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BIOTECHNOLOGY TRANSFORMING SOCIETY

Creating an Innovative Economy and a Higher Quality of Life

Report on Biotechnology (1998–2003)

Canada

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Cat. No. Iu4-52/2003
ISBN 0-662-67835-4

Also available in electronic format on the Internet at: **http://biotech.gc.ca**

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Evolution of the biotechnology revolution

If anyone had told Canadians in the 1960s or '70s that scientists would one day identify genes that cause cystic fibrosis and muscular dystrophy, or manipulate stem cells to regenerate tissues and organs, it would have seemed an impossible dream.

Yet the world witnessed an explosion of extraordinary advances in molecular biology, genetics, cell biology and biochemistry in the final days of the 20th century that have revolutionized the way we live and think about life itself. The biotechnology innovations resulting from these scientific breakthroughs bring everything from vaccines to prevent disease, to healthier foods, to bio-fuels to replace non-renewable energy sources, to treatments enabling infertile couples to start a family.

Biotechnology is expanding the frontiers of knowledge with discoveries in fields as diverse as agriculture, energy, health care, the environment and the sustainable development of natural resources. Its impact on this century is predicted to be more dramatic and far-reaching than that of telecommunications and computers in the last, because it deals with life and living things which permeate all aspects of our own lives.

Biotechnology is viewed by most industrialized nations as a critically important engine of economic growth and social progress. However, due to its ability to manipulate life forms, biotechnology has generated controversy as well as excitement in many countries, including Canada. This transformative technology has sparked a society-wide debate about whether we should interfere with nature and potentially alter or create life. Some biotechnology innovations challenge the values and beliefs that underpin society, forcing Canadians to confront complex ethical questions never before faced.

In the late 1990s, the Government of Canada undertook consultations to gauge Canadians' concerns and priorities for this rapidly-growing field with the potential to profoundly change everything from their health care to their children's career choices. The Canadian Biotechnology Strategy Task Force was struck in 1997 to take a measure of Canadians' values, as well as to review and build on the accomplishments of the original National Biotechnology Strategy (NBS), launched in 1983. The unprecedented rate of discovery had outpaced the earlier Strategy's capacity to respond to new developments.

Public Opinion Research

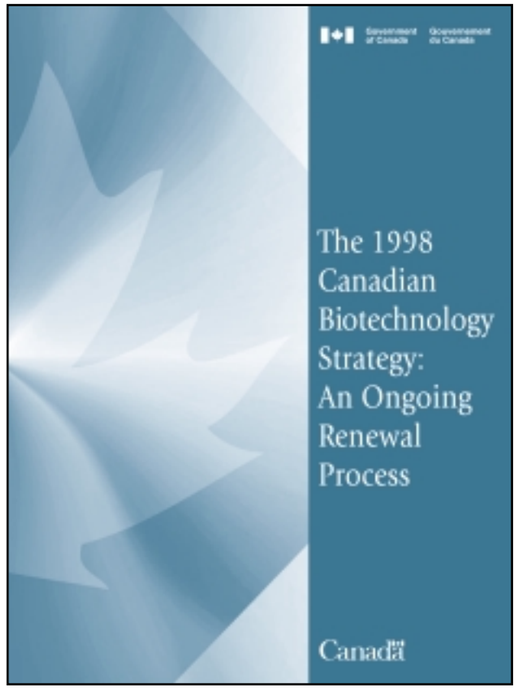
Since 1999, the Canadian Biotechnology Secretariat and its partners have maintained a large-scale tracking program of public opinion research. In the intervening years, 10 public opinion surveys have been commissioned and more than 75 focus groups conducted. This research has generated more than 17,000 data points in what is now North America's largest and most comprehensive investigation into attitudes about biotechnology and the public policy that surrounds it.

The polling program was designed to produce two waves of research each year, with a large tracking component as well as more intensive inquiry into specific issues such as genetic privacy, genetically modified food and stem cell research. The most recent wave of research, completed in March 2003, carried out a cross-national comparative study of attitudes towards biotechnology in Canada and the United States.

In the spring of 1998, the Task Force conducted consultations with provincial officials, industry, non-governmental organizations (NGOs), scientists, academics and other stakeholders concerning the Strategy's vision, goals and principles, impacts on Canada's main biotechnology industries, as well as on research and development (R&D). The Task Force also sought feedback from Canadians on how best to address their interests in the policy development process. Finally, it conducted extensive public opinion polling to learn Canadians' views about biotechnology and their need for ongoing information.

More than 5,000 individuals and organizations participated in the deliberations and in the shaping of a renewed federal policy framework. The result of this exhaustive process was the 1998 Canadian Biotechnology Strategy (CBS), a blueprint to enhance the quality of life of Canadians in terms of health, safety, the environment and social and economic development by positioning Canada as a responsible world leader in biotechnology.

Fulfilling the promise: The Canadian Biotechnology Strategy



Biotechnology Statistics Program

Knowledge is the foundation of sound decision making. To maintain and enhance the significant knowledge base created over 1999-2003, the Biotechnology Statistical Program has been strengthened to provide an accurate estimate of the magnitude of biotechnology activities in Canada.

The enhanced statistical measurement and analysis project, carried out by Statistics Canada, now includes more data on the use and development of biotechnology by business, as well as new analysis from the existing "Biotechnology Use and Development" survey to assess trends in biopharmaceuticals, bio-products and emerging technologies such as genomics and proteomics. It also covers new international initiatives to ensure compatibility of statistical measures among countries over time. An important component of this work is ensuring the research findings are shared with specialists and generalists, practitioners and policy makers, as well as funders and evaluators.

The Canadian Biotechnology Strategy aims to ensure that all aspects of the development and application of biotechnology are responsibly managed, striking a balance between the detection and management of risk, and the development of new discoveries, in order to capture the technology's long-term health, environmental and economic benefits.

It fully reflects and responds to Canadians' demands that biotechnology be developed in ways that do not pose a danger to humans, the environment or animals, and which address the social and ethical challenges these technologies pose. At the same time, it advances their overarching objective – to encourage innovations that improve health, protect the environment and stimulate economic growth – to fulfill biotechnology's promise to build a higher standard of living and quality of life for all Canadians.

The CBS does so by providing a policy framework that integrates social, ethical, health, economic, environmental and regulatory considerations into biotechnology development decisions. The Strategy's guiding principles centre on: reflecting Canadian values; engaging citizens in open, ongoing, transparent dialogue; promoting an innovative economy, sustainable development, competitiveness, public health

and scientific excellence; and ensuring responsible action and cooperation domestically and internationally.

The Strategy draws together federal departments and agencies engaged in regulatory activities, R&D, technology transfer, as well as investment and trade in biotechnology products and services, both in Canada and abroad.

Genetic Information and Privacy

Rapid advances in the field of genomics have made it possible to conclusively diagnose some hereditary diseases and to predict predispositions to others. In light of the growing accuracy of genetic testing, public concerns have been raised about the possibility that people with certain genetic predispositions might be discriminated against. Also, the highly personal nature of human genetic data, combined with its ability to confirm or refute family lineage, identify people or be used for various research purposes, has raised questions about the potential unauthorized uses of such information. Despite these concerns, Canadians do support genetic research so long as safeguards are in place.

Understanding these risks and developing responsible approaches to protect genetic information and privacy are public policy imperatives as they are prerequisites to public acceptance of biotechnology. Recognizing this, the Genetic Information and Privacy Working Group was created in the fall of 2001. Led by Justice Canada, the Working Group is taking a multidisciplinary and interdepartmental approach to policy considerations surrounding privacy and human rights, to anticipate and develop appropriate responses before problems surface. It has undertaken a research program to identify the challenges and to recommend any changes to federal laws, regulations, programs and policies that may be needed to address these concerns.

Together, the partners identified the nine overarching goals of the CBS, which guide their respective activities on this file:

- Ensure safe, accessible and effective biotechnology-based products and services
- Ensure an effective scientific base and invest strategically in R&D
- Promote awareness of, and maintain excellence in, Canada's regulatory system
- Position Canada as a responsible world leader
- Improve public awareness and understanding of biotechnology
- Solicit broadly based advice
- Support the development of human resources in the sector
- Work with partners to develop and implement action plans
- Be sensitive to the needs of developing countries in managing biotechnology

Made-in-Canada approach

Maximizing the benefits, managing the risks

The Government of Canada understands that the relentless rate of development in this fast-changing field demands that it makes sure these technologies are used wisely and safely to protect the health and safety of Canadians and the environment. Yet, it also recognizes this country's enormous potential to be a responsible world leader in biotechnology.

The Canadian Biotechnology Strategy reflects and carefully integrates these dual roles.

It creates the conditions for innovation to maximize the benefits that flow from biotechnology breakthroughs, while making sure government is a vigilant regulator, assessing, managing and communicating potential risks associated with these technologies to safeguard public and environmental health.

One of the challenges biotechnology presents to government decision makers is its broad scope and complexity. It requires an in-depth understanding of basic science, health and environmental impacts, technological adaptation, industrial applications, as well as sensitivity to social and ethical values, in order to make sound decisions. Consequently, the Canadian Biotechnology Strategy is not simply a Government of Canada initiative but complements the efforts of others, including provincial and territorial governments, the scientific community, NGOs, industry, consumer groups and interested Canadians whose differing views, priorities and expertise collectively bring a balanced focus to the issue.

The CBS acts as a catalyst in advancing the efforts of all these essential players, encouraging national discourse, nurturing partnerships and fostering strategic investments to responsibly advance Canada's biotechnology capability.

While realizing the full potential of biotechnology is a shared responsibility, there are several areas where the federal government plays a leadership role:

- Ensuring health and safety through regulatory systems
- Maximizing social, economic and environmental benefits
- Citizen engagement

Guided by expert advice

The departments and agencies advancing the Strategy undertake activities in each of these areas, relative to their spheres of responsibility. In addition to their contributions, federal decision makers also benefit from impartial expert advice.

During the 1998 CBS Task Force consultations, Canadians called for an independent advisory body that would operate at arm's length from government, to provide independent and comprehensive advice on crucial policy questions surrounding biotechnology. The Canadian Biotechnology Advisory Committee (CBAC) was created to meet this need. The Advisory Committee is composed of experts from the science, business, nutrition, legal, environmental, public advocacy, philosophy and ethics fields, as well as public interest representatives. Members serve on a volunteer basis.

CBAC advises the Biotechnology Ministerial Co-ordinating Committee, which is made up of the ministers responsible for Agriculture and Agri-Food, Environment, Fisheries and Oceans, Foreign Affairs and International Trade, Health, Industry, and Natural Resources. CBAC identifies and assesses emerging and strategic policy requirements on issues associated with the ethical, social, regulatory, economic, scientific, environmental and health aspects of biotechnology. It also conducts research in support of its advisory role and consults with Canadians to reflect their views when offering policy advice.

Ensuring a smart and secure regulatory framework

Public opinion research conducted by the CBS has consistently found that Canadians are open-minded and supportive of the benefits associated with biotechnology, particularly those related to medical discovery, an improved quality of life and new jobs. Fully two thirds describe themselves as supportive of Canada's focus on biotechnology for the future. However, as receptive as they are, Canadians want assurance that any potential risks are being carefully managed and mitigated.

The Government of Canada recognizes its stewardship role. It fulfills this responsibility through scientific research, good governance, accountability and stringent regulations in the areas of health, safety and the environment that ensure Canadian values are promoted and public and ecosystem health are adequately protected.

Recognizing its unique characteristics, Canada has put into place the *Federal Regulatory Framework for Biotechnology*. This framework provides a transparent and rigorous system to ensure Canadians have confidence in, and benefit from, safe and effective biotechnology-based products and services. If there are any questions about the safety of a product, it is not approved.

The regulatory framework is led by the Canadian Food Inspection Agency, Environment Canada and Health Canada, and supported by a number of other departments including Agriculture and Agri-Food Canada, Fisheries and Oceans Canada, Industry Canada and Natural Resources Canada.

The 2000 federal budget dedicated $30 million a year to the Canadian Regulatory System for Biotechnology (CRSB) to strengthen technical capacity and address human resource needs, improve public awareness of the regulatory system, increase the overall efficiency of the system and provide research in support of ongoing regulatory activities. This amount was increased in April 2003 to close to $35 million a year, on an ongoing basis, to enhance and improve federal regulatory capacity to keep pace with increasing demand and the explosion of developments in this field.

Creating benefits for Canadians

Biotechnology presents a new paradigm for health and medicine – potentially offering customized prevention strategies from birth, pharmaceutical and genetic treatments tailored to each individual, the replacement or repair of organs, and improved diagnosis and monitoring. Innovations in life sciences and biotechnology hold equal promise to improve the environment by reducing pressure on resources and providing innovative remediation and clean-up processes to help the world community address challenges such as climate change. The technology is also providing solutions to problems facing both farmers and consumers, such as alternatives to weed control that eliminate the need for pesticides and herbicides.

Biotechnology presents an exceptional economic opportunity for Canada in the 21st century. This enabling technology can strengthen Canada's competitiveness and open up export markets by creating valued-added industries in the health, pharmaceuticals, agriculture and natural resources sectors. It holds the key to a productive, prosperous economy that creates sophisticated jobs for today's young knowledge workers and the youth of tomorrow.

To realize this potential, the Government of Canada has formally committed itself to being a world leader in biotechnology – a position already well established with this country's world-class credentials. Canada is internationally renowned for its clusters of R&D excellence: Montréal hosts the world's largest specialized research centre for biotechnology; Saskatoon is the world's leading centre for agricultural biotechnology; and Toronto's medical research community ranks among the top four in North America.

The Government of Canada is building on these advantages through a policy framework and targeted investments that are nurturing and developing biotechnology breakthroughs.

The federal government has made important investments in knowledge development to attract and retain the finest minds in various scientific fields, to build Canada's research capacity and to establish joint research projects among universities, government and industry that lead to commercialization.

Specialized research institutes and agencies have been established to ensure focus, direct funding and to attract the world's most competitive researchers in emerging fields such as proteomics, bio-pharmaceuticals, medical diagnostic technologies and nutraceuticals. All of these efforts are developing the infrastructure to support a critical mass of research talent led by world-class public and private sector investigators.

As well, the government maintains competitive tax rates that make Canada an attractive destination to do business, and provides an array of tax incentives as well as start-up funds for private sector projects. It also helps Canadian businesses to promote their biotechnology products and services, here at home and on the world stage, creating new markets and new jobs.

To further spur excellence and Canadian leadership across all sectors of the economy, the Government of Canada has adopted an ambitious national innovation strategy – that promotes skills and learning, fosters R&D and ensures businesses benefit from the commercial application of new knowledge – to make sure Canada remains on the leading edge in the knowledge age.

While not specific to biotechnology, several goals established in Canada's Innovation Strategy will contribute to the biotechnology research enterprise, including, by 2010:

- Ranking among the top five countries in the world in R&D performance
- Doubling the amount invested in R&D by the federal government
- Developing at least 10 internationally recognized technology clusters
- Increasing the number of post-graduate and doctoral candidates at Canadian universities by 5 percent annually

Meeting expectations and demands

Even though biotechnology has already created unprecedented opportunities and promises even more, it has wrought unparalleled policy challenges for government decision makers. The rapid rate of development in these transformative technologies poses a number of social, regulatory and economic challenges – which can only be expected to escalate in the face of the unrelenting pace of scientific progress.

For example, there is the issue of public acceptance and confidence about biotechnology breakthroughs affecting human health. Controversial topics, such as reproductive technologies and the privacy of genetic information, demand public input in order to develop responsive policies that reflect Canadians' values. Citizens' views on the life-altering applications of biotechnology will play a central role in Canada's ongoing approach to the responsible development and regulation of this emerging industry.

Public opinion polling has also highlighted Canadians' concern about any potential long-term impacts of biotechnology innovations that could affect human health and the environment. Public confidence would be boosted by research into the long-term effects of biotechnology innovations and the assurance of appropriate mitigation measures if required.

A further pressure is the capacity of the regulatory systems to cope with new, complex innovations. It will be necessary to continually update the regulatory approaches – both to keep our economy competitive and to provide the public with access to products and services emerging in the global marketplace, while ensuring their health and safety are protected. This will require extensive research as well as training to build the necessary capacity.

Enabling the commercialization of biotechnology innovations, to create trade and investment opportunities that will maintain Canada's leadership in the field, is another challenge confronting policy makers in a competitive global market for risk capital.

This country's small start-up companies, many of them spin-offs from university research, often lack sufficient funding to take their products to market. In addition to inadequate access to capital, these firms must also deal with intellectual property and regulatory issues that can adversely affect investors' perceptions of the Canadian marketplace. Because of their unique nature, biotechnology products are subject to longer and more costly regulatory processes than in any other business. While the government has taken steps to facilitate bringing biotechnology ideas to market, addressing these competitiveness issues will remain a challenge for industry and government alike.

Equally important is the need to account to Canadians for the expenditure of their tax dollars and to demonstrate that their investments in research and development yield satisfactory results.

Reporting on results

This overview, along with more detailed reports contained in the following chapters from the CBS departments and agencies, demonstrates the Government of Canada's commitment to ensure the responsible and ethical development of these revolutionary technologies, and to facilitate dialogue with Canadians.

This report on the first five years of the Canadian Biotechnology Strategy, the period from 1998 to 2003, has been prepared to provide a synopsis of Canada's accomplishments, opportunites and challenges in creating an environment where biotechnology can flourish while, first and foremost, protecting human and animal health and the environment.

It profiles the range of work being carried out under the CBS Fund, with an annual budget of $9.52 million, the $35 million annual CRSB fund, the $20 million per year Genomics R&D Fund, as well as related investments by the respective departments and agencies involved. It also shows how the accountability, performance measurement and reporting requirements for CBS members are leading to effective spending and, most important, good results for Canadians. It provides a benchmark against which future efforts and results can be measured, and serves as a foundation from which to build as Canada moves forward into the knowledge economy.

Results-based Management Accountability Framework

At the heart of the Canadian Biotechnology Strategy is the recognition that its primary purpose is to serve Canadians. Its raison d'etre is to provide taxpayers with the high-quality, cost-effective, citizen-centred and results-oriented programs and services they want, expect and deserve. To ensure it meets these expectations, the CBS has developed a Results-based Management and Accountability Framework (RMAF).

The Framework entails a four-step process: identifying key results; establishing performance measurement indicators; developing a reporting framework; and preparing an evaluation plan. The objective of the RMAF is to enable the Government of Canada to measure the success of its horizontal management of the biotechnology file, and to convincingly demonstrate the intention and capacity of member departments and agencies to measure their performance against key results commitments on an ongoing basis and, periodically, through evaluation.

Moving forward

As anticipated scientific breakthroughs lead to new bio-based technologies, innovative industrial processes and enhanced environmental understanding, there will inevitably be an ongoing evolution in societal views on biotechnology development. Thus, while important groundwork has been laid, Canadians can expect to see CBS partners continue to work domestically and with the global community to promote better health care, sustainable development, social progress and an innovative economy.

This report acknowledges that all Canadians should have a voice informing decisions regarding biotechnology's ongoing growth. Consultations by CBAC, as well as by the departments and agencies involved in the CBS, provide meaningful opportunities for Canadians to express their priorities and concerns to ensure public policy will continue to respond to their needs and reflect their values – no matter what innovations the future holds.

II.

Canadian Biotechnology Advisory Committee

Canadian Biotechnology Advisory Committee

During the 1998 CBS Task Force consultations, there was a call for an independent advisory body that would operate at arm's length from government to provide impartial and comprehensive advice on crucial policy questions surrounding biotechnology. There was universal support both inside and outside of government for the development of such a body, recognizing that the public must have a voice and play an active part in the development of these transformative technologies. The Canadian Biotechnology Advisory Committee (CBAC) was created in September 1999, in part, to provide Canadians with that opportunity.

Experts, not advocates

To ensure objectivity and impartiality, the advisory committee is composed of external experts, not advocates, as well as representatives of the general public. CBAC members bring expertise in such diverse fields as science, business, nutrition, law, environment, philosophy, ethics and public advocacy. The 12 to 20 members serve on a volunteer basis.

Providing advice to government

One of the Committee's key functions is to provide the Government of Canada with comprehensive advice on current policy issues associated with the ethical, social, regulatory, economic, scientific and environmental aspects of biotechnology.

Specifically, it is mandated to advise government on ways to:

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

CBAC's activities and deliberations are communicated to Canadians via numerous publications and its interactive Web site – www.cbac-cccb.ca – which encourages the exchange of ideas, information and perspectives. CBAC posts relevant research it receives or produces, as well as minutes of the Committee's meetings and advice delivered to ministers, on its Web site. A much-improved Web site, with greater interactivity and easier navigation, was launched on March 28, 2003.

Contributing to the CBS

CBAC reports to the Biotechnology Ministerial Coordinating Committee, which is comprised of the federal ministers of Industry, Agriculture and Agri-Food, Health, Environment, Fisheries and Oceans, Natural Resources and International Trade.

The work of CBAC is supported by the Canadian Biotechnology Secretariat, which coordinates the management and operations of the Canadian Biotechnology Strategy. The Secretariat performs two main functions:

- to coordinate "horizontal" decision making across the Canadian Biotechnology Strategy departments and agencies, and
- to provide secretariat services for CBAC.

The federal government has approved $9.52 million annual funding for the Canadian Biotechnology Strategy. CBAC's allocation is $2.25 million for operational and secretariat support, research, publications, communications, and public outreach activities.

Activities

CBAC's activities are divided into two categories: general activities and special projects. When CBAC concludes that an issue requires early attention by government, it produces an advisory memorandum on the subject for the Biotechnology Ministerial Coordinating Committee.

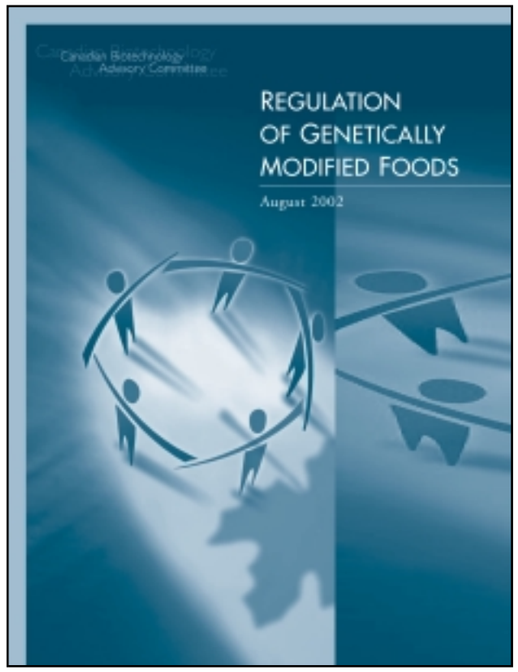
General activities

General activities are those of a broad, continuing nature. These include monitoring biotechnology developments nationally and internationally, facilitating public awareness of biotechnology issues, maintaining a forum for citizen engagement, issuing news releases, posting items on the Web site, participating in regional, national and international forums and major conferences, and expanding the exhibit program. In addition, CBAC members are active in their own right as commentators on major issues of public interest related to biotechnology.

