background work on its special projects concerning privacy and genetic information, and the incorporation of social and ethical considerations into policy making. This included sponsoring the preparation and presentation of four papers on genetic privacy and biobanks at the GE^{3}LS[1] symposium in February, and the completion of a document summarizing the feedback on CBAC's Statement of Values and Principles received while carrying out the projects on GM food and patenting of higher life forms.

CBAC augmented its communications and outreach program to make the Committee and its work more visible to the public. It enhanced its Web site to better serve both external audiences and its own members, designed a new kiosk, and expanded its exhibit program. CBAC members and Canadian Biotechnology Secretariat staff took part in several national and international forums and conferences on subjects including genomics, health, gene patents, the labelling of genetically engineered foods and other matters pertaining to biotechnology.

Special Projects: CBAC continued work on its special project designed to formulate and test a tool for framing constructive debate on contentious issues in agricultural biotechnology. In 2003, the tool (previously the Acceptability Spectrum) was reconfigured as the Dialogue Tool on Genetically Modified Foods and Feeds, and a report was produced detailing the work done on the project from its inception in 2002 to May 31, 2003. At a presentation to government representatives in November 2003, the Dialogue Tool received positive feedback. The next step is a multi-stakeholder orientation session planned for March 17–18, 2004.

The Committee launched a new special project titled Biotechnology and Health Innovation, which will provide strategic advice to governments on how best to prepare for and deal with the impacts of biotechnological innovations in health. The project is part of CBAC's ongoing examination of how Canadian institutions might be transformed to best enable Canadians to capture the benefits of biotechnology while managing the risks and social and ethical challenges.

Recent Developments in Canada and Abroad

Genomics and Proteomics: Advances in genomics and proteomics have created powerful new tools for application in several sectors, particularly human and animal health, agriculture and

1 GE^{3}LS refers to the ethical, environmental, economic, legal and social issues related to genomics research.

the environment. The scale and importance of the work required to develop these scientific areas has prompted the formation of national and international partnerships, such as the Canada–United Kingdom Structural Genomics Consortium and the International HapMap Consortium that began its first full year of work in 2003. Canada is also taking part in an international consortium to sequence the cow genome, a development that could have both human and animal health benefits, as well as economic advantages. In October 2003, the Human Proteome Organization announced the establishment of its international head office in Montréal, and the election of Dr. John M. Bergeron, of McGill University and Genome Canada, as incoming president.

Stem Cells, Gene Therapy and Cloning: Stem cell, gene therapy and cloning research also advanced significantly. Application of these advances to human and animal health remains largely exploratory. Gene therapy, for example, shows promise but still has several serious challenges. This became sadly evident in 2003 when two young children died from leukemia following gene therapy for X-SCID.[2] Gene therapy trials in the United States and France were cancelled in January 2003 until an emergency review could be completed. In March, most trials were allowed to resume except for three that were similar to the French trials.

In the case of animal cloning, while some advances have moved us closer to application in humans, significant challenges remain both from technical and from social, ethical and regulatory perspectives. The most pervasive concern about advances in cloning research is the possibility that they could lead to attempts to clone humans and, in particular, attempts to clone humans for reproductive purposes. While there is almost universal objection to reproductive human cloning, there is considerably less agreement on the acceptability of therapeutic cloning primarily related to the question of cloned human embryos as a source of stem cells for therapeutic uses.

Agricultural Biotechnology: Agricultural biotechnology continued to be a major area of development in the spheres of technology advancement, public policy and regulatory developments, and overall industrial growth. In 2003, the global area of GM crops increased 40-fold from 1996 levels, with an increasing proportion of this growth taking place in developing countries. The growth in developing countries is partly due to initiatives such as the African Agricultural Technology Foundation, which assists resource-poor farmers to obtain agricultural technology, and the Golden Rice Network, which is promoting the production of vitamin-enriched GM rice.

2 X-linked severe combined immunodeficiency (X-SCID) is an immune disorder caused by mutations in the X-linked gene IL2RG.

Several significant reports appeared in 2003, particularly in the United Kingdom as Britain neared its self-imposed deadline for deciding whether or not to allow GM agriculture within its borders. These publications included a science report, a cost-benefit study, an examination of the effects of certain GM crops on the wildlife found on farmland, and the results of an extensive public opinion survey. As well, the Nuffield Council on Bioethics released a major report in 2003 examining GM crops in developing countries, and assessing biotechnology's potential for improving agriculture in these areas.

An important publication by the International Council for Science provided a synthesis of more than 50 science-based reviews concerning the risks and benefits of applying new genetic discoveries to food and agriculture and a comparative assessment of their conclusions.

The consensus reached in Canada on defining a voluntary standard for the labelling of foods that are or are not obtained through genetic engineering was a major achievement. The Canadian General Standards Board Panel on Process Assurance forwarded the voluntary standard to the Standards Council of Canada for approval as a National Standard.

Regulatory agencies in both Canada and the United States took steps in 2003 to make their regulatory processes more transparent. The Canadian Food Inspection Agency and Health Canada began a pilot project to inform Canadians about new submissions concerning novel crops, feed, and foods (the project is voluntary on the part of companies). The United States Department of Agriculture for the first time published the number of regulatory violations by the biotechnology industry since 1990 in planting GM crop trials. In both countries, farmers took steps to halt the potential approval of GM wheat, including asking their respective regulatory agencies to add an economic study to their usual assessments.

Privacy and Genetic Information: The protection of genetic information from inappropriate disclosure or use is a continuing key concern, and several countries are gradually developing legislation in this area. For example, the ability of researchers to conduct large-scale population genetic studies and to store human genetic samples in "biobanks" is a significant privacy concern. Canada, like several other nations, is considering the legislative and regulatory implications of this issue. Public opinion research on privacy and genetic information was undertaken in Canada for the Biotechnology Assistant Deputy Ministers Coordinating Committee. The results and those of similar research are available at: **www.biotech.gc.ca**.

Gene Patents and Access to Health Care: Several bodies in Canada and abroad continued to grapple with the impact of DNA sequence patents on accessibility to laboratory tests and other procedures based on such sequences when the patent holders impose burdensome restrictions on access.

There is every indication that the opportunities and challenges presented by advances in biotechnology will continue to proliferate in the years ahead. The implications of these trends for governments in Canada and abroad are significant. CBAC will continue to monitor and report on developments in biotechnology and their implications and provide advice to the Government of Canada as appropriate.

Introduction

In 2003, advances in biotechnology continued to emerge at an accelerating pace. Research in genomics and proteomics, stem cell biology, transplantation and reproductive biology produced powerful new tools for application in several sectors, particularly human and animal health, agriculture and the environment.

However, while technology moved ahead rapidly, policy-making and regulatory systems struggled to keep pace. Individual nations and international organizations grappled with issues such as human therapeutic cloning, privacy and genetic information, the impact of gene patents on health care, the acceptability or non-acceptability of genetically modified (GM) crops and foods, and the growing technology gap between developed and developing nations.

This, the fourth Annual Report of the Canadian Biotechnology Advisory Committee (CBAC) describes some of the foregoing developments after outlining the Committee's own activities in 2003. This report contains two main sections. The first deals with the Committee's activities during the past year. The second presents an overview of developments in biotechnology relevant to CBAC's mandate.

Most of the information in the Recent Developments section is gleaned from CBAC's monitoring of world media, including the Internet. The media and Internet references are included in the report; links to the original source documents may be found on CBAC's Web site.

CBAC is a body of experts established in 1999 to advise the Government of Canada on the policy issues associated with the ethical, social, regulatory, economic, scientific, environmental and health aspects of biotechnology. CBAC also provides Canadians with easy-to-understand information on biotechnology issues, and opportunities to voice their views on the matters on which it is advising the government. CBAC reports through the Biotechnology Ministerial Coordinating Committee (BMCC). All CBAC documents and reports mentioned in this document are available on CBAC's Web site. Readers are encouraged to visit the Web site at: **www.cbac-cccb.ca**.

1 CBAC Activities

1.1 CBAC Membership

Three new members were appointed to CBAC for terms ending in December 2006, and three current members were reappointed until December 2004. The list of CBAC members appears at the beginning of this report, and biographical information about them is available on the CBAC Web site.

1.2 General Activities

Monitoring and Reporting Developments

An important part of CBAC's work is to monitor developments in Canada and elsewhere and to advise ministers on matters that it believes require the government's early attention.

Patenting of Higher Life Forms (Genetic Patents): Following the release in 2002 of its report *Patenting of Higher Life Forms*, CBAC continued to monitor pertinent national and international developments, sponsor further research, collect background information and track public opinion.

In February 2003, CBAC presented ministers with an Advisory Memorandum concerning the Supreme Court of Canada's ruling in December 2002 that the Harvard onco-mouse does not meet the definition of an invention under the *Patent Act* and is therefore not patentable in Canada. The Advisory Memorandum concluded: "If the Government of Canada wishes higher life forms to be patentable, it must propose amendments to the *Patent Act* and gain Parliament's agreement." It also encouraged the government to act on other recommendations contained in CBAC's *Patenting of Higher Life Forms* report and to address other biotechnology issues such as the impact of biotechnological inventions on regulatory systems, the impact of gene patents on access to health care and the sustainability of the health care system, and the availability of highly qualified personnel. See Appendix A for the complete Advisory Memorandum.

CBAC looks forward to receiving the government's response to its *Patenting of Higher Life Forms* report.

