Renewal of the Canadian Biotechnology Strategy

Resource Document

3

Related Resource Documents

Government of Canada Gouvernement du Canada

Canada

Related Resource Documents

Renewal of the Canadian Biotechnology Strategy

Resource Document

Renewal of the Canadian Biotechnology Strategy Resource Document 3 is available electronically on the Industry Canada *Strategis* web site at: **http://strategis.ic.gc.ca/cbs**

Additional print copies of this roundtable consultation paper are available from:

Distribution Services
Industry Canada
235 Queen Street
Room 208D, East Tower
Ottawa ON K1A 0H5
Tel.: (613) 947-7466
Fax: (613) 954-6436
E-mail: publications@ic.gc.ca

For information about the contents of this discussion paper and the consultation process, or to submit your responses to the paper, please contact:

Canadian Biotechnology Strategy Task Force
Room 799B, East Tower
235 Queen Street, 7th Floor
Ottawa ON K1A 0H5
Tel.: (613) 946-2848
Fax: (613) 946-2847
E-mail: cbstf@ic.gc.ca
Web site: **http://strategis.ic.gc.ca/cbs**

This document can be made available in alternative formats for persons with disabilities upon request.

Cat. No. C21-22/4-1998
ISBN 0-662-63401-2
51797B

CONTENTS

3.1 BIOTECHNOLOGY HUMAN RESOURCES COUNCIL 1

3.2 RESEARCH AND DEVELOPMENT 2
- 3.2.1 Canadian Biotechnology Research and Development 2
- 3.2.2 Biotechnology: Technology Transfer and Commercialization 5

3.3 REGULATORY SYSTEM 12
- 3.3.1 The Federal Regulatory System 12
- 3.3.2 Labelling of Novel Foods Derived Through Genetic Engineering 14

3.4 ETHICS 16
- 3.4.1 Background Research Papers 16
- 3.4.2 Ethics in Research 16

3.5 INTERNATIONAL ISSUES REPORT 18

3.6 1983 NATIONAL BIOTECHNOLOGY STRATEGY 19

Biotechnology is an enabling technology that has a wide variety of manifestations that cannot be dealt with in detail in the roundtable consultations. The activities listed in this resource document are part of the government's ongoing program. Individuals or organizations wishing more information are invited to follow up with the listed contact point.

3.1 Biotechnology Human Resources Council

IDENTIFYING CHALLENGES

Two years ago, the biotechnology industry sought to identify the human resource challenges facing the Canadian biotechnology industry. At the time, an overriding concern among Canadian biotechnology companies was locating qualified staff to help the company achieve commercial success. While human resource issues had been identified by a number of studies, they had never been the focus of a single study. For these reasons, the industry initiated a wide-ranging Biotechnology Human Resource Study, sponsored by Human Resources Development Canada.

KEY FINDINGS

The study concluded that Canada will not have enough people with the right skills and experience to meet the needs of the industry, unless action is taken now. Expertise will be required not only in science and technical jobs, but also in management, patenting, regulatory, manufacturing, marketing and financial positions. In order to ensure that these requirements are met, the study proposed the creation of a comprehensive human resource strategy for the biotechnology industry touching on the following elements:

- cooperative approach to strategic immigration of skilled individuals
- regionally focussed training strategy to pool resources of firms in regional biotech clusters
- stronger relationships between the biotechnology community and the academic and research community
- development of personnel in regulatory and intellectual property fields
- partnerships with the educational system, including universities and technical and community colleges.

A NEW SECTORAL COUNCIL

To follow through with the recommendations outlined in the report, the study also urged the creation of a human resources sector council focussed on biotechnology. The Biotechnology Human Resources Council (BHRC) was inaugurated on April 1, 1997, in response to this recommendation. The newly formed council will develop and implement a strategic initiative to ensure qualified, skilled and experienced people will be able to fill jobs in the Canadian biotechnology industry. The council is composed of a board of directors, executive director and specialized task forces.

The Biotechnology Human Resources Council will undertake a series of programs and initiatives to ensure that Canada's biotechnology human resource requirements are met.

For further information, contact:

Biotechnology Human Resources Council
130 Albert Street, Suite 420
Ottawa ON K1P 5G4
Tel.: (613) 235-1402
Fax: (613) 233-7541
E-mail: bhrc@biotech.ca
Web site: **http://biotech.ca/**

3.2 Research and Development

3.2.1 Canadian Biotechnology Research and Development

Issue

A key role of government is to ensure that Canada has, or has access to, the knowledge base that will enable Canadians now and in the future to enjoy an ever-increasing quality of life. In order to accomplish this goal, government financed research and development (R&D) is largely focussed directly on the challenges of protecting and providing for the health and safety of Canadians, and the protection and improvement of the environment. In many cases, the results of these investments will be new or modified products, processes and services that will be commercialized in Canada and in the global market. Science, research and development are also key parts of the government's commitment to sustainable development through the creation of a knowledge-based economy that fosters innovation.

For consideration in the renewal of the Canadian Biotechnology Strategy is how the government can best target its R&D efforts, and to work in partnership with the provinces, industry, academia and the larger community to realize the benefits of biotechnology for Canadians. In this regard, separate R&D consultations will be carried out by the Canadian Biotechnology Strategy R&D Working Group led by the National Research Council.

Background

The Canadian biotechnology industry employs more than 25 000 persons and generates revenues of more than $2 billion annually — fully 65 percent of this from exports. More than 500 companies are involved directly and indirectly in biotechnology. Although often referred to as an industry, biotechnology is recognized as well as a driving or enabling technology underlying transformation in many sectors of the economy, such as agriculture and food, pharmaceuticals, and environmental management. Biotechnology's greatest impact both in Canada and worldwide has been in the health field. More than 90 percent of the advanced biotechnology products on the world market are related to health. In Canada, 59 percent of the core biotechnology companies are in the health care sector.