More information about CBAC's general activities can be found in its annual reports, including a summary of developments during the year in genomics and proteomics, stem cells and cloning, agricultural biotechnology, patenting, genetic information and privacy, transgenic technologies and xenotransplantation.

Special projects

The Government of Canada looks to the Canadian Biotechnology Advisory Committee for advice based on the in-depth study of specific subjects that is informed by consultation with experts, stakeholder groups and the public at large. CBAC originally identified five special projects for study: regulation of genetically modified food; intellectual property issues in biotechnology; issues related to novel uses of biotechnology (such as stem cells); incorporating social and ethical considerations into policy making around biotechnology; and privacy issues related to genetic information. Major research and consultation programs were undertaken with respect to the first two areas.



GM foods

Biotechnology is not without controversy. Among the most contentious issues in Canada, and even more so in many other countries, are those related to genetically modified (GM) foods.

At its inaugural meeting in October 1999, the Canadian Biotechnology Advisory Committee highlighted the need to study and evaluate the effectiveness of Canada's systems to assess and regulate the application of biotechnology innovations. CBAC identified three sub-topics for special consideration: the science base underpinning the regulatory system; the governance and organization of regulatory processes; and the social, ethical, legal, economic and environmental aspects of food biotechnology.

In December 1999, following consultations with CBAC, the ministers of Health, Agriculture and Agri-Food, and Environment jointly announced

their intention to request the Royal Society of Canada to establish an Expert Panel on the Future of Food Biotechnology. Its mandate was to provide Health Canada, the Canadian Food Inspection Agency and Environment Canada with advice on Canada's regulatory system as well as the scientific capability the federal government requires in the 21st century to ensure the safety of new food products developed through biotechnology.

With the creation of the Expert Panel, CBAC concentrated its own efforts on the governance and organization of regulatory processes as well as the social, ethical, legal, economic and environmental aspects of food biotechnology.

In early 2000, CBAC initiated a research program on the regulation of GM foods. Following discussions with a reference group of stakeholder representatives, the committee began a series of public consultations based on a widely distributed consultation document. Roundtable discussions were held in five cities across Canada, attended by more than 90 members of various stakeholder groups. Some environmental groups chose not to participate in the consultations, but their views on various issues were accessible by other means.

After deliberating on the input it received, the Committee released an interim report in August 2001 containing draft recommendations. To further strengthen its report, it solicited comments from all interested parties. The comment period closed January 31, 2002.

Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada was released on August 26, 2002. This report represents the views of CBAC on the regulatory system for genetically modified foods after having taken into account the results of commissioned policy research studies, sector roundtables, a review of public opinion research, multistakeholder consultations, the work of the Expert Panel of the Royal Society, and public responses to the Interim Report of August 2001.

CBAC concluded that GM foods approved under the current regulatory system do not pose any greater health or environmental risk than their conventional counterparts. The report identified opportunities to improve the management of the regulatory system and to strengthen its capacity to deal with more complex GM food products, as well as to incorporate scientific and technical advances as they emerge. The report also expressed support for the initiative to establish a standard for voluntary labelling and addressed issues related to environmental stewardship, international cooperation and informed dialogue.

"Acceptability Spectrum"

In a related endeavour, CBAC initiated work on the "Acceptability Spectrum" – a tool to facilitate discussion on the acceptability of GM foods or other biotechnology-based products.

At the outset of its GM food project, CBAC identified its desire to have stakeholders engage in a dialogue on the social and ethical considerations that are not part of the normal risk-based health and environmental regulatory assessments. These included matters such as environmental stewardship (e.g., sustainability), ethical acceptability, traditional knowledge and resources, power imbalance and vulnerability, and environmental ethics and economics. During the 2001 consultations, participants suggested criteria for assessing a GM food or feed (GMFF) product. These criteria were ultimately grouped into five themes: health considerations, environmental considerations, social considerations, ethical considerations, and broader societal considerations.

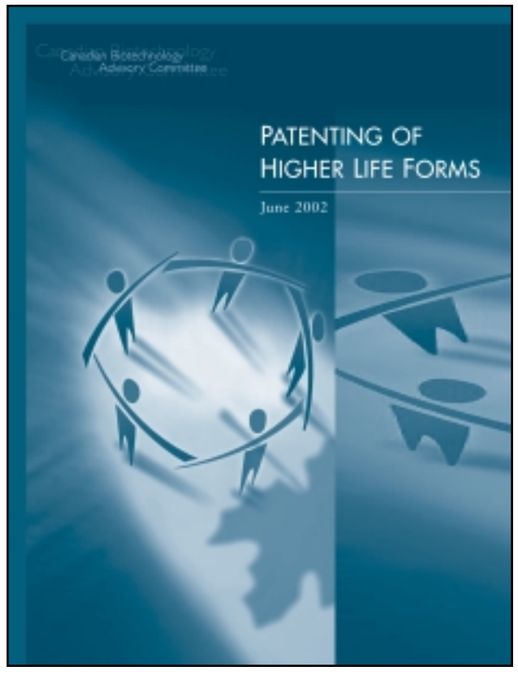
From this, a new conceptual framework emerged – designing a dialogue process around the concept of "acceptability." This concept, notionally called an Acceptability Spectrum, was first discussed at the initial consultation session in Vancouver, in April 2001, and enlarged at each subsequent consultation event. The early discussions generated considerable interest in the potential to facilitate a discussion of the acceptability of GMFFs, and the conditions that might affect this.

The framework was based on the premise that different kinds of GMFFs could be classified along a spectrum of "acceptability" – that is, as being more or less acceptable, according to a variety of criteria.

The Acceptability Spectrum consisted of four categories: acceptable; acceptable with certain conditions; unacceptable at the present time and until more is known or a given standard is met; or not acceptable under any circumstances.

A real-world parallel to the category "not acceptable under any circumstances" might be an unconditional prohibition (i.e., ban). "Not acceptable until more is known" might be likened to a moratorium. Under this framework, it might be feasible to consider either groups or classes of food or individual products as belonging to a position on the Acceptability Spectrum. These initial views could change, that is, move along the Acceptability Spectrum as knowledge improves, as society's views change, or as certain standards are either met or not met.

In 2002, CBAC initiated a three-phase pilot project to examine the "Acceptability Spectrum" and to assess its viability and usefulness as a mechanism to facilitate discussion among people with divergent views on the acceptability of GMFF. The first phase of the project involved the creation of a steering group, called the Exploratory



Committee, to develop the tool through an extensive consultation process. Phase 2 involved six stakeholder sessions, held in March and April 2002 in Montréal, Ottawa, Hamilton, Toronto and Vancouver, to review and improve the dialogue tool. The results of the sessions were compiled in a summary report, available on CBAC's Web site.

The Exploratory Committee used the knowledge gleaned from these sessions to undertake further improvements to the Spectrum tool, to prepare it for the more-challenging multistakeholder review and to design the approach for such a multistakeholder session. These included the idea of testing the Spectrum tool with a substantial policy issue to explore the full range of considerations and impacts available in the model. During the development of the policy case studies, it became clear that the purpose of the tool needed to be clarified. As a result, there has been a change of name to "Genetically Modified Food and Feed Dialogue Tool."

At the end of the reporting period, the Exploratory Committee was working on a comprehensive progress report to CBAC, recommending continuation of the Pilot Project. The report was posted on the Web site.

Patenting of higher life forms

Biotechnology has sparked a society-wide debate about the ability to manipulate life forms and, potentially, even create life. It is challenging the values and beliefs that underpin society, forcing Canadians to confront complex ethical questions never before faced. As a result, Canadians' views about the life-altering applications of biotechnology play a central role in Canada's approach to the responsible development and regulation of this emerging industry.

In early 2000, CBAC initiated a research and consultation program on the patenting of higher life forms and related issues. It chose this topic for study because the application for a patent on the Harvard "onco-mouse" – regarding a mouse genetically modified for cancer research – was before the courts in Canada.

As well, both government officials and CBAC members had identified intellectual property issues related to biotechnology generally, and to the patenting of higher life forms in particular, as areas of growing concern.

Canada currently does not permit plants and animals to be patented, while most member

countries of the Organisation for Economic Co-operation and Development (OECD), including the United States and members of the European Union, do. Many developing countries have concerns about the impact of patenting biological inventions derived from plants and animals in the absence of recognition of traditional knowledge. There is also a segment of the population that believes that patents on plants, animals or any biological material whatsoever (DNA sequences, genes, cells) should not be permitted on moral grounds. Even among countries that do consider higher life forms patentable, there is no consensus on how associated social and ethical considerations should be addressed.

Article 27.3(b) of the World Trade Organization (WTO) Agreement on the Trade-Related Aspects of Intellectual Property (TRIPs) allows member countries to exclude plants and animals from patentability. When the mandated review of this section takes place, some countries (mostly developing nations) can be expected to support maintaining or expanding this section, while other countries (most notably the United States) will likely want to either narrow or eliminate this exception. Canada will be better able to contribute to this debate by developing a domestic position on this matter prior to the commencement of these negotiations.

The report *Patenting of Higher Life Forms* was released on June 6, 2002. It represents the views and advice of the Committee on patent and intellectual property issues after having taken into account the results of commissioned policy research studies, sector roundtables, review of public opinion research, multistakeholder consultations, and public responses to the Interim Report of November 2001.

In its report, CBAC recommended that patents not be granted on the human body at any stage of development, and that higher life forms meeting the criteria of the *Patent Act* be patentable subject to certain limits. The report discussed pertinent social and ethical considerations, made recommendations on improving the patent system, and addressed issues related to the equitable sharing of the benefits of biotechnological inventions and the recognition of traditional knowledge.

The CBAC report figured prominently in the Supreme Court of Canada's deliberations on the Harvard Mouse case. There was substantial congruence between the Court's findings and CBAC's report. The Court, in a decision released in December 2002, concluded that the Harvard Mouse did not meet the definition of an invention and therefore is not patentable. However, it did not take a position on whether higher life forms ought to be patentable, leaving this matter for legislators to decide.

New work plan

Following completion of its two special projects in 2002, CBAC developed a new articulation of the general theme of its ongoing work, namely, *Biotechnology in Canadian Society*. A statement on this matter was presented at the Government of Canada's National Summit on Innovation and Learning held November 18-19 in Toronto.

CBAC will examine how Canadian institutions, both within and outside government, might be transformed to enable them to best capture the benefits of biotechnology while managing risks and facing social and ethical challenges. These transformations may involve changes in how institutions are organized and perform their functions, the development of new organizations, and/or the cultivation of new partnerships, alliances and networks. The institutional transformations fall into two categories: those that focus on social and economic development (e.g., education, research, knowledge transfer, risk capital) and those that focus on regulatory matters (e.g., risk assessment, management and communication, health, environment and respect for core social values). The exploration of this topic will involve research to determine its parameters, examination of the short-term issues and opportunities associated with biotechnological innovations, and assessment of the pathways for longer-term institutional transformation.

III.

Agriculture and Agri-Food Canada

Agriculture and Agri-Food Canada

Securing Canada's food supply

Advances in agri-food science and technology are accelerating the development of a wide range of new industrial, health and nutritional products obtained from plants, animals and microorganisms. Agriculture and Agri-Food Canada (AAFC) – which is responsible for all matters relating to agriculture, including food products derived from biotechnology – relies on science and innovation as the cornerstone of its efforts to make Canada's agriculture and agri-food sector the world leader in food safety and environmentally sound production.

The department works to improve Canadians' quality of life by undertaking research and development programs that support the production of safe and nutritious food, maintain a healthy environment and develop innovative technologies. Biotechnology is an important tool in helping AAFC's scientists secure this goal. Specifically, it helps them develop better diagnoses and treatments of human, animal and crop diseases, breed new crops that are more stress tolerant, nutritious and higher yielding, and reduce the need for pesticides and fertilizers in food production.

In September 1999, the Canadian Council of Grocery Distributors initiated a project with the Canadian General Standards Board (CGSB) to develop a national standard for the voluntary labelling of genetically engineered (GE) foods. AAFC has played a lead role in coordinating and developing departmental, portfolio and Government of Canada positions on certain key aspects of the labelling standards that were developed through analysis and consultation with agri-food industry stakeholders on the CGSB committee, as well as other government departments and agencies.

The CGSB process is indicative of the importance of the Canada's Agricultural Policy Framework. This framework recognizes that consumers are becoming much more discerning and demanding in their food choices. It aims to ensure farmers and the agriculture and agri-food sector have the tools to better meet these demands. Such tools include systems for crop segregation, tracking, traceback, identity preservation, and testing of crops and foods. These tools, in turn, support the voluntary labelling standard that will help to ensure the retention and enhancement of consumer confidence by providing transparency and information on modern biotechnology and its use.

Science at the centre of innovation

Agriculture and Agri-Food Canada's labs across the country offer a wide range of scientific expertise including molecular biology, crop physiology, weed science, natural products chemistry, agronomy, entomology, bioinformatics, pathology, and genetics. This integrated expertise is essential to finding useful genes, understanding their functions, and incorporating them into germplasm and crop varieties for the benefit of the Canadian agri-food industry.

The Canadian Crop Genomic Initiative is a major departmental biotechnology project aimed at identifying the structure and function of key crop genes. This work is helping to develop Canadian crops – specifically corn, soybeans, canola and wheat – with disease and insect resistance, cold and drought tolerance, and better yield and quality attributes. The results of this initiative will contribute to positioning Canada as a world leader in food safety, innovation and environmentally responsible production.

Good for consumers, good for the economy

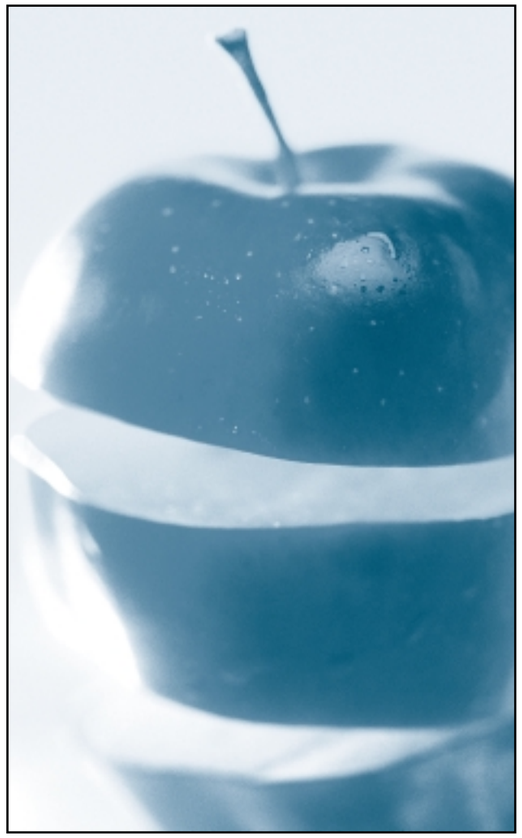
AAFC's innovations are helping Canadians use knowledge, technology and entrepreneurial skills to capitalize on opportunities in the knowledge-based global economy. Canada's agri-food industry generates some $44 billion annually in revenue. Total agri-food exports are about $20 billion a year. As it accounts for 15 percent of Canadian employment and 9 percent of gross domestic product, the sector represents a significant driver of the Canadian economy.

A number of factors mean Canada's food producers will increasingly depend on biotechnology. With most of its potentially arable land already in production, Canada's capacity to meet the ever-expanding demand for more and better food products by a growing world population will depend on such innovations. In addition, the developed world's aging population has created new markets for functional foods and nutraceutical products with health-promoting attributes.

As scientists learn more about what makes plants grow and what their various parts are, they can find many non-food uses for them. As an example, the agri-food and health industries are rapidly converging with the creation of new agri-food-based health products; their combined economic activity in biotechnology tops out at over $700 million a year in Canada. It is predicted that, in the years to come, farmers will produce as much medicine and industrial products as they do food.* Increasingly, many will turn their crops or components of them into a wide array of new food and non-food products.

*Note: Taken from an article in the *Western Producer,* 14 Dec. 2000, on the AAFC Web site, quoting AAFC Minister Lyle Vanclief speaking at an Ottawa biotechnology conference.

Through investments in biotech, AAFC can help ensure Canadians reap the benefits of these innovations and their associated economic spin-offs. But the net gain for Canada goes beyond mere dollars and cents. For instance, scientific advances in biotechnology are spawning new diagnostic technologies to help Canada's regulatory system ensure a safe and wholesome food supply. This instills confidence in Canadian agricultural and agri-food products, both at home and abroad. A further benefit is that this country's scientific community is stocked with the best minds the world has to offer. This keeps Canada on the vanguard of science, attracting further talent into the fold. It also helps to create and retain high-tech jobs, and contribute to national science objectives.



Early successes

Fight that grey with an apple a day

Food research scientists in Guelph are putting a new shine on the old expression about an apple a day. Apples, particularly apple peels, are high in antioxidants that have been linked to increased health and reduced disease in human trials. They help the body defend against cancer, heart disease, high blood pressure and other common ailments of aging.

An AAFC study of antioxidant phytochemicals in Ontario-grown apples shows that some varieties, and some parts of the apple, have more beneficial phytochemicals than others. Making use of the best part of the apple in foods could curb oxidation in the body, and prevent cell and tissue damage. Scientists now want to work on economical ways to get the antioxidant chemicals out of apple waste.

Natural fungus targets dandelion

AAFC weed scientists in Saskatoon have discovered an indigenous fungal species that controls dandelions and several other broadleaf weed species in turf grass when applied before weeds emerge. This naturally-occurring weed control product may provide a new option for weed control in instances where there is risk of exposure to vulnerable groups of people or possible environmental harm. Field studies show that dandelions may be controlled up to 95% and chickweed up to 80% throughout the growing season. Negotiations are under way to collaborate on additional research that will lead to development of the fungus as a viable commercial product.

DNA test helps spot food poisoning bacteria

A technology developed by Agriculture and Agri-Food Canada's food labs in Summerland, British Columbia, and Ottawa, Ontario, will show whether ground beef has been contaminated with the pathogenic strain of *E. coli*. The technique uses DNA arrays and can distinguish between different strains of the same bacteria, a boon when dealing with the extended *E. coli* family. The technology offers a significant time advantage over conventional testing for food-borne pathogens that can take several days. The rapid detection and identification of potentially harmful bacteria helps reduce the risks associated with pathogenic microorganisms.

Food-borne viruses under scrutiny

A team of specialists from Agriculture and Agri-Food Canada and the Canadian Food Inspection Agency is taking a hard look at food virology. The researchers are using molecular genetics to detect food-borne viruses and purify them from different foods. So far, the team has been able to use molecular techniques to detect viruses such as Hepatitis A, Rotavirus and Norwalk. The next step is to develop efficient extraction and recovery methods of viruses in samples taken from different agri-food products.

Wheat genetics put the bite on blight

AAFC researchers have identified and characterized wheat genes that allow plant breeders to more efficiently incorporate resistance to wheat leaf rust and fusarium head blight into new wheat varieties. The $5.1 million three-year study, part of the AAFC's Genomics Initiative, has also led to the discovery of genes involved in basic disease resistance pathways not specific to one disease-causing organism. These genes may provide resistance to multiple pests such as tanspot, septoria leaf blotch, wheat midge, hessian fly and wheat stem sawfly.

Researchers have also identified previously unknown regions of the wheat genome that govern wheat quality. Knowledge of these genes and chromosome regions will allow breeders to develop varieties that target customer demands, ensuring Canada's reputation as a supplier of top quality wheat.

Gene identification will help make better canola

The department's research teams have worked for more than three years to compile a database of over 25,000 gene sequences and over 2,000 microsatellite markers (regions which indicate particular sequences of DNA) for Argentine canola, *Brassica napus*. The mapping of the genome for *Brassica napus* will lead to the identification of genes that control a wide range of processes including resistance to fungal pathogens and insect pests, tolerance to cold, as well as protein, oil and glucosinolate accumulation, and fatty acid modification. Once these genes are identified they may be used in new varieties which will reduce the use of chemical fungicides and insecticides, enhance cold tolerance and give higher yields of oils and proteins.

IV.

Canadian Food Inspection Agency

Canadian Food Inspection Agency

Protecting the food supply

A significant aspect of the public's response to products of biotechnology is concern about the food they eat. In its mandated role to protect Canada's food supply and the health of plants and animals, the Canadian Food Inspection Agency (CFIA) conducts safety assessments for the environmental release of plants, feed, seed, and veterinary biologics – including those derived through biotechnology. In doing so, the Agency establishes that products developed from these agricultural commodities are safe for Canadian consumers, animals, and the environment. Through independent inspections and research, the CFIA also enforces food safety and nutritional quality standards established by Health Canada.

Science: the foundation of public safety

The key to reliable regulation for consumer protection is sound science. The CFIA has undertaken numerous research initiatives to enhance its detection and identification capacity for various biotechnology-derived products, including plants with novel traits (PNTs) and novel livestock feeds.

The Agency has commissioned several studies to build on its existing knowledge of biotechnology. These studies have focused on potential environmental impacts of novel agricultural products, whether they have been derived through mutagenesis, recombinant DNA, or any other biotechnology techniques. The research studies include the effect of Bt. corn pollen on monarch butterflies, herbicide resistance management for PNTs, the movement of canola pollen in the environment, and computer modelling that predicts pollen flow.

Learning from independent experts

Biotechnology is not static but a constantly-evolving field that demands continual upgrading of the regulatory system in order to keep pace with emerging developments. The CFIA is committed to adapting its regulatory system to be able to respond to future needs and the ongoing challenges of agricultural biotechnology. To assist with this task, it draws on the knowledge and expertise of recognized experts in the field.

Two groups of independent experts, the Royal Society of Canada (RSC) and the Canadian Biotechnology Advisory Committee (CBAC), were engaged by the federal biotechnology ministers to provide recommendations on how to best enhance Canada's regulatory system in this fast-changing environment.

In February 2001, the Royal Society of Canada released to federal ministers and the public the report of its expert scientific panel's recommendations, entitled *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada*.

In response, government departments and agencies released an action plan in November 2001 to address the RSC's 53 recommendations. To date, four progress reports have been published, outlining the key milestones achieved for each of the elements in the action plan. The fifth progress report of the Royal Society is scheduled for release in December 2003.

Similarly, in August 2002, CBAC released its final report, entitled *Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada*. The government departments

responding to this report are in the process of finalizing a coordinated response.

Information for sound decisions: labelling systems

In addition to enforcing health and safety labelling requirements set by Health Canada, the CFIA is also responsible for the development of general food labelling policies and labelling regulations not related to health and safety. As well, the Agency is directly involved in domestic and international discussions about labelling of biotechnology-derived foods.