Genetically Modified Foods: Following the release of its report *The Regulation of Genetically Modified Foods* in 2002, CBAC continued to take an active interest in matters pertaining to GM foods. It met with interested parties to discuss and explain the recommendations contained in the report, tracked pertinent national and international developments, particularly with regard to labelling, monitored public opinion, and sponsored research and background studies. In June, the Executive Director of the Secretariat for the External Advisory Committee on Smart Regulation attended a CBAC meeting to explain the smart regulation committee's mandate and work and to solicit observations from CBAC members on regulatory matters, particularly as they pertain to biotechnology. An Agriculture and Agri-Food Canada representative attended CBAC's October meeting to describe the development of the Responsible Introduction of New Agricultural Products (RIONAP) program and to receive comments from members. CBAC looks forward to receiving the government's response to its *Regulation of Genetically Modified Foods* report. It will then work with federal agencies as required as they address the recommendations.

Privacy and Genetic Information: The purpose of this project is to examine the adequacy of the existing mechanisms that protect the privacy of genetic information in Canada. Currently, most such provisions appear in more general legislation, such as the Canadian Charter of Rights and Freedoms, laws governing professional confidentiality, data protection (privacy) and human rights laws, etc., many of which were drafted before genetic information became an issue. The collection and storage of large-scale population genetic data in biobanks raises particular privacy concerns. Many institutions and countries including Canada are either developing or planning such biobanks. Four papers[3] commissioned by CBAC on privacy and biobanks were presented at the Genome Canada GE^{3}LS Symposium in February. In October, a senior Justice Canada representative attended a CBAC meeting to explain the work of the Interdepartmental Working Group on Genetic Information and Privacy, and to solicit comments on several options within the federal jurisdiction for balancing privacy protection with research and health.

Incorporation of Social and Ethical Considerations into Policy Making: The purpose of this project is to facilitate the integration of biotechnology's social and ethical dimensions into public policy decision making and administration. In 2003, CBAC published a summary of the feedback it received on its Statement of Values and Principles, titled *Incorporating Values and Ethical Principles into Biotechnology: CBAC's Experience*.

3 The four papers are: Mylène Deschênes and Geneviève Cardinal, *Survey of National Approaches to the Development of Population Genetic Biobanks*; Michael Yeo, *Toward a Comprehensive Information Privacy Regime for Research and Biobanks*; Edna F. Einseidel, *Whose Genes, Whose Safe, How Safe? Publics' and Professionals' Views of Biobanks*; and Patricia Kosseim, *Biobanks, Research and Privacy: Overview of Canadian Legislation.*

Communications and Outreach

Communications: CBAC launched its enhanced Web site on March 31, highlighting new and improved features for both external and internal communications. To improve external communications, a ListServe was added, which allows individuals and organizations to register their e-mail addresses in order to be notified of certain CBAC activities. As well, a portal to Canada NewsWire was added, which allows users to automatically receive CBAC news releases and backgrounders.[4] CBAC made its Web site documents more accessible by posting all those issued in fiscal year 2002–03 in both text and HTML formats as well as PDF. The Web site also provides links to selected reports from other organizations. To enhance internal communications, a member site was created, which includes meeting minutes, opportunities to comment on draft documents, administrative assistance, a discussion forum and other features.

Outreach: As part of its mandate to increase public awareness of biotechnology and CBAC activities, the Committee designed a new kiosk and expanded its exhibit program to reach 15 fairs across the country. CBAC's outreach program also targeted senior government officials and members of Parliament, particularly following the Government of Canada's leadership change. A document titled *Biotechnology in Canadian Society* was distributed as a means of outlining important issues in biotechnology for senior government officials and members of Parliament.

Forums and Conferences: CBAC and several partners[5] hosted the GE^{3}LS symposium, held on February 6–8, in Montréal. More than 200 experts in philosophy, law, anthropology, sociology, genetics and other branches of science and policy making met to discuss a range of ethical, environmental, economic, legal and social issues related to genomics and proteomics. CBAC members actively contributed to the symposium as co-chair (Timothy Caulfield), panellist (Professor Bartha Maria Knoppers) and participant (Denny Warner). CBAC sponsored the preparation and presentation of four papers on genetic privacy and biobanks.

Dr. Naimark was keynote speaker at the Insight Conference on Genetic Patents on February 10 in Ottawa. He discussed the Committee's intellectual property project and some key challenges that lie ahead concerning gene patents.

4 Annual Report readers are invited to register for this service by contacting the CBAC Web site (**www.cbac-cccb.ca**).

5 Genome Canada, Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council, National Research Council, Social Sciences and Humanities Research Council, and Health Canada.

Dr. Mary Alton Mackey attended the March 11–14 meeting of the Codex *Ad Hoc* Inter-governmental Task Force on Foods Derived from Biotechnology in Yokohama, Japan, as CBAC representative on the Canadian delegation. She also attended the 31st session of the Codex Committee on Food Labelling in Ottawa on April 28 to May 2.

Dr. Alton Mackey attended the National Research Council's 2025 Scenario Workshop in Ottawa on March 19–20.

Dr. Alton Mackey appeared before the House of Commons Standing Committee on Health in March and May to describe CBAC's position on the labelling of GM foods and to comment on the progress of the development of the voluntary labelling standard. A copy of her presentation is available on the CBAC Web site.

Dr. Naimark gave the keynote address at the Friends CIHR (Canadian Institutes of Health Research) symposium and public forum on May 14, where he spoke on Biotechnology: Inventing a Future.

Dr. Naimark addressed the annual gala dinner sponsored by Partners in Research on the topic of Biotechnology: Balancing Scientific and Social Ingenuity.

CBAC and Secretariat representatives attended BIO 2003 in Washington, D.C. in June as part of the Canadian delegation. Some 16 000 biotechnology leaders from 52 countries gathered to mark the 10th anniversary of the BIO convention.

The Secretariat's Marnie McCall made a presentation on Biotechnology and Health Innovation: The Policy Imperatives, to the Health Services Research for Genetic Diseases workshop on October 3.

CBAC had an exhibit at the first joint meeting of the American Society of Bioethics and Humanities and the Canadian Bioethics Society in Montréal on October 23–26. The booth generated significant interest, particularly among U.S. participants who wanted to know more about the Canadian model used to provide bio-related advice to government, and among participants and other exhibitors concerning CBAC's ListServe.

The CBAC Chair and members were also active individually at various forums on issues of public interest concerning biotechnology.

1.3 Special Projects

Dialogue Tool on Genetically Modified Foods and Feeds: The project, designed to formulate and test a tool (the Acceptability Spectrum) for framing constructive debate on contentious issues raised by agricultural biotechnology, was reconfigured as the Dialogue Tool on Genetically Modified Foods and Feeds.[6] This was done on the basis of extensive and intensive review by the Exploratory Committee, which was established to guide the project. The Exploratory Committee refined the project's objectives, outputs and outcomes, and assessed the usefulness of the tool and its potential for further development. It also produced a report detailing the work done on the pilot project from its inception in 2002 to May 31, 2003.[7] In November 2003, CBAC made a presentation on the Dialogue Tool to some 60 representatives of the departments under the ministers comprising the Biotechnology Ministerial Coordinating Committee as well as of the Privy Council Office, and received positive feedback. The next step is a multi-stakeholder orientation session scheduled to take place March 17–18, 2004.

Biotechnology and Health Innovation: In 2002, CBAC articulated its overarching program development theme under the rubric Biotechnology and Canadian Society. Under this theme, CBAC has embarked on an ongoing examination of Canadian institutions, both within and outside government, to assess how they might be transformed to enable Canadians to capture the benefits of biotechnology while managing the risks and social and ethical challenges in three areas of study — health, the economy and the environment.

The project Biotechnology and Health Innovation (BHI) was chosen as the initial focus of activity. The purpose of the BHI project is to provide strategic advice to governments on how best to prepare for and deal with the impacts of biotechnological innovations in health. Biotechnology is expected, over time, to have significant impacts on disease prevention, medical care and public health. Moreover, health is the largest sector of Canada's knowledge-based economy, employing thousands of Canadians and valued at more than $100 billion per year.

Throughout 2003, CBAC held workshops, commissioned research, consulted with other departments and agencies, made presentations to senior government officials, and developed an exhibit program focussing on health seminars and conferences. It is expected that the results of CBAC's BHI project will be presented to ministers in Spring 2004.

6 The Dialogue Tool is a framework that enables individuals to discuss the possible implications of individual GM food products and processes under five categories: health, environmental safety, social considerations, ethical considerations and broader societal considerations. Participants can debate the issue, share information and perspectives, and plot their dialogue along a spectrum from fully acceptable to not acceptable under any circumstances. While the tool was designed in the context of GM foods and feeds, it has the potential to be useful in other areas as well.

7 The report *Developing a Dialogue Tool on Genetically Modified Foods and Feeds (GMFF) in Canada*, submitted to CBAC in June 2003, identified progress to date and lessons learned, and recommended that the project continue.

2 Recent Developments in Biotechnology

This section briefly summarizes some of the significant developments during the reporting period that are particularly relevant to CBAC's work or that may influence its activities in the future.

2.1 Genomics, Proteomics and Related Matters

The year 2003 marked the 50th anniversary of the discovery of the double helix structure of DNA, possibly the most significant discovery in biology. This led to the new scientific discipline of molecular biology and laid the groundwork for modern genetic engineering. Another major turning point — arguably of equal significance — occurred almost half a century later when the human genome was sequenced, introducing vast new possibilities in sectors such as agriculture, energy and, particularly, health and health care.

Canada is committed to being a leader in the field of genomics and proteomics. On February 18, the Government of Canada granted Genome Canada an additional $75 million to invest in genomics and proteomics large-scale research projects related to health. The agency has, as of the end of 2003, received $375 million, which it will more than double with commensurate funding from other sources.

Human Genomics and Proteomics: The Canada–United Kingdom Structural Genomics Consortium was formed in 2003, under the leadership of the University of Toronto, to map the structure of 350 human health-related proteins. The three-year initiative will utilize the vast resources of the Human Genome Project to explore the structure and function of proteins, and provide information about their role in health and disease. The consortium is funded by Canadian agencies and by private sources such as the Wellcome Trust and GlaxoSmithKline. It will immediately deposit all protein structures in databases that will be freely available to researchers (*Science*, April).

