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PATHWAYS TO GROWTH:

Opportunities in Biotechnology





Canada

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Introduction

As the needs of the industry and Canadians have continued to evolve in biotechnology, so too has Canada's biotechnology strategy. The CBS provides the guiding principles, goals and a vision of "enhancing 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."

Biotechnology is one of the world's fastest growing industries. Although a great deal of attention has been given to this sector, it is actually a very new industry. The first biotechnology companies were founded in Canada and the United States around 1980, meaning biotechnology's pioneers are barely 20 years old and most firms are less than 10 years old. Although some biotechnology companies have sales, products, profits and an ability to raise capital, most are much less advanced. While they show great promise and are maturing rapidly, they have not yet reached their full potential.

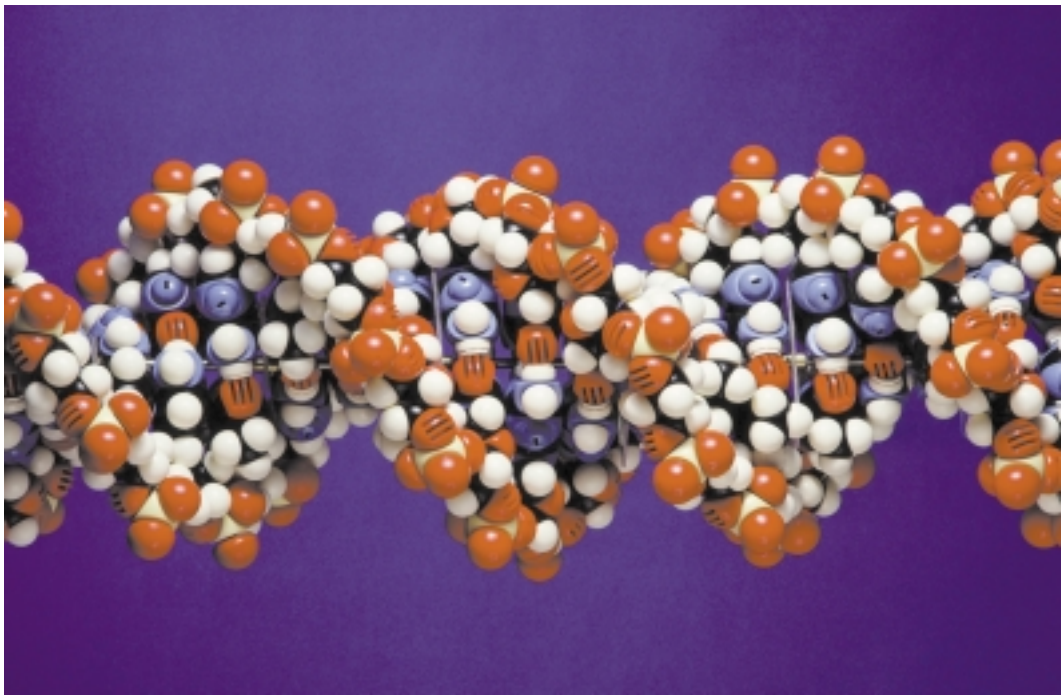
Today, the United States is the dominant force worldwide in biotechnology, with Canada and the United Kingdom in a virtual tie for second place. In the past several years, Canadian governments, the research community and industry have combined efforts to create a strong base in biotechnology. Based on excellent research, the Canadian industry has achieved international recognition for developing several important products, particularly in health and agriculture. Science-based organizations and biotechnology companies are now found everywhere across the country.

However, the competitive pressure on Canada is increasing. Most countries have targeted biotechnology as vital for the 21st century and are pouring enormous resources into research and development (R&D) and financing. To ensure Canada's future success, government must work with industry to support the growth of this dynamic, highly productive industry, which has the potential to provide the wages, employment and other spillovers into the overall economy.

Canada's success in biotechnology is in part due to its early development of a national biotechnology strategy in 1983. This strategy evolved from having a largely R&D focus in the early 1980s to including a regulatory framework in the early 1990s. As the needs of the industry and Canadians have continued to evolve in biotechnology, so too has Canada's biotechnology strategy. The new Canadian Biotechnology Strategy (CBS), announced in August 1998, had input from more than 5000 individuals and organizations across the country. The CBS provides the guiding principles, goals and a vision of "enhancing the quality of life of Canadians in terms of health, safety, the environment, and social and economic development by positioning Canada as a responsible world leader in biotechnology."

THE CANADIAN BIOTECHNOLOGY STRATEGY (CBS)

In August 1998, the Canadian government announced the CBS which has three strategic directions to help advance policies and programs — stewardship, benefits and citizen engagement — and improves the government's ability to manage this horizontal issue. Stewardship relates to the federal government's efforts to ensure the health and safety of people, animals and the environment, and ensure respect for Canadian values. The benefits are in health, the environment and the economy. Citizen engagement will come most notably through CBAC, which has a mandate to hold dialogue with Canadians on key biotechnology issues.



Industry Canada focuses on accelerating sustainable economic benefits from biotechnology.

The CBS also established an arm's-length Canadian Biotechnology Advisory Committee (CBAC) to consult Canadians on biotechnology issues and advise the government on future directions. The CBAC work plan, announced in February 2000, identified the first two areas for study and public consultation: the regulation of genetically modified food; and, intellectual property as it relates to the patenting of higher life forms.

The renewed CBS has three main pillars: benefits (i.e., health, environmental and economic), stewardship, and public consultation. The federal government is involved in all three spheres, however, Industry Canada focuses primarily on accelerating sustainable economic benefits from biotechnology. This paper discusses both the challenges for all partners in biotechnology and their opportunities to contribute substantially to Canada's success in the knowledge-based economy.

The strategic plan developed in this paper addresses issues raised in a variety of fora. It reflects the input of the CBS consultations and draws on the work of the National Biotechnology Advisory Committee (NBAC), which advised the government from 1983-98. It reflects the work of numerous federal organizations involved in biotechnology (listed in the acknowledgements), input from recent consultations with industry leaders and from academics and interested consumers. These contributions,

PUBLIC CONSULTATION AND THE CANADIAN BIOTECHNOLOGY ADVISORY COMMITTEE

Canadians and consumers internationally have expressed their interest in biotechnology and concerns about it. The government established CBAC following extensive consultations, to provide comprehensive advice to develop policy on the ethical, social, regulatory, economic, scientific, environmental and health aspects of biotechnology. CBAC's mandate also includes engaging Canadians in an open dialogue. This committee fulfils part of the government's commitment to citizen engagement. It advises a committee of Ministers from CBS departments.

along with information garnered from wider-ranging reports and bodies, such as the Advisory Council on Science and Technology (ACST), were the resources for this plan. This plan addresses the following key opportunities and challenges for the biotechnology industry:

- R&D and technology transfer and commercialization;
- financing and access to capital;
- skills development and human resources;
- regulation and intellectual property; and
- foreign investment and trade.

PUBLIC-HEALTH BENEFITS AND BIOTECHNOLOGY

Biotechnology is already a tool for public health, used in disease surveillance, diagnosis, treatment and prevention. Disease surveillance uses a variety of tools and techniques to identify risks in food, water, the environment, pesticides, drugs and medical devices. Biotechnology improves disease surveillance; the investigation of how diseases increase or spread increasingly requires biotechnology. It permits researchers to identify disease agents that traditional methods have failed to uncover (for example, molecular cloning in blood analysis to reveal the causes of some human diseases).

Biotechnology also facilitates earlier detection of disease, and this can mean milder treatment and less hospital time or surgery. For example, cellular markers are normally found in blood, urine or tissue during the onset of particular diseases. A number of diagnostic procedures already use biotechnology to exploit this fact to achieve early detection and diagnosis. Advances in biotechnology will produce even more efficient and less invasive diagnostic methods.

A new generation of therapeutic products, such as human insulin and hormones, has resulted from biotechnology. These have contributed to safer and less costly treatment of several diseases, including diabetes, anemia and several forms of cancer. Researchers in biotechnology are seeking better ways to control cardiovascular, neurological and viral diseases. Emerging treatments include biopharmaceuticals, immunotherapies, gene therapy and xenotransplantation.

Prevention relates to those aspects of health care concerned with prolonging life and preventing disease. In the immediate future, the most tangible prevention benefit of biotechnology will be in vaccines because, for a broad range of viral infections, prevention is still the only means of control.

BioChem Pharma Inc.
Laval, Quebec

BioChem Pharma is an innovative and fast-growing biopharmaceutical company focused on infectious diseases and cancer. Founded in 1986 by three researchers who envisioned a Canadian biopharmaceutical business, BioChem Pharma's first therapeutic discovery, 3TC (sold in most markets as Epivir) is the most widely prescribed therapy worldwide for the treatment of HIV infections and AIDS. The product is available in more than 100 countries. 3TC was this biotechnology company's breakthrough drug discovery and its activities currently focus on therapeutics and vaccine products.

Today, BioChem's high-quality activities focus primarily on cancer and infectious diseases — universally regarded by health-care authorities as priority areas or urgent unmet medical needs. BioChem leverages its in-house expertise through a network of strategic investments and partnerships, ranging from collaborations on basic research with universities, research institutes and smaller firms to global development and commercialization alliances with leading multinationals.

QLT Phototherapeutics Inc.
Vancouver, British Columbia

Vancouver's QLT Inc. is a pioneer and global leader in the field of photodynamic therapy, a new field of medicine that uses light-activated drugs to treat disease. In April, the US Food and Drug Administration approved QLT's therapy for the treatment of the leading cause of severe vision loss in people over the age of 50, the wet form of age-related macular degeneration (AMD). Visudyne represents the first real treatment for patients with AMD, offering respite from a condition that seriously diminishes quality of life. Visudyne is injected intravenously, accumulating in higher concentrations in the abnormal vessels in the eye. The drug is activated by shining non-thermal laser light into the patient's eye; once activated, Visudyne causes a reduction of growth of the abnormal blood vessels and a corresponding reduction or stabilization of vision loss.

The Canadian Biotechnology Industry: An Overview

Biotechnology uses living organisms or parts of living organisms to make new products or provide new methods of production.

The Canadian biotechnology industry is a new but rapidly growing industry.

Resource-based industries, such as forestry and fisheries, are also beginning to use biotechnology to improve their productivity, product quality and sustainability.

Biotechnology is an umbrella term covering a broad spectrum of scientific tools and techniques, ranging from traditional uses of living organisms, such as yeast in bread, to more advanced techniques, such as genetic engineering. Biotechnology uses living organisms or parts of living organisms to make new products or provide new methods of production.