The Canadian government has made substantial investments in biotechnology R&D and in 1997 these expenditures exceeded $750 million. Federal organizations such as Agriculture and Agri-Food Canada, the Canadian Food Inspection Agency, Department of Fisheries and Oceans, Environment Canada, Health Canada, Natural Resources Canada and the National Research Council carry out research and development related activities. These federal organizations add strategically to Canada's critical mass in biotechnology R&D. The federal activity is split into basic research, innovative research and research related to supporting their regulatory functions. The government also provides generous tax and financial incentives to industry for research and development in industry.

The government is responsible for the protection of its citizens' health, safety and environment and it accomplishes this task largely through a comprehensive regulatory system. To be effective, the regulatory system needs to be supported by R&D that provides the government with the capacity to test, analyze and assess new or modified products, processes and services, as well as continue to monitor domestic and imported products and processes. Through research and development, health biotechnology provides the basis for developing more effective and safer methods and procedures for the surveillance, monitoring, diagnosis and prevention of a wide range of diseases, as well as protection and improvement of the environment. Biotechnology also is involved in such cross-sectoral issues as biodiversity, biosafety, climate change and greenhouse gases, as well as sustainable development. This activity accounts for about 15 percent of total federal expenditures on biotechnology.

Federal funding, which is provided for R&D projects undertaken by universities, government or industry, takes into consideration of a number of factors for "good practices" in research, clinical trials, contracting and manufacturing. These include the evolving ethics guidelines for animal and human subject research developed by various organizations such as the Canadian Council for Animal Care, Medical Research Council, Natural Sciences and Engineering Research Council and Social Sciences and Humanities Research Council.

Biotechnology is a rapidly growing strategic technology that is present in a wide range of sectors. Science-based organizations and core biotechnology companies are broadly distributed throughout Canada, with a major presence in Saskatchewan, Quebec and Ontario. In Quebec, the provincial government has made a concerted effort to develop biotechnology and pharmaceuticals as a key knowledge-based part of their economy. British Columbia has a strong bio-health care sector in part due to the prolific university spinoff activities and favourable venture capital and Vancouver Stock Exchange listing procedures. Saskatchewan, with a strong infrastructure of government, university and federal departments, has attracted agricultural-based biotechnology firms. Biotechnology momentum is also growing in Atlantic Canada with strong initiatives in health care and aquaculture. The financial community is located in Quebec and Ontario. Ontario plays an important role in financing biotechnology companies throughout Canada.

The key thrust of Canada's commercialization of biotechnology comes from industry. A 1997 Statistics Canada survey revealed that 348 firms reported industrial biotechnology R&D, up 68 percent from 207 firms in 1989. From 1989 to 1995, expenditures have tripled from $116 million to $341 million. NRC's Industrial Research Assistance Program (IRAP) and Industry Canada's Technology Partnerships Canada (TPC) program play important roles in assisting firms in technology transfer and commercialization phases, respectively, of biotechnology.

International

From an R&D perspective, Canada undertakes about 3 to 4 percent of the world's R&D, based on patents and publication. However, a recent citation index review (1992 to 1997) showed that Canadians have strong citation ratings of 6 percent or more in a dozen biotechnology-related fields such as monoclonal antibodies, gene probes, genomic and bioinformatics, gene therapy, DNA amplification, somatic embryogenesis, biobleaching, microbionoculants, bioremediation and marine biochemistry. These strengths have not gone unnoticed internationally. Several American and European organizations have located in Canada to take advantage of the excellent research base and infrastructure. For example, major foreign investments in human health care have been made in Montreal, Toronto and Vancouver. New ag-biotechnology firms are locating in Saskatoon.

Canada's biotechnology sector currently ranks in the top four internationally. However, among the G-7 countries, Canada's total investment in R&D is low, ranking above only Italy. Furthermore, key competitor countries recognize the strategic importance of biotechnology. Federal spending of about $300 million (including the granting councils) is dwarfed by the level of commitment by other leading countries. For example, U.S. federal spending on biotechnology is US$6 billion annually. Members of the European Union have a combined budget for biotechnology of over $4.4 billion (with Germany alone at $900 million per year); Japan has made a $1 billion strategic commitment over the next 10 years to neurosciences and another $1 billion investment is planned for marine biosciences. These enhanced investments by other countries will lead to advances that will require that the stewardship and regulatory functions of governments in Canada be continually monitored and updated; otherwise, the competitiveness of the Canadian biotechnology sector may be impaired.

Technology Transfer

Biotechnology accounts for almost 10 percent of overall Canadian expenditures on R&D and it is increasing in importance as a technology for delivering economic and social benefits to Canadians.

Technology transfer requires specialists, network systems and resources to identify technology-based areas of opportunities and to strategically manage intellectual property protection, exploitation and the pathways to commercialization. Technology transfer also needs the cooperation of both host organizations and their researchers to become more aware of, and take advantage of, opportunities involving application and commercialization of technology.

It is becoming clear in the biotechnology field that R&D networks and bundling of technologies are key infrastructure elements of a national innovation system. These components are needed to develop the intellectual property and critical mass of receptors within which technology transfer, diffusion and application can be carried out efficiently. Canada must therefore focus efforts to optimize biotechnology transfer and to use this as a means of protecting health and the environment and achieving sustainable development and competitive advantage in key global market niches.

Financing of Innovation

It has been reported that there were over 100 biopharmaceutical products under development as of June 1996, including products in the technology pipeline all the way from pre-clinical to Phase IV clinical trials. In addition, over 800 field trials to use genetically modified plants were approved in 1997 (up from 200 in 1992). Most of these field trials involved canola and potatoes.

Capital financing amounted to $2 billion for the period 1991 to 1996, with over 90 percent of this funding allocated to the human health care sector. It is important to recognize that it is costly to develop, test and secure approval for biotechnology products. For example, a new drug for human use costs over $250 million to develop. For a new animal or plant biotechnology-based product, $10-30 million may be necessary. Thus, there is a need to expand sources and levels of funds currently available in order to complete the development in Canada of products already in the pipeline whether they be for human health care or in agriculture, forestry, environment, etc. Foreign investment and strategic alliances with Canadian firms will increase in importance.