As a technical advisor, the CFIA has contributed to the development of a domestic voluntary labelling standard for biotechnology-derived foods, an initiative being led by the Canadian General Standards Board (CGSB). The committee responsible for the standard held its 11th meeting in May 2003 to discuss outstanding issues. The standard was revised and a third ballot was issued in the summer of 2003. Consensus was reached on the draft standard by the committee, and if approved by the Standards Council of Canada, a national standard could be published as early as February 2004.

Canada is also involved with the Codex Alimentarius Commission task force that develops international standards for food safety. The Commission is responsible for developing standards, guidelines and other similar texts to protect consumers' health and to ensure fair trade practices in global food trade. It also promotes the coordination of food standards work done by international government and non-governmental organizations. The CFIA has been involved in several Codex initiatives, providing pivotal leadership to ongoing discussions of labelling at the Codex Alimentarius Committee on Food Labelling and participation in the task force on Foods Derived From Biotechnology.

Strengthening international understanding and co-operation

As a responsible member of the world community and global leader in biotechnology, Canada has worked hard over the past five years to contribute to the international regulatory framework. The CFIA and other government bodies are members of several international organizations that deal with the regulation of products derived through biotechnology.

These organizations include: the Asia-Pacific Economic Cooperation (APEC) forum, the World Health Organization (WHO)/Food and Agriculture Organization (FAO) Codex Alimentarius Commission Committee on Food Labelling (CCFL), and the Organisation of Economic Co-operation and Development (OECD). The CFIA has enhanced its efforts to contribute to, and support the work of, these global bodies.

In addition, Canada is a signatory to the Cartagena Protocol on Biosafety. Although a non-party, Canada has continued to work in the international arena to help clarify the provisions of the Protocol. This level of international participation gives the Agency the opportunity to communicate its commitment

to a science-based approach to biotechnology, while contributing to sound international policy.

Rigorous and responsive regulatory system

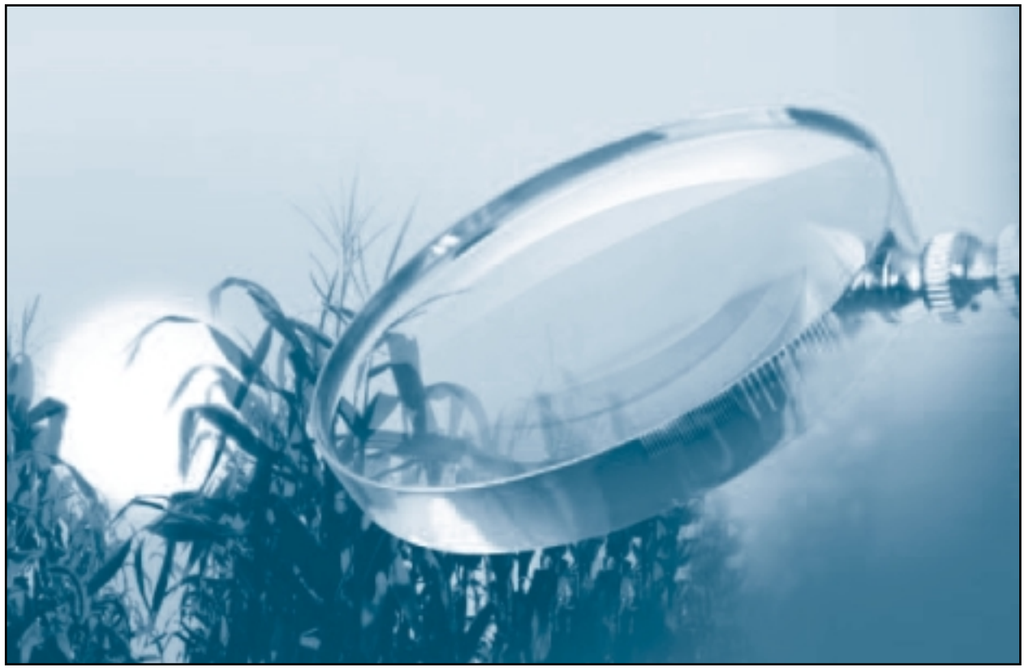
The Government of Canada is committed to ensuring that its regulation of foods derived from biotechnology is appropriate for the state of the science and the types of products that are being developed through research. To that end, it allocated $90 million in Budget 2000 specifically to enhance the regulatory system for products derived through biotechnology.

An annual investment of $10 million in the regulatory system for biotechnology-derived products has enabled the CFIA to continue to strengthen its "safety first" regulatory approach to keep pace with the next generation of scientific discoveries. This funding has allowed the CFIA to:

- increase capacity for monitoring, inspection, surveillance and enforcement by carrying out training to update the skills of its current staff
- increase capacity to enhance the CFIA's ability to provide good policy to meet current challenges and anticipate future challenges before they appear
- generate research to underpin regulation by acquiring new tools, methodologies and knowledge for risk assessment, risk management and monitoring
- strengthen international regulatory cooperation and harmonization by negotiating international agreements and by designing standard-setting protocols
- maintain and heighten the public's confidence in Canada's regulatory system while continuing to improve its communications with the public and stakeholders

Early successes

Biotechnology is an ever-expanding science that has posed several challenges to the Agency since its creation in 1997. Although the Agency is still new, its highly qualified and dedicated employees have consistently proven themselves equal to these challenges, forcefully responding to Canadians' safety and information needs, and playing a strong role in the national and international arenas of agricultural biotechnology.



Enhancing regulatory rigour: improving and evolving

Protecting consumers, animals and the environment is the CFIA's top priority, which is reflected in the rigour of its regulatory system. The Agency is committed to incorporating new knowledge arising from advances in science and its increasing experience in regulating products of biotechnology within the regulatory system.

The CFIA is updating its regulatory directives and guidelines on plants with novel traits (Regulatory Directive 94–08: *Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits*) and livestock feeds derived from plants with novel traits (Regulatory Directive 95–03: *Guideline for the Assessment of Livestock Feed from Plants with Novel Traits*).

With respect to specific types of new products (one example being molecular farming), the CFIA has completed the *Interim Amendment to Directive 2000-07 for Confined Research Field Trials of PNTs for Plant Molecular Farming* to explicitly state appropriate terms and conditions for confined research field trials of plants with novel traits for molecular farming.

In regards to animal biotechnology, the CFIA has been involved in several important initiatives. In 1998, the CFIA and other departments hosted the "Consultation on Regulating Livestock Animals and Fish Derived from Biotechnology," which was attended by representatives from non-governmental organizations, industry, industry associations, university communities, First Nations and government, as well as interested individuals. The purpose of the consultation was to seek advice and identify areas where improvements could be made to Canada's existing regulatory system dealing with livestock animals and fish derived through biotechnology, and to raise awareness of the technology, its use and applications.

In 2003, some 45 participants, including representatives of stakeholder groups (biotechnology companies, livestock breeders, university researchers and the Canadian Council on Animal Care) and government (Agriculture and Agri-Food Canada, Environment Canada, Health Canada, and Industry Canada), attended a CFIA-organized focus group aimed at providing stakeholders and regulated parties with a forum to discuss the current status and anticipated developments in the regulation of animal biotechnology in Canada. It also provided an opportunity to formulate recommendations on the future role of the CFIA in the regulation of animal biotechnology.

The CFIA is working with Environment Canada, as well, providing scientific expertise to draft notification guidelines for the regulation of livestock animals that are products of biotechnology under the *New Substances Notification Regulations* of the *Canadian Environmental Protection Act, 1999*.

Reaching out to the public

Canadians feel strongly about having access to credible information as it relates to foods available in the marketplace. Because of its commitment to openness and transparency, the CFIA has not only maintained, but heightened the public's confidence in Canada's regulatory system while continuing to improve its domestic and international communications with the public and stakeholders alike.

The CFIA has frequently engaged the public in consultations to help develop guidelines and regulations for biotechnology-derived agricultural products. These consultations have included workshops, multi-stakeholder meetings, online feedback forms and draft documents for review and comment, along with independent reviews by experts.

To date, some of the topics discussed have been:

- regulations and safety assessments for biotechnology-derived products
- labelling of biotechnology-derived foods
- plant molecular farming

Enhanced understanding helps consumers to formulate their own views about biotechnology in Canada and the global marketplace. An important area of public information surrounds the labelling of genetically modified (GM) foods. The Agency has developed a range of tools that enable Canadians to access the most up-to-date information as well as the opportunity to respond and ask questions.

The CFIA has committed itself to increasing the public's access to, and understanding of, the regulation of all biotechnology-derived products. Some of these activities include:

- posting more information on the CFIA Web site
- designing information products, such as consumer fact sheets, that are written in "plain language"
- developing information kits
- designing a poster that provides an overview of some of the agricultural biotechnology regulation milestones that have occurred over the last 15 years

In addition, the CFIA, on behalf of several other government departments, led responses to a number of petitions submitted under section 22 of the *Auditor General Act* to the Commissioner of the Environment and Sustainable Development. The responses to these petitions were made available to the public on the CFIA Web site well before this level of transparency applied to all petitions.

On October 21, 2003, the CFIA launched the Notices of Submission Project, in conjunction with Health Canada. These notices will describe the product – a new Plant with Novel Trait (PNTs), or novel feed or food derived from a PNT – and summarize the information provided for its safety assessment.

The launch of this project means that, for the first time in Canada, the public will be notified of new biotechnology crop, feed and food product submissions while they are under review. As well, it is the first time the public will have access to a list of scientific studies conducted on new products regarding safety, and they may provide input on scientific matters relevant to the safety assessment of each new product submission.

Demonstrating effective programs management: responding to StarLink™

The CFIA's inspection functions include border inspections for biotechnology-derived products that have not been approved for safety in Canada. StarLink™ corn – approved in the U.S. for animal feed and industrial purposes, but not for human consumption – is one such product. It has not been approved in Canada for any purpose and therefore cannot be imported.

The CFIA, the Canadian Grain Commission, as well as the Canada Customs and Revenue Agency undertook a major joint initiative to keep StarLink™ corn from entering the country. They worked together to verify that shipments had appropriate documentation, proving no StarLink™ content, and to sample shipments on a random basis. Between October 2001 and December 2002, approximately 60,000 shipments of whole grain corn from the U.S. were reviewed. In December 2001, the government issued a detailed response to the Greenpeace Canada petition. The response gave an overview of the comprehensive way that Canada regulates biotechnology-derived foods and in what ways the regulatory system continues to evolve to meet challenges such as those posed by the StarLink™ case.

Working with world partners to develop "smart standards"

The CFIA participates in several international organizations and discussions on a range of matters related to its mandate, and frequently helps to develop Canada's position on these issues. The CFIA participates in the OECD's *Working Group on Harmonisation of Regulatory Oversight in Biotechnology*. The main task of this working group is to achieve harmonization in countries' regulation of biotechnology, focusing on environmental safety.

Also, in 2000, CFIA became the Shepherd of the Research, Development, and Extension of Agricultural Biotechnology (RDEAB) Sub-Group of APEC. This sub-group was formally established to be a place for member economies to discuss regulatory transparency, discuss capacity building, encourage the development of effective communications and further technical cooperation and information exchange.

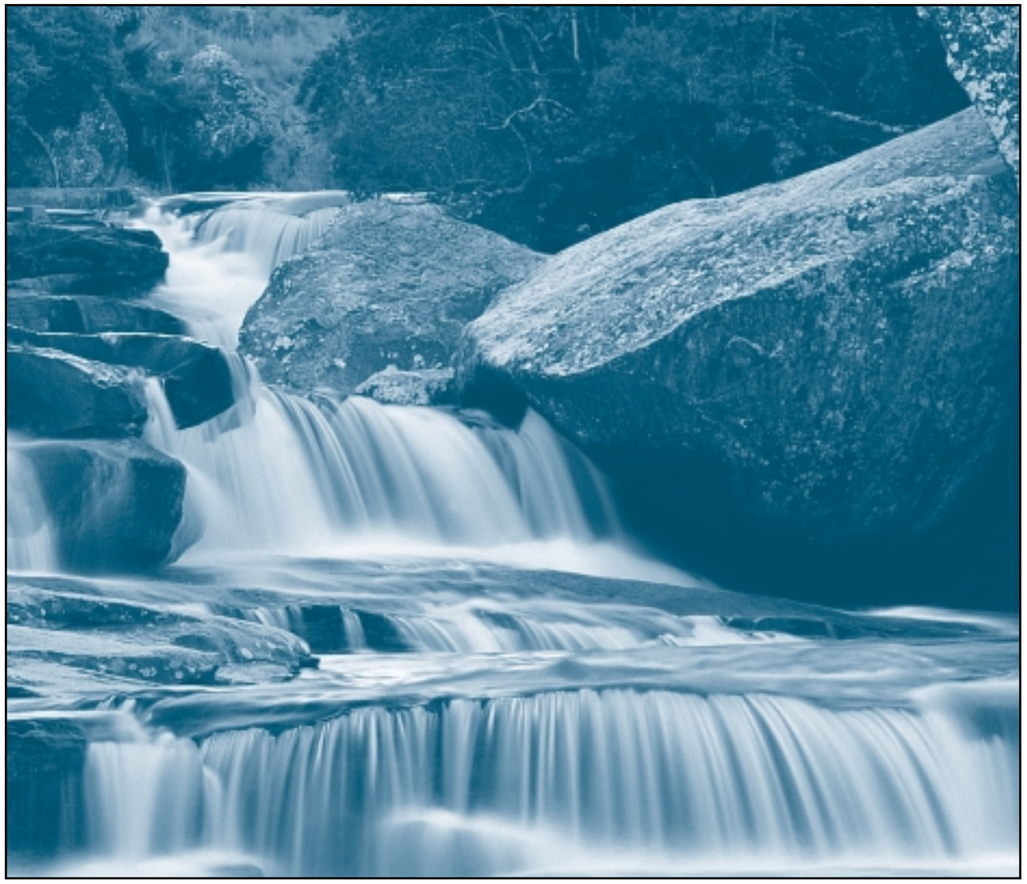
V.

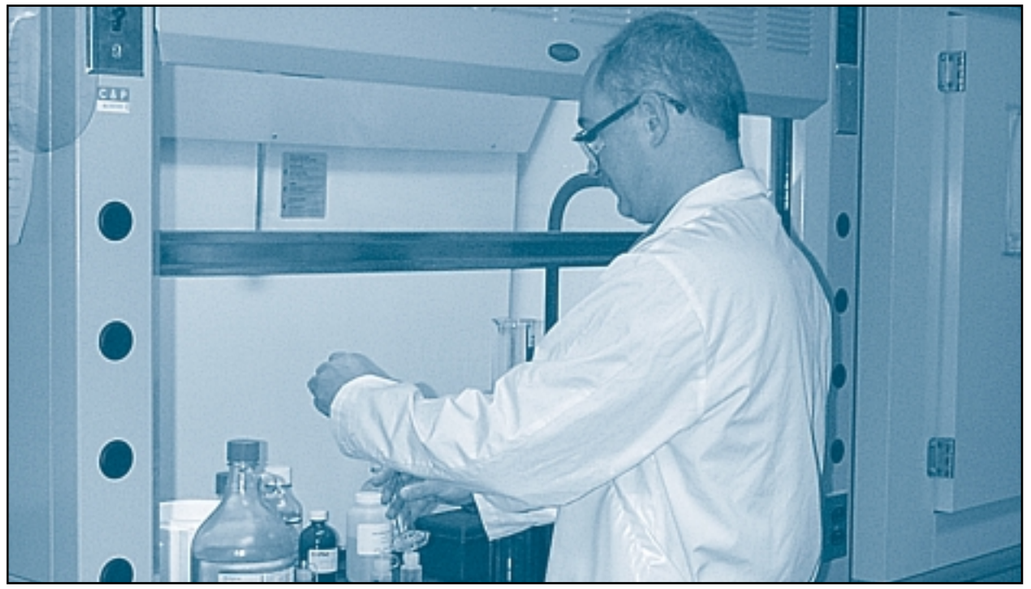
Environment Canada

Environment Canada

Promoting sustainable development

Environment Canada's mission is to make sustainable development a reality in Canada by helping Canadians live and prosper in an environment that needs to be respected, protected and conserved. Biotechnology simultaneously provides opportunities and risks to achieving this mission, which reflects the central challenge of sustainable development. On the one hand, biotechnology challenges existing approaches to protecting human health and the environment; as biotechnology is applied in more industrial sectors, the department needs to be aware of, and control, how the products of these new technologies impact the natural environment. On the other hand, biotechnology can provide significant environmental, economic and social benefits to Canadians; new products and processes, such as bio-fuels and phytoremediation may result in lower environmental impacts than their non-biotechnology alternatives. Biotechnology also provides new tools to help us better understand and protect our wildlife.





Environment Canada advances its mandate by helping people make responsible decisions that will sustain this country's natural heritage for the benefit of present and future generations. The department is developing knowledge on the interaction of biotechnology and ecosystems, and how to manage potential risks. Through its activities in regulation, research and development, innovation and stewardship, the department is uniquely positioned to address the risks that biotechnology may pose to the environment. Along with others, it also contributes to the base of knowledge on biotechnology and its potential impacts and uses in relation to sustainable development.

Legislative framework

Environment Canada is guided in its work by the *Department of the Environment Act*. With respect to biotechnology, EC has responsibilities under the *Canadian Environmental Protection Act, 1999* (CEPA), and the *United Nations' Convention on Biological Diversity*. In addition, biotechnology plays a part in helping the department to fulfill its responsibilities under the *Wildlife Act* and the *Species at Risk Act*.

CEPA 1999 requires the Government of Canada to "protect the environment, including its biological diversity, and human health, by ensuring the safe and effective use of biotechnology." Specifically, it ensures all new substances are assessed for their potential to harm human health or the environment, prior to their import or manufacture. CEPA 1999 applies, unless it has been determined that another federal act and regulations meet the requirements of CEPA. As the biotechnology sector continues to grow, this involves assessing an increasing number of the products of biotechnology.

Environment Canada's work on biotechnology – which encompasses assessment, research, policy development and international agreements – is geared towards stewardship of the environment and protection of biodiversity. The department is moving forward on four fronts to help ensure biotechnology contributes to sustainable development.

Regulation

One of Environment Canada's primary functions in the field of biotechnology is the administration of regulations that ensure the development and application of animate products of biotechnology occurs in a manner that protects the health and safety of Canadians and the environment. The department conducts assessments and, where necessary, regulates products of biotechnology that fall under CEPA.

The *New Substances Notification Regulations* (NSNR) of CEPA 1999 are an integral part of Canada's strategy to prevent pollution before it occurs. Before chemicals, polymers and animate products of biotechnology are introduced into Canada through import or manufacture (and have the opportunity to reach the Canadian environment), Environment Canada is notified so it can assess whether they are potentially toxic and establish appropriate control measures. The ability to act early makes the New Substances Program an essential component of the Government of Canada's approach to responsibly manage toxic substances.

Budget 2000 invested a total of $90 million for the Canadian biotechnology regulatory system, of which $5 million over three years was provided to Environment Canada. This funding was renewed in 2003 for another three years. A portion of these funds have been used to develop a national working group to build capacity, specifically regarding biotechnology, to promote compliance with EC's NSNR regime. The department has developed an action plan to improve compliance of transgenic research and development (R&D) facilities, strengthen the language for R&D exemption, and fully implement a sectoral approach for regulating biotechnology products. Providing advisory materials regarding the action plan has resulted in the university and industry R&D community being much more aware of its regulatory obligations.

Research and development

Environment Canada undertakes scientific studies and develops tools to identify, understand, and measure the ultimate fate and effect of animate products of biotechnology in the environment, including ecosystems, wildlife and biodiversity. Part of the department's work involves research and development to understand the potential impacts of biotechnology on the environment. Its R&D activities support the Government of Canada's regulatory development and inform its ability to protect the environment through three primary endeavours:

Regulatory research – EMBRR

EC's Environmental Management of Biotechnology for Regulation and Research (EMBRR) program has developed new tools for consortia identification and compliance verification. Over the past three years, $400,000 has been provided for EMBRR to support the development of a number of techniques including a prototype DNA microarray to simultaneously provide a DNA fingerprint for complex arrangements of microbial products of biotechnology, and screen the product for the presence of pathogens and genetic traits such as toxin production and antibiotic resistance.

EMBRR program has also provided support for:

- the development of a microbial identification laboratory to support the enforcement for compliance verification activities of the department;
- the development of guidelines for pathogenicity and toxicity testing requirements for microbial substances under the *New Substances Notification Regulations*; and
- research on toxicological effects of genetically modified organisms (GMOs) in the aquatic environment.

Aquatic research – National Water Research Institute

Given Canada's vast supply of fresh water resources, it is important that the Government of Canada have a sound understanding of the potential impacts of GMOs and other products of biotechnology on aquatic environments, so it is in a position to make sensible decisions.

Environment Canada's National Water Research Institute (NWRI) is Canada's pre-eminent freshwater research facility. With partners in the Canadian and international science communities, NWRI conducts a comprehensive program of ecosystem-based R&D in the aquatic sciences, generating and disseminating scientific knowledge needed to resolve environmental issues of regional, national or international significance to Canada, and to sustain our natural resources and freshwater ecosystems. Specifically, it has been working in partnership with the National Research Council's Biotechnology Research Institute and the University of Guelph to explore new DNA techniques that better characterize complex arrangements of microbial products of biotechnology. Better identification allows the department to track down their sources and to investigate their environmental fate and potential effects in freshwater ecosystems.

To support the development of biotechnology in an environmentally sustainable manner, the NWRI has begun a research program in collaboration with other departments, agencies and universities. A laboratory has been equipped to do research on effects of genetically modified organisms (GMOs) in aquatic and terrestrial environments. Some of the studies include:

- An investigation to determine how long an antibiotic resistance gene contained in most GMOs can survive in the environment. Presumably, the longer the antibiotic resistance gene persists in the environment, the greater chance it could be absorbed by some bacteria, leading to potential antibiotic resistance spread.
- An investigation into the distribution of native bacteria that can take up the antibiotic resistance genes, and thereby become antibiotic resistant, to identify hotspots where the absorption is most likely to occur in the environment.

The NWRI is also collaborating with the Canadian Cooperative Wildlife Health Centre and the Canadian Wildlife Service to develop DNA-based methods to screen microbial biotechnology products and processes for the presence of potentially harmful wildlife pathogens.

Wildlife research – Canadian Wildlife Service

For the Canadian Wildlife Service (CWS) and its partners in Canada and internationally, genomics techniques are becoming increasingly important tools in a number of fields of interest including toxicology, species-at-risk recovery, and wildlife management. Examples of their application to CWS work include:

- Replacing capture-recapture studies of birds, which are useful for only a few species, with ones based on DNA collected from samples such as feathers. Information about bird migration can be used to implement international cooperative agreements.
- Doing research to discover unique sub-populations of animal species and to identify how these sub-populations contribute to the diversity of the whole species. This information can be used to better inform wildlife management practices and to plan effective recovery programs for species at risk.
- Detecting contaminant-induced effects on DNA and gene expression, which can be associated with toxic effects in wildlife. This knowledge increases the understanding of the toxic effects of environmental contaminants.