The Canadian biotechnology industry is a new but rapidly growing industry in which three quarters of the businesses are small or medium-size enterprises (SMEs). Statistics Canada undertook the most extensive survey of the biotechnology industry so far and published it in 1998. It is currently expanding and updating this survey, and new information will be available in 2001. According to the survey, the Canadian industry consists of almost 300 core biotechnology firms, one quarter of which are publicly traded. Small entrepreneurial companies are the mainstay of the industry; British Columbia, Ontario and Quebec predominate, with more than three-quarters of the companies and jobs. Three-quarters of all Canadian biotech companies are in the health or agri-food sectors. Traditional industries, such as those producing pharmaceuticals and agri-food, are increasingly focusing on gene-based research to develop new products. Other resource-based industries, such as forestry and fisheries, are also beginning to use biotechnology to improve their productivity, product quality and sustainability. Information and examples can be found throughout this document, illustrating the uses of biotechnology in a wide range of industries, as well as in areas such as public health and the environment.

Biotechnology is still a research-based industry. With almost $600 million in R&D expenditures

Key Industry Data by Company Size

(financials in $ millions)

	SMALL	MEDIUM	LARGE	TOTAL
Number of firms	204	43	35	282
Biotech Sales	$183	$137	$698	$1 017
Other Revenue	$49	$47	$23	$119
Total Biotech Revenue	$231	$183	$721	$1 135
R&D	$192	$153	$240	$585
Exports	$95	$43	$275	$413
Total Positions	4 155	2 678	4 890	11 723

Small (1–50 employees) Medium (51–150 employees) Large (>151 employees)

Source: Statistics Canada, Biotechnology Firm Survey, 1998

(90 percent of this in the health sector) the industry's R&D-revenues ratio is very high. Canadian industry strength and growth potential lies in its research. More than half of the firms are already using DNA-based technologies and many are starting to focus on technologies such as bioinformatics and molecular modelling.

The Canadian industry's overall revenues exceeded $1 billion in 1997, of which 90 percent came from biotechnology sales; other revenue sources included royalties, investment income and contract research. The health and agri-food sectors accounted for almost 95 percent of sales. It is expected that about three-quarters of world biotechnology demand will continue to be in the health sector, with most of the remaining demand for biotechnology products being in the agri-food sector. Canadian sales account for less than five percent of the global biotechnology market, but this share could double to 10 percent by 2005.

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BIOPHARMACEUTICALS

Currently, more than 90 percent of biotechnology products on the world market are health related. It is expected that about three-quarters of world biotechnology demand will continue to be in the health sector. The biopharmaceutical segment of this sector promises major social and economic benefits. Its medicines, vaccines and other health-related devices and products have helped to reduce or eradicate many diseases and improve life expectancy. World sales of biopharmaceuticals have grown more than seven-fold over the past decade, and should exceed US$18 billion by 2003. Canada is well positioned to be an important player in this transition; of the 24 biopharmaceuticals approved for sale on the world market, three were developed by Canadian firms: 3TC, by BioChem Pharma Inc. for the treatment of HIV/AIDS; Photofrin, by QLT Phototherapeutics Inc. for the treatment of various cancers; and Truquant BR, by Biomira Diagnostics Inc. for the detection of breast cancer. A January 2000 survey of selected biopharmaceutical firms conducted by the Canadian Institutes of Health Research (CIHR) found that this group had more than 400 products in the pipeline.

Canada's biopharmaceutical expertise is gaining recognition. For example, in 1997, Aventis Pasteur announced a $350-million project to develop therapeutic vaccines for cancer, and in June 2000 Merck Frosst Canada announced a $250-million investment in new research labs and the upgrade of its manufacturing and administrative facilities. Such announcements reflect the recognition of Canadian research excellence in both the private and public research sectors.

Aventis Pasteur Limited
Toronto, Ontario

According to a recent survey, Canadians rank vaccinations at the top of the list of scientific achievements of the 20th century. And for more than 80 years one Canadian-based company, Aventis Pasteur Limited (formerly Connaught Laboratories), has been a world leader in the development of vaccines against diseases such as polio, rabies, diphtheria, tetanus, pertussis and many others. Today, the company is on the leading edge of scientific progress, producing the newest in combination vaccines, such as the five-in-one-shot PENTACEL™ vaccine. Aventis Pasteur also heads a 10-year, $350-million research and development program to develop therapeutic vaccines for cancer. The program employs the latest biotechnology methods in the field of immunology and involves a network of Canadian researchers from across Canada.

Hemosol Inc.
Toronto, Ontario

Hemosol, an integrated biopharmaceutical company, is developing multiple products for global markets based on technologies for use (at least initially) in the treatment of hemoglobin deficiencies. The company's main product is a highly purified human-derived hemoglobin replacement product. Potential benefits of Hemolink™ include universal compatibility with all blood types; a reduced risk of allergic or immune reaction that may occur with donor blood transfusion; and shelf life of more than one year, compared with 42 days for donor blood.

Nymox Pharmaceutical Corporation
Montreal, Quebec

Nymox Pharmaceutical Corporation is a pioneer in the research and development of products for the diagnosis and treatment of Alzheimer's disease, which afflicts more than 20 million people worldwide. Nymox offers the world's only accurate, non-invasive test to aid in the diagnosis of the disease, and the company is now developing drug therapies that could lead to the effective treatment of Alzheimer's disease. They are also developing a new class of antibacterial agents to treat urinary tract and other bacterial infections that have proved highly resistant to conventional antibiotic treatments as well as a treatment for *E. coli* bacterial contamination in hamburger meat and other food and drink products. Nymox has a majority interest in Serex Inc., a New Jersey corporation with proprietary tests in the fields of geriatric, cardiovascular, metabolic, and musculoskeletal diseases and a proprietary platform for quantitative point-of-care testing.

R&D, Technology Transfer and Commercialization

Research and Development

Most of the 282 core Canadian biotechnology companies have been built on discoveries originating in Canadian universities, research hospitals and government laboratories. Basic-research funding is critical to fuelling the innovation pipeline, and, according to Statistics Canada, the federal government spent more than $3.5 billion on R&D in 1998/99 and more than $310 million on biotechnology R&D in 1997/98. Announced funding in the 1999 and 2000 budgets will include an additional $215 million for biotechnology R&D.

Strong government and industry support for research is crucial to fuelling innovation. Over the past several years, the federal government has substantially increased its support for R&D, funding the Canada Foundation for Innovation, Canada Research Chairs, Network Centres of Excellence, and the Canadian Institutes of Health Research (CIHR, formerly the Medical Research Council), as well as providing additional support to federal research. Such investments support biotechnology research, including a Network Centre of Excellence on genomics. Genomics, which aims to decipher and understand the entire genetic content of an organism (e.g., human, plant, pathogen), is revolutionizing all aspects of science and is now fundamental to biotechnology research. It is opening new avenues for treating disease; improving crop, animal, aquacultural and forest yields; cleaning waste; and detecting and monitoring environmental releases of organisms.

Recognizing the importance of biotechnology and genomics, the 2000 budget provided $160 million for Genome Canada, a not-for-profit corporation that will lead Canada's genomics research effort, in partnership with

GENOMICS

Genomics is a discipline that aims to decipher and understand the entire genetic information content of an organism (e.g., human, plant, pathogen). Genomics-related industries are represented by the group of companies that focus on DNA-related products, services and information as the basis for their business. Genomics cuts across a broad range of traditional industry sectors: health, agriculture, aquaculture, forestry, environment, and informatics and software.

About 30-35 small and very small companies conduct R&D in genomics in Canada. This is a very young industry in which new companies are forming quickly and most companies are university spinoffs less than five years old. Nevertheless, it is of great strategic importance, as the vast majority of new biotechnology products and services will be derived from genomics. Segments of the industry involve production of sequencing hardware and related software and informatics services, or "bioinformatics." The recent funding for Genome Canada will increase Canadian advances in R&D, attract investment and develop Canada's international profile in this area.

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Genomics is revolutionizing all aspects of science and is now fundamental to biotechnology research.

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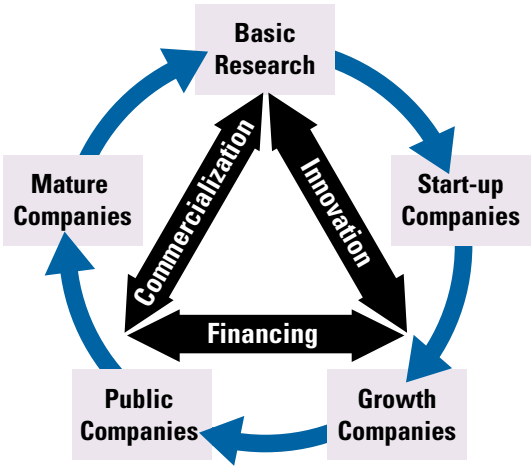
The challenge will be to focus resources in areas of Canadian strengths and to maximize opportunities to translate new discoveries into social and economic benefits.

Significant federal investments in basic research, universities, research hospitals, and government laboratories increasingly contribute to the creation of the next generation of biotechnology companies.

industry, federal and provincial government researchers, universities, hospitals and other not-for-profit organizations. It will create Genome Centres to link existing institutes with centres of expertise, each with a distinct focus (e.g., human disease, agriculture, the environment), and provide mandates to support the research community regionally and nationally. The Genome Centres will provide expertise, and undertake large-scale research projects, and create technology platforms (e.g., sequencing, genotyping, functional genomics, proteomics, bioinformatics). A final core component of Genome Canada will be work on the social, ethical, environmental and legal aspects of genome science. Public consultation and communication are also integral to planned activities. Genome Canada will also focus on two areas of significance discussed in this paper — commercialization and human resources.

These investments illustrate the Canadian government's commitment to R&D on biotechnology. However, governments internationally have been investing heavily in genomics in recent years. To derive the maximum benefit from investments to date, and to continue advancing in biotechnology R&D, Canada must make strategic choices in research programs, foster linkages among research performers, and increase research funding. The challenge will be to focus resources in areas of Canadian strengths and to maximize opportunities to translate new discoveries into social and economic benefits. While health and agricultural applications in biotechnology have predominated to date, recent advances in genomics and biochemistry have made environmental biotechnology one of the key developments. Environmental biotechnology has the potential not only to solve current environmental problems but also to prevent future ones without pitting industrial development against environmental protection.

Basic Research Contributes to a Strong Industrial Base



Source: Industry Canada, 1999

The government will continue to identify R&D needs and support future efforts in biotechnology. It will work in partnership to identify strategic directions, based on research advances, such as by working to ensure that a proportion of the newly funded Canada Research Chairs will facilitate biotechnology R&D. Future areas of focus may include diagnostic testing, based on genomics; agriceuticals (e.g., vaccines from plants); robotics (bioapplications, analysis and screening, based on the sequencing information obtained from the human genome); organic engineering (mammalian cells and microchips); protein therapy; and nanotechnology (micro manufacturing to the billionth of a metre).