Federal–Provincial Partnerships

At the working level, there are already significant interactions and collaborations between federal departments/agencies and provincial/regional organizations, including with universities and industry. Examples include co-locations for research in agriculture, health and forestry. In the environment area, cooperative programs for test sites related to hazardous waste cleanup are being set up in a number of locations. There are also a number of regional and national industry associations and policy groups in place that have a research interest in biotechnology. Some banks have set up special funds for biotechnology initiatives in collaboration with federal regional agencies.

Local networking initiatives have played an important role. This has contributed to building towards a critical mass (e.g. Montreal, Toronto, Vancouver, Saskatoon and Atlantic Canada) and has fostered significant socio-economic development. While much has been accomplished, challenges remain in terms of developing partnerships and strategies to enhance coordination of R&D, technology bundling and transfer, as well as creation of social and economic benefits for Canadians.

A number of provinces are becoming major players in fostering the development of viable clusters. These and other groupings offer significant opportunities to lever and integrate new developments by bringing in the needed skills and resources and also sharing the risks. Links with the biotechnology associations assist in this aspect and help to build the climate for biotechnology.

For further information contact:
National Research Council
Industrial Research Assistance Program
1500 Montreal Road
Ottawa ON K1A 0R6
Tel.: (613) 993-1790
Fax: (613) 952-1079
E-mail: IRAP.info@irap.nrc.ca

3.2.2 BIOTECHNOLOGY: TECHNOLOGY TRANSFER AND COMMERCIALIZATION

Introduction

One of the most important assets a country has for supporting future quality of life, sustainable development, innovation, industrial competitiveness and commercial success is the quality of its public research infrastructure (university, hospital and government laboratories). Technology transfer is the process that helps make the research and knowledge base resident in the public and private sector research infrastructure yield economic and social benefits for the country.

Why Focus on Biotechnology Transfer and Commercialization?

Biotechnology is a set of techniques for producing goods and services through the use of living organisms or parts of organisms. In the next 25 years, biotechnology is predicted by some to have an even greater socio-economic impact globally than computer and telecommunications technologies. The present global market for products of biotechnology is estimated to be $20 billion and within 10 years it is expected to exceed $100 billion. The great potential of biotechnology is to transform production processes, products and services, that is, change the basis for innovation and competition, in a wide range of sectors. It is already delivering significant benefits in the health and agriculture sectors and the potential is enormous for contributing to sustainable development through more environmentally friendly processes in the resource sectors (agriculture, forestry, aquaculture/fisheries, mining and environment).

Given the significance of biotechnology-related knowledge for the future and the major investment Canada already has in biotechnology R&D, it is imperative to focus on delivering the social and economic benefits of biotechnology to all Canadians. Technology transfer is the linchpin in linking public sector knowledge and research to industry and to those government agencies responsible for protecting human health and the environment. Investments in resources to support biotechnology transfer are likely to have socio-economic paybacks, especially if they lever on the significant investment already being made in biotechnology R&D in both the public and private sectors.

Other governments around the world are also focussing on biotechnology as a strategic technology for future economic growth and job creation and have ramped up their investments in biotechnology R&D and technology transfer. Since Canadian federal spending on biotechnology R&D (approximately $300 million/year) is considerably less and growing more slowly than that in the United States ($6 billion/year), Germany ($900 million/year) or the United Kingdom ($1.3 billion/year), Canada needs to develop a more efficient national system for targeting and linking public sector biotechnology research to its regulatory and stewardship roles and to Canadian industry to achieve competitive advantage and commercial success in key global market niches. Further, given the levels of investment in other countries, it is also important to enhance Canadian capacity to transfer foreign technologies into Canada.

Major Themes

Balancing Stakeholder Interests: Four stakeholder groups are involved in the technology transfer and commercialization of a product or process: the researcher, the research organization (university, government), the receptor (usually industry) and the Canadian taxpaying public. All four groups need to benefit either directly or indirectly from the transfer of technology in order to have an incentive for playing their role in the process. In addition, there are technology transfer intermediaries, usually technology transfer officers/managers, who act on behalf of the research institutions to help identify, evaluate and patent technology. They work to identify companies that can be technology receptors and to negotiate agreements with those companies for the transfer of technology and know-how.

- **Researchers:** The researchers want to ensure the successful commercialization of their ideas, usually without undue negative effects or demands on their careers. Stable funding for research and development is an absolute necessity to ensure the continued supply of innovative ideas for commercialization. However, it is also important that the framework for providing such funding, as well as the criteria for career advancement of researchers, address incentives to transfer technology, especially to Canadian companies. Otherwise, research will be published rather than patented or any patents will be licensed to the highest bidder, risking the loss to Canada of downstream investment, revenue and employment.

- **Research Institutions:** The public research laboratory or institution is concerned with receiving funding to build its capacity for continuing further work in the field. Technology transfer must be seen as an absolute necessity by its host institution — providing a real benefit to the researchers, the institution and industry. To this end, stable and adequate funding and scientifically qualified human resources for the technology transfer offices are essential. Generally, funding comes either directly or indirectly from government (federal or provincial). Because government research budgets have been under pressure for a number of years, the capacity of both research and technology transfer has typically been weakened.

- **Industry:** Industry wants to have access — most often exclusive access — to leading-edge technology and know-how at a cost that takes into account the present stage of development as well as the downstream risks and costs involved in taking the technology into the marketplace. Canadian industry is already actively working with public research institutions in collaborative research projects designed to support technology transfer and commercialization. However, there is room to increase significantly the level of interaction in biotechnology-related areas. The Canadian tax system provides some of the most generous incentives in the world for performing R&D in Canada, but other business climate issues (see "Optimizing the Business Climate for Commercialization" below) also come into play to increase or diminish the incentive for industry to commercialize the technology.

- **The Public:** The commercialization of innovations produced by government-funded researchers should provide benefits to the Canadian public who support public R&D, technology transfer infrastructure and a portion of industrial R&D through the tax system. Therefore, the benefits of biotechnology research and development should provide a return on investment to Canadian taxpayers. Whether the technology stays in Canada and is commercialized by a Canadian company to create jobs and wealth, as well as improved products and services, or is licensed abroad for future royalties, the objective should be to maximize the benefits to Canada, both economic and social.