Among its results, the NWRI has confirmed that genes introduced through biotechnology (e.g., those that improve herbicide tolerance) can be transferred by pollen from GM canola to its wild relatives, especially wild *rapa* (an economically important weed worldwide). However, further research has shown that locating the new gene on specific canola chromosomes not found in wild rapa reduces the likelihood of the gene's incorporation into the weed's chromosomes thus minimizing the gene's persistence. This information could be helpful in developing future candidate crops.

Over the past five years, CWS has also completed a variety of capacity-building projects such as a Web-based wildlife genetics primer. This primer provides CWS staff and others with the basic concepts necessary to understand how modern molecular techniques can be applied to the management and conservation of wildlife.

Long-term effects research strategy

The Environmental Conservation Service received approximately $350,000 in funding from the CBS during the fiscal years 2002-03/2003-04 to develop an interdepartmental research strategy to determine the ecosystem effects of genetically modified organisms. The purpose of the strategy is to guide the research that will strengthen the Government of Canada's understanding of long-term and ecosystem effects of novel animate products of biotechnology, including GMOs. This research is a crucial component of Canada's responsible stewardship of biotechnology, and is an interim response to advice offered by both the Canadian Biotechnology Advisory Committee (CBAC) and the Royal Society of Canada (RSC). Both bodies advised the federal government to put into place a research program to determine long-term and ecosystem effects of these new organisms.

To support the strategy, Environment Canada commissioned a number of studies and reports to increase understanding of the present and ongoing work in this research area, including:

- a survey of Canadian research in this area
- a draft stewardship framework for genetically modified organisms, and
- a survey of international research in this area

Among other things, this work has helped to identify gaps in the Canadian system that will need to be dealt with to successfully implement a program to address ecosystem effects of new animate products of biotechnology, including genetically modified organisms.

Innovation

The department promotes the development of stewardship tools, protocols and methodologies, as well as environmental protection applications. Environment Canada invests approximately $2 million annually towards basic and applied research in the development of bio-based solutions that detect, monitor, prevent or remediate environmental pollution, as well as provide insight into the impact of genomics on environmental quality.

EC has worked with partners to investigate the potential of plants as a viable technology for cleaning up contamination, also known as phytoremediation. The results obtained to date indicate this has the potential to be an excellent clean-up technology for the Canadian environment. Further study will be conducted to understand its potential in a variety of conditions.

For the past five years EC has commissioned studies on the opportunities and challenges of moving from a petroleum-based to a bio-based economy. It is trying to determine whether the anticipated benefits of such a transition will reduce greenhouse gases, mitigate their effects, or allow agricultural and forestry practices to adapt to changing climactic conditions both regionally and at the national level.

Biomass from the agricultural and forestry industries is expected to fuel a bio-based economy in Canada. To minimize the environmental effects associated with increased expansion in these industries, Environment Canada is developing a strategy to mitigate any adverse effects to Canada's soil and water resources, wildlife, endangered species and habitat. Fostering increased scientific capacity in the area of sustainability assessment will bolster public confidence in biotechnology and bio-based products, and enable Canada to be more competitive in a global bio-based economy.

Stewardship

To encourage public participation and action, Environment Canada leads by example in environmental stewardship and the sustainable development of biotechnology at home and internationally.

The Cartagena Protocol on Biosafety

Environment Canada has been designated the national focal point for the Cartagena Protocol on Biosafety and as such, leads in policy development and implementation of the Protocol. The Protocol is a treaty under the United Nations Convention on Biological Diversity designed to address the risk to biodiversity that may be posed by the international movement of living modified organisms (LMOs). LMOs are genetically modified organisms capable of replicating and passing on their genetic material to subsequent generations. The potential benefits of products of modern biotechnology such as LMOs are widely anticipated and many people are keen to see these benefits realized. However, there are potential risks which must be recognized and managed.

Canada signed the Biosafety Protocol on April 19, 2001. The following year, Environment Canada published a set of draft regulations under CEPA 1999 that would give effect to the Cartagena Protocol once it is ratified. The Government of Canada held a public consultation process in September 2002 to solicit views from the public on the proposed regulations and about how Canada should proceed with the Protocol. The time since then has been spent addressing outstanding concerns identified by some stakeholders such as documentation requirements for commodity shipments as well as an electronic information clearinghouse. Concurrently, EC has been involved in negotiations on bilateral arrangements with importing countries that would provide stable conditions for continuing trade following the coming into force of the Protocol.

Access and benefit-sharing

It is estimated that Canada has approximately 140,000 species that represent a potentially vast reservoir of genetic heritage and opportunity. The new bio-based economy promises opportunities for the commercial use of these resources. It is essential to take measures to ensure Canadians benefit from biotechnology and pharmaceutical innovation based on Canada's genetic resource heritage. This will be equally important to ensure Canadian innovators have access to global biodiversity for the development of new products and services, which will drive the future growth of the bio-based economy and the Canadian biotechnology sector.

Environment Canada's objective in developing benefit-sharing policies and mechanisms is to make sure they contribute to the conservation and sustainable use of biodiversity, both in Canada and around the world.

The Biodiversity Convention Office has been officially designated as Canada's National Focal Point on Access and Benefit-sharing. Canada was actively involved in the drafting of the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization, which were adopted by the Conference of the Parties to the Convention on Biological Diversity in 2002. Canada has also begun to take measures in support of Canadian implementation of the voluntary Bonn Guidelines.

Another important Canadian policy objective is to respect, maintain and preserve traditional knowledge of indigenous and local communities so that this ethno-botanical knowledge can be used to their benefit and to that of society at large. Canada has spent almost $700,000 over the last five years to ensure the participation of Aboriginal representatives at international meetings of the Convention on Biological Diversity and the World Intellectual Property Organization concerning traditional knowledge and genetic resources.

VI.

Fisheries and Oceans Canada

Fisheries and Oceans Canada

Safeguarding our seas and shoreline

Canada's wealth of marine resources is one of many reasons European explorers were attracted to, and eventually settled on, Canada's shores. Since then, the fishery has played a pivotal role in shaping this country's history. As Canada makes the transition to the knowledge-based economy, those same resources – enhanced by new knowledge and technologies, which ensure their sustainable development – will continue to provide social, environmental and economic benefits to Canadians in the 21st century.

Fisheries and Oceans Canada's (DFO) responsibilities include maintaining sustainable fisheries and aquaculture, as well as healthy and productive aquatic ecosystems. Increasingly, biotechnology contributes to this goal. It is becoming an important tool in fulfilling some of DFO's science sector responsibilities, which include: providing science advice; developing and providing products and services; conducting monitoring; managing data; and carrying out targeted research.

The department applies biotechnology tools to a variety of functions, such as establishing genetic profiles of commercially valuable species for stock identification and harvest management, preserving the genetic diversity of endangered species, and selecting broodstock in aquaculture development. DFO is also developing an aquatic animal health program, which is based in part on molecular diagnostic methodologies, to meet international requirements for the identification and control of aquatic animal diseases. This is critical to Canada's trade status and the movement of Canadian seafood products in international markets.

In recent years there has been an increasing amount of research and development in the area of genetically modified fish in many countries to develop aquaculture strains for enhanced food production. The authority to assess environmental and indirect human health effects of genetically modified aquatic organisms rests with the *Canadian Environmental Protection Act* (CEPA) of 1999, until equivalent regulations are developed under the *Fisheries Act*. In the mean time, DFO assists Environment Canada and Health Canada with this assessment under CEPA 1999.

Early successes

Scientific innovations

DFO has taken leading-edge biotechnology developments and applied them to marine science operations. Working with partners in other government departments, universities, industry and foreign institutions, the department has been instrumental in developing breakthroughs in DNA fingerprinting of marine species, molecular diagnosis of aquatic animal diseases and the development of model strains of transgenic fish.

DNA sequences are like barcodes identifying the various products you buy at a store. DFO scientists are working on making DNA sequencing an analytical tool so powerful that it does not require sophisticated scientific experimentation to develop a genetic profile of an organism. By using this innovative tool on samples of undigested blood or scales, individuals, species and populations of fish can be identified by matching samples to a databank of these DNA sequences.

Scientists begin by collecting DNA samples of species from geographically distinct stocks around the world and use molecular techniques to identify different DNA within these samples. Once mapped, these differences allow scientists to, for example, distinguish one population of Atlantic lobster from another and understand its distribution pattern. Before the development of these genetic probes, scientists relied on time-consuming live captures of huge numbers of organisms, which could then be tagged, released and eventually recovered. Genetic analysis opens the door to understanding a variety of aspects of marine life, such as the differences between populations and stock status.

In the regulation of aquatic animal health, DFO laboratories are developing, testing, improving and validating novel molecular-based methods of disease diagnosis. DFO scientists used a newly developed polymerase chain reaction-based (PCR) test to differentiate between MSX and SSO infections in oysters during the 2002 outbreak in the province of Nova Scotia. The differentiation allowed the control measures to be concentrated on areas affected by the more pathogenic MSX infections and limited the economic impacts of culture operation closures. As a result of the Canadian diagnostic experience, the OIE (Office international des épizooties) has declared the PCR confirmation as the international standard for the diagnosis of MSX and SSO infections in oysters.

DFO's transgenic fish research has produced genetically modified salmon that have been reared in contained, land-based facilities. The DFO-developed transgenic salmon strains are used to obtain factual information on performance characteristics, fitness parameters and food safety characteristics. This information is important to assess any potential impacts that escaped genetically modified fish might have on wild populations. The transgenic strains are also used by other federal regulatory authorities and other countries so that assessments of environmental impacts and food safety are comparable.

Understanding the genetic blueprint of living marine organisms forms a powerful base to develop applications and to seek solutions for a wide range of challenges. As the technologies continue to mature and costs decline, the broader adoption of biotechnology in day-to-day operations will be possible.

All of these scientific innovations are contributing not only to a sound regulatory capability, but also to sustainable fisheries, competitive aquaculture and strengthened environmental protection.

Sustainable fisheries

DFO scientists are building genomic libraries of Canadian marine species. For example, DNA profiling of various sockeye sub-populations

returning to the Fraser River has been completed. In 2002, more than 9,000 samples were analyzed and compared to the established population profiles in daily operations. This new information allowed fisheries authorities to temporarily close the fishery on days when the late run, which is associated with high spawning mortality, appeared earlier than expected. This type of work has helped to minimize harvest pressures upon particularly sensitive species and populations.

DFO's DNA fingerprinting technique can also be used by enforcement officers in forensic analysis to identify confiscated products and trace them to their species or stock of origin. This acts as a strong deterrent against poaching or illegal harvesting and improves the enforcement of regulations and protection of marine resources. The department has successfully prosecuted cases dealing with salmon and abalone based on DNA evidence.

By charting each species, population by population, scientists can better assess which populations can support fisheries and how to prevent the loss of genetic diversity in designing breeding programs. Endangered species could also be identified and protected to ensure the genetic variability each needs to survive and thrive. The goal of these genomic libraries is to build a clear understanding of population dynamics well before any harvest pressures build.

DFO scientists are also using DNA analyses in supportive breeding (salmon enhancement) and selective breeding (aquaculture) programs. In Atlantic salmon enhancement, DNA fingerprinting is used to trace adults, progeny and returnees in order to determine the success of different enhancement strategies. In Pacific salmon aquaculture, DNA analysis is used to monitor any genetic diversity loss in aquaculture strains and to distinguish wild from cultured salmonids.

Strengthened environmental protection

Canada's aquatic resources are an integral part of the fabric of this nation. Extensive DNA surveys and the tracking of the genetic diversity of endangered species are yielding valuable information in designing marine protected areas. These genetic surveys are also leading to a better understanding of the impacts of human activity on wild stocks. Because of genetic research, fish management experts are better able to give fragile populations a chance to survive, recover and ultimately lead to stronger, healthier fisheries for the future. Research is also ongoing to evaluate the effectiveness of sterilization of male and female salmonids to prevent the breeding of escaped farmed fish with wild fish stocks.

The National Centre for Offshore Oil and Gas Environmental Research is working on restoring the productive capacity of contaminated sites in coastal environments. The Centre is developing new sensitive, cost-effective and rapid assays, based on recent advances in biotechnology, for monitoring recovery in habitat quality. Advances in site remediation and environmental health assessments are required to meet Canadians' expectation that the government should be more proactive in its efforts to protect the environment and sustainability of our aquatic resources.

Sharing knowledge and expertise

DFO initiatives are defining the way marine biotechnology is applied and developed. The department's core expertise is concentrated at specialized research centres. The applications developed at the centres are then transferred to other laboratories and integrated into day-to-day operations and policy development. DFO works in close partnerships with key organizations, both nationally and internationally, to share its knowledge and expertise in this fast-evolving field.

Fisheries and Oceans Canada, the Canadian Food Inspection Agency, Health Canada, Environment Canada and other federal departments are working together to maintain efficient coordination in the federal biotechnology regulatory system. This partnership approach reinforces the commitment of CBS member departments and agencies to responsibly manage all aspects of the development and application of biotechnology. It also underscores their shared determination to work cooperatively and strategically, among themselves as well as with other partners, to strike a balance between the detection and management of risk, and the development of new biotechnology discoveries.

VII.

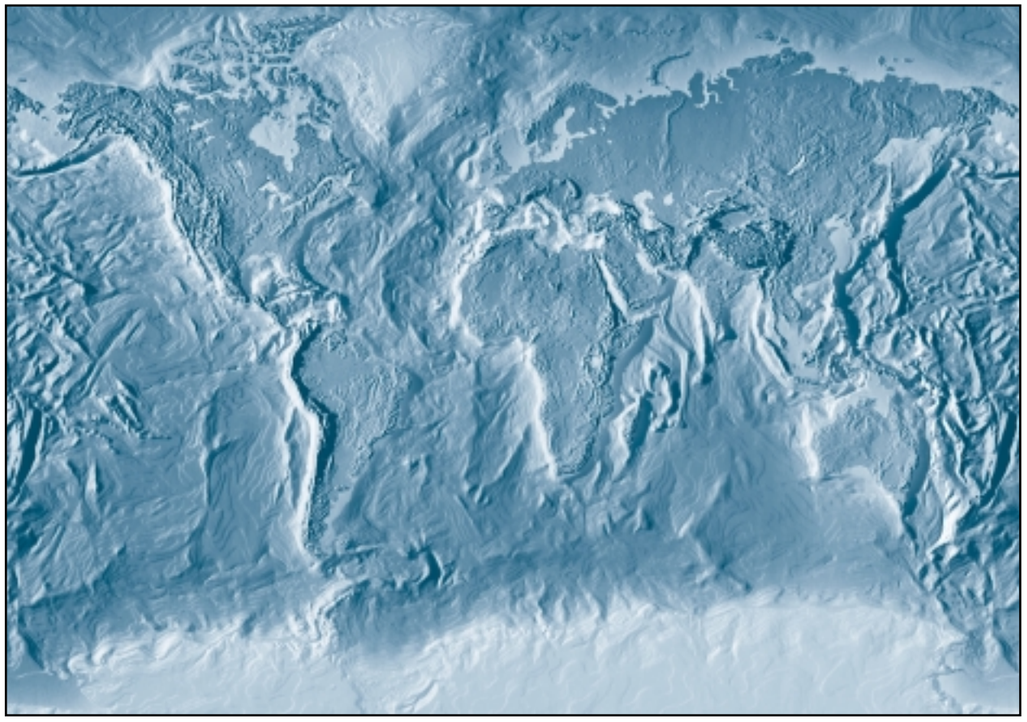
Department of Foreign Affairs and International Trade

Department of Foreign Affairs and International Trade

Marketing Canadian expertise to the world

The rapid growth of biotechnology, with its multitude of existing and potential applications, means it is poised to become a dominant force in the global economy. Biotechnology is being targeted by most industrialized countries as one of the most important sources of jobs and economic and social progress in the 21st century.

Canada's position as a responsible leader in biotechnology is internationally recognized. Our country is home to over 400 bio-based firms – the second largest number of biotechnology companies in the world – generating revenues that rank third internationally, behind the United States and the United Kingdom. The Department of Foreign Affairs and International Trade (DFAIT) is actively engaged in promoting Canadian capability in biotechnology in the global marketplace. Through the Trade Commissioner Service, the Science and Technology Division, the Technical Barriers and Regulations Division and other divisions in the Trade Policy Bureau, DFAIT works to improve market access for Canadian biotechnology products, manage trade relationships and support Canadian business.



Open international markets, combined with a stable and transparent trading environment, are at the core of Canada's growth and prosperity. However, impediments that limit access to international markets, such as trade disputes, invariably arise within most trading relationships. Often these challenges are related to trade involving innovative products, such as those derived through biotechnology. DFAIT, through its various divisions and often in concert with other government departments and agencies, works to ensure Canadian biotech producers have the best possible access to foreign markets and that they receive fair treatment internationally.

The Technical Barriers and Regulations Division (EAS) within DFAIT's Trade Policy Bureau illustrates one of the ways the department supports Canadian biotechnology industries. EAS identifies international barriers to trade as they arise and works to reduce those barriers through negotiation, making representations in various international fora and organizations, and by pursuing outreach efforts that help build fair, transparent regulatory capacity in other countries.

The Trade Commissioner Service (TCS) is another area of DFAIT that promotes and supports the economic interests of Canada internationally by providing Canadian firms with business contacts, market information, local company and visit information, face-to-face briefings and troubleshooting services. TCS assists companies that have researched and selected their target markets, and can demonstrate their commitment to succeed in the global marketplace.

Finally, DFAIT's Science and Technology Division (TBR) contributes to strengthening Canada's biotechnology international presence by providing support to the Canadian biotechnology community, including the private sector, to identify foreign technology and potential financing (venture capital) partners.

Contributions to the CBS

International technology and financing partnering

The Science and Technology Division organizes events focused on venture capital and technology partnering around the world in countries where there are complementary technologies and where foreign financing is available. In most cases, TBR partnering events take place in conjunction with major international industry conventions to provide added value to Canadian participants and to promote Canada's image at these world events. Since 2001, TBR has organized partnering meetings to help Canadian biotechnology companies and research organizations explore technology and financing partnership opportunities with targeted foreign delegations at the Biotechnology Industry Organization (BIO) annual convention and exhibition. Canada hosted BIO2002 in June of that year in Toronto. The Division also leads biotechnology venture financing and technology partnering missions to Europe and Asia, and organizes partnering seminars in collaboration with Canadian missions abroad. Canadian and foreign participants to such events pay their own way to attend.

Canadian involvement in international organizations related to trade

Canada is actively involved in international organizations such as the World Trade Organization (WTO) and participates in WTO committees that preside over trade issues related to products of biotechnology. The WTO Agreement on Technical Barriers to Trade (TBT) defines the international rights and obligations of members with respect to the development and application of standards-related measures that affect trade. The Agreement is based on the principle that countries have the right to adopt and apply mandatory technical regulations, as long as these regulations do not restrict international trade more than is necessary, to achieve a legitimate objective. TBT-related measures are subject to WTO rights and obligations, including dispute settlement provisions. EAS, in concert with other DFAIT divisions and government departments, promotes wide acceptance of and adherence to the TBT Agreement with respect to trade in the products of biotechnology as well as the TBT Agreement's Code of Good Practice, which applies to voluntary standards.

The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) governs food safety and animal and plant health, including products of biotechnology. The Agreement stipulates that SPS measures must be based on scientific principles and scientific evidence, must be applied only to the extent necessary and must

not result in unfair discrimination or disguised restrictions on trade. In force since 1995, the SPS Agreement established the Committee on Sanitary and Phytosanitary Measures (SPS Committee), which is responsible for the operation and implementation of the Agreement. The Committee generally meets three times a year. Here again, DFAIT works with other government departments to ensure Canada's representation and active participation in SPS Committee meetings.

Canada is playing a leading role in setting international standards for biotech foods and their labelling through the Codex Alimentarius Commission, established jointly by the Food and Agriculture Organization and the World Health Organization.

Canada chairs and participates in the Codex Committee on Food Labelling, which is developing guidance on the labelling of foods derived through biotechnology, and has chaired an international drafting group to provide further technical input on guidelines for the labelling of these foods. Through its participation in these committees, Canada is working to facilitate Canadian access to international markets which, in turn, fosters the development of Canadian biotech industries.

Training in biotechnology for the Trade Commissioner Service

To support its ongoing effort to improve the Trade Commissioner Service, the Canadian Biotechnology Strategy provided the Market Support Division of DFAIT with funding to deliver a series of six courses entitled *Capacity Building in Biotechnology*. The training was for trade commissioners, business development officers, science and technology counsellors, policy analysts posted abroad at Canadian missions and officers from other government departments who focus on major issues influencing the success of international business development and partnerships in biotechnology. The courses, delivered across Canada from July 2000 to June 2002, were developed in partnership with Canadian biotechnology associations, including: AgWest; BioNova; BC Biotech; BioQuebec; and the Ottawa Life Sciences Council.

The intensive two-day courses covered topics such as intellectual property rights, including copyright, trade marks, trade secrets, patents, accessing, vetting and qualifying key interlocutors. This training has enabled officers to help Canadian biotechnology organizations, companies and firms requiring assistance to advance and maintain international business relationships.

Early successes

Multilateral initiatives to reduce trade barriers

Under the WTO Technical Barriers to Trade (TBT) Agreement, DFAIT has lobbied hard for the removal of unnecessary or inappropriate regulatory, standards-based and conformity assessment-based trade barriers to maintain or enhance market access and lower costs to Canadian producers and exporters. Canada has raised concerns over other countries' proposals for unwarranted or unjustifiable barriers to products derived through biotechnology, as well as over mandatory requirements for non-product-related process and production method labelling of such products.

To assist the TBT Committee in addressing the labelling of biotech products, Canada has developed a framework for informal discussions which covers topics such as policy instruments for labelling, mandatory versus voluntary measures, harmonization and equivalency, and developing country considerations. The document can be found on the WTO Web site under its official document number G/TBT/W/174.

Canada also works to improve transparency, promote regulatory reform and good regulatory practice by WTO members, align or harmonize standards internationally and with trading partners and, if appropriate, negotiate mutual recognition agreements (MRAs) on conformity assessments. On this point, Canada has developed a policy approach to MRAs that assesses proposals on a case-by-case basis. The approach includes full consultation with federal and provincial regulatory and trade officials in their areas of jurisdiction as well as with stakeholders, including industry. This document is also available on the WTO Web site under document number G/TBT/W/167.

Bilateral initiatives to reduce trade barriers

DFAIT represents Canadian business interests in making both formal and informal bilateral representations on issues related to trade in products of biotechnology. Canada has undertaken outreach efforts whereby authorities from other countries are invited to visit Canada to meet with government officials, including those involved in regulation, in order to better understand Canadian policy with respect to products of biotechnology. In doing so, it is hoped that the Canadian regulatory model for biotech products will be reflected in the regulatory approaches taken by our trading partners, thereby reducing trade impediments for Canadian producers.