Technology Transfer and Commercialization

Significant federal investments in basic research, universities, research hospitals, and government laboratories increasingly contribute to the creation of the next generation of biotechnology companies. For example, the National Research Council (NRC) has spun off more than 20 biotechnology companies in the last three years alone from its five biotechnology laboratories.

Statistics Canada's 1998 Survey of Intellectual Property Commercialization in the Higher Education Sector indicated that universities have helped to establish 90 biotechnology companies so far, representing 25 percent of all university spinoff companies.

However, the 1998 NBAC report identified several impediments to effective technology transfer and noted that US universities are twice as effective as Canadian universities at getting industrial uptake of their patented ideas. The path from basic research to commercialization presents numerous challenges such as identifying and patenting promising discoveries, demonstrating commercial potential ("proof of concept"); fostering linkages with industry and the financial community, determining the best commercialization vehicle (e.g., licensing to an existing company or creating a new one), nurturing a company through its early development, and assessing the technology to determine its environmental sustainability.

Increased Support to Technology-Commercialization Offices

Advancing the commercialization of Canadian research discoveries will maximize the economic and social returns from our investments in basic research. The 1998 NBAC report noted that the technology-commercialization offices of universities, research hospitals and government laboratories play a pivotal role in ensuring that research discoveries (including those in biotechnology) are identified, patented and commercialized. The May 1999 report of the Expert Panel on Commercialization of University Research prepared for the Prime Minister's ACST also examined and provided advice on commercialization, including a recommendation to strengthen the commercialization function of universities.

The Intellectual Property Management (IPM) Program of NSERC (Natural Sciences and Engineering Research Council) provides funding to support the commercialization function of universities; however, hospitals are currently not part of the program although they undertake considerable biomedical research. Building on NSERC's well-established IPM program, and specifically focusing on support of biotechnology commercialization, the Canadian Institutes

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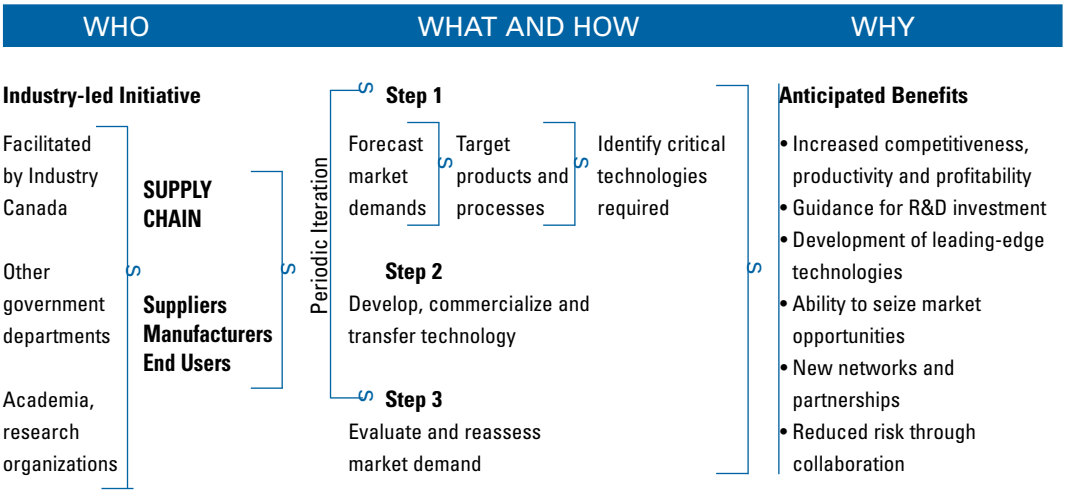
Technology Roadmap Overview



Source: Industry Canada, 1999

Timely information flow between all stakeholders can accelerate the pace of technology transfer and improve the odds of commercializing discoveries.

Technology roadmapping helps companies and industries to reduce risk through collaboration and increase their competitiveness and profitability.

Over the last few years the government has made a concerted effort to link the various players in regional innovation systems.

Industry Canada will work with industry and other partners to develop a technology roadmap for the biopharmaceutical industry.

of Health Research (CIHR) will work with NSERC to expand the program to include research hospitals.

Strengthen Linkages with Industry and Technology-Commercialization Offices

Linkages between industry and the research and financial communities are essential throughout the continuum of research, discovery, and commercialization. Timely information flow between all stakeholders can accelerate the pace of technology transfer and improve the odds of commercializing discoveries. Networking among technology-commercialization offices stimulates activity and encourages the adoption of best practices and bundling of intellectual property to build more feasible commercial opportunities.

CIHR, NSERC, NRC and Industry Canada will work with the biotechnology industry and key partners such as Genome Canada to facilitate networking fora to share best practices in the commercialization of the biotechnology discoveries of universities, research hospitals and government laboratories. These partners will also try to increase the interaction between the biotechnology industry and financial communities.

Technology Foresight

In July 1999, the Conference Board of Canada reported that technology roadmapping helps companies and industries to reduce risk through collaboration and increase their competitiveness and profitability. It also noted that participation from industry, government and academia may bring the greatest benefit, as government and academia can help companies compete globally. Canadian companies, particularly SMEs, which tend to concentrate on short- to medium-term business priorities, need better forecasting to plan their research and marketing.

In the new economy, we need better technology foresight to plan research strategies. Over the last few years the government has made a concerted effort to link the various players in regional innovation systems (including other research, capital, training and commercialization organizations) to map out innovation strategies and action plans. Developing technology roadmaps is important in advancing strategic information in the science and technology (including biotechnology) communities. Based on the results of a May 2000 feasibility study including consultations with stakeholders, Industry Canada will work with industry and other partners to develop a technology roadmap for the biopharmaceutical industry; other targeted subsectors may include agricultural and environmental applications. Roadmaps serve as a basis to build understanding and determine needs within various industry, university and government communities. Federal science-based departments and agencies have a key role to play as well in this area.

ENVIRONMENTAL BIOTECHNOLOGIES

Industrial environmental biotechnologies can be divided into several groups:

- remediation — use of natural and engineered organisms to clean up pollution (e.g., "bioremediation," using microorganisms, and "phytoremediation," using plants to break down hazardous substances in contaminated soils and groundwater);
- abatement — use of natural and engineered organisms to prevent pollution; and
- cleaner production — use of enzymes and microorganisms to develop processes that require less energy than their conventional chemical-process counterparts and reduce greenhouse gas emissions and pollutant loading.

Products and processes less harmful to the environment and more sustainable are in increasing demand. This is fostering development of new genomics-based diagnostic tools to detect, monitor and assess the environmental impacts of microorganisms.

The global market for bioremediation technologies is currently worth about $1 billion, and for enzymes it is also worth about $1 billion and growing at 10 percent annually, according to the Organisation for Economic Co-operation and Development.

Visible Genetics Inc.
Toronto, Ontario

A leader in the emerging field of pharmacogenomics, Visible Genetics Inc. uses genetic information in the identification and analysis of genes linked to disease in order to improve patient care and reduce healthcare costs. This company manufactures and markets high-performance automated DNA sequencing systems and complete kits for the analysis of human or infectious organism genes. Visible Genetics has received US Food and Drug Administration authorization to initiate human clinical studies of its TruGene HIV-1 Genotyping kit and related OpenGen DNA sequencing system. This technology has the potential to significantly improve the management and well-being of individuals with HIV/AIDS.

Aqua Bounty Canada
St. John's, Newfoundland

Aqua Bounty Canada is a cutting-edge biotechnology company, with operations in Newfoundland and Prince Edward Island, that is applying years of scientific research in transgenic technology to develop superior brood-stock for aquaculture. The primary goal of the company is to produce fish for aquaculture with enhanced growth characteristics. This is being accomplished through a combination of selective breeding and the use of a novel, all-fish gene construct consisting of the chinook salmon growth hormone gene linked to an antifreeze gene promoter sequence from the ocean pout. The company has developed AquAdvantage™ salmon, a line of Atlantic salmon that exhibit growth rates four to six times that of standard salmon. The company is now focusing on supplying all the information required to gain regulatory approval for the AquAdvantage™ rapidly growing salmon. In the future, the company intends to broaden the application of this technology to other aquaculture species to develop lines of fish exhibiting traits such as increased cold tolerance and disease resistance.

Philom Bios Inc.
Saskatoon, Saskatchewan

Philom Bios is the only Canadian-owned inoculant company delivering a range of microbial products to prairie farmers. Philom Bios's microbial products are based on natural microorganisms, such as fungi and bacteria, which are used to stimulate plant growth and generate yield gains for the farmer. Philom Bios was established in 1980 and is an innovative microbial technology company dedicated to improving plant productivity for farmers through the development, manufacture and marketing of natural microbial products for commercial agriculture.

Financing and Access to Capital

If Canadian biotechnology companies are to fully exploit growth opportunities, they will need access to a steady flow of capital on reasonable terms and at reasonable costs. A large proportion of Canadian biotechnology firms are SMEs. Many have moved or are moving from the strictly R&D stage to the preclinical and/or commercialization stage. These stages have larger capital requirements, which means access to capital will be a priority for industry success. In addition, the number of products in the development pipeline is growing rapidly, and it is reasonable to assume that the overall capital requirements of the biotechnology industry will increase accordingly.

Even conservative estimates of capital requirements call for rapid growth in available funds. Improving the practices used to supply capital will allow the industry to achieve its full potential. A lack of capital for Canadian biotechnology companies can result in company failure or takeover. Further analysis of financing issues faced by Canadian biotechnology companies is underway to evaluate whether Canadian financial markets can provide enough capital and to determine whether policy responses can improve efficiencies.