Optimizing Canadian Technology Transfer Capabilities: The broad scope of technology transfer activities requires a wide variety of skills: technology, financing, management, marketing, regulatory policy, negotiating, intellectual property protection, etc. Technology transfer is in part a "people skill" and technology transfer officers must be committed, knowledgeable and enthusiastic. It is also in part a systems issue where networks and strategies must be coordinated among a wide range of organizations to achieve success.

Technology transfer is a profession. Government, universities and professional organizations are already working together to identify ideal skills and qualifications required for technology transfer officers working in the biotechnology field and to use these to develop training and accreditation programs to ensure high and consistent standards in technology transfer officers.

- **Technology Evaluation Skills:** Currently, there is a shortage of technology evaluation skills in public research facilities. In depth technical and

business knowledge are needed for early assessment of a technology, product or process. One estimate is that less than 2 percent of all innovations submitted to most technology transfer offices for consideration actually represent commercial opportunities.

- **Market Information:** An accurate assessment of an innovation or technology requires up-to-date information on both national and international markets. Globalization of biotechnology markets highlights the importance of national and international market information. Technology transfer officers need access to and the skills to interpret international market surveys that include competition analysis and information on technical developments. This information is very expensive and most technology transfer offices have relatively few resources to generate or purchase this kind of strategic information. With this information, however, technology transfer officers can also assist researchers to focus on research areas that are associated with significant societal needs that are also business opportunities (market pull versus technology push).

  The greatest difficulty associated with transferring technology is that public sector researchers tend to have little knowledge of or experience in the market in which products will be sold. Successful R&D projects in the private sector tend to be shaped and adapted from the earliest stages to provide a good fit with market demands. By their nature, public institutions tend to have relatively little knowledge of markets and, as a consequence, their inventions tend to be poorly adapted to market needs. One method for overcoming this difficulty is to conduct commercially oriented research in collaboration with firms that can provide the necessary market orientation. This is problematic for some government departments with a regulatory mandate. However, universities and agencies that do not have regulatory roles have used this approach for many years. Another possibility involves contracting out research. The June 1991 federal policy on ownership of intellectual property when research is contracted out is currently under review.

- **Skills for Managing Intellectual Property Protection:** Biotechnology inventions are the domain of experts, but new inventions should only be patented if there is commercial viability and can only be patented if there is no prior art. Clearly, it is important to carry out a patent search and a market analysis early in every new research project. Training and mentoring technology transfer officers to strategically manage the process of protecting intellectual property as well as to know when to bring in such patenting expertise is key to capturing the economic benefits of innovation carried out in a research organization. To achieve this, the intellectual property protection strategy and commercialization strategy need to work together.

  The need to publish (experienced by both professors and graduate students) is often at odds with the need to protect intellectual property. The rate of publication in refereed journals is often used to assess research quality and output for grant applications, promotion and tenure. Technology transfer officers need the skills and resources to inform the scientific community that early disclosure could mean loss of value of a patent or that excessive exposure of information in a patent preamble could prevent future patents. They also need help to influence their own organizations to include patents and licences in the considerations for promotion and tenure, thus providing an added incentive for researchers to play a proactive role in technology transfer.

- **Communication Skills:** Biotechnology may be considered an especially challenging area for technology transfer and commercialization. This is not only because of its global explosion of research and innovation, but also because of the great number of disciplines involved and the cultural disparities among proponents (often microbiologists in universities) and potential receptors (often engineers in companies). These make it difficult to understand and communicate the nature of biotechnology-based opportunities. Technology transfer officers need training and mentoring to deal with these communications challenges.

- **Technology Transfer Networks:** Because of the wide variety of skills required for successful technology transfer and because of the importance of establishing contacts with receptors locally, nationally and internationally, there should be more emphasis placed on the development of technology transfer networks to help mentor and assist especially the smaller (often one-person) technology transfer shops. Better use should be made of programs, such as the Industrial Research Assistance Program (IRAP) of the National Research Council (NRC) and the Canadian Technology Network (CTN), as well as newsletters, web sites, etc., to share information and provide this type of help. Also, technology networks (e.g. Networks of Centres of Excellence) could be used to facilitate the movement of people back and forth between the research and receptor communities: from research institutes and academia to industry and back again. Ideally, this movement would include both researchers and technology transfer officers, would focus on business, marketing and finance issues and would be regional, national and sometimes international in scope. This would encourage transfer of technology, know-how and people not just between academia and industry, but among various research institutes as well.

- **Standardization of Agreements and Best Practices:** Both technology developers and receptors benefit from efforts made to standardize methodology for technology transfer (e.g. non-disclosure agreements, licensing agreements, research contracts) or at least develop a "best practices" manual. For example, federal laboratories in the United States have a standard Cooperative Research and Development Agreement (CRADA) for collaborative R&D with industry. Organizations such as the Federal Partners in Technology Transfer (FPTT) and the Association of University Technology Managers (AUTM) could play a role in the development and application of methodology standards as well as in performance benchmarking on a national and international basis.

Optimizing the Business Climate for Commercialization: Commercialization is the attempt by a firm to profit from innovation by incorporating new technology into products, processes or services brought into the marketplace. Successful commercialization depends on many factors that are influenced by the business climate, including the ability to:

- find and develop new technology
- acquire complementary skills and technologies to make the innovation useful
- finance innovation, production and marketing
- hire and train skilled employees
- protect the innovation from imitators in order to recoup its investment
- meet any necessary standards and regulations
- gain market acceptance.

Key business climate issues for commercialization of biotechnology in Canada are:

- **The Need for Good Managers:** The Canadian bio-industry consists of several hundred firms, mostly small companies, that are managed for the most part by people with a technical background. Canada also produces a reasonable number of entrepreneurial scientists with novel technologies so new businesses can be seeded. For these small companies and researchers, the greatest impediment to consummation of investment deals is a shortage of good management experienced in the strategic development of biotechnology businesses. The obvious place to recruit experienced managers of innovation in the short term would be from large multinational firms. However, relatively

few of the large multinational firms in Canada carry out innovative research from a Canadian base. Importing suitable candidates from the United States is reported to be difficult because of cost handicaps arising from personal tax differentials and the weak Canadian dollar. Opportunities are likely better for attracting experienced managers from Europe. Clearly, the longer term solution is development of specialized training programs in Canadian universities where science and business skills can be combined.