Biotechnology partnering

The department's Science and Technology Division received $50,000 in CBS funding through the Market Support Division (TCM) to develop and produce a biotechnology-partnering brochure when Canada hosted the BIO2002 convention and exhibition in June 2002. The

funding enabled the Division to develop an effective tool to enhance international awareness of Canada's R&D strength in biotechnology and to facilitate foreign investments in Canada's biotechnology R&D through international partnerships. These international technology and financing partnerships are resulting in technology and product commercialization in this country, providing high value-added employment for Canadians.

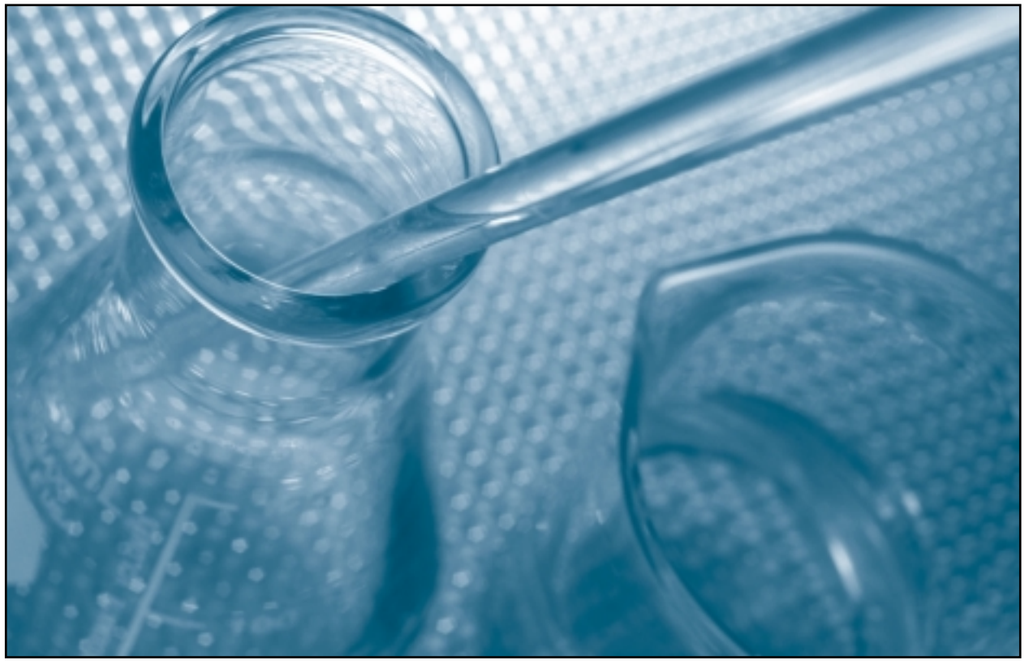
Positioning Canada's bioscience opportunities and capabilities

Identifying and capitalizing on Canada's competitive advantages – including a comparative analysis of innovative strategies and policies that support the industry's growth in major biotechnology centres around the world – are the objectives of initiatives being developed by the Trade Commissioner Service, with the support of CBS funding. The information gained will be compiled and made available to Canadian stakeholders to influence Canada's bioscience communications and marketing activities, including ways to raise awareness in target markets of Canada's comparative strengths and opportunities. The resulting communications and marketing activities will help raise the profile of, and better position, Canadian biotechnology companies in the world's most lucrative markets in advance of the thousands of new biotech products that will soon be on the market and the thousands more currently in the pipeline. This will help to ensure Canada stays ahead of the world's competition with the advent of new biotech products coming on-stream. It will also improve current product development in Canada by attracting and encouraging new partnerships, investment and future marketing opportunities.

International leadership

Canada is an active participant in the ongoing work programs of the TBT Committee and was a full participant in the Third Triennial Review of the Implementation and Operation of the Agreement on Technical Barriers to Trade conducted in November 2003. The review provided Canada with an opportunity to work toward further implementation of the Agreement. Canada's participation facilitated increased clarification, transparency, and implementation of the various rights and obligations stipulated in the Agreement, which may reduce technical barriers to trade among Canada's trading partners and facilitate the flow of Canadian goods to other countries.

Canada succeeded in encouraging Committee members to address and strengthen their approaches in areas such as transparency in the application of the Agreement, to commit to conducting information exchanges between members on good regulatory practices, to develop a work programme with a view to improving and promoting a better understanding of members' conformity assessment systems and to continue work in the provision of technical assistance to developing countries. The full report of the Third Triennial Review is available at the WTO docsonline Web site (http://docsonline.wto.org) under its official document number G/TBT/13.



Over the last year, the Sanitary and Phytosanitary Measures (SPS) Committee has continued to focus its efforts on the implementation concerns of developing countries. In particular, the Committee has considered, as a priority, the implementation constraints facing developing countries, including accessing the special and differential (S&D) treatment provisions of the SPS Agreement. Canada tabled a proposal that would provide members with information concerning the provision of S&D treatment through the transparency obligations of the Agreement, thereby encouraging more extensive use of the S&D provisions. The Committee has also considered issues such as equivalence, transparency and technical assistance.

The SPS Committee is increasingly being used by Canada and other WTO members, including developing-country members, as a forum for raising bilateral issues. In 2002, WTO members raised more bilateral issues than ever before. Canada introduced 13 bilateral issues, including the European Union's moratorium on genetically modified organisms (GMOs) and China's regulations governing GMOs.

International business development

Sectoral learning programs administered by the Marker Support Division of DFAIT, supported by the CBS, have greatly augmented the capacity of the Trade Commissioner Service and other personnel engaged in international trade to increase the number of Canadian biotechnology companies successfully exploring international business. Officers based in Canada and posted abroad have been trained to effectively troubleshoot on behalf of Canadian biotechnology interests, particularly in areas of prospective strategic alliances, intellectual property rights and the regulatory environment as it affects commercial and research institute relationships.

The programs have also increased the level of interdisciplinary expertise vis-a-vis all applications and component technologies of biotechnology. This has been accomplished by developing and facilitating module courses, ensuring information is available online, and arranging for key personnel to attend activities and events in biotechnology that will further result in the increased capacity and effectiveness of the Trade Commissioner Service.

Heightened international awareness of Canada's strength in biotechnology

Many organizations in Canada, including government and industry, play a role in promoting Canadian bioscience capabilities. U.S. Business Development Division (NUB) determined that these partners could benefit from sharing information and working together to maximize assistance to the 400 or so biotech companies operating in Canada. It became apparent that common messaging and look in public outreach materials would be essential to "brand" Canada's biotech sector.

Under the leadership of NUB, a team was struck and became known as the Canada Bioscience Group. Its goal is to ensure that information about the sector looks and sounds alike, all of which contributes to a powerful, coherent and integrated marketing effort. The team has created a marketing strategy and information kit for trade commissioners to use in the U.S. marketplace to promote Canada's bioscience capabilities in the U.S. market.

The Group is linked by a password-protected extranet site, which houses the marketing kit. Partners are encouraged to use these shared material and messages when promoting Canadian capabilities. Messages are evergreen and updated regularly by partners to ensure currency, consistency and accuracy.

By organizing partnering events in Canada and targeted foreign countries, the department's Science and Technology Division has also raised the global profile of Canada's biotechnology strength and technology partnering opportunities. Several international collaboration agreements concluded between Canada's leading biotechnology organizations and their foreign counterparts are the result of leads generated at these international partnering events. In fact, many of these leads are still being developed by Canadian participants.

VIII.

Health Canada

Health Canada

Maintaining and improving Canadians' health

Biotechnology, like any new technology, offers both potential benefits and risks. While Canadians readily accept innovations such as new vaccines to prevent disease, replacement heart valves that are better accepted by the body, or treatments for human infertility, they have understandable reservations about biotechnology applications that may compromise public or environmental health and safety.

In keeping with Health Canada's mandate to maintain and improve Canadians' health, Health Canada manages biotechnology's potential risks while garnering its benefits. Key to capturing the benefits is strong research and policy development, solid science-based regulation, accessible information for sound decision making, and involving Canadians directly in decisions about the technology's development.

Research

Health Canada undertakes biotechnology-related research in health policy, regulation, population and public health, healthy environments and consumer safety, and health products and food. Research projects at Health Canada fall under the following themes:

- building biotechnology capacity (scientific, technical and human resources)
- public awareness
- efficiency, effectiveness and timeliness of the regulatory system
- generating knowledge
- genomics

Policy development

Health Canada works with other federal departments/agencies and international organizations to develop sound, science-based policies for the regulation of biotechnology. Some areas of policy development include:

- social and ethical considerations factored into the risk management of biotechnology products, including genetic technology
- the impact of intellectual property on Canada's health system, particularly concerning higher life forms and human genetic material
- pharmacogenomics (the study of how an individual's genetic inheritance affects the body's response to drugs)
- human genetic information and privacy
- governance of health research involving humans
- assisted human reproduction and related research
- assessment of technology for determining genetic health
- genetics and public health
- risk management

Health Canada is a member of the Biotechnology Assistant Deputy Minister Coordinating Committee (BACC), a government-wide committee that provides federal leadership and policy direction, which identified three "pillars" to guide the work of the Canadian Biotechnology Strategy: Stewardship; Citizen Engagement; and Innovation. Health Canada chairs the "Stewardship" pillar and was key in establishing a BACC sub-group to specifically address stewardship and regulatory issues.

Early successes

Health Canada has many successes in its contribution to responsible regulation and use of biotechnology in Canada. Following are some of Health Canada's important milestones:

Framework for biotechnology

Health Canada has a framework for biotechnology, which clearly describes the department's responsibilities and priorities, identifies opportunities and challenges, and lists guiding principles and strategies. Priority areas include:

- Enhanced scientific and regulatory capacity to keep ahead of the technology as it evolves
- Genetic technology and its social impacts
- Evaluation of any potential long-term environmental and health impacts of genetically modified organisms
- Preparation for potential emergencies such as bioterrorism
- Public awareness of and engagement of Canadians on biotechnology

Biotechnology stewardship

In growing recognition that appropriate governance of biotechnology is broader than a science-based regulatory system, Health Canada is leading the Government of Canada's effort to develop a federal biotechnology stewardship framework. This framework will further protect the health and safety of Canadians and their environment, while ensuring social and ethical issues are addressed and that the economic impacts of this transformative technology are considered.

As the lead department for stewardship, Health Canada hosted a workshop in June 2003 to develop a common understanding of biotechnology stewardship and government's role, and to develop a path forward to create a stewardship framework. Health Canada's Environmental Assessment Unit was established in 2001 to assess the environmental impacts of biotechnology substances in products governed by the *Food and Drugs Act*, as well as their potential for indirect impacts to human health.

Internationally, Health Canada receives world-wide recognition as having a first-class regulatory system. This has resulted in many requests for capacity building in lesser-developed countries and for inquiries from foreign biotechnology companies wanting to invest in Canada.

Enhancing regulatory rigour

Canada already has one of the most rigorous regulatory systems in the world for the

protection and enhancement of Canadians' health, protection of the environment and innovation in health care. In December 1999, the ministers of Health, Agriculture and Agri-Food, and Environment asked the Royal Society of Canada to establish an independent expert panel to examine future scientific developments in food biotechnology and to advise the federal government on the science capacity it needs to continue to ensure the safety of new food products developed through biotechnology.

The Royal Society released its report and recommendations in February 2001. The Government of Canada, led by Health Canada, responded with a detailed action plan to address each of the recommendations. Since then, Health Canada has provided four progress reports. Steps taken to date, in response to the Royal Society's advice, have helped ensure the effective regulation of biotechnology-derived food products.

Developing a Canadian labelling system for genetically engineered (GE) foods

Health Canada has the mandate to ensure appropriate labelling when there are health and safety issues, such as the presence of an allergen in a food, or when the nutrition or composition of the food has been changed. Labelling for health and safety remain its priority. Under a committee established by the Canadian General Standards Board (CGSB), a draft Canadian standard was developed for voluntary labelling to indicate whether a food has – or has not – been developed through the use of biotechnology. Over 50 organizations, including a broad range of stakeholders – consumer groups, food producers and manufacturers, universities and government – were involved in this process. Consensus on the labelling standard was reached in September 2003. The purpose of the labelling standard is to provide guidance to industry on labelling of GE foods to develop meaningful criteria for labelling, understandable messages for consumers that are not false or misleading and a consistent policy to verify the truthfulness of labels and, in so doing, provide consumers with informed choice.

Assessing the safety of foods derived from biotechnology

Health Canada is a key player in regulating biotechnology-derived food products. This includes genetically engineered (GE), genetically modified (GM) and other novel foods. The department's scientists – with individual expertise in molecular biology, toxicology, chemistry, nutritional sciences and microbiology – look at the process used to develop a food product. They assess the chemical and nutritional composition of the food and whether there is the presence of, or potential for, production of a toxin or allergenic substance in the food. Only if all of Health Canada's stringent criteria are met is a biotechnology-derived food allowed for sale in Canada.

Draft revisions to guidelines for assessing novel foods

Consistent with its commitment to continually enhance regulatory processes and protocols, Health Canada updated its *Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms*. These Guidelines detail the information requirements that must be considered in assessing the safety of GM and other novel foods derived from plants and microorganisms. As well, the Guidelines reflect advances in science and relevant national and international expert advice on safety assessment.

Public/stakeholder engagement

Because public engagement and input is essential to understanding biotechnology's potential benefits and risks, Health Canada has informed and sought feedback from individual Canadians and other stakeholders on biotechnology-related issues through numerous initiatives since 1999, including:

- Stakeholder consultations on genetic information and privacy, as well as governance of health research involving humans
- Public consultation on xenotransplantation[1]
- Public opinion research on biotechnology issues conducted twice yearly over four years
- Citizen conference on food biotechnology
- Public consultations on the regulation of genetically modified and other novel foods
- Public consultation on revised guidelines for the safety assessment of genetically modified and other novel foods
- Public consultation on revised guidelines for the environmental assessment of genetically modified plants
- Health Canada's Public Advisory Committee (PAC) consultation on Health Canada's Communications Plan for biotechnology

Health Canada is currently drafting guidelines for the Safety Assessment of Livestock Animals and Fish Derived from Biotechnology. They will also be the focus of ongoing consultations with Canadians.

Keeping pace with new technologies

Federal departments, including HC, are working cooperatively to establish clear authorities, regulations and guidelines for animal biotechnology in Canada. Health Canada also continues to collaborate with international experts to establish a sound approach to the regulation and assessment of animal biotechnology related to global trade.

Other new technologies include "molecular pharming," which involves growing and harvesting genetically modified crops for the production of biological pharmaceuticals or industrial materials, rather than for food production. The department works closely with its partners to determine the issues to consider regarding this technology.

Improving transparency

Health Canada and the Canadian Food Inspection Agency (CFIA), in cooperation with CropLife Canada – the trade association representing developers of biotechnology-derived plant products for use in agriculture – are conducting a pilot project to post information on the Internet about the safety assessments of biotechnology-derived crops, livestock feeds, and foods.

[1]Xenotransplantation is the transfer of living cells, tissues and/or organs from one species to another, including animal to human.

This is the first time in Canada that the public will be notified of new biotechnology product submissions under review by government and have access to a list of the scientific studies conducted on the products regarding safety. The project gives Canadians an opportunity to provide input, via the CFIA Web site, on scientific matters relevant to the safety assessment of new products.

Responding to emergencies

Health Canada plays an essential primary role in national emergencies, whether caused by humans or a natural disaster, in order to protect the health of Canadians. The department's Centre for Emergency Preparedness and Response serves as the country's single coordinating point for health security in Canada and for dealing with public health emergencies. The Centre, which is active 24 hours a day, seven days a week, works closely with departmental experts in areas such as infectious disease, food, blood, nuclear emergencies and chemicals.

Scientific expertise

Health Canada's National Microbiology Laboratory is Canada's first biosafety Level 4 laboratory, which allows scientists and researchers to work safely with the most serious human and animal pathogens (e.g., hantavirus, hepatitis and influenza viruses), and to carry out research and diagnostic programs with some of the most virulent strains of viruses (e.g., SARS, West Nile virus, the Ebola virus, Marburg virus and Lassa fever). It was scientists at the National Microbiology Lab who isolated the SARS virus and, in collaboration with the British Columbia Genome Centre at the B.C. Cancer Agency, identified the genetic sequence of the virus.

Health Canada at work with global partners

Biosafety Protocol

Canada is a signatory to the Cartagena Protocol on Biosafety, which was negotiated under the United Nations Convention on Biological Diversity. The Protocol addresses transboundary movement of living modified organisms that are products of modern biotechnology. This allows countries to determine whether such movement could have adverse effects on their biodiversity. Health Canada, along with other federal departments, is developing tools of ratification (e.g., new regulations) that would put Canada in a position to ratify the Protocol.

Organisation for Economic Co-operation and Development (OECD)

Health Canada actively participates in the OECD Working Group on Harmonization of Regulatory Oversight in Biotechnology, and the Task Force for the Safety of Novel Food and Feeds. The department also plays a significant role in shaping international policies that impact all OECD member countries, including Canada. The OECD guidance document on the use of taxonomy in risk assessment of microorganisms (which Health Canada co-wrote with the U.S. Environmental Protection Agency), was published in 2003. Health Canada also sits on the Working Group on Human Health-Related Biotechnologies and the Working Party for Biotechnology, and contributes to activities related to issues such as: xenotransplantation;[2] genetic testing and privacy; infection and immunity; and drinking water. The department also coordinated Canada's involvement in OECD's *International Survey of Quality Assurance in Genetic Testing Labs*, and will co-chair the spring 2004 OECD Workshop on Human Genetic Information in Research Databases – Issues of Privacy and Security.

Codex Committee on Food Labelling (CCFL)

The CCFL, part of the international Food and Agriculture Organization based in Rome, is responsible for preparing international standards and guidelines for labelling food products. The Committee also studies specific problems, such as the labelling of genetically modified (GM) foods. In Canada, Health Canada leads this international work in conjunction with the Canadian Food Inspection Agency (CFIA).

[2]Xenotransplantation is not currently a recognized medical practice in Canada. When put in place, a new regulatory framework would facilitate the review of clinical trial applications for xenotransplantation, and help ensure the safety of patients, their families and all those involved.

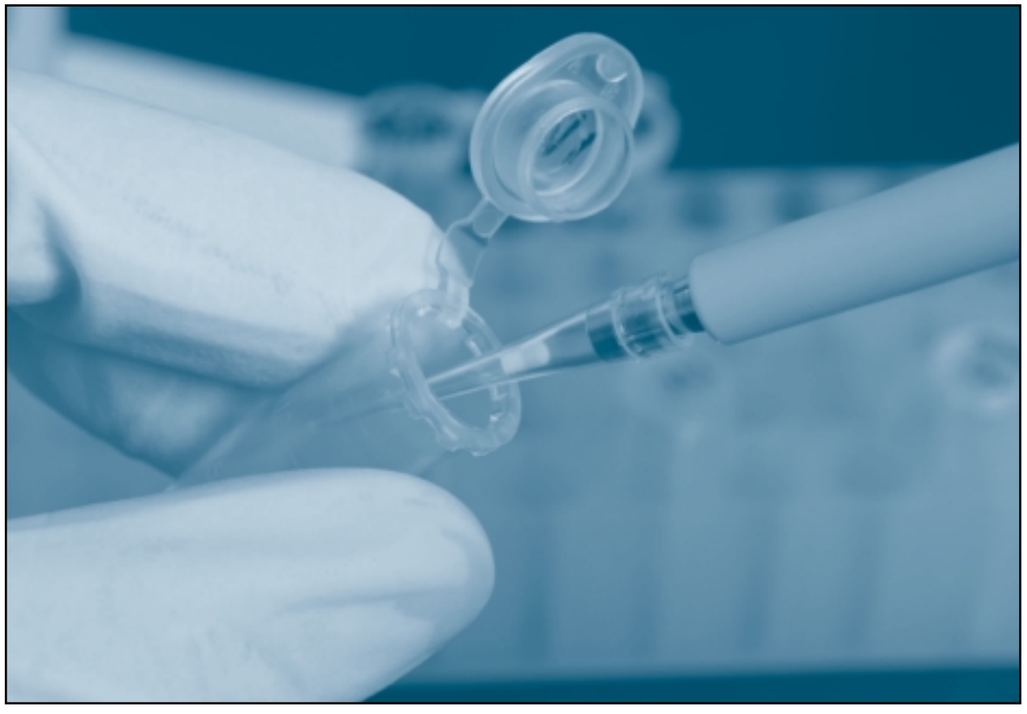
IX.

Industry Canada

Industry Canada

Harnessing the benefits of biotechnology

An explosion of extraordinary advances in molecular biology, genetics and biochemistry – the life sciences – has spawned a broad array of biotechnology products and services which are transforming everything from the foods people eat, to the integrity of the physical environment, to the quality of health care Canadians receive. A key contributor to the knowledge-based economy, biotechnology generates new jobs and business opportunities, and supports the competitiveness of some of Canada's most important industries.



Industry Canada (IC) enables biotechnology's development by ensuring that Canadians can conduct research, commercialize, adopt technology and, as a result, grow stronger, more productive businesses. The department provides access to information technology so Canadians can acquire the necessary knowledge to develop their skills, stay abreast of new technological developments, conduct business transactions and gain access to new ideas that lead to innovative technological advancements.

Equally important, IC fosters the stability and efficiency needed in the Canadian marketplace to conduct business and maintain consumer trust in business transactions as well as the goods and services produced. It works to increase investor awareness and confidence in Canada as an investment location of choice and to encourage domestic and foreign direct investment, which benefits Canadians in business development and job creation. Among its many services, the department introduces Canadian businesses to new technologies, helps them upgrade their management and marketing skills, and provides wider access to markets. It also works with Canadians to increase the number of exporting firms, which are typically more profitable and generate more jobs, providing higher salaries to employees of these firms.

Contributions to the CBS

Investing in discovery

Most Canadian biotechnology discoveries have been built on research originating in Canadian universities, research hospitals and government laboratories. To fuel this innovation, basic research funding is critical. Industry Canada contributes to scientific breakthroughs by funding the Canada Foundation for Innovation, the Canada Research Chairs Program, Networks of Centres of Excellence and Genome Canada.

Genome Canada, for example, was set up by IC to enable Canada to become a world leader in genomics and proteomics research in key areas such as agriculture, environment, fisheries, forestry and health. New drug therapies, improved diagnostics, personalized medicines, more nutritious foods, more bountiful crop yields and a cleaner environment are just some of the benefits deriving from genomics research. More details about the work of Genome Canada can be found on page 62 of this chapter.