Meeting the capital requirements to finance the growing number of biotechnology products in the development pipeline will be challenging. Current estimates indicate a fivefold increase in annual capital requirements in the next decade, reaching $5 billion annually by 2010. Part of the capital will come from self-financing, especially for large companies. However, biotechnology companies will have to obtain a large part of their financing externally. External sources of capital include angel and venture capital, private placements, public capital markets, strategic alliances, and government programs such as Technology Partnerships Canada (TPC) and the NRC's Industrial Research Assistance Program (IRAP). In addition, under the Canada Small Business Financing Act, SMEs with annual gross revenues of less than $5 million can obtain loans from authorized lending institutions to finance up to 90 percent of the cost of the purchase or improvement of fixed assets, and the Business Development Bank of Canada also offers a variety of financial products to support the long-term growth of Canadian businesses, such as venture loans, innovation loans and venture capital. Industry Canada designed its $ources of Financing Web site (**http://www.strategis.ic.gc.ca/sources**) to

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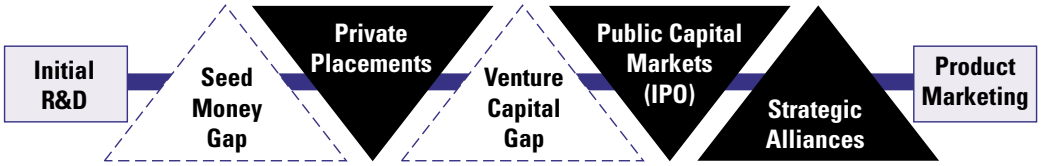
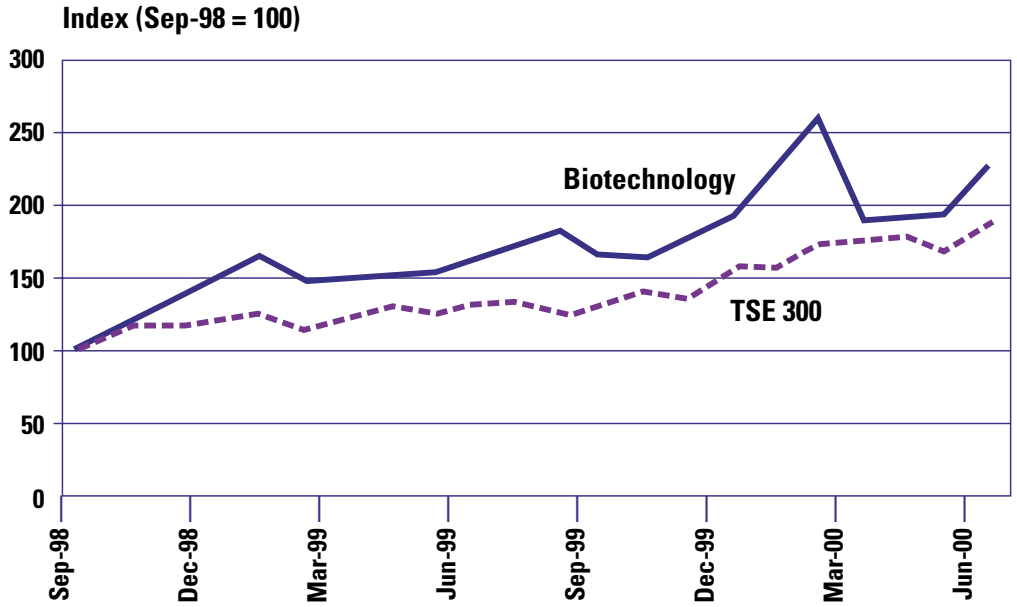
Financial Gaps in the Commercialization of Biotechnology Products



Source: Industry Canada

It is very difficult to attract private-sector funding for this proof-of-concept stage.

Indications from Capital Markets



Source: TSE

increase SMEs' awareness of available financing options; the site provides information on various private- and public-sector financing options.

Early-Stage Funding

Before investors will commit resources to demonstrate the commercial potential of a discovery, they usually require further research and some development. Funding for this demonstration work typically ranges from $100 000 to $1 million. Given the nature of the risks involved, it is very difficult to attract private-sector funding for this proof-of-concept stage. Canadian biotechnology SMEs face particular competitive disadvantages given the resources available to multinational enterprises (MNEs). Despite these challenges, major progress has been achieved over the last few years. For example, organizations such as T2C2, Milestone Medica, University Medical Discoveries Fund, Innovatech, Foragen and others have invested preseed rounds of $50 000 to $500 000 in more than 70 precompany projects. However, demand still outstrips the supply of capital and some sectors of biotechnology (i.e., environment, agriculture) have not been as successful as the health sector in capturing preseed funding.

IRAP provides technical assistance to SMEs to help boost their productivity, profitability and international competitiveness. IRAP staff includes several hundred Industrial Technology Advisors (ITAs), who work at more than 150 locations across Canada, including universities and government laboratories. However, they are not yet at research hospitals affiliated with universities. New strategically located ITAs will increase connectivity between IRAP clients and the technologies created in research hospitals. These ITAs will provide early-stage funds to SMEs to allow them to participate in the transfer of technology from health-related institutions. IRAP will partner with CIHR in these activities to help ensure that Canada benefits from this biotechnology-related research.

Support for Company Incubation

Biotechnology companies in their early stages need access to laboratory and office space, business and technical expertise and proximity to research institutions. Many start-up biotechnology companies in Canada are housed temporarily in academic laboratories, until they can locate affordable and more appropriate space. Given the financial constraints of most start-ups and the primarily scientific background of those involved, a growing new business needs support and advice. Incubator facilities will significantly increase the likelihood that start-up companies survive to become part of a region's industrial base.

All levels of government have recognized the benefits of developing biotechnology incubator sites and are supporting increased activity. In the province of Quebec, Centre québécois d'innovation en biotechnologie (CQIB, Quebec Centre for Innovation in Biotechnology) completed its second phase in May 1999 with the financial support of the provincial government. The only one of its kind in Quebec, QIBC offers researcher-entrepreneurs private laboratories, scientific equipment, and business-mentoring services to help launch innovative biotechnology companies. In June 2000, Ontario announced its support for the creation of two biotechnology incubation facilities, one in Ottawa and another in Toronto. The Toronto Biotechnology Commercialization Centre currently includes the University of Toronto, five Toronto research hospitals, the Centre for Addiction and Mental Health, the City of Toronto, and the federal government. The NRC, Agriculture and Agri-Food Canada, the region of Ottawa-Carleton and local universities are among the partners in the Ottawa Biotechnology Incubation Centre. The NRC and regional development and provincial organizations are discussing a planned incubator facility in Winnipeg, and NRC biotechnology labs are planning other partnership-based incubators in Halifax and Saskatoon.

These initiatives will provide Canadian best-practice models and act as focal points for the workshops and seminars intended to help early-stage biotechnology companies, as discussed in the "Skills Development and Human Resources" section of this document. These facilities can also help develop technology roadmaps for biotechnology, as discussed in the "Technology Foresight" section above.

Later-Stage Funding

The NBAC report and industry representatives have indicated that biotechnology companies need financial support at the later stage of product development. Unlike other sectors, biotechnology has an extremely long time frame and very high costs to get from basic research to commercialization. This is due to its highly complex and innovative products and processes and the important need to

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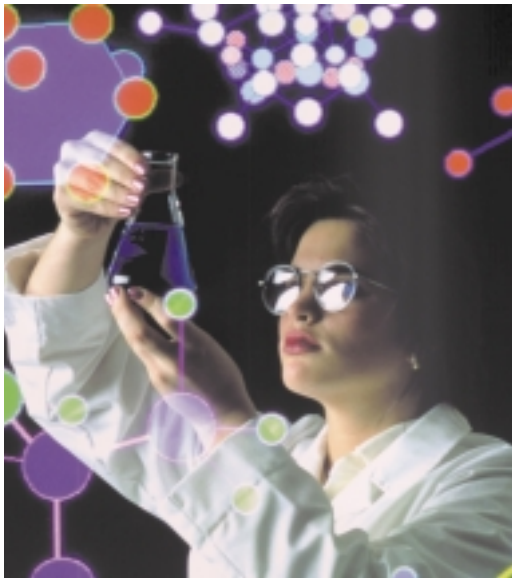
TPC supports the development of Canada's biotechnology sector with strategic investments to encourage private-sector investment and so maintain and increase the technology base and technological capabilities of Canadian industry.

demonstrate product safety. For example, to develop a biopharmaceutical product can require up to $500 million and 10 years of work. This expanded time frame requires sustained financial support throughout the product-development life cycle, including the later, near-commercialization stage.

The cash squeeze facing most biotechnology companies in Canada forces them to license their intellectual property too early. They form partnerships with MNEs and let these large established companies finalize development of products and undertake regulatory approvals and marketing. While some level of partnering is beneficial, domestic companies would serve the national interest better if they could move as far down the product-development path as possible before making licensing arrangements. This would not only bring greater profits to Canadian SMEs but also enable Canadians to develop expertise in key areas of company development, such as regulatory-approval processes and marketing.

Federal support for later-stage product development will help address some of these issues, allowing Canadian companies to retain ownership of their technologies and innovations and leading to greater value added and spinoff benefits for Canada. Support will allow for a greater number of projects to be funded at the later stages in the innovation cycle. This will help develop a core of mature Canadian companies with their own manufacturing, marketing and distribution networks and potentially provide a Canadian option for SME partnering.

The major government program to provide assistance in this area is Industry Canada's TPC. It supports the development of Canada's biotechnology sector with strategic investments to encourage private-sector investment and so maintain and increase the technology base and technological capabilities of Canadian industry. As of May 2000, TPC's investments in eight biotechnology companies accounted for



$204 million of its portfolio of $1.2 billion. These investments will leverage $750 million in new R&D investment and create more than 2000 jobs in Canada. Examples include TPC's 1997 contribution of $60 million to Pasteur Mérieux Connaught Canada (now Aventis Pasteur), which enabled the company to take on a world mandate to develop and produce new therapeutic vaccines to combat eight forms of cancer. In April 2000, TPC invested $80 million in BioChem Pharma to allow the company to evolve into a fully integrated biotechnology company in the field of recombinant protein vaccines. Through strategic shared-cost approaches such as this, TPC is helping Canadian biotechnology firms move up the value-added chain.

Tax Measures

The biotechnology sector is composed of mainly small businesses. Small businesses have greater difficulty than larger firms in obtaining adequate financing, a fact that impedes their ability to grow. The federal income tax system contains several special provisions to encourage investment in these companies and reduce their reliance on external financing.

For example, the five-year tax reduction plan contained in Budget 2000 seeks to make the

Canadian economy more innovative and internationally competitive. It provided an additional $4.2 billion to support an innovative economy. By 2004-2005 the budget will provide $1 billion in annual tax relief to the private sector to make the economy more competitive. This includes a reinstatement of full inflation indexing, an increase in the amount of income Canadians can earn tax free, and an increase in the level of income at which the top tax rate begins to apply. Individuals will be able to defer capital gains from eligible small-business investments if they reinvest the proceeds in another eligible small business. The capital-gains inclusion rate will also be reduced from three-quarters to two-thirds to ensure that businesses have access to the capital they require in an increasingly competitive and knowledge-based economy. Investors in qualifying small businesses benefit from a Lifetime Capital Gains Exemption, which applies to the first $500 000 of capital gains. Budget 2000 also enhanced the Small Business Deduction (SBD). Beginning in January 2001, SMEs will benefit from a new 21 percent corporate tax rate on business incomes between $200 000 and $300 000. SBD addresses difficulties faced by small businesses in accessing external financing by increasing the proportion of business profits they can retain for expansion and investment.