- **The Need for Expertise Related to Manufacturing:** As the Canadian bio-industry grows in numbers and firms advance toward commercialization, the need is increasing for experienced personnel in production scale-up, manufacturing and regulatory affairs. Canada has relatively few individuals with these skills and the small number of individuals in Canada with well-developed skills in these fields are continually attracted south of the border where salaries and operational budgets are significantly higher.

- **Availability of Capital:** The biotechnology industry is driven by a voracious need for capital because of its intensive research nature and the long time required to bring a product to market. The major sources of capital are venture capital, the public equity markets and strategic alliances with multinational corporations. Canada has significant quantities of available venture capital, especially with the establishment of labour-sponsored funds and specialty funds that have biotechnology as one of their areas of focus. For the health-bio sector, the problem of capital availability has diminished for the present due to the growth of the public equity markets and the willingness of multinational pharmaceutical companies to invest in biotechnology firms to supplement their own internal product pipelines. Capital markets and multinational business strategies are cyclical and therefore the situation may change. Outside of the health-bio sector, availability of capital, especially intelligent and patient capital, remains a continuing impediment to commercialization in Canada.

  From the perspective of strategic development, Canada needs to have a variety of financing tools available to fund various modes of innovation and wealth creation. Canada lacks a cadre of smaller "merchant banks" capable of carefully evaluating projects and of high-risk, high-return lending. In other countries, such sources of funding are available to support technology commercialization. To a degree, government fills the deficiency as the Business Development Bank of Canada and Technology Partnerships Canada both provide project funding.

- **Regulations:** The products of biotechnology are often complex. An effective regulatory regime that protects health and the environment is a key government role. It can also be an important factor in supporting the credibility and accountability of biotechnology products. However, poorly defined regulatory approval requirements, unnecessarily slow turnarounds and high fees can add to testing and reporting costs and delay the market introduction of new biotechnology products.

  Regulation can also drive demand for the commercialization of biotechnology products that support cleaner industrial processes by penalizing inefficient, wasteful processes or by prohibiting environmentally damaging processes and products. In a number of sectors now being infused with biotechnology (e.g. agriculture, aquaculture, forestry and environmental applications), the regulatory context (including provincial regulations and other interprovincial trade barriers) is of paramount importance. When a product has the potential to be sold in a number of countries, international harmonization of regulations and mutual recognition of regulatory decisions is of great value.

- **Transfer to Regulators:** It is important to encourage timely and efficient transfer of major scientific developments in biotechnology from universities,

research institutes and companies to scientists involved in regulatory research or regulatory review. This reinforces the capacity of regulatory departments to carry out their stewardship role in an effective manner.

Maintaining the scientific capacity of regulators helps to ensure effective fulfilment of their responsibilities. It can also reduce delays in commercialization of transferred technology because, if regulators understand the scientific basis of the innovation, they can efficiently assess potential risks to health, safety and the environment.

- **International Dimension — Barriers to Trade, Immigration and Technology Diffusion:** Canada only accounts for a relatively small percentage (2–8 percent, depending on the scientific field) of biotechnology innovation on a global basis. A meaningful national policy on technology management, transfer and commercialization must also address technology transfer into and out of Canada and how to deliver the maximum socio-economic benefits to Canada. Thus, it is important to identify policy options to facilitate the transfer of domestic and international technology into Canadian companies.

  International science and technology (S&T) agreements can help facilitate international technology transfer. It is important to maximize the advantage that these agreements can provide. Care must be taken in drafting international agreements, such as the Protocol on Biosafety, to ensure that technology transfer is not unnecessarily impeded.

  In the most general sense, technology can be transferred when it is embedded in commercial products, for example, equipment, biological materials and organisms, computer programs, skilled human resources as well as licenses. For this reason, Canada needs to have trade policies that ensure the free flow of safe and effective technology into this country. Unnecessary trade barriers or restrictive practices need to be minimized so domestic laboratories, regulators and firms can readily access the technological resources they require.

  The business climate for biotechnology R&D and commercialization (relative cost of doing R&D or setting up manufacturing, availability of highly skilled human resources, efficiency of regulatory system, etc.) exerts a strong influence on where biotechnology is transferred, developed and commercialized. Canada has a very attractive business climate for R&D and a number of foreign firms have transferred their R&D into Canadian operations to take advantage of this.

- **Industrial Organization:** Transfer of technology between firms is also an important aspect of technology diffusion and commercialization. In a number of fields, including biotechnology, small firms are more efficient at innovation than large firms, but the larger firms are typically much better at regulatory affairs, manufacturing and marketing. Policies (e.g. those affecting availability of investment capital) that are supportive of populations of firms of differing sizes in the same industrial sector are therefore supportive of transfer of technology and human resources between firms.

- **Spinoff of New Companies:** In cases where receptor companies do not exist or are not readily available, the potential may exist to foster the creation of new companies to undertake the development and commercialization of innovations or technologies. This may be done by facilitating the flow of financial resources, mentoring for entrepreneurs, experienced foreign entrepreneurs and strategic alliances to support fledgling companies. Technology transfer officers can also play a role in identifying opportunities for spinning out new companies and in marshaling both public and private resources to support them in their formative stages.

- **Clustering:** Perhaps the most effective method of ensuring a favourable climate for commercialization of biotechnology is through a close association between researchers, companies and supporting infrastructure. This has spawned the formation of "technology transfer hot spots" (clusters or networks). Areas like the Silicon Valley in the United States are prototypes for centres composed of a network or cluster of researchers, industry and

venture capitalists. Saskatoon has developed a strong focus on plant biotechnology. Montreal, Toronto and, more recently, Vancouver have an emerging critical mass in health care biotechnology. The formation of clusters or networks is difficult in Canada because of the size and the generally diffuse distribution of research laboratories and industry; however, the Networks of Centres of Excellence provide a model for geographically distributed clusters.