Another consortium to which Canada belongs, the International HapMap Consortium, began its first year of work in 2003, announcing in December its goals and methods for the next three years. The purpose of the project is to map the patterns of DNA sequences that all individuals share onto the reference genome sequence produced by the Human Genome Project. The result will be a tool that allows researchers to more efficiently find the genes involved in various complex diseases. Bartha Maria Knoppers, Université de Montréal, will supervise the study of the ethical, environmental, economic, legal, and social aspects of the project (**http://www.genomecanada.ca/select.asp**).

A symposium took place September 11–12, titled "Health Technology Assessment in Genetics and Policy Making in Canada: Towards Sustainable Development." The Federal/Provincial/Territorial Coordinating Task Force on Genomics and Health prepared a background paper for the symposium titled *What Health Policy Needs from Health Technology Assessment in the Area of Genetic Technologies*.

In October, the Human Proteome Organization (HUPO) announced the establishment of its international head office in Montréal, and the election of Dr. John M. Bergeron, Professor and Chair of the Department of Anatomy and Cell Biology, Faculty of Medicine, McGill University, to the position of incoming president. Dr. Bergeron is also Director of Genome Quebec/Genome Canada Montréal Proteome Centre (**http://www.genomecanada.ca/select.asp**).

The U.S. Department of Energy awarded a grant of US$9 million over three years to the Institute for Biological Energy Alternatives, headed by genome pioneer Craig Venter, to scale up the company's project sequencing the DNA of every microbe in the Sargasso Sea **(www.nature.com/nsu/030428/030428-8.html).**

In the U.S., the National Human Genome Research Institute released a major paper titled *A Vision for the Future of Genomics Research* (**www.nhgri.nih.gov/11006873**) and launched a US$36-million pilot project to study one percent of the human genome in order to develop knowledge about how to determine the roles of selected genes (*San Jose Business Journal*, October 20).

Plant Genomics: The field of plant genomics continued to grow rapidly. Genome Canada sponsored several research projects in this area. One project involves research to better understand the genes involved in the seed development and composition of canola with the aim of improving existing or developing canola varieties. Another is focussed on the functions of several potato genes, particularly those related to disease resistance and those that would facilitate commercial processing of potatoes. A third endeavour is working toward a better understanding of how genes control berry ripening in different growing environments so that viticulturalists can fine-tune vineyard management and develop new grape varieties. Successful outcomes of these projects would generate significant economic benefits for Canada's agricultural industry.

Animal Genomics: The completion of a draft of the chimpanzee genome was an important achievement in 2003. Because chimps and humans succumb to different diseases (chimps, for example, do not get AIDS or malaria), the information is expected to provide new approaches

A 2003 study found that 99.4 percent of the most critical DNA sites are identical in humans and chimpanzees. The finding suggests that chimps and humans belong not only to the same taxonomic family but also to the same genus (New Scientist, May 24).

to fighting human disorders. It is also expected to lead to an understanding of how chimps and humans differ and, hence, the essence of "what makes humans human" (*Los Angeles Times*, December 11; *National Post*, December 12).

Canada is part of a US$53-million international effort to determine and publish the DNA sequence of the cow genome, which could lead to breeding cattle that are more disease resistant, have tastier, leaner beef, produce more milk and perhaps emit less methane. It could also contribute to human health through improved food safety (*Calgary Herald*, August 21).

Impact of Genomics on Human Health: Work continued in 2003 in advancing the use of genomics and proteomics to prevent, investigate and diagnose diseases, to predict responses to treatment, and to develop new drug therapies. However, while startling new advances are regularly reported in the media, this area of research remains largely exploratory in terms of its impact on human health.

In 2003, Italy announced that it would soon begin human testing of the first vaccines obtained from GM plants. Tuberculosis and diarrhea vaccines were obtained from GM tomatoes and potatoes, respectively (Agenzia Nazionale Stampa Associata (in English), November 21).

Genetic testing, for example, though a rapidly growing field, remains an uncertain science, given that it cannot yet predict with certainty that a specific disease will actually occur in a given person. Recent developments in genetic testing make it possible for people to perform some of these tests at home, using over-the-counter tests directly available to the public. In 2003, the United Kingdom Human Genetics Commission recommended that off-the-shelf genetic tests be regulated by legislation similar to that governing conventional medicines. Some tests

would be prescribed and managed through health professionals, while others, such as those relating to genealogy, may be less strictly regulated[8] (*BioMedNet*, February 5).

Gene therapy — using genes themselves to treat or prevent disease — is still at the experimental stage. The challenges that remain to be overcome include the short-lived nature of gene therapy, the body's immune response, the fact that many diseases result from multi-gene, rather than single-gene disorders and finding safe, effective ways to deliver genes to the target site.[9] Progress in the latter connection was made through liposomes coated in polyethylene glycol (PEG) to get genes into the brain, a major achievement as viral vectors are too big to get across the "blood–brain barrier" (*New Scientist*, March 20).

In 2003, scientists continued their search for other ways to intervene at the genetic level, such as using the technique of RNA interference, which switches off existing genes rather than inserting new ones (*New Scientist*, March 13). Gene therapy experienced a setback in 2003 when, following the death due to leukemia of two young children in France who had been treated with gene therapy for X-SCID[10] ("bubble boy" disease), the U.S. and France in January cancelled all gene therapy experiments for this disease until an emergency review could be completed.[11] In March, a U.S. Food and Drug Administration advisory panel recommended that most gene therapy trials resume but that a two-year delay be imposed on three of the gene therapy trials that were similar to the French trials (*Science*, March 7).[12]

A Sampling of Gene Discoveries and Related Developments in 2003

- A gene responsible for the spread of cancer through the body (*BBC News*, March)
- A new gene, DEP1, that causes depression and acts on a pathway not previously associated with depression (*Biospace News*, February 4)
- The oil-producing gene in canola, which could help increase oil production from canola seeds and meet market demand (University of Lethbridge: **http://staffweb.uleth.ca/news/display.asp?ID=4594**)
- In nine of 10 ovarian cancer tissue samples, the gene OPCML was found to be functioning improperly (*BBC News*, June 23)
- A gene chip to test for variations in two genes, which will help determine how a person will react to medications (*Reuters*, June 25)
- A set of genetic mutations that cause progressive hearing loss (*The American Journal of Human Genetics* 73 (5): November)
- People with a certain type of inherited Type 2 diabetes respond to treatment differently from people with other types of diabetes, demonstrating a clear link between genetic makeup and disease treatment (*The Lancet*, p. 362)
- A novel way to make human proteins using yeast, which could lead to new ways to brew sophisticated medicines in huge quantities (**www.pewagbiotech.org**; *Newsroom*, August 29; *The Guardian*, August 29; *Science*, August 29)

8 Concerns were expressed that providing genetic testing services would place too large a burden on the National Health Service, especially as there may be too few professionals with the required skills. There may be delays in these services but, overall, it was felt that genetic testing must be done by health professionals (*BioMedNet*, February 5).

9 While viral vectors are the most commonly used in gene therapy studies, they present potential problems to the patient such as toxicity, immune responses, gene control and targeting issues, and the fear that the viral vector may recover its ability to cause disease.

10 X-linked severe combined immunodeficiency (X-SCID) is an immune disorder caused by mutations in the X-linked gene IL2RG.

11 The U.K. Gene Therapy Advisory Committee did not suspend its X-SCID trials, as none of the U.K. patients showed signs of leukemia and the design of the vector differed from the one used in France (*New Scientist*, January 15).

12 Subsequent tests on the two boys showed that the DNA was inserted either inside or near a cancer-promoting gene called LMO-2. It was speculated that, as the two boys were the youngest in the treatment group, perhaps their stem cells were too immature for the treatment (*Miami Herald*, May 4).

2.2 Stem Cells, Gene Therapy and Cloning

Stem Cell Research: While stem cell research continued at an impressive rate in 2003, the one therapeutic use of stem cells such as in direct implantation, to grow replacement tissues, or in screening for drugs and toxins, is still largely an area of exploration. Currently, blood-forming stem cells in bone marrow are the only type of stem cell commonly used for therapy. However, new discoveries are reported almost weekly and scientists continue to investigate several important issues such as the similarities and differences between embryonic and adult stem cells, and how each might be used to best advantage.

Examples of Stem Cell Advances in 2003

- Discovery of a "master gene" largely responsible for giving embryonic stem cells their regenerative ability (*Washington Post*, May 30)
- Identification of mutant stem cells that may be the cause of certain cancers (*Science*, September 5)
- A new system for producing stem cells that sidesteps the need to generate a viable embryo (**www.news.bmn.com**, September 22)
- Transformation of mouse embryonic stem cells into sperm cells (*Wall Street Journal*, September 17) and, in another study, into egg cells (*Associated Press*, December 11)
- Restored feeling to paralysed patients by harvesting stem cells from their blood and returning the cells to the body (*Gold Coast Bulletin*, November 22)
- Deletion of a disease gene from the stem cells of laboratory animals, which could lead to the development of cell lines without the genes responsible for the immune reaction (*Reuters Health Information*, February 10)
- Creation of bone in the shape of part of a human jaw from rat bone marrow stem cells (*Journal of Dental Research*, December 1)

The sidebar gives an indication of the types of research that took place in 2003 in laboratories and clinical trials around the world as well as a glimpse of what the future may hold.

Cloning Research: Several species were added to the "cloned" list in 2003, including a mule, horse and Asian banteng (an endangered species of wild cattle) from a frozen specimen of an animal that died 20 years ago. The horse is the last of the major livestock animals to be cloned, and some experts see this as a sign that cloning is quickly moving from the possible to the routine, making ethical questions more urgent (*Boston Globe*, August 8). For example, new questions about the health of cloned animals were raised in 2003 when three pigs cloned from adult animals died of heart attack before age six months (*Animal News Center, Lab News*, September 9).