In addition to these new measures, Canada is further refining its Scientific Research and Experimental Development (SR&ED) tax credit program. Canada's SR&ED program is one of the most generous in the world; it encourages businesses — particularly small and start-up firms — to conduct R&D in Canada.

In consultations, small companies, including biotechnology companies, indicated that they had difficulty understanding the SR&ED program requirements and needed more certainty to facilitate project financial planning. To respond to these concerns the Canada Customs and Revenue Agency (CCRA, formerly Revenue Canada) has instituted a number of refinements. For example, Science Access is a suite of advisory services available for taxpayers to consult before they make SR&ED claims. Science Access includes outreach, public seminars, individual taxpayer education, services for first-time claimants, and the Preclaim Project Review (PCPR) service. The PCPR service addresses the need for greater up-front certainty about the eligibility of SR&ED projects. CCRA is also establishing national technology-sector specialists — including specialists in biotechnology, pharmaceuticals, agriculture and aquaculture — to enhance consistency, improve service, and establish stronger relationships with industry associations. National technology-sector specialists will have offices near the geographic concentrations of the industry sectors.

By 2004-2005 the budget will provide $1 billion in annual tax relief to the private sector to make the economy more competitive.

Canada's SR&ED program is one of the most generous in the world.

BIOAQUACULTURE

The growth potential of aquaculture remains enormous, both in meeting increasing food requirements and in offsetting the collapse of the wild fisheries. The Food and Agriculture Organization of the United Nations calculated that the annual demand for seafood will outstrip the ability of wild fisheries to supply it by some 55 million tonnes by 2025. To compensate for this shortfall, aquaculture production will have to increase by 350 percent. Biotechnology will play an important role in increasing both the quality and quantity of resource yields, and the Canadian aquatic biotechnology industry is world renowned in broodstock development, quality control, health and environmental management, education and research. In Canada in 1996, the farm catch of salmon surpassed that of wild fisheries by $350 million, and the gap has continued to widen since that time.

SemBioSys Genetics Inc.
Calgary, Alberta

SemBioSys is a molecular farming company focused on commercializing products based on its oleosin/oil body technology. SemBioSys has the technology to cost-effectively extract the oil body/protein assembly from the genes of plants. The oil body/protein assembly mechanism can then be used directly in applications where the emulsion characteristics of oil bodies enhance formulation or delivery such as in food and cosmeceuticals, or used as a starting point for low-cost purification when a pure protein is required. SemBioSys's production and purification system works in a variety of oilseed crops.

Biorem Technologies Inc.
Guelph, Ontario

Air pollution, consisting of a wide range of contaminants emitted by industrial manufacturing, agriculture production, transportation, energy generation and municipal waste management, has become an increasing issue manifested in problems of global warming, public health and quality of life. Biorem Technologies Inc. is a technology and commercial leader in the design and installation of biological air filters, or biofilters, for the removal of odours and organic contaminants from air emissions. This low-cost technology utilizes the power of microbes to biologically oxidize the offending emissions without consuming chemicals or other energy sources. Successful installations have been completed at food- and chemical-processing plants, municipal sewage and composting facilities and surface-coating industries. Biorem provides complete design and turnkey installation of biofilter systems across the United States and Canada.

Æterna Laboratories Inc.
Ste. Foy, Quebec

The Quebec-based biopharmaceutical company develops drugs for treatment in fields such as cancer, dermatology and ophthalmology. Æterna's lead compound, Neovastat, is an angiogenesis inhibitor. Angiogenesis, a scientific term for the formation of blood vessels, facilitates the development of cancer and other diseases that require the development of new blood vessels to supply them with essential nutrients for growth. Preclinical and clinical data suggest that Neovastat has an effect on diseases that are dependent on angiogenesis. Neovastat is among the few antiangiogenesis products that are in Phase III clinical trials.

Skills Development and Human Resources

Canada's biotechnology industry will need all of the elements of success to prosper and grow in the knowledge-based economy. Internationally, the biotechnology industry is moving to the next phase — a 10-year period of rapid expansion in global demand. Canada's ability to take advantage of this growth and develop its industry will depend on several strategic factors, most particularly the implementation of creative and flexible solutions to address skills-development needs and build entrepreneurial strength.

Skills Gap

In 1997, employment in the Canadian biotechnology industry was at about 10 000, a fourfold increase from a decade earlier, and the industry was unable to fill many positions for highly skilled people. Estimates suggest employment will reach nearly 16 000 by 2001. This rapid growth is causing shortages of researchers in the expanding field of genomics, as well as shortages of experienced business managers and regulatory affairs specialists.

Evidence points to skills issues as significant challenges to biotechnology industry growth in Canada. The Paget report concluded that the major skills gap related to the biotechnology industry's need for people with multidisciplinary backgrounds; for example, combining several scientific specialties with nonscientific specialized skills, such as knowledge of regulatory processes or intellectual property regimes. The ACST skills report noted a persistent and generalized shortage of essential management skills among graduates of post-secondary schools. It emphasized that, because a smaller cohort of youth would be reaching working age over the coming decade, new workforce entrants had not only to be technically competent, but also to be adequately prepared for the world of work. The results of a recent Statistics Canada study on the characteristics of rapid growth in Canadian biotechnology firms confirmed that managerial competencies are difficult to find and that this could become a major obstacle to growth in the Canadian biotechnology industry.

Consultations carried out with the biotechnology industry by the Biotechnology Human Resources Council (BHRC) and Industry Canada suggest that new hiring is difficult in research, manufacturing and production. BHRC points out that regulatory affairs and executive management positions are very hard to fill. Industry priorities for training and "capability boosting" were identified in the areas of bioinformatics and lab software, regulatory compliance and marketing (research and strategies). Industry members cited competition with the

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Biotechnology Employment by Company Size

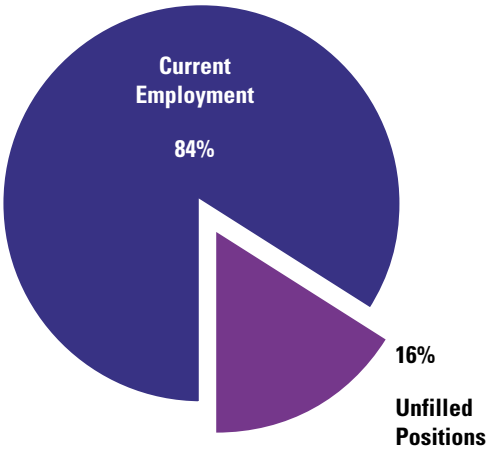
	SMALL	MEDIUM	LARGE	TOTAL
Employees	3 125	2 397	4 302	9 823
Unfilled Positions	1 031	281	587	1 899
Total Positions	4 155	2 678	4 890	11 723

Small (1–50 employees) Medium (51–150 employees) Large (>151 employees)

Source: Statistics Canada, Biotechnology Firm Survey, 1998

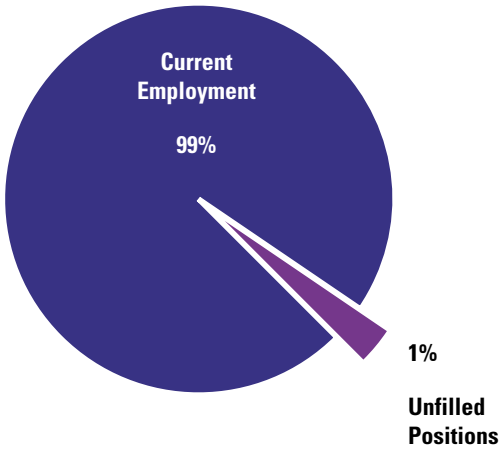
Working with partners, Genome Canada will work to catalyze innovation and business clusters around its Genome Centres. This will, in turn, provide opportunities for Canadians to develop crucial business skills in areas such as product development, marketing and regulatory approvals.

Total Biotechnology Employment, 1997



Source: Statistics Canada, Biotechnology Firm Survey, 1998

Total Employment All Sectors, 1997



Source: Industry Canada

United States for the same pool of skilled professionals as a key concern for Canadian biotechnology companies.

Skills Development

Human Resources Development Canada (HRDC), BHRC and others are working to help the biotechnology industry meet its human resource needs. BHRC offers an inventory of biotechnology-related programs across Canada, a regulatory affairs program and executive management courses (with the University of Western Ontario, Université du Québec à Montréal and the University of Saskatchewan). These initiatives are aimed at individuals already working in the biotech industry.

Planning is underway to expand existing efforts. A skills development program is required with a longer view, geared toward the current student population and related to entrepreneurial management, regulatory affairs and leadership preparation. BHRC will be working with the support of HRDC and other partners to build on existing programs toward establishing a one-year master's-level program geared specifically to the needs of Canada's biotechnology industry and aimed at new science and engineering graduates. The curriculum would include topics such as entrepreneurial management, leadership, business finance, marketing, regulatory affairs and intellectual property.

Genome Canada will also help to advance Canadian efforts. In providing funding to Genome Canada, the government was seeking not only to advance genomics research but also to provide focused support for the human resource needs of the biotechnology industry. Working with partners, Genome Canada will work to catalyze innovation and business clusters around its Genome Centres. This will, in turn, provide opportunities for Canadians to develop crucial business skills in areas such as product development, marketing and regulatory approvals. Genome Canada will also provide opportunities for young scientists and technicians through work-study and training programs, in addition to the opportunities its partners provide in their genomics research at the centres.

Needs of Biotechnology SMEs

BHRC points out that the SMEs that predominate in Canada's biotechnology industry have particularly high turnover rates and rarely have professional human resource management. Small firms also experience a high incidence of long-term vacancies, also reflecting a limited human resource management focus. The ACST Expert Panel on Skills noted that difficulties in recruitment, retention and skill development are a direct consequence of SME size and limited financial and management resources. The expansion of the NRC's planned biotechnology incubators in Halifax, Ottawa, Winnipeg and Saskatoon (as discussed in the "Technology Transfer" section) along with provincial investments in incubator development, will help small start-up biotechnology companies across the country recruit and retain employees.

Human Resource Needs of Government Regulators

Individuals working in a regulatory capacity must continue to be of the highest caliber. They must be up to date with the current scientific advances, particularly in a fast-paced environment such as biotechnology, for the regulatory system to function efficiently, effectively and with the public's confidence. The $90 million for biotechnology regulation provided in federal Budget 2000 will enable the government to meet its need for specialized and technical human resources. It will use a variety of methods to do this: aggressive recruitment strategies, contracting out for specialized knowledge, greater access to global expertise, greater use of expert advisory committees, upgrading training opportunities for current regulatory staff, and establishing programs to develop regulatory expertise, such as sponsoring graduate courses on regulation.

Difficulties in recruitment, retention and skill development are a direct consequence of SME size and limited financial and management resources.