- **Intellectual Property:** Intellectual property can be a company's most important asset because it affects the firm's ability to access both capital for development and markets for its products. The Canadian Intellectual Property Office (CIPO) administers Canadian patent laws, grants patents and provides information on existing patents. It is an essential part of the Canadian technology transfer and commercialization system. Its policies, services and level of expertise relating to biotechnology can greatly impact their ability and the time required to patent biotechnology inventions in Canada. Some corporations and researchers argue that differences in patent law between Canada and its international partners and relative delays in processing patent applications impede commercialization of biotechnology products in Canada (e.g. breadth of patents, the ability to patent higher life forms, filing seeds as proof of patent, the length of time to assess a patent application).

- **Technology Bundling:** As biotechnology continues to evolve and its complexity increases, single innovations or advances in technology become less and less likely to form the basis for a robust technology-based opportunity. They must often be combined with other technologies and innovations (which may have to be licensed) in order to develop a marketable product. Canadian research organizations and companies need to develop a greater capacity to cross-license and combine diverse biotechnologies to develop technology platforms with robust intellectual property protection. This may be the only way that the individual researcher, research institution or small biotech company can hope to compete with major multinationals and R&D consortia. This is especially true if there is an expectation of capturing a major portion of the commercial benefits flowing from their research.

- **Best Practices for Technology Transfer:** Initiatives such as the Federal Partners in Technology Transfer and the Canadian Technology Network (CTN) are working toward better national coordination of technology transfer. Technology transfer offices and organizations across the country share a number of issues that are also faced in biotechnology, including how to deliver benefits back to their institutions and the taxpaying public, protect intellectual property, attract domestic and international financing and identify receptors, as well as how to educate, train and motivate both researchers and technology transfer officers. The rapid advancements occurring in biotechnology are creating opportunities for the federal and provincial governments to work together to develop a coordinated approach to the transfer and commercialization of biotechnology. Greater collaboration will help ensure that the social, economic and environmental benefits of biotechnology are captured in Canada.

3.3 Regulatory System

3.3.1 THE FEDERAL REGULATORY SYSTEM

Current Federal Legislative Framework for Biotechnology Products

Biotechnology is defined in Canadian legislation as "the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms." This broad definition covers all organisms, their parts and products, whether developed traditionally or through the newer molecular techniques such as genetic engineering. As biotechnology is a series of techniques and not a product, it is applied in many sectors to develop goods and services of value to the economy.

The Federal Regulatory Framework for Biotechnology (1993) is intended to ensure that the benefits of biotechnology products and processes are realized in a way that protects health, safety and the environment. The Framework resulted from an agreement among federal regulatory departments on principles for an efficient and effective approach for regulating biotechnology products with a high priority on health, safety and the environment. The Framework also addresses Canada's international commitments under the United Nations Commission on Sustainable Development and the United Nations Convention on Biological Diversity. The principles adopted by the regulatory departments include:

- maintaining Canada's high standards for protecting the health of Canadians and the environment
- using existing laws and regulatory departments to avoid duplication
- developing clear guidelines for evaluating biotechnology products that are in harmony with national priorities and international standards
- providing a sound, scientific knowledge base on which to assess risk and evaluate products
- ensuring that the development and enforcement of Canadian biotechnology regulations are open and include consultation
- contributing to the prosperity and well-being of Canadians by fostering a favourable climate for investment, development, innovation and the adoption of sustainable Canadian biotechnology products and processes.

A key principle of the federal framework is the use of existing legislation and institutions to clarify responsibilities and avoid duplication. This principle means that departments now regulating products developed using traditional biotechnology techniques and processes will be responsible for regulating products developed using the newer biotechnology techniques and processes. Regulatory departments such as the Canadian Food Inspection Agency, Health Canada, the Department of Fisheries and Oceans and Environment Canada have developed considerable expertise over a period of many years in addressing safety questions related to a variety of products including traditional biotechnology products.

In the federal government, legislative responsibility for health and environmental assessment of biotechnology products is divided primarily among four departments: Environment Canada, Health Canada, the Canadian Food Inspection Agency and the Department of Fisheries and Oceans. A description of which products fall under which regulations is set out in Table 1.

The *Canadian Environmental Protection Act* is a key part of the framework. It ensures that new biotechnology products are assessed for health and environmental impacts under CEPA regulations, unless they undergo such an assessment under other legislation. Therefore, there are no gaps in the provision for health and environmental assessments under the framework.

The *Food and Drugs Act* provides the authority to Health Canada for the assessment and control of the nutrition, quality and safety of food, the safety and effectiveness of human and veterinary drugs and medical devices, and the safety of cosmetics. This

TABLE 1
Legislative Responsibility for Biotechnology

Products regulated	Federal department(s)	Act	Regulations
Products for uses not covered under other federal legislation	Environment Canada, Health Canada	*Canadian Environmental Protection Act*	New Substances Notification Regulations
Drugs, cosmetics, medical devices, and foods	Health Canada	*Food and Drugs Act*	Food and Drugs Regulations, Medical Devices Regulations, Cosmetics Regulations
Fertilizer supplements, including novel microbial supplements	Canadian Food Inspection Agency	*Fertilizers Act*	Fertilizers Regulations
Feeds, including novel feeds	Canadian Food Inspection Agency	*Feeds Act*	Feeds Regulations
Plants, including plants with novel traits, including forest trees	Canadian Food Inspection Agency	*Seeds Act*	Seeds Regulations
Veterinary biologics	Canadian Food Inspection Agency	*Health of Animals Act*	Health of Animals Regulations
Pest control products	Health Canada	*Pest Control Products Act*	Pest Control Products Regulations
Aquatic organisms (under development)	Fisheries and Oceans	*Fisheries Act*	Fisheries Regulations

authority also applies to products from biotechnology. Under this authority, Health Canada can establish conditions for the manufacture, sale and advertisement of food, drugs, medical devices and cosmetics.