While several types of mammals have been successfully cloned, hundreds of attempts to clone monkeys have failed. Scientists speculate that perhaps primates cannot be cloned due to the biological make-up of their eggs, in that the first cell division divides the genetic material unevenly (*BBC News*, April 10).

Much of the work involving the cloning of transgenic animals has to do with human health. For example, in 2003, South Korean researchers announced that they had genetically modified cows to be resistant to diseases, and unveiled four cloned calves that they believe are resistant to "mad-cow" disease. These and other soon-to-be-born calves will be monitored at a testing facility in Japan for three to five years, as the symptoms of mad cow disease emerge only in older cattle (*United Press*, December 13; *Edmonton Journal*, December 11). Scientists also succeeded in cloning a miniature pig modified to knock out the genes involved in immediate immune rejection, which could be helpful in the future in transplanting pig organs into humans (*New Scientist*, January 13).

While animal cloning is advancing quickly, obstacles remain. Among them are the fact that relatively few embryos survive the cloning process and, of those that do and are born, a large proportion are deformed, too large (a problem that can happen with *in vitro* fertilization in general), and/or have other physiological problems.

Dolly, the first mammal to be created by cloning, was euthanized in February 2003 at age six due to a lung infection. A news release from Roslin Institute, where Dolly was created, said that the infection is not uncommon in older sheep (four to five years old) and that there was no evidence that cloning was a factor in Dolly's contracting the disease. However, the sheep's relatively early demise renewed discussion in the media of possible premature aging in cloned animals

(www.cnews.canoe.ca/CNEWS/Science/2003/02/14/26265-ap.html).

Animal cloning also raises important policy and regulation issues with which countries have been grappling, for example, the safety of food products derived from cloned animals. In 2003, the U.S. Food and Drug Administration tentatively concluded that milk and meat from cloned animals are safe to consume, and that cloned animal food products would not require labelling as long as they are deemed to be as safe as traditional foods[13] (*Planet Ark*, June 26). The Food and Drug Administration will receive public comment on the regulation of cloning, including labelling, in Spring 2004.

Policies Regarding Cloning for Human Reproductive and Therapeutic Purposes: The most pervasive concern about cloning research is the possibility that it could lead to human cloning. While there is almost universal opposition to reproductive human cloning, there is considerably less agreement on therapeutic cloning.

In December, the United Nations General Assembly agreed to delay discussion of a global treaty against cloning for one year. Almost all of the 191 member states are in favour of banning human reproductive cloning, but Costa Rica, the United States and about 50 other

13 It is believed that food products from cloned animals could be on the U.S. market as early as 2004.

Biotechnology and Bioterrorism

- Trans Ova cows, bred with human genes, cloned and inoculated with such biological agents as anthrax, smallpox and botulism, are on the cutting edge of U.S. efforts to defend itself against a potential bioterrorism attack. The hope is that the cows will eventually produce human antibodies that could be administered as an antidote following a biological attack (*Chicago Tribune*, August 26; *CBC News*, September 12).
- Researchers in Northern Ireland have developed significantly faster DNA fingerprinting techniques for organisms that could be used in a bioterrorist attack (*Yahoo News*, March 10).

countries, mainly developing nations, want a ban on all forms of cloning that use human embryos including therapeutic cloning. Britain, Russia, China, Japan, Belgium, France and Germany support a ban on cloning babies, but want individual countries to decide whether or not to allow human cloning for research and medical experiments. The one-year postponement means that the issue will be included in the Assembly's next session, which begins in September 2004 (*Montreal Gazette*, December 15; *Associated Press*, December 9).

The European Union remained divided on the question of therapeutic in 2003. The U.K. ended its ban on stem cell research using human embryos, including those produced by cloning. Germany and Austria continued their prohibitions, while other European Union nations have no regulations on the matter at all. In 2003, the European Parliament voted to fund embryonic cell research, a development that could force those countries banning it to reverse their decision (*United Press International*, November 25).

In the U.S., the House of Representatives approved a bill banning all human cloning, including therapeutic cloning, and prohibiting the importation of medical therapies derived from cloning (*New York Times*, February 28). In France, the National Assembly backed draft legislation making human reproductive cloning a crime against humanity and banning cloning for therapeutic purposes and other key techniques used in embryo research (*Reuters*, December 11). In both countries, the bills must pass through other government entities before becoming law.

In Australia, the Australian Capital Territory aligned its legislation with the country's national approach by prohibiting cloning and regulating research involving excess human embryos (*Australian Broadcasting Corporation*, November 27). In Canada, the House of Commons passed legislation in October banning human cloning and regulating stem cell research (Bill C-13). The Senate Committee on Social Affairs, Science and Technology is scheduled to hold hearings on the legislation during the next session of Parliament, which opens in February 2004 (*Ottawa Citizen*, October 15). In Israel, the government awarded the Israel Stem Cell Therapy Consortium $15–20 million to coordinate the efforts of local companies, scientists, and hospital research centres developing technologies for stem cell therapy (**www.worldhealth.net/p/416,4629.html**).

2.3 Agricultural Biotechnology

Global Growth of GM Crops[14]

The total area devoted to GM crops around the world grew at a double-digit rate for the seventh consecutive year and reached an estimated total of 67.7 million hectares in 2003.[15] This represents a 40-fold increase over the 1996 level, with an increasing proportion of the growth (30 percent) taking place in developing countries.

GM crops were grown in 18 countries on all five continents by seven million farmers. However, six countries accounted for 99 percent of the world's transgenic crop area: the United States (63 percent of the total area), Argentina (21 percent), Canada (6 percent), Brazil (4 percent), China (4 percent) and South Africa (1 percent). Canada's area planted grew by 26 percent in 2003 over the 2002 area, reaching 4.4 million hectares of canola, maize and soybean. China and South Africa showed the most significant growth (33 percent).

Two countries, Brazil and the Philippines, approved the planting of GM crops for the first time in 2003. Brazil officially approved herbicide-tolerant soybean in late September, just before the planting season, while the Philippines grew approximately 20 000 hectares of Bt maize hybrids, special varieties that produce the same toxin as the bacterium *Bacillus thuringensis* (Bt), which protects them against pests.

Worldwide, distribution of the four most widely used commercial GM crops is as follows: soybean (61 percent of global GM area), maize (23 percent), cotton (11 percent) and canola (5 percent). Herbicide tolerance and insect resistance continued to be the features of GM crops of greatest interest.

GM crops are projected to reach approximately 100 million hectares in 25 or more countries by 2005, with the proportion of small farmers from developing countries expected to increase. The global market value of GM crops, estimated at US$4.5–4.75 billion in 2003, is expected to reach US$5 billion or more in 2005.[16]

14 Figures in this section are taken from C. James, "Preview: Global Status of Commercialized Transgenic Crops," *ISAAA Briefs* 30 (Ithaca, NY: International Service for the Acquisition of Agri-biotechnology Applications, 2003).

15 This includes a provisional conservative estimate of three million hectares of GM soybean in Brazil (the final tally of area planted could be significantly higher). Without the Brazilian hectarage, the growth rate was 10 percent.

16 The market value of the global transgenic crop market is based on the sale price of transgenic seed plus any technology fees that apply.

GM Crops in Developing Countries

In 2003, the United Kingdom's Nuffield Council on Bioethics released a report, titled *The Use of Genetically Modified Crops in Developing Countries: A Follow-up Discussion Paper*, which reviews the recent scientific, regulatory and policy-related developments in the use of GM crops in developing countries. The council also assessed the potential of the technology to improve the effectiveness of agriculture under the difficult conditions that often prevail in developing countries (**www.nuffieldbioethics.org/**).

Among the several case studies cited in the report is one concerning Bt cotton in China and South Africa. The study found that the use of Bt cotton resulted in more efficient and selective pest control, reduced applications of pesticides, reduction of environmental degradation, increased health benefits for farm workers and increased profits for farmers.

Vitamin A deficiency is a public health problem in 118 countries, particularly in Africa and Southeast Asia. It is the leading cause of preventable blindness in children and raises the risk of disease and death from severe infections. In pregnant women, it causes night blindness and may increase the risk of maternal mortality (**www.who.int/nut/vad.htm**). The Golden Rice Network, which brings together researchers from India, China, Indonesia, Vietnam, Bangladesh, the Philippines and South Africa, has been undertaking research on Golden Rice, which, according to proponents, could significantly alleviate this disorder. While a laboratory strain of Golden Rice has been available since 2000, field trials are being delayed in the network member countries due to difficulties in obtaining regulatory approvals (**www.nuffieldbioethics.org/**).

The African Agricultural Technology Foundation is a not-for-profit organization, headquartered in Nairobi, Kenya, established to respond to the needs of resource-poor farmers in sub-Saharan Africa. In pursuing its mission of food security and poverty reduction, the foundation acquires technologies from technology providers through royalty-free licences or agreements, along with associated materials and know-how for use by the African farmers. It also establishes partnerships with existing institutions to adapt agricultural technology to African circumstances, and undertakes other initiatives to link farmers with potential technological solutions (**www.aftechfound.org/**).