Syndel Laboratories Ltd.
Vancouver, British Columbia

Syndel Laboratories Ltd. operates a successful and growing business in the manufacture and distribution of veterinary pharmaceuticals for the aquaculture industry. The company is a world leader in aquatic animal reproduction and provides proprietary products and services for aquatic animal health and nutrition. Syndel Laboratories Ltd. was founded in 1977 and currently markets products worldwide, including Africa, North and South America, South and Southeast Asia, Australasia and Europe.

Ocean Nutrition Canada Limited
Bedford, Nova Scotia

Ocean Nutrition Canada is focusing on research, development and manufacture of marine-based nutritional supplements and nutraceuticals and functional foods. Nutraceuticals and functional foods are foods or ingredients that prevent or treat specific deficiencies or diseases. This company operates the largest privately held R&D facility for natural marine products in Canada.

Nexia Biotechnologies Inc.
Ste. Anne de Bellevue, Quebec

Founded in 1993 by Dr. Jeffrey Turner, then a McGill University Professor, Nexia is currently Canada's leading animal transgenic company. Nexia's mandate is to produce performance biomaterials and pharmaceutical proteins in the milk of transgenic animals, using leading-edge recombinant techniques. This technology uses the natural lactation (dairy) process and recombinant DNA technology to produce products without the need for complex fermentation or chemical equipment.

Spider silk, for example, has been a material sought by engineers because of its extreme performance properties, particularly strength. Nexia's proprietary transgenic silk production system is an innovative approach, proven successful in producing the most authentic, man-made spider silk to date. The result is BioSteel™, a family of spider silk proteins. Applications of BioSteel™ performance fibers include industrial (personal body armour) and medical (fine sutures) uses.

Regulation and Intellectual Property

A fair, efficient and competitive marketplace is the foundation for investment, innovation, trade and economic growth. As knowledge-based firms have considerable latitude in choosing where they do business, it is crucial for Canada to attract and retain firms while meeting Canadian standards and policy objectives. Marketplace framework policies must recognize rapidly advancing technological change and be fair, efficient and timely in their administration.

Two marketplace frameworks are key to the biotechnology industry: intellectual property and the regulatory system. Numerous reports and studies — including the 1998 NBAC report, CBS consultations, and the Ernst and Young Canadian Biotechnology Industry Reports — have stressed the importance of intellectual property and regulations for enhancing Canada's competitive position internationally.

Regulation

Canadians view health, safety, the environment, and economic and social well-being as fundamental to their quality of life. The government's regulatory activities in these areas are part of its responsibility to serve the public interest. The regulatory system is also a linchpin between innovation and product commercialization, and regulatory policy is a key determinant in attracting foreign direct investment (FDI) and retaining Canadian-based investments and jobs.

A public opinion survey undertaken in 2000 indicated that few Canadians understood their regulatory system, most wanted strong protection for health and safety, and most expected their government to provide this protection. The growing number of biotechnology products, along with their uniqueness and complexity, has led to a substantial commitment from the government on a variety of fronts (Health

Regulatory policy is a key determinant in attracting foreign direct investment (FDI) and retaining Canadian-based investments and jobs.

In the 2000 budget, the government announced funding of $90 million specifically for the regulation of biotechnology.

Canada anticipates a 500-fold increase in biotechnology applications in the next decade and the Canadian Food Inspection Agency indicated that more than 5000 ag-biotech products are presently in field trials).

Canada has had a regulatory framework for products of biotechnology since 1993. It seeks to ensure:

- Canada's high standards for protection of health and the environment;
- clear product evaluation guidelines in harmony with national and international standards;
- a sound scientific basis for risk assessment and product evaluation;
- transparent development and enforcement of regulations, as well as open consultation; and
- the prosperity and well-being of Canadians.

In the 2000 budget, the government announced funding of $90 million specifically for the regulation of biotechnology. Recognizing the importance of the regulatory system, the government is emphasizing four strategic initiatives:

- developing government technical and human resources (discussed in the "Skills Development" section);
- generating knowledge to support the regulatory system;
- increasing the efficiency, effectiveness and timeliness of the regulatory system; and
- increasing awareness of the regulatory system.

Generating Knowledge to Support the Regulatory System

In carrying out regulatory activities, government undertakes risk assessments on new products and processes to determine potential risk to humans, plants, animals or the environment. It bases its risk assessments on knowledge from the organization applying for product approval and/or publicly available scientific literature. Scientific discoveries and techniques are accelerating exponentially in biotechnology. Therefore, credible, science-based decisions require enhanced R&D to assess new products.

AGRICULTURE AND AGRI-FOOD

Technology has always been essential to productivity gains in agriculture. Since the first commercial planting of genetically modified crops in 1996 adoption of this technology has been steadily accelerating, surpassing adoption rates of previous technological advances. In 1999, the estimated percentage of total area planted to GM crops was 77 percent for canola, 20 percent for soybeans, 42 percent for corn, and 8.5 percent for potatoes. The first generation of GM crops provided input traits, beneficial to producers, such as herbicide tolerance. The next generation of GM crops will most likely have output traits of benefit to processors and consumers, such as vitamin-fortified crops and other functional foods that influence human health. These types of crops would have advantages for consumers in both developing and developed countries. The prospects for continued growth of GM crops in agriculture are positive with projected global sales of transgenic crops expected to reach about $6 billion by 2005. Agriculture and Agri-Food Canada has always been a key contributor to Canada's agricultural research initiatives. It is now developing a targeted genomics research initiative, Functional Genomics of Canadian Cereals and Oilseed Crops, a coordinated set of biology-driven projects led by Agriculture and Agri-Food Canada scientists. The project incorporates Canada's historical strength in cereal and oilseed breeding and plant biology into a genomics-based gene-discovery initiative.

Government also requires enhanced knowledge to develop diagnostic tools and methods for inspection, monitoring, and post-market surveillance to assess the potential risks or effects of new products on health, safety and the environment.

Research will be carried out in the following areas:

- detection of allergenic proteins;
- transmission of animal pathogens to humans;
- disposal of plants used for bioremediation;
- biological interactions and ecological effects;
- genetic diversity;
- detection of genetically modified organisms;
- long-term effects;
- pathological, toxicological and immunological baseline studies; and
- assessment of foreign DNA persistence in the environment.

Increased Effectiveness, Efficiency and Timeliness of the Regulatory System

Regulatory departments and agencies will be improving their consultative and foresight mechanisms, developing guidelines and regulations in emerging areas (e.g., animal biotechnology), and increasing their capacity to assess, monitor and inspect products, conduct post-market surveillance of them, and enforce regulations. They will benchmark Canada's regulatory system for health products against key international competitors (e.g., European Union) to ensure Canada's regulatory system is responsive and timely for the biotechnology industry while maintaining Canada's high standards. Greater capacity will be required to work with major trading partners in international fora, where efforts are underway to harmonize technical and risk assessment standards (e.g., the Biosafety Protocol, Codex Alimentarius) and to establish regulatory agreements to facilitate product assessment and access.

Speed to market has always been critical for products with a finite period of patent exclusivity and is usually presented as the highest priority by industry. Consumers of new technologies may also be at a disadvantage if products available in other countries are unavailable in Canada, however, regulatory speed cannot compromise safety. Health Canada's proposed streamlining of clinical-trial regulation requirements, together with a cost-recovery link to performance, is a step toward a more efficient system that will help provide Canadians with access to research while still protecting health and safety.

In addition to the government's efforts, CBAC will be reviewing, consulting and advising the government on issues in the regulation of genetically modified food. It will examine the social, ethical, legal, economic and environmental aspects of the issue.

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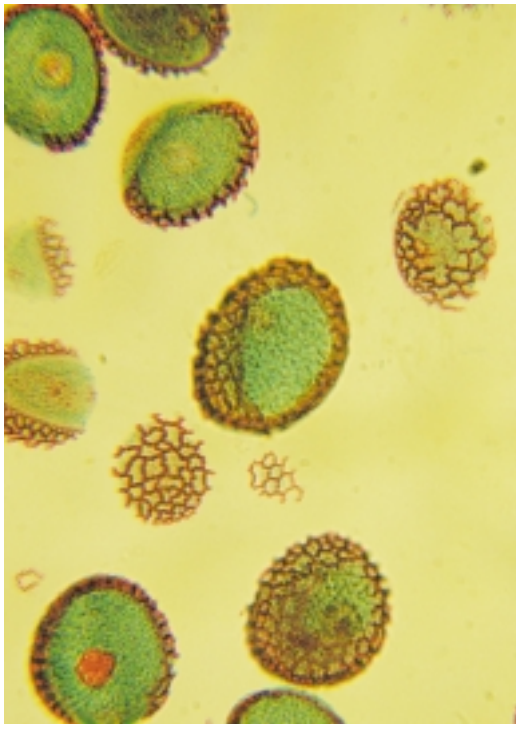
LABELLING THE PRODUCTS OF BIOTECHNOLOGY

Labelling the products of biotechnology is an important issue for consumers. Surveys have shown that Canadians have the highest international acceptance (74 percent) of agricultural biotechnology. However, media coverage, events in Europe and growing awareness of biotechnology are leading to increasing consumer demands for more information, including demands for a strengthened labelling system. The Canadian Council of Grocery Distributors has launched a project to develop a Canadian standard for voluntary labelling of foods derived from biotechnology, which it will develop with the participation of consumer groups, food companies, producers and interest groups.

A new Biotechnology Regulatory Assistance Virtual Office (BRAVO) identifies Canadian federal and provincial Acts and regulations, as well as many of the guidelines currently or potentially affecting various aspects of biotechnology.

Knowledge is the most critical asset in the technology-intensive biotechnology sector.

Canada must adapt its delivery of intellectual property services to the competitive conditions of a global, technology-intensive, fast-paced industry.



Increasing Awareness of the Regulatory System

To raise Canadians' awareness of the regulatory system for biotechnology products, the government will make a proactive effort to provide clear and accessible information. Complementing the planned efforts of regulatory departments and agencies, Industry Canada is developing a Web site called Biotechnology and the Consumer that will give consumers a gateway to information on biotechnology issues. It will focus on regulations, health and safety, science and the benefits and risks of biotechnology.

Industry Canada has also worked with partners to provide a "starting point" for industry and others interested in knowing more about the regulatory process. A new Biotechnology Regulatory Assistance Virtual Office (BRAVO) identifies Canadian federal and provincial Acts and regulations, as well as many of the guidelines currently or potentially affecting various aspects of biotechnology.