The *Fertilizers Act* requires that manufacturers demonstrate the safety and effectiveness of fertilizers and supplements (including novel supplements) both in terms of human health and environmental safety. Specifically, the legislation outlines four key activities: standards and labelling, experimental research, registration and post-registration monitoring.

The *Feeds Act* specifies that all single ingredient feeds be evaluated prior to their use in livestock feeds, including novel feeds. The legislation applies to imported or domestically manufactured products. The assessment of feeds focusses on toxicity to livestock, human safety in terms of transfer of harmful residues to human foodstuffs, safety of workers handling feeds and safety to the environment.

The *Seeds Act* regulates the inspection, testing, quality and sale of seeds in Canada. Seeds that are developed through genetic engineering processes also undergo the same requirements. Testing involves field testing under confined conditions and unconfined conditions (larger commercial production). The Canadian Food Inspection Agency also carries out environmental assessments on plants with novel traits, including thorough characterizations of the novel proteins and the modified plant, considerations of weediness, ability to pass genetic information, potential to

become a pest, potential to cause unwanted interactions with other organisms in the environment and potential to cause negative impact on biodiversity.

The *Health of Animals Act* controls the importation of "all organisms that could be injurious to animals, regardless of the breeding method or process used to produce them." The legislation and regulations provide authority to regulate the production, importation, field testing and registration of veterinary biologics in Canada, produced by modern techniques of biotechnology or by traditional methods.

Under the *Pest Control Products Act*, all pest control products, including microbial pesticides developed using genetic engineering, must be registered prior to being used, imported or sold in Canada. Prior to registration, microbial pest control products are subject to a stringent and comprehensive assessment of the risks to human health and the environment. The value of the product, including product performance and contribution to sustainability, are also assessed.

To ensure no ecological harm would result, regulations under the *Fisheries Act* require anyone who wishes to "deposit" a fish in any water to apply for a permit. ("Fish" is defined in the Act to include finfish, shellfish, crustaceans and marine animals.) This requirement would apply equally to transgenic and non-transgenic organisms. Regulations that will enhance the current powers are being drafted and will provide for the gathering of information on transgenic aquatic organisms, containment procedures and environmental assessment. This approach is consistent with the framework's principle vis-à-vis the use of existing legislation.

The present legislative framework provides guidance to the public, industry, international agencies and other governmental departments on the requirements for regulatory approval by the federal government, the legislative basis for the approval process, and the responsible department. It provides for a government-wide regulatory process that addresses the needs of the Canadian public and industry and the requirements under Canada's international commitments.

3.3.2 LABELLING OF NOVEL FOODS DERIVED THROUGH GENETIC ENGINEERING

Health Canada is responsible for setting labelling policies on health and safety matters. Responsibility for developing non-health and safety food-labelling regulations and policies, including those pertaining to new foods derived through biotechnology, rest with the new Canadian Food Inspection Agency.

Over the past four years, general principles for labelling foods from biotechnology have emerged from a series of multi-stakeholder consultations. Specifically, there is support for labelling in the case of a health or safety concern such as allergenicity or a significant nutritional change in the food. Voluntary negative ("does not contain") or positive ("does contain") claims are permitted, providing the claims are truthful and not misleading. As these principles are consistent with the *Food and Drugs Act*, changes to these regulations are not required.

Canada is a member of CODEX Alimentarius Commission and works with the CODEX Committee on Food Labelling to arrive at a common international position on this matter. The next meeting of the CODEX Committee is in May 1998.

More information is available at the following web sites or by contacting the offices listed below.

1. CFIA web site
   - Information Bulletin — Labelling of Genetically Engineered Foods in Canada: **http://www.cfia-acia.agr.ca/english/food/biotech/labele.html**
   - Information Bulletin — CODEX Alimentarius Commission: **http://www.cfia-acia.agr.ca/english/food/biotech/codexe.html**
2. Health Canada
   - Definition of Novel Food: **http://www.hc-sc.gc.ca/datahpb/datafood/english/main_e.htm**
   - Novel Food Decisions 1994–1997: **http://www.hc-sc.gc.ca/datahpb/datafood/english/main_e.htm**

3. Biotechnology in Agriculture and Agri-Food Information Kit — Food Derived from Biotechnology: **http://www.cfia-acia.agr.ca/english/food/biotech/food.html**
4. Health Canada's Guidelines for the Safety of Novel Foods: Volumes I and II, September 1994: **http://www.hc-sc.gc.ca/datahpb/datafood/english/main_e.htm**
5. Technical Workshop on Labelling of Novel Foods Derived Through Genetic Engineering — Proceedings, November 24–25, 1994.
   Not available on web site — coming soon.
6. Communiqué — Labelling of Novel Foods Derived Through Genetic Engineering, December 1995: **http://www.cfia-acia.agr.ca/english/food/foodinsp/engcomm.html**
7. Information Letter — Summary of Comments on the Communiqué, April 1997: **http://www.cfia-acia.agr.ca/english/food/foodinsp/infolete.html**
8. Statements of Intent — April 1997: **http://www.cfia-acia.agr.ca/english/food/foodinsp/infolete.html**

Biotechnology Strategies and Coordination Office
Canadian Food Inspection Agency
59 Camelot Drive
Nepean ON K1A 0Y9
Tel.: (613) 225-2342
Fax: (613) 228-6604
Web site: **www.cfia-acia.agr.ca**

Office of Scientific and Regulatory Affairs
Health Protection Branch
Health Canada
Tunney's Pasture
Ottawa ON K1A 0L3
Postal Locator 0702E4
Tel.: (613) 941-3160
Fax: (613) 954-9981

3.4 Ethics

3.4.1 BACKGROUND RESEARCH PAPERS

The Federal Interdepartmental Working Group on ethics in biotechnology recently commissioned the following background research papers as input into its ongoing review of the social and ethical implications of biotechnology. The views expressed in these papers are those of the authors and do not necessarily reflect government policy. Copies of these reports are available from the Task Force Secretariat or the web site.

Ethics and Biotechnology: The Role of the Government of Canada, by Derek Jones, 1997.

What is "Ethically Acceptable"? Individual Ethics versus Societal Ethics, by Ted Schrecker and Margaret A. Somerville, March 1997.