Science

The International Council for Science (ICSU) in June released a report that provides a synthesis of more than 50 science-based reviews published in 2000–03, assessing the risks and benefits of applying new genetic discoveries to food and agriculture. The reviews, which were commissioned by national science academies, governments, international organizations and private

agencies on various aspects of modern genetics, have mobilized considerable scientific expertise worldwide. The ICSU overview marks the first time a comparative assessment of their conclusions has been undertaken. The study investigated five key questions: Who needs GM foods? Are they safe to eat? Will they affect the environment? Are the regulations adequate? Will they affect trade? Very broadly, the report concluded that there is demand for more, cheaper and/or better-quality food worldwide; that currently available GM foods are safe to eat; that the environmental effects may be positive or negative, depending largely on the specific genetic application, the agricultural system and the environment in which it is used; that there is broad agreement regulatory systems need to be science-based and transparent, yet involve public participation, and safety assessments should be undertaken on a case-by-case basis; and that trade implications are increasingly important and there is a need for science-based, internationally agreed-upon standards to enable trade in GM foods and commodities. The complete documentation for the study is available at the ICSU Web site at: **www.icsu.org**.

In the U.K., the Royal Society reported that the risk to human health from current GM crops is very low but that future crops may pose greater risk management challenges. It also found that the most important issue for the current generation of GM crops is their potential impact on the wildlife found on farmland, an aspect that was being studied in the U.K. by the Farm Scale Evaluations project (**www.gmsciencedebate.org.uk/background/pn210703.htm**).

Labelling

In Canada, the Canadian Council of Grocery Distributors and the Committee on the Voluntary Labelling of Foods Obtained or Not Obtained Through Genetic Modification announced on September 8 that consensus approval had been reached for a voluntary standard. The committee, which represents a cross section of consumers, producers and general interest groups such as governments (six federal departments) and universities, has been working on the standard since November 1999. The Canadian General Standards Board Panel on Process Assurance forwarded the voluntary standard to the Standards Council of Canada for approval as a National Standard.

The British government is considering forcing biotechnology companies to use DNA bar coding to identify genetically modified organisms. The National Institute of Agricultural Botany in Cambridge, U.K., received a patent in February on a technique for detecting modified DNA that would make it easier for regulators to trace GM food or detect crops that have been contaminated by GM strains. The premise is to add the same unique sequence to all GM organisms, regardless of how else they are modified. This means that a single, simple DNA test could identify any product as being genetically modified if it contains intact DNA. As such

a sequence would not code for any protein, it would not affect a plant's properties (*New Scientist*, February 13). Meanwhile, in China, scientists developed a device to detect GM products that works more quickly (50 minutes) than similar devices. China requires that all products made from or containing GM materials be labelled (*Xinhua News Agency*, December 8).

Regulation

Farmers in both Canada and the U.S. took steps in 2003 to halt the potential approval by their respective regulatory agencies of Monsanto's Roundup Ready Wheat.[17] In Canada, the Canadian Wheat Board urged the federal government in April to add a cost-benefit analysis to the food, feed and environmental assessments being done on the wheat. In May, it called on the company to voluntarily withdraw its environmental safety application currently before the Canadian Food Inspection Agency. As well, the Council of Canadians linked up with the National Farmers Union in a campaign against the product, and Greenpeace activists protested at a government research farm in Manitoba where the GM wheat is being grown (*Planet Ark*, June 9). In the U.S., farmers and consumer groups filed a petition with the U.S. agricultural department, requesting that the government study the economic impact of GM wheat and that development of the GM wheat be halted until it is determined if it would harm exports if put on the market.[18]

The Canadian Food Inspection Agency and Health Canada began a pilot project in 2003 aimed at increasing transparency in the regulation of novel crops, feed, and foods (**www.inspection.gc.ca/english/plaveg/bio/subs/subliste.shtml**). Under the project, the public will be notified on the Internet of new submissions concerning such products, and will have access to a list of the scientific safety studies to be conducted on them. The project is voluntary on the part of companies. The first posting, by Dow AgroSciences Canada Inc. seeking approval for the environmental release and livestock feed and food use of corn genetically engineered for insect resistance, was announced December 1. The pilot project is consistent with advice given to government by CBAC and the Royal Society of Canada in their respective reports on the regulation of GM food. Canadian Food Inspection Agency sets the rules for how individual field trials of GM crops are to be conducted and monitors them to ensure that all conditions of the trial are being met.

17 In December 2002, Monsanto applied to the Canadian Food Inspection Agency to permit the release of the GM wheat and to allow it to be used as livestock feed. A separate review on the safety of the wheat is before Health Canada. If the wheat gains approval it could be on the market as early as 2004. However, Monsanto has promised not to release the product until a separate grain handling system has been devised, including a way of paying for it, and until the farm market accepts it. As well, farmers must be trained on how to use the seed without spreading it to adjoining fields, and standards must be developed for acceptable levels of GM wheat in shipments of regular grain (*Life Sciences Network*, January 9; **www.Monsanto.co.uk/news/ukshowlib.phtml?uid=6932**).

18 An Iowa State University study concluded that if the U.S. adopts Monsanto's GM wheat for use in the U.S., the country's wheat industry could lose 30–50 percent of its foreign spring wheat business. Several importers have warned the U.S. industry that if it adopts the GM wheat, they would buy elsewhere (*Planet Ark*, March 13).

Canadian Food Inspection Agency figures show that in Canada from 1999 to 2003 there were 1541 confined research field trials authorized and, of these, 132 (8.56 percent) had compliance problems during their initial growing season. The majority of the problems were associated with insufficient isolation distance to related species and pollen trap breakdown (a pollen trap is a device for removing pollen loads from the pollen baskets of incoming bees). All were easily rectified with no harm detected to the environment or the food and feed supply.

According to the Canadian Food Inspection Agency, of the 205 GM crop field trials conducted in 2003 in Canada, 138 were done by companies and 36 by universities.

The United States Department of Agriculture also took a step toward more transparency by publishing for the first time the number of violations the biotechnology industry has committed in planting GM crop trials. The statistics show that companies and research universities have violated U.S. regulations on planting experimental GM crops 115 times since 1990. This represents less than 2 percent of the 7400 field trials authorized in that time. The United States Department of Agriculture said it considered most of the infractions minor, such as dirty farm equipment and not enough isolation between conventional crops. It also stated that none of the infractions resulted in any harm to agriculture, the food supply or the environment. Environmental and consumer groups said they believe that many infractions go unreported due to the lack of U.S. Department of Agriculture resources and personnel (*Reuters*, October 30). Meanwhile, government statistics reported previously (*USA Today*, September 11) showed that as many as 21 percent of farms in 10 midwestern states that grow corn genetically modified to produce its own pesticides are not following federal planting requirements (15 percent did not, as required, plant conventional corn, and 6 percent planted less than what is required).

In March, the U.S. government announced it had developed stricter rules for GM crops that produce pharmaceuticals or industrial chemicals. The new rules call for test plots to be inspected five times per year instead of once, greater distances between food crops and test plots, and separate storage, planting and harvesting equipment. Another new rule for corn and other crops genetically engineered to make industrial products requires that biotechnology companies obtain federal permits for the cultivation and handling of industrial crops (*New York Times*, March 7). Similar rules were already in place for GM crops developed for making vaccines and other pharmaceuticals.

Regulation of GM Fish

No GM fish are approved in Canada for commercial use. To date, the federal regulator, Health Canada, has not received any official requests for pre-market assessment and approval of GM fish, or food products derived from these. Health Canada is in the process of revising existing Novel Food Guidelines and developing specific guidance for the food safety assessment of GM fish.

In the U.S., a study by the Pew Initiative on Food and Biotechnology stated that the current rules may not allow the Food and Drug Administration to consider the environmental risks of GM fish and that the agency lacks the expertise to deal with GM fish (*New York Times*, January 15). In 2003, a U.S. company applied for FDA approval of its "AquAdvantage" salmon, which grows to full size in just 18 months. Another firm unveiled plans in 2003 to market a tropical zebra fish infused with the gene of a sea anemone that makes it glow fluorescent red. The U.S. government said it would not be regulating the zebra fish as it is not being used for food purposes and poses no threat to the food supply (*Montreal Gazette*, November 23; *International Herald Tribune*, December 10).

Economics

In the U.K., a cost-benefit study of GM crops by the Cabinet Office Strategy Unit concluded that existing GM crops could offer some cost and convenience advantages to U.K. farmers but that the economic benefits to the U.K. as a whole will likely be limited, at least in the short term, as few existing GM crops are suited to U.K. conditions and as weak consumer demand is likely to limit take-up. It also found that there may be future benefits but that the overall balance of future costs and benefits will depend on public attitudes and the ability of the regulatory system to manage uncertainties (**www.pm.gov.uk/output/page4127.asp**).

In the U.S., a study prepared for the Council for Biotechnology Information reported that half of the $40 billion value of the corn, soybeans, cotton, and canola crops grown in 2002 was attributable to GM varieties. The report also stated that in the previous two years, field tests had been conducted on 100 new biotechnology crop traits by 40 universities and 35 companies. The items ranged from a new variety of corn with an improved nutritional profile for use as animal feed, to a type of wheat that can better withstand droughts (**http://www.apec.umn.edu/faculty/frunge/plantbiotech.pdf**).

Environment

The Farm Scale Evaluations project in the U.K., which looked into the effects of three herbicide-tolerant GM crops — maize, beet and spring oilseed rape — on farmland wildlife, produced mixed results. Wildlife suffered in the fields of some GM crops, but flourished in others. The project compared conventional and genetically modified crops of the three plants, growing the traditional and GM crops side by side, using different weed killers on each, and monitoring the wildlife in the fields.[19] The results were passed to the Advisory Committee on Releases to the Environment, which will advise the government on the implications of the findings. The government will use that advice to decide its position on whether or not these crops should be approved for commercial cultivation in the European Union (*Dow Jones*, October 16).

The media reported two environmental mishaps in the U.S. in 2003. One involved traces of GM crops found in wheat even though GM wheat has not been approved for release in North America (it is believed the contamination occurred during storage and transportation)

19 Insects were recorded more often in and around the conventional crops because there were more weeds to provide food and cover. There were also more weed seeds, which are important food sources for some animals, in conventional beet and rape crops than in their GM counterparts. However, there were more weeds in and around the herbicide-tolerant GM maize crops, more butterflies and bees around at certain times of the year and more weed seeds. Environmental groups criticized the study as being too narrow in range and for its use of the weedkiller Atrazine, which the government has decided to phase out, with the conventional crops (*Dow Jones*, October 16).