BRAVO is available at **http://www.bravo.ic.gc.ca** and provides:

- a Web-based information tool with faster, more comprehensive and focused access to regulatory information for biotechnology;
- a 'one-stop shopping' resource centre of national regulatory compliance requirements in biotechnology;
- comprehensive summaries of acts and regulations at all levels of government that govern the use of biotechnology for various industrial activities;
- important guidelines applicable to biotechnology industrial activities;
- relevant government contacts; and
- information on all biotechnology product sectors, including agriculture, agri-foods, health environment, aquaculture, forestry, energy and mining.

Intellectual Property (IP)

Knowledge is the most critical asset in the technology-intensive biotechnology sector. The effective management, protection and dissemination of knowledge is an essential component of any strategy to foster competitiveness, growth and jobs.

The IP regime must support biotechnology innovation and investment in Canada. This requires effective and globally competitive protection of intellectual property that starts with an effective legislative framework. Government must increasingly support its legislative framework with determined efforts to clarify the rules in the global marketplace so investment decisions related to biotechnology will have a sound, predictable IP environment. Canada must adapt its delivery of intellectual property services to the competitive conditions of a global, technology-intensive, fast-paced industry.

The 1998 NBAC report made several recommendations to strengthen Canada's regime for protection of IP, including changes to the *Plant Breeders' Rights Act*, *Patent Act*, and the Canadian Intellectual Property Office's (CIPO) examination and administrative processes.

Legislation

Canada has amended and modernized its *Patent Act* over the last 20 years, guided by its commitment to enable everyone to share the benefits of patenting. Biotechnology innovators and users of the patent system have benefited from changes to the *Patent Act*. These changes include a first-to-file system that provides greater certainty in the determination of patent rights; the publication of patent applications 18 months after date of filing to encourage and facilitate early diffusion of new technology; an exemption for the use of patented inventions for research; and, a patent term of 20 years from date of filing.

Given the importance of agricultural biotechnology to Canada, modernization of intellectual property legislation for this sector is crucial. The amendments to the *Plant Breeders' Rights Act* introduced in Parliament in spring of 1999 are expected to satisfy the recommendations of the 1998 NBAC report.

The patentability of higher life forms is the most significant outstanding issue, particularly for the ag-biotech sector. When developing Canadian policy on patenting of higher life forms, the government will carefully examine the results of CBAC's public consultations, scheduled to begin in the spring of 2001.

International Intellectual Property Agenda

Increasingly, international negotiations influence the domestic IP agenda for biotechnology. As a currency in a global, knowledge-based economy, intellectual property will continue to be important. This is evident from discussions in the World Trade Organization (WTO); ongoing challenges to certain provisions of Canada's Patent Act, under the WTO dispute-resolution process, and ongoing discussions in the World Intellectual Property Organization.

The government will continue to consult Canadians in developing its positions on intellectual property at international fora,

Biotechnology innovators and users of the patent system have benefited from changes to the Patent Act.

The patentability of higher life forms is the most significant outstanding issue, particularly for the ag-biotech sector.

As a currency in a global, knowledge-based economy, intellectual property will continue to be important.

particularly with regard to the Trade Related Aspects of Intellectual Property Rights (TRIPs) agreement and the process in the WTO for managing IP issues in biotechnology.

Delivery of Intellectual Property Services

To deal with the expansion of patent applications in the field of biotechnology, CIPO has recently increased the number of patent examiners. However, the government will begin further discussions on service delivery with the biotechnology industry to ensure that the CIPO provides globally competitive services in this fast-moving area.

Genetic Privacy

Advances in genetics have the potential to produce many health benefits, but they raise concerns about possible violations of genetic privacy and discrimination based on one's genetic makeup. To ensure that genetic research can be used to improve health and health care, privacy and discrimination issues must be addressed. Forms of genetic discrimination could include discriminatory practices in hiring, access to credit or insurance, or even in policies related to reproduction and education. Canada's Privacy Commissioner has reported that existing laws will not prevent privacy abuses through genetic testing, and that greater legal controls need to be developed. The CBAC has identified genetic privacy as one of the five key issues that it will address in consultations with Canadians.

Biomira Inc.
Edmonton, Alberta

Biomira Inc. is a biotechnology company applying its technology in immunotherapy and organic chemistry for the development of cancer therapeutics. Biomira is developing therapeutic cancer vaccine products that it believes will lead to a new generation of safe and effective anti-cancer therapeutic agents. Cancer cells differ from normal cells in that they have carbohydrate, and peptide or protein molecules called antigens on the cell surface that are not expressed by normal cells. These antigens on cancer cells are regarded as foreign by the immune system and their presence would normally trigger the production of cancer-fighting antibodies and white blood cells called lymphocytes. However, in cancer patients, the immune response to the cancer antigens is suppressed. Biomira has developed a method to synthesize a number of cancer antigens that mimic the natural cancer antigens. The end product is a therapeutic cancer vaccine designed to stimulate the body to develop an immune response directed against the patient's cancer. This is called active specific immunotherapy.

MDS Inc.
Toronto, Ontario

MDS Inc. is a Canadian international health and life sciences company. In many of its products and services, it is among the largest and most respected companies in the world. MDS employs more than 11 800 highly skilled people at its global operations on five continents. The corporate head office is in Toronto.

MDS Pharma Services is one of the world's leading contract research organizations providing R&D services to the international biotechnology and pharmaceutical industry. The company is a global leader in early-stage through proof-of-concept pharmaceutical development and has a growing presence in late-stage pharmaceutical development. Headquartered in Montreal, Quebec, MDS Pharma Services employs more than 3 900 people in 20 countries around the world.

MDS Proteomics Inc. is a synergistic base of scientific expertise, knowledge and technology in the field of proteomics. That technology platform uses advanced knowledge of protein-protein interactions, target discovery, validation and a proprietary bioinformatics database of core interactions to redefine the development of diagnostics and therapeutics for disease. Proteomics is a rapidly emerging segment of the life sciences industry, which uses an understanding of human proteins to design new treatments for disease.

Foreign Investment and Trade

The attraction and retention of investment is vital to the Canadian economy and presents some particular challenges in biotechnology.

In its International Investment Strategy, the federal government has recognized the need to attract more foreign direct investment and has developed an action plan, including the targeting of sectors (such as biotechnology).

Foreign Investment

The attraction and retention of investment is vital to the Canadian economy and presents some particular challenges in biotechnology. Canada depends on foreign direct investment for one job in 10. According to a joint report of Industry Canada and the Department of Foreign Affairs and International Trade, *The Impact of Foreign Direct Investment on Job Creation and Economic Growth: Evidence from the WEFA Canada Macro Economic Model*, $1 billion in foreign investment creates 45 000 new jobs and increases real gross domestic product by about $4.5 billion over five years.

While government financing and venture capital are vital to the development of the biotechnology industry, it also requires the participation of well-funded multinational companies. These companies invest in clinical trials, take equity positions or develop various types of R&D or market alliances with Canadian biotechnology companies, invest in basic research, build research facilities (decisions greatly influenced by Canadian research excellence), and build or expand Canadian subsidiaries for product development and manufacturing. Past performance indicates that the health and agricultural biotechnology sectors are most likely to attract foreign investment. Resource-based industries (such as forestry or mining) have also demonstrated the potential for much greater use of biotechnology, especially in developing more environmentally friendly processes.

International Biotechnology Investment Strategy

In its International Investment Strategy, the federal government has recognized the need to attract more foreign direct investment and has developed an action plan, including the targeting of sectors (such as biotechnology), countries and companies. Recognizing that many investors have overlooked Canada, the federal government, in consultation with the provinces, has embarked on two pilots to market "Brand Canada" to US investors. One of these, a pilot in Boston, will include biopharmaceuticals

and nutraceuticals. The research phase of these pilots is scheduled for completion in the fall of 2000, and program design and execution will run until January 2002.

Specific issues related to attracting investment for the biotechnology industry exist and they require sector-specific intervention. Challenges related to biotechnology include: business climate issues; a long product development cycle relative to other "hot" investment sectors (e.g. information technology) and the need to build greater international awareness of Canadian excellence in biotechnology.

The Federal Investment Strategy identifies biotechnology as a priority area, and, along with increased intellectual-property protection and government support to R&D, it has helped Canada attract numerous investments. These come primarily from pharmaceutical companies (which need biopharmaceutical innovations to fill their product pipelines) and from large agricultural biotechnology companies. On the biopharmaceutical side, examples include the AstraZeneca Research Centre in Montreal and the Amgen Institute in Toronto. Examples in agricultural biotechnology include investments by Dow AgroSciences and Aventis CROPScience in Saskatoon.

However, building greater international awareness of Canadian expertise in biotechnology requires sophisticated, specialized communications tools used in conjunction with targeted conferences, expositions and sector-based marketing. Canada has set the stage to promote Canadian biotechnology internationally with the establishment of CIHR, Genome Canada, Phase 2 of the research program of CIHR and Canada's research-based pharmaceutical companies as well as Health Canada's proposed streamlining of clinical-trial regulation requirements.

More than two years ago, the Medical Research Council (now CIHR), Industry Canada and Investment Partnerships Canada, together established the Life Science Research Investment Initiative to link Canadian R&D to industry interests. The program has concentrated on investment in the drug development cycle, including research at universities, hospitals, research organizations and in biopharmaceutical companies. This model will be retained and attention will be given to expanding it under CIHR and replicating it to capture biotechnology innovation outside the health field through such partners as NSERC.

Building greater international awareness of Canadian expertise in biotechnology requires sophisticated, specialized communications tools used in conjunction with targeted conferences, expositions and sector-based marketing.

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Canada must seek a balance between improving the position of the Canadian biotechnology industry in existing markets and seeking out new markets abroad.

Trade

Trade Promotion

The Canadian biotechnology industry has grown tremendously in recent years, and exports of Canadian biotechnology products almost doubled from 1993 to 1997. According to Statistics Canada, of some $1 billion in sales of biotechnology products in 1997, $413 million (37 percent) came from exports of primarily agri-food (58 percent) and health (39 percent) products. In the agri-food sector, genetically modified canola, soybeans and corn made up the bulk of exports. In health biotechnology it was vaccines, diagnostics and contract research services.

With its small domestic market, Canada relies on trade. However, because biotechnology is so new and its applications are so wide-ranging, Canada's biotechnology industry requires detailed study of the export potential of existing subsectors (e.g., forestry, agriculture, health, environmental biotechnologies) to plan appropriate trade strategies. One area where considerable work is required is the collection and analysis of trade data and statistics. No country has yet developed statistical standards for the biotechnology industry, and Canada will be a forerunner in this field through collaborative efforts like Statistics Canada's 1998 survey on the biotechnology industry. The results of this survey are the only available source of detailed subsectoral statistical analysis on the national level. As noted earlier, Statistics Canada is updating the survey and increasing its scope; the update will be available in early 2001.