Given the breakneck pace of such developments, much of Canada's biotechnology research has become increasingly complex. It often involves teams that operate globally, huge repositories of research and observational data, and high performance computers to perform simulations and visualize results. Innovation, therefore, requires access to information technology infrastructure. Industry Canada supports world-class biotechnology research by investing in organizations like CANARIE Inc., a not-for-profit corporation working to expand Canada's national research network to allow Canadian researchers to create high-capacity connections and computing resources.

To fully capture the social and economic benefits of federal investments in basic research and information technology, there must be opportunities to translate new discoveries into biotechnology products and services through commercialization. To facilitate and accelerate these developments, Industry Canada has created the Life Sciences e-Technology Transfer, a searchable database of domestic and international licensing opportunities, as well as the Commercialization Portal, a comprehensive source of information on business development.

In addition, government programs such as Technology Partnerships Canada provide repayable investments to spur the evolution of innovative technologies. Investment Partnerships Canada (IPC) raises awareness of Canada internationally as a location of choice for foreign investment. When foreign firms are looking to invest in Canada, IPC offers assistance in providing site selection data, advice on programs, regulations, transportation and taxation, as well as introductions to key government and private sector contacts. And the Business Development Bank of Canada, a financial institution wholly owned by the Government of Canada, announced in 2002 that it would target $200 million in venture capital investments to the biotechnology sector over the following five years.

Industry-government partnerships also bolster the development of biotechnology products and services. These partnerships allow timely information flow among all stakeholders to accelerate the pace of technology transfer and to improve the odds of commercializing discoveries. For instance, Industry Canada supports Bio-Products Canada, an industry-led, not-for-profit organization. Given that bioproduct technologies embrace many sectors – from wood-based products to chemicals and fuels – Bio-Products Canada plays a critical coordinating role in identifying opportunities and providing advice to drive research and development agendas.

Finally, technology foresight is essential to plan effective research strategies that will eventually lead to the commercialization of bio-based products and services. Industry Canada

has worked over the last few years to link research, capital, training and commercialization organizations, encouraging them to look 10 to 20 years into the future in order to determine what the market will require.

Having determined those needs, industry then identifies the technologies that must be developed to meet future market demand and strategizes the best way to attain these targets. Industry Canada representatives act as facilitators and catalysts in developing these "technology roadmaps" for high-growth sectors such as biopharmaceuticals.

Creating a better business climate

The growth of the biotechnology industry requires world-class business and regulatory regimes that nurture innovation and build public trust and confidence. Industry Canada supports such a competitive business climate by monitoring key marketplace frameworks such as intellectual property and regulations. The department then participates in initiatives to promote the creation of optimal conditions to attract and retain biotechnology companies while also protecting the public interest.

Given the complex nature of biotechnology, the examination and processing of biotechnology patent applications generally takes longer compared with other technologies. The Canadian Intellectual Property Office (CIPO) provides an online Manual of Patent Office Practice that describes the scope of patentable subject matter, including in the field of biotechnology, as well as the manner of application of the patentability criteria. The recruitment and hiring of new examiners has been stepped up appreciably to cope with the increasing volume of applications and to reduce the time required to grant patents. CIPO's current performance standard is a 24-month turn-around. The Office is committed to reducing the time to process applications to 18 months by 2004.

With its advanced level of electronic filing and e-commerce, CIPO remains one of the leading mid-sized intellectual property offices in the world, employing innovation in its business practices to enhance its services and performance. Given the importance of intellectual property and regulatory systems in strengthening Canada's biotechnology community, Industry Canada has worked with partners to provide online information products for industry and others interested in knowing more about the Canadian federal and provincial acts and regulations.

As crucial as marketplace frameworks are highly qualified people who can capitalize on a competitive business climate. The biotechnology community has stated there is a critical need for experienced senior management in Canadian biotechnology companies. Often, biotechnology failures are attributed to a lack of experienced managers who can take a firm beyond the initial development stages to successful licensing and commercialization. For biotechnology to flourish in Canada, the current skills gap faced by the sector must be addressed.

Industry Canada is working with industry to develop, attract and retain talent, and upgrade the skills of the population to fuel Canada's innovation performance. Efforts have been undertaken to improve processes to recognize foreign credentials, encourage multidisciplinary skills development and provide incentives to increase in-house training and apprenticeships.

A feasibility study published in 2001 recommended a one-year national training program to support the sector. In 2002, the department, in collaboration with the Biotechnology Human Resource Council (BHRC), developed the design and cost estimates for the graduate level program which will focus on regulatory requirements and processes, business development, technology transfer, intellectual property and management skills.

Consumer concerns surrounding biotechnology are addressed within Industry Canada by the Office of Consumers Affairs (OCA), whose mandate is to protect and promote the consumer interest. In order to understand consumers' reactions to and perceptions of biotechnology, the OCA has funded a number of research projects. The research results contribute to the formulation of government policies to ensure they reflect and respond to public consumer policy priorities, such as the issues surrounding genetic privacy and the labelling of genetically engineered foods. The OCA has worked on the Canadian General Standards Board Committee to develop a Standard for the Labelling of Foods that are and are not products of genetic engineering, and participates in a working group on Genetic Information and Privacy, established under the Canadian Biotechnology Strategy.

The Life Sciences Branch of Industry Canada also participates in the same working group on Genetic Information and Privacy. During the 2002-2003 fiscal year, it commissioned a Statistics Canada survey of Canadian biotechnology companies to gain a better understanding of how much material is being held by companies, how they are obtaining and storing this material, and what steps are being taken to protect the privacy of Canadians.

Supporting investment and trade

Attracting and retaining investment is vital to the Canadian economy and the biotechnology industry in particular. A long, costly and risky development process requires significant investment and venture capital from domestic government financing as well as multinational corporations.

Securing new investments and building greater international awareness of Canadian excellence in biotechnology requires sophisticated communications tools used in conjunction with targeted conferences, expositions and sector-based marketing. Industry Canada, Investment Partnerships Canada and the Canadian Institutes of Health Research established the Life Sciences Investment Roundtable to link Canadian R&D with industry interests. It has helped Canada attract numerous investments, primarily from multinational pharmaceutical and biotechnology companies.

With a small domestic market, Canadian biotechnology companies rely on international trade for growth. Recognizing the increasing number of products in the pipeline, the Government of Canada and industry have been marketing Canada's biotechnology capability more aggressively abroad.

Over the past five years, partnering events have taken place in New York, Boston, Tokyo, Singapore and Taiwan. With its sector expertise, Industry Canada coordinates efforts among other federal departments at international biotechnology trade shows, incoming and outgoing business missions, seminars and match-making events. Biotechnology firms also benefit from IC's programs and services for new exporters, which are delivered through International Trade Centres located in every province across Canada.

The department worked with the federal community to launch the Canadian presence at Biotechnology Industry Organization (BIO), held in June 2002 in Toronto. BIO is the world's largest and most important biotechnology conference and trade show. The 198 firms that completed a detailed questionnaire during BIO 2002 reported that 97 percent of the Canadian companies exhibiting identified sales leads and 73 percent made on-site sales.

Early successes

Industry Canada strives to foster a growing, competitive, knowledge-based Canadian economy. Many of the department's policies, programs and services specifically focus on accelerating sustainable economic benefits from biotechnology to improve Canadians' quality of life. The department funds the work of the following organizations and agencies which are at the forefront of biotechnology innovation:

The innovative research of the Networks of Centres of Excellence has spun off 15 biotech companies in the past three years. Among them is GLYCODesign Incorporated, which became publicly traded in 2000 and now employs almost 100 people. The company's lead anti-cancer compound, GD0039, blocks the production of specific carbohydrates that coat the outside of cancer cells and restores some degree of growth control. In animal models, tumour growth has been slowed by the compound and the spread has been blocked. The anti-cancer product is in Phase II clinical trials and is targeted at treating metastatic renal cancer, which is resistant to chemotherapy. The compound may be used in conjunction with chemotherapy for other cancers, which could allow smaller toxic doses than usual. The company expects to have this treatment on the market in 2005.

Networks of Centres of Excellence

Networks of Centres of Excellence (NCE) are unique partnerships among universities, industry, government and non-governmental organizations aimed at turning Canadian research and entrepreneurial talent into economic and social benefits for all Canadians. An integral part of the federal government's Innovation Strategy, these nation-wide, multidisciplinary and multisectoral research partnerships connect excellent research with industrial know-how and strategic investment.

The Government of Canada, through NCE, has invested close to $30 million annually since 1998 in seven networks undertaking work with biotech dimensions, including: the Canadian Bacterial Diseases Network, the Canadian Genetic Diseases Network, the Protein Engineering Network of Centres of Excellence, the Canadian Network for Vaccines and Immunotherapeutics, the Canadian Arthritis Network, the Canadian Stroke Network and the Canadian Stem Cell Network. In addition to their own research studies, more than 770 researchers at these centres are training over 1,600 students and other highly qualified personnel for the biotechnology sector.

The leading-edge research carried out at these networks is resulting in improved treatments of the most common human diseases and developmental deficits as well as new vaccines. Examples of NCE innovations include the development of a cattle vaccine against the deadly *E. coli* bacteria. Canadians are familiar with *E. coli* because of the Walkerton tragedy in which seven people lost their lives and more than 2,000 became ill. The vaccine reduces the number of organisms in cattle and cattle manure which, in turn, reduces the risk of contaminating food and water.

Canada's Innovation Strategy

More than 10,000 Canadians, including members of the biotechnology community, voiced their views about how to create a culture of innovation and learning across Canada during public consultations held in 2002. This input helped to shape the Government of Canada's Innovation Strategy, which aims to move Canada to the front ranks of the world's most innovative countries.

Biotechnology has the potential to be a major contributor to many of the Innovation Strategy's targets and objectives, including the government's goal to double R&D, better commercialize Canadian research, and modernize our business and regulatory policies. More important, there is a clear potential for the biotechnology sector to provide health and environmental benefits for Canadians. The recommendations and commitments received from the biotechnology community will help to shape the government's national action plan for innovation.

Canada Foundation for Innovation

The Canada Foundation for Innovation (CFI), established in 1997 as an independent organization operating at arm's length from government, is helping universities and research institutes to build up Canada's research infrastructure. The CFI fosters innovative, multidisciplinary research by providing state-of-the-art research facilities and equipment in Canadian universities, colleges and hospitals. A significant and growing portion of the CFI's federally funded budget is dedicated to enabling fundamental biological research, the foundation of biotechnological advances.

To date, the CFI has helped finance 650 research projects in biotechnology valued at $350 million. This funding provides the essential research equipment needed to support research teams. It also enables institutions to recruit outstanding new researchers and to retain Canada's current research leaders.

The CFI's funding supports research in a broad and diverse range of areas, including: genomics and stem cells; vaccines; improving the quality and sustainability of the Canadian natural environment and its forest industry; and in the treatment of waste water. This research is making significant contributions to the Canadian economy, the environment and to the health and well-being of Canadians, and is helping to keep Canada among the leading countries in biotechnology research.

Canada Research Chairs

In 2000, the Government of Canada provided $900 million to support the establishment of 2,000 Canada Research Chairs to enable Canadian universities, together with their affiliated research institutes and hospitals, to achieve the highest levels of research excellence to become world-class research centres in the global, knowledge-based economy. As of June 2003, the Government of Canada had invested $220.5 million to create 201 Canada Research Chairs focused on biotechnology.

This represents an investment of $192 million from the Canada Research Chairs Program and $28.5 million in infrastructure funding from the CFI. These biotech researchers are making advances in areas as diverse as identifying genes that cause food and water-borne illnesses, developing artificial limbs, researching effective treatments for blood vessel abnormalities and examining the implications of genetic engineering.

Technology Partnerships Canada

The Technology Partnerships Canada (TPC) investment program is a key instrument of Canada's Innovation Strategy that is helping innovative Canadian biotech companies advance great ideas to get them to market. TPC's biotech investments enable companies to develop pioneering technologies, pursue significant medical breakthroughs, strengthen their R&D capacity through a wide variety of alliances, and provide new career opportunities within businesses across the country.

TPC-funded initiatives include promising Canadian biotechnology applications ranging from health care to agriculture, energy and aquaculture. Biotech investments in health, particularly, are helping position Canada as a location of choice for medical biotech R&D and strengthening Canada's position as a world leader in cancer vaccine research.

TPC investments have enabled successful medical breakthroughs such as the revolutionary cancer treatment Theralux™, developed by Celmed BioSciences of Montréal. The company believes it has discovered the answer to the challenge of helping the 70 percent of cancer patients who need a bone marrow transplant but are unable to find a compatible donor.

After determining this leading-edge technology was worthy of taxpayers' backing, in November 1999, TPC invested $4.6 million to advance clinical trials on Theralux™. The company's photodynamic therapy (PDT) technology is designed to destroy cancer cells in a patient's own bone marrow or blood outside the body. Theralux™ works by using a proprietary drug, TH9402, to selectively kill cancer cells when exposed to light.

More than 100,000 heart patients worldwide who annually require heart transplants could soon benefit from TPC investments in Ottawa-based World Heart Corporation, developers of the HeartSaverVAD™ ventricular assist device that helps a patient's weakened heart circulate blood. Only about 4,000 transplantable hearts are available each year, leaving roughly 95 percent of heart patients in need of treatment. This technology is projected to fill that gap; it is believed that HeartSaverVAD™ may, one day, become as common as a pacemaker.

In 1996, World Heart acquired the worldwide rights to ventricular assist device (VAD) technology, the basis for the HeartSaverVAD™, from its developers at the University of Ottawa Heart Institute and, with a $9.98 million repayable investment in November 2001, from TPC, undertook clinical trials in partnership with the university. With continued investment from TPC, the improved device should be available on the market by 2007.

Online information products and services

Online information products available at the Biotechnology Gateway (http://strategis.gc.ca/bio) strengthen Industry Canada's capacity to promote public awareness of biotechnology, increase the transparency of the regulatory system and merge scientific innovation with business knowledge, thereby fostering growth in the Canadian life sciences industry.

Additional sites with valuable information about biotechnology can be accessed through the department's Life Sciences Web site (http://strategis.gc.ca/lsb), including:

- Life Sciences e-Technology Transfer (LSeTT) provides one consolidated access point to licensing opportunities worldwide
- The Commercialization Portal enables life science companies to unite their scientific innovations with the requisite business knowledge needed for successful product commercialization
- BRAVO – the Biotechnology Regulatory Assistance Virtual Office – is a guide that provides industry with access to various governmental acts, regulations and guidelines that apply to Canadian biotechnology products and applications
- *Biotechnology and the Consumer* is an information tool to help Canadian consumers better understand biotechnology products and surrounding issues by examining the science, ethics, and social and regulatory impacts of biotechnology

Genomics **is a discipline that aims to decipher and understand the entire genetic information content of an organism; it is fundamental to all biological and biotech research. It differs from classical biological research in its large scale, broad scope and intense reliance on data collection, analysis and information technology (bioinformatics). It is widely recognized as the key to the future of the biotechnology industry, providing the essential science base for a wide range of biotech applications.**

Proteomics **is the study of the full set of proteins encoded by a genome.**

Genome Canada

Genomics is rapidly changing the way we understand nature, including the nature of humans. This fast-evolving field, aimed at "cracking the code of life," holds the promise of unprecedented scientific breakthroughs that may lead to new treatments and even cures for diseases, plentiful, healthier foods and a cleaner environment.

Genome Canada is an arm's length, not-for-profit corporation that serves as the primary funding and information resource for genomics and proteomics in Canada. Its mission is to develop and implement a national strategy in genomics and proteomics research for the benefit of all Canadians.

The corporation has received $375 million from the Government of Canada to date to establish five Genome Centres across the country (Atlantic, Quebec, Ontario, Prairies and British Columbia) and to ensure that Canada becomes a world leader in genomics and proteomics research. Together with its five Centres and other partners, Genome Canada invests and manages large-scale research projects in selected areas such as agriculture, environment, fisheries, forestry, health and new technology development. Genome Canada also supports research projects studying and analyzing the ethical, environmental, economic, legal and social issues related to genomics research.

Genome Canada has leveraged its federal contribution by securing approximately $300 million more from provincial governments, industry, not-for-profit organizations, international agencies and other partners. When these contributions are added, this amounts to almost $680 million available for the 57 innovative science and technology platforms and genomics and proteomics research projects undertaken thus far.

Some of these projects will help develop tools that will bridge the gap between basic discovery research and practical application in hospitals and community clinics. A recent example was the sequencing of the SARS virus through the use of Genome Canada's funded platform in Vancouver. The investments made by Genome Canada and Genome BC in that platform allowed Canada to be first in the world to sequence the virus.

Other research projects focus on finding solutions to agriculture pollution and environmental challenges. One such Genome Canada project is looking at alternatives to high-cost fertilizers like *Sinorhizobium meliloti*, a soil bacterium that shares a natural symbiotic relationship with plants. By sequencing these bacteria, researchers will be able to use them as replacements for harmful nitrogen fertilizers.

Genome Canada is conducting some of the most interesting, innovative and significant genomics and proteomics research in the world, positioning Canada at the leading edge for years to come. Genome Canada is also connecting Canada's best researchers with the world's best. Genome Canada's International Consortium Initiative program led to the approval, in March 2003, of the largest international health research project ever funded in Canada: the Structural Genomics Consortium. The $95 million project, aimed at unravelling the structure of hundreds of proteins, is believed to be significant to human health. Partners include four other Canadian organizations, the United Kingdom's Wellcome Trust and the pharmaceutical company GlaxoSmithKline.

Genome Canada has a number of international agreements and collaborates with many countries including Denmark, the Netherlands, Spain, Sweden, the UK and the USA in multinational projects. One such initiative is the International HapMap Project, a $150 million international consortium aimed at speeding the discovery of genes related to common illnesses such as asthma, cancer, diabetes and heart disease.

Because the potential of genomics is so profound, it is essential that Canadians have a firm grasp of its implications in order to make informed decisions about its many applications. In 2003, Genome Canada launched a major public outreach and education project – the GEEE! in Genome – an interactive multidimensional exhibit, officially opened by the Prime Minister at the Canadian Museum of Nature in April, that is travelling to nine cities across Canada. Through this exhibition, Canadians will learn about the structure of DNA, the role of genes and proteins, and catch a glimpse of the substantial role Canada is playing in the genomics revolution.

For a complete list and comprehensive description of all 57 projects and information about Genome Canada programs, policies and initiatives, please visit: www.genomecanada.ca/projects

National Research Council Canada

National Research Council Canada

Science at work for Canada

Research and innovation are critical to Canada's continued economic growth and an improved quality of life for its citizens. To remain internationally competitive in the 21st century, Canada must become recognized as a nation of innovators – one in which all sectors of society benefit from a globally focused, networked and innovative knowledge economy. Innovation, however, does not simply happen; it requires long-term and strategically directed investments in research, people, infrastructure, networks and relationships.

The National Research Council Canada (NRC) is committed to providing leadership in biotechnology innovation and creating long-term benefits for Canadians. By working with industry, academia, and government, NRC is increasing the effectiveness of Canada's innovation system by fostering national and international networks, and community-based technology clusters. Such efforts are helping better Canadians' quality of life, improve the environment, protect health and create new sources of wealth.

NRC's biotechnology program

A reflection of the technology's growing importance to Canada is NRC's investment in biotechnology research, which has mushroomed from $80 million in 1998 to $130 million in 2003. There are some 1,500 scientists, students and guest workers currently conducting biotechnology-related research at NRC sites across the country.

NRC has organized its biotechnology strengths into a strategic group that includes plant biotechnology (NRC Plant Biotechnology Institute in Saskatoon), marine biosciences (NRC Institute for Marine Biosciences in Halifax), biopharmaceutical research (NRC Institute for Biological Sciences in Ottawa and the NRC Biotechnology Research Institute in Montréal), and biodiagnostics (NRC Institute for Biodiagnostics in Winnipeg).

NRC capacities in other fields – such as information technology, new materials, manufacturing technologies, nanotechnology, metrology and photonics – are being coupled with dedicated biotechnology resources to address critical issues in health, the environment, agriculture, aquaculture and other fields of importance to Canadians. The NRC Industrial Research Assistance Program provides technology support to Canadian firms while the NRC Canada Institute for Scientific and Technical Information provides information access and dissemination.

NRC at the frontiers of discovery

Today's research creates tomorrow's opportunities. NRC's biotechnology program pursues strategically focused research and development (R&D) to strengthen Canada's innovation and technology capacity, to support Canadian industry, to seek solutions to national challenges in health, agriculture, the environment and aquaculture, and to lay the knowledge foundations for Canada's future growth.

Building national R&D capacity

NRC has invested in biotechnology R&D facilities, programs and networks in every part of Canada. These investments are helping Canada build reserves of knowledge, the most important currency in a knowledge economy. NRC's contributions to national infrastructure create new opportunities and provide leverage to Canada's R&D investments.

In 2002, NRC established its National Institute for Nanotechnology (NINT), a $120 million world-class facility to be located on the campus of the University of Alberta in Edmonton. NINT is multidisciplinary in scope, integrating NRC and its partners' strengths in physics, chemistry, engineering, biotechnology, informatics, pharmaceuticals, medicine and new materials. Biotechnology-related research projects are anticipated to focus on:

- "lab-on-a-chip" nanotechnology, integrating biology with electronics to build biosmart devices
- quantum and molecular computing, the next generation of computing technologies
- nano-engineered devices with new surface properties such as biocompatible medical implants
- protein and DNA tools that produce self-assembled devices
- genomics

Recently, the NRC launched another new biotechnology research institute – the NRC Institute for Nutritional Biosciences and Health – in Charlottetown. This institute will initially represent a $20 million five-year investment and focus on developing bioactive compounds from natural products which can make a positive contribution to human health.

The National Research Council's Genomics and Health Initiative (GHI) was initiated in 1999 to bring the benefits of revolutionary advances in the genome sciences and health research to a variety of Canadian industrial sectors and regions. Since its inception, GHI has established and continues to make use of a shared infrastructure in the form of key technology platforms in DNA microarray, proteomics, and DNA sequencing. Several of these platforms have been partnered with Genome Canada to create joint NRC-Genome Canada facilities.

Following a highly successful initial phase (1999-2002), the program has now entered a new period of growth and has expanded to incorporate eight major research programs. GHI is advancing fundamental and applied technical research in areas such as the diagnosis of disease, aquaculture, human pathogens, crop enhancement, environmental remediation of pollution, cancer, neurobiology and protein assembly. GHI has transformed NRC biotechnology programs towards high priority genomics, proteomics and health research programs. NRC institutes reallocated over $33 million towards GHI programs between 1999-2003. With over 500 talented researchers and personnel, and a program budget of over $24 million (2002-2003), NRC's Genomics and Health Initiative is truly "Bringing Science to Life for a Healthier Tomorrow."

Worldwide growth in life sciences, genomics and biotechnology is accelerating rapidly, creating a pressing need to organize and analyse the large data sets that are fundamental to research in these fields. As a result, NRC has established the Canadian Bioinformatics Resource (CBR) to offer Canadian researchers a unique tool for their research.