(*Planet Ark*, June 3). The second item concerned the improper disposal of 400 offspring of bio-engineered pigs by the University of Illinois, which may have resulted in the pigs entering the food supply (it was considered very unlikely that there would be a risk to human health)[20] (*United Press International*, February 5).

International Agreements

The Cartagena Protocol on Biosafety took effect on September 11. The Protocol is the first international convention governing the transboundary movement of living modified organisms resulting from biotechnology. It establishes a harmonized set of international rules and procedures designed to ensure that nations are provided with the information they need to make informed decisions before agreeing to import living modified organisms. It also ensures that such shipments are accompanied by appropriate identification documentation. Canada has not ratified the treaty as it is pursuing clarification of how several of the protocol's provisions will be implemented (**www.biodev.org/**).

The Codex Alimentarius Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology held its fourth and final meeting on March 11–14 in Yokohama, Japan. The Task Force was established in 1999 with a four-year mandate to address the concerns of some organizations about GM foods. At its fourth session, the task force completed work on the *Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Microorganisms*, undertook a final discussion on product tracing/traceability and provided recommendations for future work by Codex regarding foods derived from modern biotechnology (should the Codex Alimentarius Commission decide to continue work on this subject). The task force had previously developed two other documents, namely, *Draft Principles for Risk Analysis of Foods Derived from Biotechnology* and *Draft Guideline for the Conduct of Safety Assessment of Foods Derived from Recombinant-DNA Plants*. The Codex Alimentarius Commission adopted all three documents at its 26th session in June and July.

The 31st session of the Codex Committee on Food Labelling (CCFL) took place in Ottawa from April 28 to May 2. Some 205 delegates attended, representing 38 member countries and 30 international organizations. The committee continued its work toward an international labelling standard by considering a number of ongoing matters, including definitions. Prior to the meeting, Canada submitted a discussion paper describing an approach to facilitate progress within

20 The U.S. Food and Drug Administration sent letters to universities informing them that research involving GM livestock must be reported to the Food and Drug Administration and that plans for disposing of the GM animals must be documented. However, no official policy exists on regulating research on GM animals of a type of species that is commonly eaten (*USA Today*, May 18).

CCFL on elements on which there is international consensus. The committee decided to create a working group to develop options for the management of this agenda item. The working group met in Calgary in October. The management options developed by the working group will be considered at the CCFL meeting in Montréal on May 10–14, 2004.

In December, a European Union panel of food experts returned a split decision on allowing a genetically modified product, BT11 corn, to be imported. The matter was then transferred to the European Union agriculture ministers, who will vote on the application early in 2004. This was the first time the European Union has considered approving a new type of biotechnology food or animal feed since 1998, when the bloc imposed a moratorium on GM products. Earlier in 2003, the U.S., along with Canada and several other countries, asked the World Trade Organization to rule that the moratorium is illegal.

In 2003, Brazil moved to allow the planting and sale of GM soybeans. In September, the Brazilian Congress accepted a presidential decree allowing Brazilian farmers to plant GM soybean seeds generated by Monsanto Co. The decree, which as of December had not yet passed through the Senate, effectively limits the planting to the state of Rio Grande do Sul. It allows only farmers who already have the seeds to plant them, and prohibits their sale to farmers in other states. The farmers must sign a government agreement taking financial responsibility for any environmental damage caused by planting the seeds (*Associated Press*, December 20; *Corn and Soybean Digest*, November 1; *Economist Intelligence Unit*, November 25). In June, in an attempt to claim lost profits from the illicit use of its seeds in Brazil, Monsanto demanded that exporters sign licensing agreements and pay royalties[21] (*Associated Press*, June 13). While the dispute continued through 2003, it reached partial resolution in January 2004 when the state cooperatives federation and Monsanto announced that the farm sector in Rio Grande do Sul had agreed to pay royalties (*Reuters*, January 28, 2004). Both sides said the fee was still under discussion.

In the U.K., the extensive public opinion report *GM Nation?* presented to the government in September, revealed that the U.K. population is generally uneasy about GM food, shows little support for early commercialization of GM crops, mistrusts the government and the large companies involved in genetic modification, and generally wants to know more and wants more research to be done (**www.gmpublicdebate.org/ut_09/ut_9_6.htm**).

21 Monsanto does not charge royalties in other countries as the seeds are legal there. Instead, it licenses seed sellers, who pass on the cost to the farmers who buy them.

2.4 Privacy and Genetic Information

In February, public opinion research was undertaken for the Biotechnology Assistant Deputy Minister Coordinating Committee on a range of genetic privacy issues.[22] The research depicts a comprehensive picture of the views of Canadians on matters such as genetic testing, access and confidentiality and biobanks, and presents three overall impressions:

- Canadians have not yet engaged in any profound way in thinking about the privacy implications of personal genetic information.
- Genetic information is generally seen in the same light as health information, although many believe it to be more fundamentally personal with more implications for abuse.
- On the whole, most people believe there are more benefits than drawbacks from knowing more about our genetic information.

The protection of genetic information from inappropriate disclosure or use, which can lead to discrimination, is an important key in realizing the promise of genetic research for improved health. While few western countries have legislation dealing specifically with genetic privacy and discrimination, the move toward such legislation is growing, especially in the U.S.[23]

The ability of researchers to conduct large-scale population genetic initiatives involving the collection and storage of hundreds of thousands of human genetic samples in biobanks offers major benefits in terms of health and health care, but also raises significant privacy concerns. Numerous large-scale population genetic studies are either under way or at the discussion and planning stages. In 2003, for example, Howard University in the U.S. announced plans to create the first large-scale collection of DNA from African-Americans in order to learn more about health patterns in this group, which has higher rates of diabetes, high blood pressure and prostate cancer than both Caucasians and Africans (*Washington Post*, May 28).

Canada, too, is currently considering a large-scale population genetic study that could begin as early as 2005. The proposed "Canadian Lifelong Health Initiative," which is still at the planning stages, would follow the health of 30 000 infants from across Canada for a defined time

22 The research, conducted by POLLARA Inc. and Earnscliffe Research and Communications, involved a telephone survey of 1200 Canadians and two focus groups. The report *Public Opinion Research into Genetic Privacy Issues* is available at **www.biotech.gc.ca**. The Canadian Biotechnology Secretariat since 1999 has maintained a large-scale tracking program of public opinion research. During that time it has commissioned 10 surveys and more than 75 focus groups. The eighth wave of research was completed in March 2003, for the first time involving a cross-national study of attitudes toward biotechnology in Canada and the United States. All of these research reports are available at **www.biotech.gc.ca**.

23 In 2003, the U.S. Senate Committee on Health, Education, Labor and Pensions unanimously approved a bill preventing employers and insurers from discriminating against individuals based on their genetic make-up, six years after it was first introduced (*New York Times*, May 21).

period. It would involve early psychometric testing to evaluate intellectual, emotional and social development as well as detailed environmental measures. The proposed study is much smaller than many similar initiatives, such as UK Biobank, which expects to involve 500 000 individuals, and the Estonian Genome Project, which will entail some 1 million individuals (about three quarters of Estonia's population).[24]

On March 25, the United Kingdom House of Commons Science and Technology Committee released a report evaluating the work of the Medical Research Council (MRC), in which it criticized the MRC's funding and planning practices, particularly with regard to the biobank project. It alleged that UK Biobank is politically driven, has inadequate support from the research community, and that the consultations surrounding it were designed more to secure support than to build consensus on the project's aims and methods. The government responded in June, stating that while it recognizes the challenges facing the MRC and its need to improve in certain areas, the MRC's research strategies are done in consultation with a broad range of organizations and that the scientists initiated the biobank.[25]

In May, in anticipation of bankruptcy, the U.S. company DNA Sciences Inc. sold substantially all of its assets, including its "Gene Trust" biobank, to Genaissance Pharmaceuticals. While Genaissance Pharmaceuticals said it does not intend to continue the Gene Trust, the transaction raises several legal and ethical questions concerning the storage of genetic materials, and highlights the need for firms to employ defensive legal strategies to obviate the possibility that biobanks may be sold off as assets in the case of financial hardship or bankruptcy proceedings.[26]

2.5 Gene Patents and Access to Health Care[27]

The patent offices of all developed countries grant patent rights over DNA sequences, the use of those sequences and methods of making or isolating them. While the issue of granting patents over DNA sequences has been settled by patent offices, controversy continues over the wisdom of this and of its implications. A key concern involves the implications of permitting these patents in health and agriculture.

24 Lorraine Sheremeta, "Biobanking in Canada: Ethical, Legal and Social Issues," synthesis paper prepared for CBAC.

25 *Ibid.*

26 *Ibid.* Biobanks such as the one Canada is currently considering will be less problematic in that participants will be informed about how their samples may be used, and can therefore consent or refuse such uses. However, significant uncertainty remains on whether, or to what degree, patients can legally and ethically consent to unforeseen future uses, and to the legality of parental consent in the research setting.

27 Information in this section is derived from the report, Richard Gold, "Genetic Patents and Health: Recent Policy Discussions," prepared for CBAC.

Some countries and international organizations, as well as some Canadian provinces, are investigating various aspects of DNA sequence patents, particularly with respect to health care. In January, the Government of Ontario released *Genetics, Testing, Gene Patenting — Charting the Future* identifying the need to review the patent system in light of the particular issues raised by gene patenting (**www.health.gov.on.ca/english/public/pub/ministry_reports/geneticsrep02/report_e.pdf**).