The government will also continue to support Trade Team Canada BioIndustries, one of the 12 industry-specific teams created to coordinate efforts among the Department of Foreign Affairs and International Trade, Agriculture and Agri-food Canada, and Industry Canada. Industry and government need to market the Canadian biotechnology sector more strongly abroad, particularly given the increasing number of products in the pipeline. Three priority markets for exports have been identified: the United States, the United Kingdom and "Australasia" (Australia, China, Korea and Japan). These markets have been chosen based on trading patterns and given their function as entry points to larger regional trade blocs. Canada must seek a balance between improving the position of the Canadian biotechnology industry in existing markets and seeking out new markets abroad. Export promotion through international trade shows, partnering events, and local and international seminars must continue to be a priority.

Trade Policy

International Trade Agreements

Trade policy for the biotechnology industry must address several key challenges.

- Many existing international agreements were negotiated before the expansion of the Canadian biotechnology industry and may not adequately represent its interests.
- Several agreements that do apply to biotechnology are not enforced by all countries, notably the World Trade Organization's principle of science-based criteria to determine the acceptability of a product.
- Canadian companies have shipped domestically approved biotechnology products to countries which then re-evaluate the products. This has occurred in most importing countries and constitutes a tremendous impediment to trade, notably of Canadian agricultural biotechnology products.
- The Biosafety Protocol, if implemented, will entail additional requirements for the handling and provision of information and documentation by exporters of living modified organisms (LMOs). Fair and equitable application of this protocol by all countries will be necessary to maintain the competitiveness of Canadian exports of LMOs.

Canada must seek expanded access to global markets for biotechnology products through bilateral, regional and multilateral trade agreements, such as the ongoing WTO negotiations. A key objective in all trade negotiations will be to maintain a transparent and enforceable science-based approach to regulatory decision making.

Mutual Recognition Agreements and Harmonization

In addition to negotiating trade agreements, Canada can increase efficiency through Mutual Recognition Agreements (MRAs) and other harmonization approaches. When two or more countries review biotechnology products by using the same or similar regulatory requirements, it adds costs and delays in getting products to market. The benefits of MRAs and harmonization have been recognized internationally; however, the pace of change has been slow for a number of reasons, including national sovereignty and jurisdictional issues and the focus on higher-profile trade negotiations.

To assist Canada's biotechnology industry, greater government efforts will be directed to identifying priority markets with sound regulatory systems, initiating MRA negotiations and investigating opportunities where foreign regulatory bodies will accept Canadian standards as equivalent to their own.

NATURAL RESOURCES BIOTECHNOLOGY

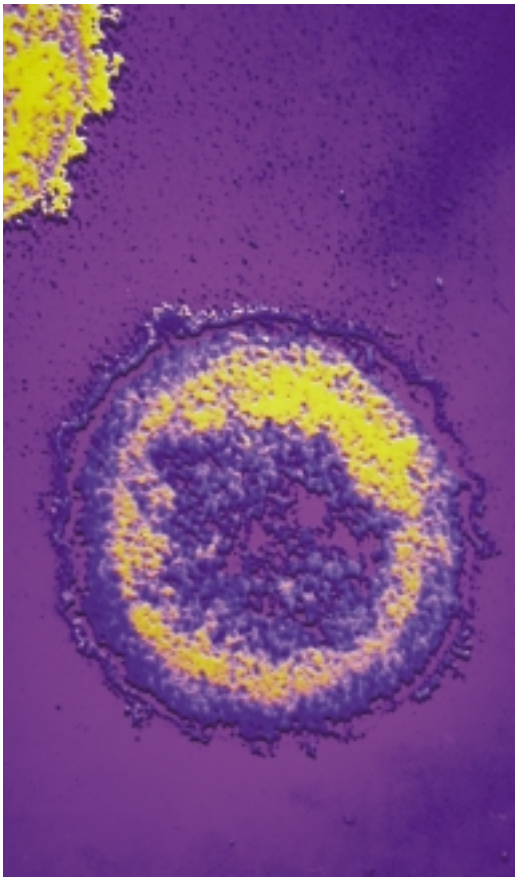
The global demand for wood continues to increase at a time when it is impossible to sustainably increase cutting rates. Biotechnology can help meet this increasing demand through tree improvements. Pressure is also increasing on wood, pulp and paper manufacturing companies globally to use cleaner, more energy-efficient processes to reduce their costs and minimize the discharge of pollutants. Tree genetic engineering and the use of enzyme biocatalysis are alternatives for achieving cleaner manufacturing and increased energy efficiency. Companies are also working to genetically engineer trees to facilitate lignin removal from the cellulose. The use of such trees could reduce chemical consumption in bleaching by about 30 percent.

Biotechnology in energy and mining is largely focused on developing cost-efficient ways to reduce greenhouse gas emissions, such as through fuel ethanol from cellulose biomass and bio-upgrading of petroleum using microorganisms to remove sulphur and reduce viscosity. Biotechnology also has great potential in metals extraction. Bioleaching can help in the environmentally sensitive use of low-grade remote resources. Mining biotechnology applications are being developed to reduce environmental pollution from organic contaminants. A variety of microorganisms and plants (phyto- and bioremediation) can degrade or remove organic contaminants in soil, mine effluents and sludge.

Canada must seek expanded access to global markets for biotechnology products through bilateral, regional and multilateral trade agreements.

Conclusion: Canada in the Biotech Century

Canada is set to continue as a world leader in biotechnology. It has internationally renowned scientists, increasing numbers of leading-edge biotechnology companies with worldwide markets and the right economic conditions. The government is committed to continuing to work in partnership with all stakeholders to enable the biotechnology sector to become one of Canada's leading pathways into the knowledge-based economy. This strategy provides the groundwork upon which the government will continue to build, in partnership, in the future. While a great number of individuals and organizations have contributed to this plan, input from interested parties is welcome. Contact the Life Sciences Branch, Industry Canada, 235 Queen Street, Ottawa, Ontario, K1A 0H5 or at **biotech@ic.gc.ca**.



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ManTex Canada Inc Marvin Silver Scientific Ltd. MBEC Biofilm Ltd. MBI Fermentas Inc Medicago Inc. Medicorp Inc. Medicure Inc. Merck Frosst Canada Inc. Metabolic Modulators Research Ltd. MethylGene Inc. MicroBio RhizoGen Corporation Microbix Biosystems Inc. MICROKIL Inc. Micrologix Biotech Inc. Microtek International Ltd. MicroXpress Limited Millenium Biologix Inc. Mnemotech Molecular Mining Corp. Monsanto Canada Inc. Multiplants in Vitro MycoLogic Inc. Mycota Biosciences Inc. Nanodesign Inc. Natunola Health Inc. NeuroArt Pharmaceuticals Inc. Neuroart Pharmaceuticals inc. Neuro-Biotech Inc. Neurochem Inc. NeuroMed Technologies Inc. Neurotrophic Bioscience Inc. New Leaf Biotechnology Inc. Nexia Biotechnologies Inc. Nidacon Canada Inc. NIM Biomedical Inc. NoAB Diagnostics Norac Technologies Inc. Norgen Biotek Corp. Northern Lipids Inc. Nortran Pharmaceuticals Inc. Norwest Labs Norzyme Inc. Nova Molecular Inc. Novacor Research & Technology Corp. NovaCure NovaDx International Inc. NovaNeuron Inc. Novartis Pharmaceuticals Canada Inc. Novo Nordisk Canada Inc. Novopharm Biotech Inc. NovoScience Pharma Inc. NovoScience Pharma Inc. NPS Allelix Pharmaceuticals Inc. Nutribios Corp. A member of Sentex Systems Ltd. Group. Nymox Corp. Ocean Nutrition Canada Ltd. Ocean Pharmaceuticals Inc. Ocean Produce International Octopus Diagnostics Group Okanagan Biotechnology Inc. Oligopharm Ltd. Omega Laboratories Ltd. OncoDynamics Inc. Organogel Canada OriGenix Technologies Inc. Ortho Biotech Oxoid Inc. Pacific Biotechnologies Inc. Pacific Fermentation Industries Ltd. Pacific Regeneration Technologies Inc. Paladin Laboratories Inc. Palliser Animal Health Lab. Ltd. PAPRICAN Paracel Laboratories Ltd. PBR Laboratories Inc. PDF Scientific Inc. Performance Genomics Inc. Performance Plants Inc. Phage Tech Inc. Pharmacor Inc. PharmaDerm Laboratories Ltd. Pharma-G Inc. Phenogene Therapeutics Inc. Phero Tech Inc. Pheromone Science Corp. Philip Analytical Services Corp. Philom Bios Inc. Phyto Diagnostics Company Phytocultures Ltd. Phytogen Life Sciences Pioneer Hi-Bred Limited Pisciculture des Alleghanys Inc. PlantSelect Biotechnology Systems Ltd. Prairie Plant Systems Inc. Precision Biologicals Inc. Premier Tech Ltéée Process Research Associates Ltd. Procrea Bioscences Inc. Procrea Genetic Services Procyon BioPharma Inc. ProMetic Biosciences Inc. PTM Molecular Biosystems Ltd. Purdel Co-op Agro-Alimentaire QLT PhotoTherapeutics Inc. QuantaNova Canada Ltd. Quantum Biotechnologies Inc. Quéélab Laboratories Inc RabbitHutch Biotechnology Corp. Remediation Resources Canada Ltd. Renaissance Life Science Inc. (formerly Vetrepharm Inc.) REPLICor Inc. Resolution Pharmaceuticals Inc. Response Biomedical Corp. RGS Genome Inc. Richelieu Biotechnologies Inc. Roche Ltd., Consulting Group RTP Pharma Inc. SalPep Biotechnology Inc. Sanexen Environmental Services Inc. Sanofi Diagnostics Pasteur Saskatchewan Wheat Pool Schering Canada Inc. Scicorp Systems Inc. Seagram Co. Ltd. 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Tm Bioscience Corp. TMG Services Inc. Tourbièères Lambert Vaccinium Technologies Inc. Valoraction Inc. Vancouver Biotech Ltd. Vancouver Island Antibodies Ltd. Vascular Therapeutics Canada Inc. Vasogen Inc. Vaxis Therapeutics Corporation Veragenics Limited Vetrepharm Canada Inc. Viridis Biotech Inc. Virocell Inc. Viron Therapeutics Inc. Viscount Pharma Inc. Visible Genetics Inc. W.G. Thompson & Sons Ltd. Wardrop Engineering Inc. Welichem Technology Corporation Wesleyville Hatchery Western Biologicals Ltd. Western Growers Seed Xenon Bioresearch Inc. Yes Biotech Labs (Anogen) B.C. Research Inc. Aventis Crop Science Canada Co. Hologene Genetic Technologies Inc. Epicore Networks Inc.