CBR is a distributed network of over 40 servers and workstations at seven NRC sites that can be used by any researcher working in a university, hospital, government department or industrial setting. The resource gives researchers high-speed access to 70 databases covering the range of biotechnology research; provides researchers with a complete set of software tools for sequence assembly and molecular visualization; and serves as a national source of bioinformatics technical advice, as well as a complementary platform to GHI infrastructure and programs.

Advances in biotechnology

Significant breakthroughs have been made over the last few years as a result of NRC's biotechnology program, including:

Saving lives – new test for colon cancer: a new, inexpensive, non-invasive and almost fool-proof test was developed at the NRC Institute for Biodiagnostics in Winnipeg which could prevent thousands of deaths through earlier detection of colon cancer. The test, which involves analysis of stool samples using a magnetic resonance spectroscopy machine linked to special computer software, is 98 percent accurate and it costs much less than previous tests. Until now, screening techniques were only 50 to 75 percent accurate. NRC entered into negotiations with a company to produce the equipment, while a new NRC spin-off company will sell the software and technique to hospitals.

Nova Scotia seaweed – an international success: working in partnership with the NRC Institute for Marine Biosciences, Acadian Seaplants Limited has transformed a low-value, renewable marine resource – seaweed – into high-value products marketed in over 65 countries around the world. The company buys its raw seaweed from more than 1,000 harvesters in Nova Scotia and Prince Edward Island, employing 130 people year-round, plus 70 summer workers.

Better canola – better markets: scientists at the NRC Plant Biotechnology Institute in Saskatoon have developed canola seed with far less anti-nutritional substances. This important scientific achievement will be commercialized through conventional breeding and selection of superior cultivars to provide better products to Canadians.

Combatting the threat of bioterrorism: the U.S. National Institutes of Health awarded a grant to an NRC team for research to support the overall effort to combat bioterrorism. The funding was used to develop a vaccine against a highly virulent bacterium recognized as a potential biological warfare agent. NRC's success was due in large part to its patented novel vaccine delivery system and its demonstrated expertise, facilities and equipment for cutting-edge vaccine research at the NRC Institute for Biological Sciences in Ottawa.

Decontaminating explosive soils: researchers at the NRC Biotechnology Research Institute in Montréal have developed soil quality guidelines for TNT-contaminated soils. These tools will help environmental risk assessors and managers of sites contaminated with explosives to determine "how clean is clean."

Protein folding – better understanding of diseases: molecular biologists from the Biotechnology Research Institute, working in collaboration with McGill University, have moved a step closer to understanding exactly how proteins are folded, particularly a molecular machine known as the calnexin cycle. This finding has important implications for diseases such as cystic fibrosis, hereditary emphysema and other genetic diseases. Decoding the structure of calnexin, a key protein involved in protein folding and quality control, is the culmination of a 10-year research effort by the team.

Value for Canada: taking technology to market

Research creates new ideas and advances the frontiers of knowledge. To put this knowledge to work, it must be transformed into new technologies, products and services for the global marketplace. Over the period 1998-2003, NRC's biotechnology program has turned potential into the following results:

Discoveries
- 1,900 scientific publications
- 340 patent applications
- 123 patents issued

Technologies transferred to the marketplace
- 43 licences signed
- $10 million licensing revenue

Research partnerships
- 80 collaborations with industry per year average
- 35 collaborations with universities per year average
- 70 collaborations with other public organizations per year average
- Value of the collaborations: $33.4 million per year average

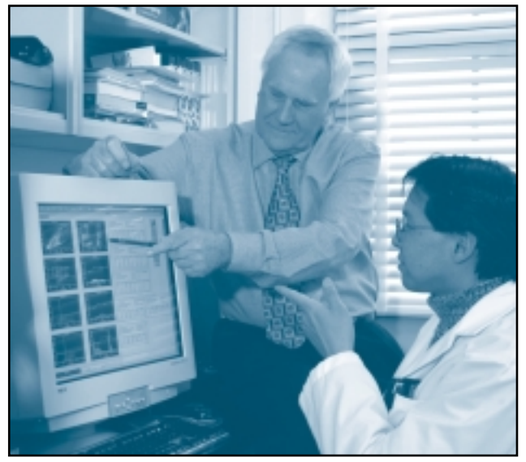
15 new companies created

NRC Industry Partnership Facilities
- 36 Co-locators and Industrial Partnership Facility Tenants per year on average
- Industrial Partnership Facilities in Saskatoon, Winnipeg, Ottawa, Montréal, Halifax

Meningitis-C vaccine approved for Canada

In 2002, NRC and its partners – Shire Biologics and Baxter Corporation – celebrated the launch of a major breakthrough in vaccine technology with the approval by Health Canada of the Neis Vac-C vaccine, developed by Dr. Harold Jennings at the NRC Institute for Biological Sciences. This highly effective new vaccine protects people of all ages, including children as young as two months of age, against Meningitis-C. The vaccine's capacity to effectively protect young children, the group hardest hit by Meningitis-C, sets Neis Vac-C apart from traditional vaccines in North America.

The vaccine was originally launched in Britain and will continue to be introduced in other parts of the world. Aside from its health benefits, the payback to Canadian taxpayers has been impressive. This new vaccine generated a single royalty payment to NRC of almost $3 million – the highest ever made to a federal government organization.



Incubators/spin-offs and start-up firms

Creating value for Canada involves helping to grow new science and technology-based firms. Incubation accelerates the process of starting and growing such firms as well as helping them to stay in business. NRC's biotechnology institutes have established industry partnership facilities to incubate new, small, technology-based firms. They act as magnets that attract innovative firms to NRC. Often the fastest and most effective way to commercialize a new technology or product is to create a new Canadian company. New ventures can either be a spin-off firm (formed by NRC employees) or a start-up firm (created by non-NRC principals using NRC technologies). In either case NRC helps to ensure that scientific breakthroughs translate into economic opportunities for Canadians.

Increasing innovation capabilities of Canada's small and medium-sized enterprises (SMEs)

Canada's small and medium-sized biotechnology companies are the key drivers of careers and wealth in the bioeconomy. One of NRC's primary objectives in stimulating wealth creation in Canada is to link its diverse networks, programs and infrastructure to SMEs to help them access, develop and exploit new technologies and the knowledge essential for their growth and prosperity. NRC's primary vehicle to stimulate the innovation capabilities of SMEs is its NRC Industrial Research Assistance Program (NRC-IRAP). Regarded worldwide as one of the best programs of its kind, NRC-IRAP is a vital component of NRC's innovation strategy and a cornerstone of Canada's innovation system.

NRC-IRAP fuels wealth creation by providing technology advice, assistance and services to SMEs that help them build their innovation capacity. Through expert technical and business advice, financial assistance, access to business information, contacts, and national and international networks, the program provides tailor-made solutions to Canadian biotechnology SMEs. Customized services are provided by 260 technology advisors located across Canada. A special Biotechnology Sector group oversees the provision of NRC-IRAP services to the Canadian biotechnology industry.

Knowledge for Canada – A vital currency

The NRC Canada Institute for Scientific and Technical Information (NRC-CISTI) has assumed increased importance in the knowledge economy. Not only is NRC-CISTI Canada's leading science library, it is also the largest national scientific publisher and principal dissemination resource of scientific, technical and medical information. NRC-CISTI maintains, publishes and provides access to the information essential to Canada's researchers. It provides access to Canadians through information centres across Canada as well as virtually via the Internet. In 2001-2002, NRC-CISTI provided nearly one million documents worldwide. The NRC Research Press published close to 6,400 peer-reviewed submissions from authors in Canada and around the world.

Community-based innovation: building technology clusters across Canada

NRC works with communities across the nation to increase their capacity in key technology fields through jointly developed innovation strategies that support the sustained growth of technology clusters. Some examples from the biotechnology program are as follows:

- The NRC Biotechnology Research Institute in Montréal is a key player in the Montréal biopharmaceutical cluster, the largest biopharmaceutical centre in Canada. DSM Biologics, a leading contract manufacturing organization located adjacent to the Biotechnology Research Institute, is investing more than $500 million to expand its existing facilities in Montréal for the commercial production of monoclonal antibodies and therapeutic proteins. This investment will create 400 jobs by 2008 and will enable Canada to become a world player in bioprocessing.
- The NRC Institute for Biodiagnostics in Winnipeg is leading a cluster on medical devices and expanding into precision and virtual manufacturing of medical technologies.
- The Institute for NRC Plant Biotechnology is building new dimensions for Saskatoon's already world-leading agro-biotechnology cluster. The NRC is working on a five-year $10 million "crops for enhanced human health" research program that will enable greater participation by rural communities in valued-added activities. The program focuses on high-quality crops to produce functional foods that enhance human health as well as naturally derived plant compounds. This research will support the accelerated growth of a competitive, Prairies-based nutraceuticals/functional food industry based on research, technology development and transfer, and industrial research assistance strengths in the region.
- Prince Edward Island: NRC is co-leading with partners the creation of a nutritional sciences and health cluster, building on Canada's economic strengths in primary resources.
- Nova Scotia: Through the Greater Halifax Partnership, this region is emerging as one of the smartest and fastest growing research centres for life sciences in Canada. The NRC Institute for Marine Biosciences is an active and paying member of this partnership. NRC has increased its R&D capacity in genomics, proteomics, bioinformatics and advanced imaging by allocating $15 million to the NRC Institute for Marine Biosciences and by building an Industrial Partnership Facility for the institute to increase technology transfer and commercialization strengths. Recently, the NRC invested in a new Brain Repair Centre associated with Dalhousie University and local hospitals.
- Alberta: Experts are predicting that the economic impact of nanotechnology will be in the range of $100 billion annually within the next decade. Through its collaboration with universities and industry locally, nationally and internationally, the National Institute for Nanotechnology will work to stimulate the emergence of new nanotechnology-based industries in Alberta and across Canada. NRC will be the R&D anchor and provide its commercialization strengths to nurture the growth of this cluster.

Global reach: NRC at work on the world stage

Innovation is a global issue, rooted in each nation's ability to create, exploit and transform new knowledge into innovative products that can create a competitive edge in global markets. Canada's participation in international science and technology (S&T) is vital to gain access to the knowledge and information Canada needs to succeed in the knowledge economy.

NRC has created international S&T networks of strategic importance for Canada. It has agreements in biotechnology with many countries such as Thailand, Spain, England, Germany, France, the European Union, Japan, China and many more. The NRC Industrial Research Assistance Program undertook a number of technology missions around the world to help SMEs, resulting in MOUs, contracts and partnership agreements. NRC uses these linkages and networks not only to transfer S&T information back to Canadian firms, universities and public sector partners, but also to generate new business opportunities for Canadian SMEs.

NRC conducts R&D in areas such as marine biosciences and seafood safety, medical diagnostics and devices, agricultural and pharmaceutical biotechnologies and biometrology that are vital to ensuring public health and safety, not only for Canadians, but for people around the world. Based on its world-class strengths in the production of Certified Reference Materials, the NRC Institute for Marine Biosciences is currently leading an international team of scientists from Canada, Australia, New Zealand, Taiwan, Singapore, Japan and the United States in a project to develop and validate new analytical methods and produce new marine toxin standards and reference materials. For the millions of people in the Pacific region dependent on seafood for their livelihood and main source of protein, this project has life-saving implications.

Leading the development of Canada's biometrology efforts to support international trade and commerce in products of biotechnology is a priority for the NRC Institute of National Measurement Standards (NRC-INMS). Canada's effective commercial success, resulting from advances in biotechnology, depends upon a reliable and internationally accepted measurement system for not only the detection, but quantification of physical, chemical and biochemical parameters in biological and bio-molecular systems. This is particularly critical in light of the growing international concern surrounding genetically modified organisms. In partnership with other departments and agencies, such as the Canadian Food Inspection Agency, NRC-INMS has been developing capabilities in biometrology to enhance Canada's innovation system and export-driven economy by providing the necessary measurement research and service infrastructure. It also works to maintain Canada's international reputation and continued effective participation in various international cooperations and Mutual Recognition Arrangements concerning measurement standards and the consequent benefits to our international trade.

NRC's global reach has also extended to disaster assistance in times of need. For example, in the aftermath of the September 11 attack on the World Trade Center, the leader of the NRC's Canadian Bioinformatics Resource collaborated with a U.S. company to develop software to identify victims of the attack. The software was the first of its kind able to handle such a vast array of information and data with the goal of identifying the victims as quickly as possible.

Outstanding people: outstanding achievements

NRC's success in biotechnology lies with nearly 1,000 dedicated, knowledgeable, creative and talented research, technical and support personnel who work with domestic and international partners to advance Canada's biotechnology potential. Within the NRC Biotechnology Program:

- NRC institutes engaged more than 500 guest workers and students from Canadian and foreign universities, companies and public and private sector organizations. Not only does NRC benefit from the participation of these skilled workers in collaborative projects, their home organizations gain equally from the training provided and the transfer of knowledge and know-how from NRC.
- The demands of the knowledge-based economy create an ever-growing need for a well-educated and skilled workforce. NRC makes a major contribution to Canada's skilled workforce, especially biotechnology workers, through its own recruitment and training activities as well as through support for programs of other government agencies and universities in Canada and internationally.
- NRC has fostered creativity and innovation by adopting unique approaches, such as connecting the arts and science. The newly created Artist in Residence program between NRC and the Canada Council for the Arts promotes artists working hand-in-hand with researchers in NRC labs to open new channels of communications and break down barriers between the worlds of scientists and artists.

NRC commercialization – 340 patent applications, 43 technology licenses, 15 new companies (5 years). p. 66

From Discovery to Innovation – NRC's cutting-edge laboratories act as magnets to attract innovative Canadian firms. p. 67

NRC research – a highly effective new vaccine to protect people of all ages against Meningitis-C. p. 69

Some 1,500 scientists, students and guest workers conduct biotechnology-related research in NRC laboratories across Canada. p. 71

NRC research – 3D modeling of drug molecules. p. 84

XI.

Natural Resources Canada

Natural Resources Canada

Supporting sustainable development

Natural Resources Canada (NRCan) supports the Government of Canada's commitment to the sustainable development of our natural resources – ensuring that they retain their economic importance and continue to contribute to a healthy environment, strong society and communities. Central to successful sustainable development is research and the adoption of innovative practices and technologies. Through knowledge, innovation, technology and global leadership, the department works to ensure the quality of life of Canadians – now and for the future.

Within NRcan, the Canadian Forest Service (CFS) has the lead on biotechnology issues and plays a strategic role in science and technology research as well as national policy coordination. CFS scientists have been involved for many years in research designed to improve the quality of wood fibre, protect forests from insect pests and disease, reduce exploitation pressures on forests and speed up the growth of harvestable trees. Forest biotechnology provides alternative tools that could play a pivotal role in sound forest management practices, including tree species improvement and protection. It also offers knowledge of forest ecosystems that can be used for conservation purposes and which has the potential to spawn new Canadian technology firms.

The development and use of biotechnology in the forest sector supports the CFS in advancing its mission of promoting the sustainable development of Canada's forests and competitiveness of the Canadian forest sector to maintain a high standard of living and quality of life for all Canadians.

Building a better tree

Trees are a big challenge to scientists due to their large size, long reproductive cycle and exposure to ever-changing environmental conditions. Traditional tree improvement methods are too slow to produce trees with the qualities required to meet our current and future wood and fibre needs. Yet the sustainable use of Canada's forests and the maintenance of Canada's share of the world market of wood and wood products depend on our ability to quickly improve the productivity of managed forests. Increasingly, biotechnology is helping to fill the gap.

CFS scientists are using novel methods to design improved trees with desirable characteristics like better quality wood, insect or disease resistance and faster growth, while ensuring that environmental impact considerations are addressed. An example of these innovative methods is genetic engineering using recombinant DNA techniques. Research on genetically engineered forest trees is currently underway in CFS laboratories, greenhouses and in small-scale controlled field trials all across Canada.

NRCan has applied biotechnology research to identify genetically superior trees and genetic diversity as well as to promote tree propagation through tissue culture, tree improvement through genetic modification, forest protection using biological pest control methods and the assessment of environmental effects of biotechnology-derived products. As research advances, biotechnology will offer more tools and approaches to protect Canadian forests and improve forestry.

Encouraging cooperation in the protection and wise use of forests

As the largest Canadian organization involved in forest biotechnology, the CFS also acts as a facilitator, encouraging and supporting the efforts of other Canadians and global partners committed to sustainable development. It plays a key role in defining strategic research orientations, advising on environmental regulations, developing skilled workers, increasing public awareness of forest biotechnology, and coordinating activities with industry, academia, other government departments and agencies, and other nations. For example, with input from the Canadian public, forest industry representatives, environmental groups, provincial officials and forest science experts, the CFS provides advice to the Canadian Food Inspection Agency (CFIA) on ways to improve the regulations governing genetically engineered forest trees.

To ensure the safety of the environment, the CFS is working in partnership with the CFIA to focus on the environmental impact assessments of genetically modified products. It is a priority of the Government of Canada to ensure the health and safety of Canadians and the environment through regulations and legislation.

Contributions to the CBS

The Canadian Forest Service has been an active participant of the Canadian Biotechnology Strategy and contributed to its renewal, completed in 1998.

As Canada's principal forest research agency, the CFS is internationally recognized as a world leader in forest biotechnology, using advances in molecular biology and cell and

tissue culture to protect and regenerate forests. Beyond research, the CFS is also involved in advancing Canada's biotechnology regulatory framework by developing expertise within the natural resources biotechnology sector to better assist regulatory agencies (CFIA and Health Canada's Pest Management Regulatory Agency (PMRA)) in the development of sound science-based regulations. Much of its work is carried out in partnership with other federal organizations as well as with industry, academia and non-governmental groups in Canada and internationally.

Productive partnerships

From 1999 to 2003 the CBS allocated $2.1 million to finance three CFS-led projects in collaboration with other government departments, international partners, universities and industry:

- Development of Canada's capacity to assess the environmental safety of biotechnology-derived forest products, in collaboration with Agriculture and Agri-Food Canada (AAFC), the CFIA, the PMRA, Environment Canada (EC), universities and industry.
- Development of frameworks for science-based regulations and intellectual property protection, in collaboration with the CFIA, the PMRA and the provinces.
- Biotechnology of natural control agents: identification of behaviourally active and environmentally acceptable phytochemicals from selected native trees, in collaboration with AAFC, universities, Kew Gardens (UK), and industry.

Genomics Initiative

A total of $7 million was allocated under the CBS for the 1999-2003 period to support CFS participation in the Government of Canada's Genomics Initiative. CFS research centres are focusing on improving forest generation and protection methods while addressing environmental impact considerations. Research activities fall under four themes:

- Molecular genetics of forest tree production and protection systems
- Molecular markers for diagnosis, monitoring and early selection
- Production of genetically improved trees
- Production of environmentally acceptable forest protection methods

The Canadian regulatory system for biotechnology initiatives

A total of $3.66 million was allocated to NRCan for the 2000-2003 period to support regulatory renewal. CFS-led activities focus on reducing the amount of scientific uncertainty concerning both the performance and environmental safety of genetically modified trees and biocontrol agents. Projects focus on:

- The development of a science-based regulatory framework for transgenic trees that is compatible with provincial, federal and international requirements to protect the environment and biodiversity.
- The generation of information on both the feasibility of using transgenic trees or biocontrol agents to increase Canada's ability to use its forests in a sustainable manner and the level of risk associated with their introduction into the natural environment.

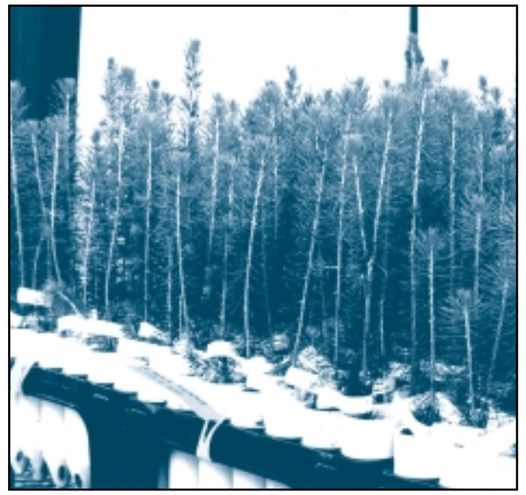
Early successes

Identification of genetically superior trees and genetic diversity

Biotechnology is providing tools to identify superior genotypes through the characterization of DNA markers associated with important silvicultural traits. The same tools are used to study the genetic diversity of tree populations. Genetic diversity is a component of biodiversity and is important in ensuring the sustainability of the forest resource.

Clarifying genetic structure and quantifying genetic components of variability in tree populations are the bases of genetic diversity studies. The CFS classifies important commercial and adaptative traits for use in advanced genetics and biotechnology. Additionally, there is great potential for obtaining rapid genetic gains by applying the most recent biotechnologies to trees already selected and bred for superior growth. In the context of developing genetically enhanced materials, the CFS is looking at the structure and function of conifer genes, focusing on the characterization of fundamental genes involved in tree differentiation and development. Understanding how trees grow will make it easier to identify potential areas for improvement.

Along the same line, the CFS is studying genes isolated from agricultural species and transferred to conifers. This kind of research will contribute to a better understanding of gene structure and function in conifers and will provide insight into the evolution of higher plants.



Tree propagation through tissue culture

Conifer somatic embryogenesis is a good example of a potential biotechnology application to conventional tree improvement. Immature embryos selected from seeds of superior trees and put under appropriate culture conditions can produce a mass of embryogenic tissues from which several thousands of somatic embryos can be obtained. Thus, somatic embryogenesis allows the production of a large number of trees from a single seed and can accelerate tree breeding cycles.

The CFS has contributed to the area of conifer tissue culture by developing somatic embryogenesis methods for micropropagating species such as white spruce, *Picea glauca* (Moench) Voss; black spruce, *P. mariana* (Mill.) BSP; red spruce, *P. rubens Sarg.*; tamarack, *Larix laricina* (Du Roi) K. Koch; European larch, *L. decidua Mill.*; and hybrid larch, *L. decidua Mill. L. leptolepis* (Siebold & Zucc.) Gord. The CFS has established demonstration plots and field tests of somatic embryo-derived trees for white spruce, black spruce, and hybrid larch, with the goal of integrating somatic embryogenesis into operational reforestation programs. Recently, CFS scientists have succeeded in developing methods to produce somatic embryogenesis in eastern white pine and jack pine.

In addition, the CFS has developed methods for the cryopreservation (storage at minus 196°C, the temperature of liquid nitrogen) of conifer tissue culture lines developed by somatic embryogenesis. This will permit integration of tissue culture into conventional breeding cycles by allowing the safe storage of lines until the materials have been tested for field performance. Cryopreservation is also used for the preservation of lines of endangered species and for the storage of commercially valuable tree genotypes.