The Government of Canada came under increased pressure in January to amend patent legislation to prevent private firms from patenting human genes after Ontario announced the expansion of genetic breast cancer testing despite legal threats from Utah-based Myriad Genetics Inc., which owns Canadian patents to specific mutation genes called BRCA1 and BRCA2. The company also holds a patent for the method of diagnosing the predisposition for breast cancer and ovarian cancer. Quebec, Manitoba and Alberta also provide the genetic screening test for breast and ovarian cancer despite the risk of legal action. British Columbia suspended its testing program last year after threats from Myriad (*Edmonton Journal*, January 10).

The Australian government has taken the lead in investigating the links between DNA sequence patents and the health care system. At the request of the government, the Australian Law Commission is investigating "the impact of current patenting laws and practices, including licensing, related to genes and genetic and related technologies" on research, the biotechnology industry and "the cost-effective provision of health care in Australia."[28] The commission is to report back to the government by June 2004.

These concerns have turned policy makers' attention to the way in which patent holders are using their patents and, in particular, how easy or difficult it is to obtain licences from them at reasonable prices. Those who have examined the issue of links between DNA sequence patents and the health care system agree in general that some adjustments, perhaps through the issuing of non-binding guidelines, through statutory reform or a combination of the two, may be required.

28 *Terms of Reference: Intellectual Property Rights Over Genetic Materials and Genetic Related Technologies*, available on-line at **http://www.alrc.gov.au/inquiries/current/patenting/terms.htm**.

Canada's Biotechnology Sector[29]

In 2002, Canada's biotechnology sector consisted of 417 firms, including both public and private companies, employing almost 7800 people, an 11-percent increase over 2001 employment levels. At the end of 2002, Canada was second only to the U.S. in the number of biotechnology companies.

The greatest concentration of biotechnology companies in Canada continues to be in the therapeutics sector (58 percent), followed by agriculture, animal health and aquaculture combined (15 percent), genomics, proteomics and bioinformatics combined (12 percent), environment (4 percent), diagnostics (4 percent), and other applications (4 percent).

Canada's biotechnology sector is distributed across the country. The dominant players are Quebec with 151 companies, Ontario with 115, and British Columbia with 71. Quebec, Ontario, Alberta and British Columbia are strong in the health care sector. Saskatchewan is a global leader in agricultural biotechnology. Atlantic Canada excels in aquaculture, forestry and biodiversity.

In 2002, annual revenues reported by Canada's publicly traded biotechnology firms exceeded US$1.4 billion, a 44-percent increase over 2001 revenues.

The number of start-up biotechnology companies in Canada continued to grow through 2002 and beyond due to several key factors: government funding of various research facilities, generous refundable research and development tax credits from federal and provincial government, and fairly easy access to para-government and private seed capital.

29 Information in this section derives from Ernst & Young, "Beyond Borders: The Canadian Biotechnology Report 2002."

Appendix: Advisory Memorandum

February 24, 2003

Canadian Biotechnology Advisory Committee
Advisory Memorandum

Higher Life Forms and The Patent Act

Background

In early 2000, the Canadian Biotechnology Advisory Committee (CBAC) initiated a research and consultation project on the patenting of higher life forms and related issues.

In August 2000, the Federal Court of Appeal found in favour of Harvard, which had appealed the decision of Canada's Commissioner of Patents to refuse to grant a patent on its onco-mouse, a genetically modified strain used in medical research. Shortly thereafter, CBAC issued an Advisory Memorandum addressing the issues raised by the appeal court's ruling.

In October 2000, government lawyers representing the Commissioner of Patents filed an application seeking leave to appeal the decision to the Supreme Court of Canada (SCC). Leave was granted, and in May of 2002, the Supreme Court heard the case.

In the meantime, CBAC proceeded with its project on the patenting of higher life forms and related issues. It commissioned background research, held workshops with scientists, industry members, and non-governmental organizations, developed a consultation document to guide national consultations, held roundtable meetings in five regional centres, invited comments from the public by e-mail, telephone and letter, and issued an interim report in November 2001. After taking account of all the earlier input and the responses to the interim report, CBAC issued its recommendations in its report of June 2002.

On December 5, 2002, the Supreme Court of Canada issued its decision in the case of *Harvard* v. *The Commissioner of Patents*, concerning the patentability of the Onco-mouse.

The CBAC Report

CBAC's report, *Patenting of Higher Life Forms*, addressed and made recommendations on three categories of issues:

- matters pertaining to the patenting of higher life forms,
- other matters of principle related to biotechnological intellectual property, and
- operational issues in the current patent system.

The majority of CBAC members recommended that non-human higher life forms (defined as seeds, plants and animals) be patentable, *subject to* the incorporation of certain provisions in the patent regime. Annex A contains an overview of the final report and the complete List of Recommendations.

The Supreme Court Decision

The only question before the Supreme Court of Canada was whether Harvard's onco-mouse was a "composition of matter" and therefore fit within the definition of "invention" in section 2 of the *Patent Act*. In a 5–4 decision, the Court ruled that the mouse was not a composition of matter and, therefore, was not an invention.

The majority pointed out that it was not up to the courts to decide whether higher life forms *should* be patentable. Justice Bastarache wrote that, due to the controversial nature of patenting of higher life forms and the complex issues raised, higher life forms should only be considered to be patentable under the clear and unequivocal direction of Parliament.

The Court also noted that the *Patent Act* is currently ill-equipped to deal with the complex issues that arise in relation to higher life forms; the Court considered this an indication that it was not Parliament's original intent to patent higher life forms. The fact that genetically modified higher life forms are living and self-replicating raises concerns and issues that other types of inventions do not.

Some of the matters mentioned by the majority in their decision related to recommendations in CBAC's final report on the patenting of higher life forms, namely:

- farmers' privilege
- innocent bystander protection
- a research and experimental use exception from claims of infringement
- non-patentability of humans at all stages of development.

The minority of the Court concluded that Harvard's onco-mouse was a composition of matter and therefore patentable. Despite this conclusion, the justices were not prepared to rule that the patents should be granted; rather, they would have sent the patent application back to the Commissioner to re-examine the patent claims related to the entire mouse.

The majority decision quotes fairly extensively from the CBAC report and the minority refers to it, noting that its recommendations were properly directed to Parliament. Both use the report in support of their arguments.

Congruence Between the SCC Decision and CBAC's Conclusions and Recommendations

Both the majority and the minority opinions made a number of references to CBAC's report. Without endorsing specific recommendations, the Court cited the CBAC report a number of times, as providing useful information for discussions about patenting of higher life forms.

The Supreme Court of Canada was in agreement with the issues CBAC identified as being within the purview of the *Patent Act*.

> ...several of the issues raised by the intervenes and the literature are more directly related to the patentability and to the scheme of the *Patent Act* itself. These issues which pertain to the scope and content of the monopoly right accorded to the inventor by a patent, have been explored in depth by CBAC, ...the report recommends that higher life forms should be patentable. Nonetheless, it concludes, at p. 7, that given the importance of issues raised by the patenting of higher life forms and the significant "values" content of the issues raised, Parliament and not the courts should determine whether and to what degree patent rights ought to extend to plants and animals.
>
> Para. 169

Furthermore,

> ...CBAC has recommended that higher life forms (i.e., plants, seeds and non-human animals) that meet the criteria of novelty, non-obviousness and utility be recognized as patentable. The concerns above therefore are not raised to justify a position that higher life forms should not be patentable, but rather serve to illustrate that the *Patent Act* in its current form is not well suited to address the unique characteristics possessed by higher life forms. The lack of direction currently in the *Patent Act* to deal with issues that might reasonably arise signals a legislative intention that higher life forms are currently not patentable. In addition, the discussion of the issues raised by the CBAC and other groups illustrates the complexity of the concerns. In my view, this Court does not possess the institutional competence to deal with

> issues of this complexity, which presumably will require Parliament to engage in public debate, a balancing of competing societal interests and intricate legislative drafting.
>
> Para. 183

In both opinions, the justices made it clear that human beings are not patentable, although they differed on whether it would be necessary to spell this out in the *Patent Act*.

The majority also acknowledge that the judicially created research exemption may no longer provide suitable guidance because the legislation being considered in the court case which established it has since been changed. The Court identified many of the same points raised by CBAC about the need to clarify what researchers may and may not do without requiring a licence from the patent-holder. Such a clarification would benefit both researchers and patent-holders.

The Supreme Court also concurred with CBAC's approach to dealing with many of the wide range of peripheral issues that various groups sought to use as justification for changes to the *Patent Act*. The SCC argued, for example, as had CBAC, that:

> These issues are only tenuously linked to the patentability of higher life forms and more related to the development and use of the technology itself... It is preferable to address this issue through existing or new regimes for protecting animal welfare. Similarly, if it is determined that additional measures are needed to protect the environment from the products of biotechnology, this may be effected through the *Canadian Environmental Protection Act*, R.S.C. 1985, c. 16 (4th Supp.), or other comparable regulatory mechanisms.
>
> Para. 168

Implications of the SCC Decision

Several inventors and developers expressed disappointment in the Supreme Court decision. BIOTECanada, in a news release issued the day of the decision, went so far as to say that it "stops our pursuit of knowledge and innovation dead in our tracks. It is a great loss to Canada at both the social and economic level." Yet, at a certain level, nothing has changed. Canada's Patent Office still does not grant patents on higher life forms while those of most other OECD countries do. Inventors and developers are still free to apply for these patents outside Canada. Even within Canada, they can still apply for patents on modified DNA sequences in higher life forms or the processes used to create them. The full impact of the Supreme Court's decision requires further in-depth analysis and will be on CBAC's agenda in the coming months. Nonetheless, there is immediate concern that inventors and developers who were anticipating

that the Federal Court of Appeal ruling would be upheld may view the Supreme Court of Canada ruling as an indication that Canada is not sufficiently supportive of biotechnology.

If the availability of patents on higher life forms is seen by the biotechnology industry in Canada as crucial to their ability to continue growing, one implication of the Supreme Court's decision will be pressure on the government to bring Canada's patent regime into line with those of its main trading partners. CBAC saw this as an important argument in favour of higher life forms being patentable. However, as noted in our report, higher life forms are different from other types of inventions. Simply amending the *Patent Act* to declare them patentable, without addressing their special characteristics, was not seen by CBAC as an appropriate way to achieve that end.

The patent regime is not the only way in which governments in Canada, both federal and provincial, support biotechnology. It should be remembered that, although other countries have allowed patents on higher life forms for many years, the biotechnology industry/sector has flourished in Canada, to where this country is now second in the world in the number of biotechnology companies. Other mechanisms may be available for encouraging research and development in Canada, such as the legislated research exception proposed in our report.

Sorting out the implications of the special characteristics of higher life forms for the patent regime will not be accomplished overnight. Taking the time to do so carefully and thoroughly, however, is, in CBAC's view, a worthwhile endeavour. Working through the questions raised by CBAC and mentioned in the Supreme Court decision does not mean that researchers, inventors, and industry are unprotected in the meantime. Most patent applications contain many claims. For example, although Monsanto was not granted a patent on Round-Up Ready canola, its patent on the particular modified gene sequence which conferred the "readiness" enables it to exercise its patent rights over the plants in which that modified gene sequence appears.

Conclusions

If the Government of Canada wishes higher life forms to be patentable, it must propose amendments to the *Patent Act* and gain Parliament's agreement. Patentability can no longer be extended, as it has been in other countries, and was in Canada with regard to single-celled organisms, through administrative or judicial action. This gives Canada the unprecedented opportunity to ensure that the special characteristics of biological inventions are taken into account throughout the *Patent Act* and not only in the definition of "invention."

We encourage the Minister of Industry to introduce, as soon as is practicable, amendments to the *Patent Act* based on our Recommendations 1–5 (making non-human higher life forms patentable with certain safeguards), 10 (guidelines for biotechnological inventions) and 13 (opposition procedure).

CBAC further encourages the Government of Canada to identify responsible departments and/or mechanisms for addressing

- the non-*Patent Act* issues identified in Recommendations 6–9 (liability, access to genetic resources, benefit-sharing, and handling of traditional and local knowledge), and
- other issues raised by biotechnology, such as the impact of biotechnological inventions on regulatory systems, the impact of gene patents on access to health care and sustainability of the health care system, and the availability of highly qualified personnel.

Annex A

Following is an overview of CBAC's June 2002 report together with the complete List of Recommendations.

Patenting of Higher Life Forms is a report to the Biotechnology Ministerial Coordinating Committee of the Government of Canada that arose from a project undertaken by the Canadian Biotechnology Advisory Committee (CBAC). The key issue addressed in the report is whether Canada should permit the patenting of plants, seeds and animals. The report identifies a number of factors bearing on that question. In the course of the project, it became clear that the patenting of biological material generally (whether DNA sequences, breast cancer genes, microbes, or Harvard mice) raised a number of additional issues worthy of consideration.

In arriving at our recommendations, we have commissioned research, consulted with stakeholders and the public, and considered comments received in response to an Interim Report. The present document follows the general structure of the Interim Report, except that some of the descriptive material presented there now appears in annexes to this document in order to keep the focus on our recommendations. In formulating our recommendations (reduced to 13 from 16), we took into account a Statement of Principles and Values we adopted to guide our activities.

The report is divided into four major topic areas:

Social and Ethical Concerns Raised by Biotechnology: This section of the report, describes a number of social and ethical concerns arising from or linked with the development of biotechnology. It summarizes three possible approaches to addressing these considerations.

Patentability of Higher Life Forms: After addressing the issue of the patentability of human beings, this section of the report describes the main arguments supporting or opposing the patenting of plants, seeds and animals. Four of the five recommendations in this section are linked and should be considered as a group.

Other Issues Related to Biotechnology and Intellectual Property: This section deals with other issues of a social or ethical nature that are clearly linked to the patent regime. It contains recommendations about liability for damage caused by the unwanted spread of products of biotechnology, access to genetic resources, benefit-sharing, and protection of traditional knowledge. This section also draws attention to recent developments concerning the impact of biotechnology patents on the health care system.

Improving the Administration of the Patent System: This section contains a series of comments and recommendations concerning both the operation and the policy orientation of the Canadian patent system. The advice provided to the Government of Canada in this section is intended to ensure that Canada's patent policies and procedures keep pace with developments in the Canadian biotechnology industry, while ensuring that the appropriate balance between inventors and citizens is maintained. The focus of this section is to identify a series of measures to strengthen the patent system.

List of Recommendations

Human Beings Not Patentable

1. We recommend that the *Patent Act* be amended to include the following statement: *No patent shall be granted on human bodies at any stage of development.*

Patentability of Higher Life Forms

2. We recommend that higher life forms (i.e., plants, seeds and non-human animals) that meet the criteria of novelty, non-obviousness and utility be recognized as patentable. The scope of the patent rights in respect of these higher life forms is to be determined in accordance with Recommendations 3, 4 and 5.

Farmers' Privilege

3. We recommend that a farmers' privilege provision be included in the *Patent Act*. It should specify that farmers are permitted to save and sow seeds from patented plants or to breed patented animals, as long as these progeny are not sold as commercial propagating material or in a manner that undermines the commercial value to its creator of a genetically engineered animal, respectively. The drafting of this provision must be sensitive to the differences that exist both in the nature and use of plants and non-human animals.

Innocent Bystanders

4. We recommend that the *Patent Act* include provisions that protect innocent bystanders from claims of patent infringement with respect to adventitious spreading of patented seed or patented genetic material, or the insemination of an animal by a patented animal.

Research and Experimental Use

5. We recommend that the *Patent Act* be amended to include a research and experimental use exception that includes the following statement:
   It is not an infringement of a patent to use a patented process or product either:
   (a) privately and for non-commercial purposes, or
   (b) to study the subject-matter of the patented invention to investigate its properties, improve upon it, or create a new product or process.

Liability for Damages

6. We recommend that Canada actively participate in international negotiations to address issues of liability and redress for adventitious spreading of patented seed, genetic material, or the insemination of an animal by a patented animal.

Access to Genetic Resources and Benefit-Sharing

7. We recommend that the federal government, in consultation with other levels of government and other stakeholders, develop policies and practices that encourage the sharing of the benefits of research involving genetic material. In particular, we recommend that:

   (a) the benefits of medical and pharmaceutical research based on human genetic material (including its commercial exploitation) be shared with the groups or communities who

provided the material. All bodies (public, private, and corporate) involved in funding research and/or establishing guidelines or codes of conduct for the ethical conduct of research should ensure that benefit-sharing is addressed. Health Canada should lead an initiative to engage all stakeholders in developing best practices in regard to benefit-sharing for research involving human subjects.

(b) with respect to research based on plant and animal genetic material, Canada:

- continue to participate in the ongoing processes of the Convention on Biological Diversity to address outstanding issues with respect to the voluntary Bonn *Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization* (such as user country obligations and consideration by the Working Group on Article 8(j) of the *Guidelines by Indigenous and Local Communities*);

- encourage and facilitate compliance with the Bonn *Guidelines* within Canada as well as internationally;

- sign and ratify as soon as possible the *International Treaty on Plant Genetic Resources for Food and Agriculture*, participate in the development of the standard material transfer agreement, including provisions requiring benefit-sharing, and encourage and facilitate their use within Canada; and

- generally encourage and facilitate benefit-sharing arrangements between the users of genetic resources and traditional and local communities within Canada.

Traditional Knowledge and Intellectual Property

8. We recommend that Canada support the efforts being undertaken in the World Intellectual Property Organization working group on Genetic Resources, Traditional Knowledge and Folklore to determine whether a form of intellectual property could be developed with respect to traditional knowledge.

9. We recommend that the Canadian Intellectual Property Office provide guidance to patent examiners on assessing as "prior art" traditional knowledge that has been made public through oral as well as written or published transmission.

Guidelines for Biotechnological Patents and Processes

10. We recommend that the Canadian Intellectual Property Office develop and publish interpretative guidelines concerning biological inventions. The guidelines should be updated on a regular basis and should provide direction to applicants and examiners, notably on:

    (a) the interpretation of the criteria for issuing a patent (i.e., novelty, non-obviousness, utility and breadth of claims) as they relate to biological inventions, and

    (b) the process to be followed by patent applicants and the benchmark time frames for each step, to the extent (if any) that these may differ from other patent applications.

Service Standards and Performance Reporting

11. We recommend that the Canadian Intellectual Property Office:

    (a) regularly update its service standards, based on best international practice, for processing patent applications, and

    (b) report regularly on its performance with respect to those standards and the steps being taken (such as increasing capacity and/or expertise) to meet them.

International Harmonization

12. We recommend that Canada pursue further harmonization of patent policies and procedures at the international level by:

    (a) continuing to participate in international initiatives to harmonize patent law policy, such as reform of the *Patent Cooperation Treaty*, the work of the Substantive Patent Law Committee, and work under the Agenda for Development of the International Patent System (the Patent Law Agenda), and

    (b) ratifying, as soon as possible, the *Patent Law Treaty*, which addresses the formal requirements for filing patent applications and maintaining patents.

Opposition Procedure

13. We recommend that the government introduce an opposition procedure into the *Patent Act* to permit a patent to be opposed on the grounds that it is invalid or void. As it is essential that this process be faster, less cumbersome and less expensive than the procedures currently available, we recommend that the time limit for filing oppositions be six months from the date the patent was granted and that procedures be established and resources provided to ensure that proceedings are concluded within 18 months from the date the patent was granted.