Tree improvement through genetic engineering

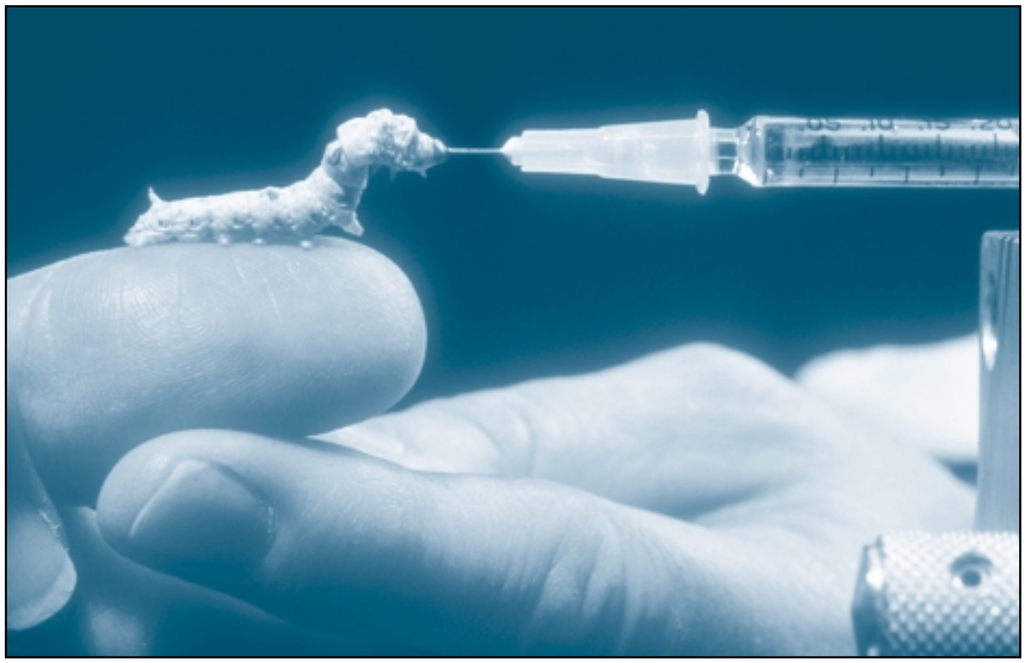
A major impediment to tree improvement is the time required for each genetic cross to reach sexual maturity. Genetic engineering could circumvent this problem by allowing the transfer of single gene traits into superior genotypes, leading to the integration of desired traits such as pest tolerance.

The CFS, along with universities and other research organizations worldwide, is developing genetic modification methods for trees. The CFS was the first organization to successfully produce transgenic black spruce and tamarack using microprojectile-mediated DNA delivery. With this method, microscopic metal beads coated with the new DNA that is to be introduced are shot through cellular membranes into the cell where the new DNA is taken up and expressed. Since then, the CFS has produced transgenic white spruce and European larch, and has successfully transferred genes for pest tolerance to black spruce.

To advance research in tree molecular biology, the CFS is developing protocols for gene delivery in various tree tissues such as flower parts and pollen. This will allow research scientists to bypass the long life cycle of tree species to verify patterns of expression of the introduced genes in mature tissues. The CFS is also conducting research with deciduous hardwood species such as poplar, aspen, and willow, with the aim of producing hardier and faster-growing trees.

Forest protection using biological pest control methods

Tree pests and diseases cause extensive losses in productivity while weeds represent a challenge in establishing tree plantations, making effective pest management strategies very important. Biotechnology has been proven to provide environmentally sound alternatives to chemical pesticides. Pioneering research at the CFS, starting as early as the 1950s, has been instrumental in the development of *Bacillus thuringiensis*, or *B.t.*, for worldwide use against a broad range of lepidopterous pests such as the spruce budworm, *Choristoneura fumiferana* (Clem.) and gypsy moth, *Lymantria dispar* (L.).



The CFS is conducting research to make *B.t.*'s mode of action more effective.

The CFS published *Genetically Engineered Baculoviruses for Forest Insect Management Applications: A Canadian Forest Service Discussion Paper* to encourage an exchange of views among members of the public and representatives of interested organizations regarding the R&D effort on baculoviruses for spruce budworm control.

More recently, the CFS obtained Canada's first registrations of insect viruses against insect pests for the redheaded pine sawfly, *Neodiprion lecontei* (Fitch), and for the Douglas-fir tussock moth, *Orgyia pseudotsugata* (McD.). Other viruses such as the nuclear polyhedrosis virus against gypsy moth are in pilot-scale production stages. Improving the efficacy of spruce budworm nuclear polyhedrosis virus through genetic engineering is being explored. Research is also underway to understand insect virus development including studies of their mode of action and environmental safety.

Other approaches involve the investigation of naturally derived products for managing forest insect pests. CFS scientists are studying the neem tree, *Azadirachta indica*, which produces azadirachtin, a substance that repels insects. Sex pheromones, or sex attractants, are also subject to intensive research for insect control and monitoring, and the CFS has identified several pheromones emitted by female insects to attract males when they are ready to mate.

The CFS is developing diagnostic kits to identify tree pathogens and researching microbial competitors of tree disease organisms and decay fungi. As well, scientists in CFS laboratories are searching for biological herbicides specific to targeted weeds and benign to the environment. Herbicides developed from fungal pathogens of weeds are called mycoherbicides. Some CFS mycoherbicides are being registered for use in Canada.

Environmental impact assessments of biotechnology-derived products

Before any biotechnology-derived product can be released into the environment, a thorough environmental safety assessment must be performed. Some of the issues requiring assessment include gene flow from transgenic trees into natural populations, the long-term stability of introduced genes and potential long-term effects of genetically enhanced trees in the ecosystem. Tools to analyze the impact of transgenic trees in intensively managed or seminatural forests and which would enable sound deployment strategies are currently being sought.

The CFS plays a crucial role in environmental research and in the assessment of micro-organisms to be used as pest control agents in forestry. In particular, CFS scientists have developed laboratory bioassays for non-target organisms. For example, the nuclear polyhedrosis viruses of the gypsy moth and the spruce budworm have been extensively tested against a large number of lepidopterans. The CFS also tests the effects of biological products on the natural microbial communities in soils from representative forest types and in aquatic environments. This type of research contributes critical knowledge and expertise to ensure that the fate and impact of biopesticides in forest ecosystems are well understood before product release.

Federal regulatory framework for biotechnology products in the forest sector

At the federal level, forest biotechnology-derived products are regulated by legislation stipulating that new products to be tested or commercialized must first be assessed for safety and efficacy. The acts include: the *Seeds Act* for genetically modified trees, the *Plant Protection Act* for imports and the *Fertilizers Act* for biofertilizers and mycorrhizae, all of which are administered by the CFIA; the *Pest Control Products Act* for microbial pest control agents, administered by the PMRA; and the *Canadian Environmental Protection Act* for microorganisms used in the pulp and paper industry, administered by EC.

The CFS contributes to the development and application of a sound, scientifically based federal regulatory framework for biotechnology products in the forest sector by providing scientific and technical expertise to the agencies that administer these acts.

XII.

Research Funding Agencies

Research Funding Agencies

Building the foundation of biotechnology innovation

Nurturing innovation

Prosperity is measured globally in today's economy in the currency of knowledge. Countries that succeed recognize that the greatest benefits derive from a readiness to innovate – to accept change, to embrace new ideas, to take greater risks. If Canada is to secure a competitive advantage in the global, knowledge-based economy, our country must proactively pursue research discoveries that will lead to innovative products and services for the international marketplace.

CIHR

The Canadian Institutes of Health Research (CIHR) is Canada's premier federal agency for health research. With its 13 institutes, CIHR partners with Canadian researchers and biotechnology companies in the commercialization pipeline, connecting academia with industry and government. In addition to funding the foundation of health research, CIHR's collaborative programs support subsequent knowledge translation, helping to bring new products and treatments to the marketplace that improve quality of life, enhance the Canadian health care system, and contribute to a robust economy. CIHR funds research in areas covering the four pillars of health research: biomedical; clinical; research respecting health systems and services; and the social, cultural and environmental factors that affect the health of populations. Through its coherent suite of programs designed to create a culture of innovation, CIHR is fueling the pipeline of discovery, catalyzing commercialization, informing health care practice and policy, and positioning Canada as a vibrant player in this century of health research.

To nurture such discoveries, the Government of Canada invests heavily in knowledge development. Canada's federal research funding agencies invest in people, discovery and innovation to improve the quality of life of Canadians and to build a strong Canadian economy. The agencies support research in universities, colleges, hospitals and other research institutions as well as the training of research scientists, engineers and clinicians. Individually, and collectively, these agencies have made valuable contributions to the development of biotechnology in Canada, one of the most innovative sectors of the economy.

The Government of Canada's three research funding agencies are:

- The **Canadian Institutes of Health Research (CIHR),** Canada's premier federal agency for health research. CIHR's mandate is to create new knowledge and translate it into better health for Canadians, a stronger health care system, and new health products and treatments. By bringing together academia with industry and government, CIHR facilitates the translation of discoveries into products and services in the marketplace where they can enhance Canadians' quality of life while contributing to a robust economy.
- The **Natural Sciences and Engineering Research Council (NSERC)** is the federal granting agency responsible for promoting and supporting research in the natural sciences and engineering. NSERC promotes excellence in the creation and productive use of new knowledge that results in a strong Canadian economy and an improved quality of life for all Canadians.
- The **Social Sciences and Humanities Research Council (SSHRC)** funds research to help Canadians better understand the world around them. This research fuels innovative thinking about real life issues confronting the economy, the environment and society, including biotechnology.

NSERC

The Natural Sciences and Engineering Research Council is the federal granting agency responsible for promoting and supporting discovery in all the natural sciences and engineering. The Council invests in university-based research and training, providing support for more than 9,000 students in advanced studies, funding over 8,700 researchers every year and encouraging in excess of 1,000 Canadian companies to invest in university research. NSERC promotes excellence in the creation and productive use of new knowledge, funding high-quality research with societal or industrial relevance. The transfer of the results to Canadian-based organizations helps to build a strong economy and improve the quality of life of all Canadians.

Publicly funded research in biotechnology is helping to guide Canada to the forefront of global innovation. New levels of biotechnology innovation are not only enhancing Canada's competitiveness – they will fundamentally improve the lives of Canadians.

Investing in innovation

Government-sponsored research is crucial to advancing scientific knowledge. The critical role of publicly funded research in biotechnology is underscored by a recent analysis of U.S. patents, which found that more than 70 percent of biotechnology citations were for research papers originating solely at public-science institutions.

Between 1997-1998 and 2001-2002, Canada's federal research agencies invested $870 million in biotechnology research and development (R&D) and the training of research scientists, clinicians and engineers. CIHR is the single largest supporter of biotechnology R&D in the federal government, investing $173 million in 2001-2002. This expenditure represents 34 percent of CIHR's annual budget. NSERC ranked second with $44 million in funding going to university-based biotechnology R&D.

Early successes

Canada's federal research funding agencies contribute to the development of biotechnology in numerous ways, from directly funding research at the start of the pipeline of innovation to providing support for the next generation of researchers who will take today's knowledge and advance it. They also help to take research discoveries the next step by working in partnership with researchers and biotechnology companies to help them enter the marketplace. Equally important, they work in concert with industry and government to ensure that the rules governing biotechnology meet the needs of industry while protecting and promoting the public interest.

Discoveries protecting the Canadian beef industry

The hero of Canada's cattle industry is Dr. Lorne Babiuk, the director of the Vaccine and Infectious Disease Organization (VIDO) at the University of Saskatchewan. Under his direction, VIDO has become an important training ground for veterinary and medical researchers. The Organization has signed agreements with dozens of companies that fund its research, pay royalties or sell VIDO's products around the world.

SSHRC

The Social Sciences and Humanities Research Council of Canada (SSHRC) funds university-based research and training in the social sciences and humanities that helps Canadians understand the world around them – what we value, what we question, our past, present and future. SSHRC-funded research helps Canada create effective public policy, compete in a global knowledge-based economy, educate our children, improve health care, build vibrant communities and secure our future in an increasingly complex world. SSHRC-funded research on the social, cultural, economic and ethical implications of biotechnological discoveries provides necessary information about this relatively new field of study and the opportunities and challenges it presents to help Canadians make informed decisions.

NSERC and CIHR funding for Dr. Babiuk's work have led to major breakthroughs for both humans and animals. He was the first to culture a rotavirus, the major cause of infant diarrhea. This research led to a vaccine that

reduced the worldwide infant mortality from the disease. He also pioneered DNA-enhanced vaccines for animals and helped develop a vaccine that kills the *E. coli* bug in cattle. Dr. Babiuk held one of the first Industrial Research Chairs, a hallmark of NSERC's research partnership programs. Today there are more than 130 active chairs involving close to 350 companies.

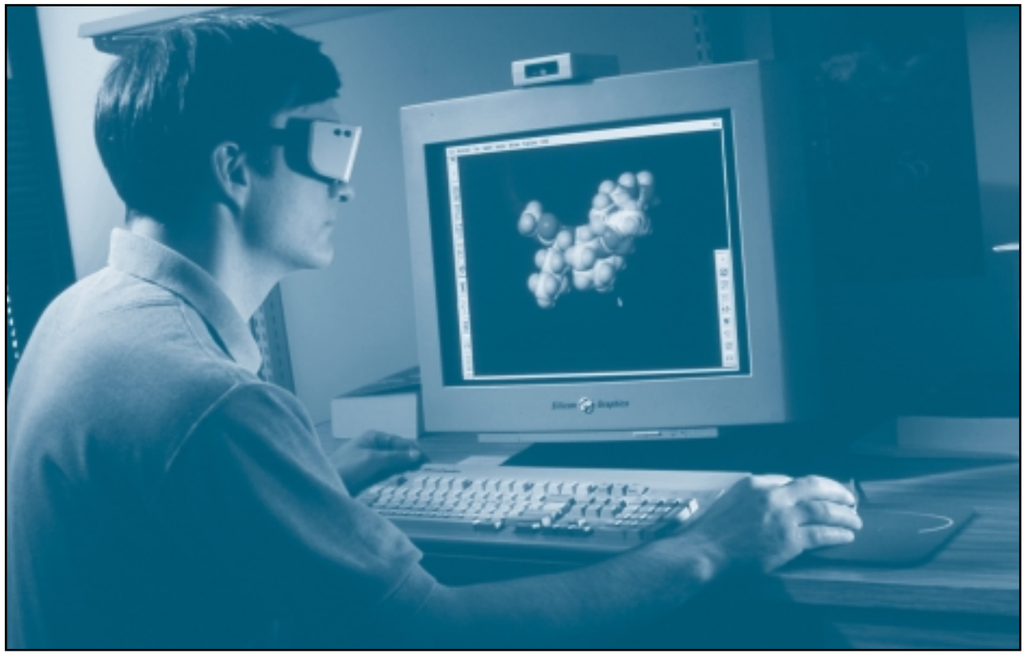
In addition to leading the fight against illnesses such as mad cow disease and *E. coli*, Dr. Babiuk is organizing a $50 million international effort to map cow DNA. The Bovine Genome Project is on the lookout for genes that make beef more tender, make dairy cows produce more milk or make cattle more resistant to disease – important discoveries for an industry worth $7.6 billion a year to Canadians.

Dr. Babiuk believes a genetic mutation may have been responsible for the mad cow case that recently crippled Canada's beef industry. Mapping the bovine genome will make it easier for scientists to identify the source of such outbreaks, which could save health authorities from slaughtering herds and might prevent other countries from banning Canadian beef.

Protecting people and animals from microorganisms

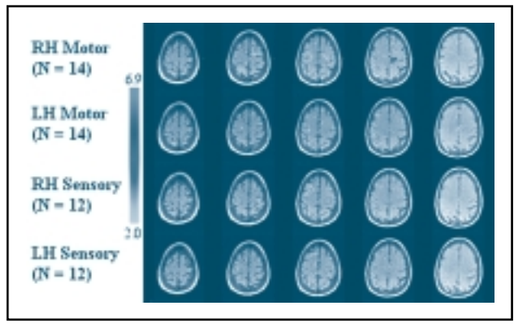
Recent events throughout Canada have highlighted the dangers of *E. coli* 157-H7, a bacterium that causes illness in some 50,000 North Americans each year and kills 500 people annually. Tragedy struck Walkerton, Ontario, after *E. coli* from cow fecal matter contaminated the town's drinking water. As a result, government inspectors adopted a policy of zero tolerance toward beef cattle that carry a particular *E. coli* strain. The slightest contamination can lead to the destruction on an entire shipment. The cost to meat producers has been staggering – as much as $5 billion annually.

All of this may change if Brett Finlay's research proves successful. With the help of NSERC and CIHR, Dr. Finlay has developed a vaccine to protect cows against *E. coli* 157-H7. It has been effective in small numbers of cows and is now being tested in more than 70,000 animals. If successful, Finlay's vaccine will help reduce the dramatic economic and health costs associated with *E. coli*.



Regenerative medicine: the promise of movement

Dr. Molly Shoichet, a CIHR-and NSERC-funded researcher from the University of Toronto, has helped rats regain movement – and her work could mean new hope for Canadians who suffer spinal cord injuries. Dr. Shoichet developed a flexible tube from materials similar to those used in contact lenses. The tube imitated the flexibility of a spinal cord, allowing nutrients to pass through so that nerves could grow inside. When implanted into rats with severed spinal cords, myelinated neurons grew into the tubes in about eight weeks, improving the rats' ability to walk.



Dr. Shoichet's work fits into a CIHR cross-cutting initiative in regenerative medicine that is focusing on human diseases as varied as juvenile diabetes and liver and heart failure, as well as spinal cord injuries. The goal is to develop innovative, cost-effective and ethically validated approaches to diagnosis and treatment to improve Canadians' quality of life.

Dr. Molly Shoichet is also winner of a 2003 NSERC Steacie Fellowship.

Responsible research

What kinds of responsibility do researchers and private enterprises working in the field of biotechnology have to society? SSHRC-funded researcher Dr. Lyne Létourneau, a professor of animal sciences at Université Laval, is collaborating with colleagues at Université Laval and the Institut national de la recherche scientifique, as well as Health Canada, to find the answer to this question. In addition to defining the responsibilities of those conducting biotechnological research, specifically in the area of genetic modification of animals, the team will examine how to put in place an action strategy for the benefit of the research community and society at large.

Creating a framework for biotechnology

Innovative technologies and advances in research can raise contentious socio-ethical issues that sometimes challenge Canadians' beliefs and values. Ethics guidance must be developed to advance promising research while at the same time respecting Canadian values. These tools must respond to shifts in public opinion and accommodate rapid, and frequently unpredictable, advances in research and technology.

CIHR, NSERC and SSHRC play a pivotal role in the development of ethics guidelines and policies. These frameworks support a culture of innovation while safeguarding societal values and ensuring that government policies and decisions are grounded in the best available scientific evidence.

CIHR, NSERC and SSHRC are committed to the implementation and further evolution of the Tri-Council Policy Statement on Ethical Research Involving Humans (TCPS). To supplement TCPS, CIHR has further taken the initiative in policy areas in need of coordination, such as the bringing together of an internationally renowned expert working group to provide recommendations on human stem cell research, which resulted in the March 2002 publication of "Human Pluripotent Stem Cell Research: Guidelines for CIHR-funded Research," as well as the establishment of a multisectoral Privacy Advisory Committee to assist in the development of Privacy Best Practice Guidelines for Health Research. In addition, CIHR contributes to the development of new knowledge through its investments in multidisciplinary integrative research on ethics. Recent examples are the Institute of Genetics' Request for Applications (RFA) on "Facing the Future: Human Genetics, Ethics, Law and Society" and the Institute for Health Services and Policy Research's coordination of an RFA on "Compelling Values: Privacy, Access to Data and Health Research."

Training the next generation of researchers

World-class research requires world-class researchers. Training the next generation of researchers will help to build a national culture of creativity, innovation and transdisciplinary research. It will address the growing demand for highly skilled and adaptable workers who can embrace a diversity of approaches in solving complex problems and applying solutions in research. That is why the three research funding agencies, CIHR, NSERC and SSHRC, are committed to capacity building by ensuring that talented researchers have the resources, tools and training they need.

The CIHR Strategic Training Initiative in Health Research brings together groups of accomplished health mentors and educators who work collaboratively to train and support research talent, much of which is centered in the field of biotechnology. For example, the CIHR Training Grant in Bioinformatics, led by Dr. Steven Jones at the BC Cancer Agency, will train emerging experts in bioinformatics (computational methods that manipulate information). His team will focus on everything from validating genes involved in disease to targeting areas for therapeutic development. Another initiative working to build human research capacity in Canada is the CIHR Interface Training Grant Program, led by Dr. Stephen Lye at the Samuel Lunenfeld Research Institute in Toronto. Dr. Lye will work with new researchers to realize potential health breakthroughs derived from the completion of the human genome.

NSERC offers a range of scholarships and fellowships for students at the undergraduate, graduate and post-doctoral levels. Students are also trained on research projects such as NSERC's Collaborative Research and Development grants, which funds university-industry research partnerships. On average, each Collaborative Research and Development project provides seven students or post-doctoral fellows with training in the essential technical skills required by industry. The training is very relevant – a recent survey showed that 42 percent of the students found employment in industry.

Taking research to market

The CIHR/Small and Medium-Sized Enterprises (SME) Research Program is jointly funded by CIHR and Canadian biotechnology companies. The program strengthens Canada's technology transfer by supporting research commercialization in start-up companies, university spin-offs and SMEs. Since 2000, the CIHR/SME Program has supported $54 million in collaborative research grants and training awards, with CIHR's contribution totaling $15 million.

Turning lab discoveries into innovative treatments is both the goal of cancer research scientists and the hope of those who suffer from the disease. Thanks to a CIHR/SME grant, Dr. Michel Tremblay, Director of the McGill Cancer Centre, and his colleague, Dr. Morag Park, are partnering with Kinetek Pharmaceuticals Inc. in Vancouver to validate novel targets for the development of new cancer-gene inhibitors. This project has potential benefits for thousands of cancer patients in Canada alone and many more around the world. Through its work the team will develop screening processes to identify compounds that can eventually be used in clinical trials.

NSERC's new I2I (Idea to Innovation) program is designed to help accelerate the pre-competitive development of promising technology and promote its transfer to Canadian companies. NSERC's other research partnership programs have a proven track record of success. More than 1,500 companies have participated in collaborative projects with universities, achieving over 95 percent success rate as judged by the participants themselves.

The Intellectual Property Management (IPM) Program, which strengthens the ability of universities and hospitals to recognize, protect and manage intellectual research property, attract potential users and promote the professional development of personnel involved in IPM. The program is managed jointly by CIHR, NSERC and SSHRC. Recently, the University of Manitoba, Brandon University, the University of Winnipeg, the Winnipeg Health Sciences Centre, and CancerCare Manitoba received an IPM grant to develop and foster a consortium that will build on that province's evolving strengths in IP management.