Biotechnology, Ethics and Government, by Ted Schrecker, Barry Hoffmaster, Margaret A. Somerville and Alex Wellington, February 1997.

For further information, contact:

Canadian Biotechnology Strategy Task Force
Room 799B, East Tower
235 Queen Street, 7th Floor
Ottawa ON K1A 0H5
Tel.: (613) 946-2848
Fax: (613) 946-2847
E-mail: cbstf@ic.gc.ca
Web-site: **http://strategis.ic.gc.ca/cbs**

3.4.2 ETHICS IN RESEARCH

Ethics in biotechnology includes consideration of a number of areas, such as research involving humans, animals, gene manipulation, gene therapy and infectious agents. In Canada, as in other countries, the ethics of research has been guided by policy statements published by the research funding councils starting in the 1960s and 1970s and covering the use of animals and humans in research. With advances in science, including biotechnology, these guidelines and policies have been reviewed and updated. The following is a short summary of the development of ethical guidelines, policies and procedures that apply to biotechnology research in Canada.

The Canadian Council on Animal Care (CCAC) was formed in 1968 with initial funding from the Medical Research Council (MRC) and the National Research Council of Canada (NRC). (CCAC is now funded jointly by MRC and the Natural Sciences and Engineering Research Council (NSERC).) CCAC was created to help ensure that animals are used in research only when necessary, and then only under high standards of care and ethical concern. CCAC guidelines and oversight cover the vast majority of research involving animals, in academic centres, government laboratories and industry, and are based on published guidelines, regular inspections of facilities and effective local Animal Care Committees. The involvement of the Canadian Federation of Humane Societies is an important component of CCAC's program.

CCAC's guidelines are under continual review. They have, for example, recently issued guidelines on Transgenic Animals, Animal Welfare and Ethics, which are available at **http://www.acs.ucalgary.ca/~browder/guidelines.html**

In 1977, MRC prepared guidelines for handling recombinant DNA molecules and animal viruses and cells. Recombinant DNA was the foundational technology of biotechnology. These guidelines were revised in 1979 and 1980 to reflect the rapid changes in perceptions of risks from the new technologies. In 1990 and again in 1996, Health Canada published *Laboratory Biosafety Guidelines*.

In 1976, the Social Sciences and Humanities Research Council of Canada (SSHRC) and MRC (1978, 1987) published guidelines on the ethics of research involving humans. A network of over 400 local Research Ethics Boards (REBs) has been established in universities and teaching hospitals where the vast

majority of research involving humans, including that by industry, is carried out. Approval by an REB of the research design and plans for the exercise of free and informed choice by potential participants in the research is required for all research projects involving human subjects before the first potential participant is approached.

In 1990, with the advances in biotechnology, MRC published ethics guidelines on research involving somatic cell gene therapy in humans.

In 1996, the three research funding councils, MRC, NSERC and SSHRC, decided to update and integrate their policies for research involving humans, which necessarily includes those aspects that involve biotechnology. A tri-Council Working Group prepared a discussion draft in 1996, which stimulated extensive comment. The Working Group's final report, *Code of Ethical Conduct for Research Involving Humans*, was published in 1997 and is available from the councils or at MRC's web site (**http://wwwmrc.hc-sc.gc.ca**).

The comments received on the Working Group's report are being integrated into a joint tri-Council Policy Statement on Ethical Conduct for Research Involving Humans, which is scheduled for publication by MRC, NSERC and SSHRC in the Spring of 1998. It will bring together in one policy statement the ethics considerations in this area, and more explicitly define the processes of REB review and approval. The new tri-Council policy will be binding on all recipients of the council's funding. In addition, the council's ethics policies are used for all university, hospital and research institute-based activity in Canada regardless of funding source.

In September 1997, the federal government's committee of Assistant Deputy Ministers responsible for coordinating science and technology, which includes representatives from the research funding councils, undertook to review the procedures by which government ensures that all research that it performs or funds meets established standards of ethics. A subcommittee has been formed under the leadership of Health Canada.

Council Contacts for Ethics in Research:

MRC:
Francis Rolleston
Director, Ethics and International
Medical Research Council of Canada
1600 Scott Street, 6th Floor, Holland Cross
Ottawa ON K1A 0W9
Tel.: (613) 954-1801
Fax: (613) 954-1800

SSHRC:
Nina Stipich
Senior Policy and Planning Analyst
Social Sciences and Humanities Research Council
350 Albert Street, Constitution Square
P.O. Box 1610
Ottawa ON K1P 6G4
Tel.: (613) 992-5127
Fax: (613) 992-1787

NSERC:
Catherine Armour
Research Ethics Officer
Natural Sciences and Engineering Research Council
350 Albert Street, Constitution Square
Ottawa ON K1A 1H5
Tel.: (613) 995-5896
Fax: (613) 943-0742

NRC:
Michel Brochu
Manager, Executive Offices Secretariat
National Research Council
Building M-58, Montreal Road Campus
Ottawa ON K1A 0R6
Tel.: (613) 993-4739
Fax: (613) 991-0398

3.5 International Issues Report

International trade in biotechnology products or services is governed by the same multilaterally or bilaterally agreed rules that apply to other commodities. The principal international instruments affecting market access for biotechnology products or services are the various World Trade Organization (WTO) agreements and, for Canada, the North American Free Trade Agreement (NAFTA).

The International Issues Report is a product of the work of the Canadian Biotechnology Strategy Task Force Working Group on International Issues. It sets out the international rules and issues governing trade and investment, which provide a framework for trade and investment in biotechnology goods and services.

A copy of this report is available from:

Technical Barrier and Regulations Division
Trade Policy Bureau
Foreign Affairs and International Trade
125 Sussex Drive
Ottawa ON K1A OG2
Tel.: (613) 944-1417
Fax: (613) 943-0346 or (613) 944-0756
E-mail: eas@extott04.x400.gc.ca
Web site: **http://strategis.ic.gc.ca/cbs**

3.6 1983 National Biotechnology Strategy

History and Achievements

In 1983, the federal government Cabinet approved the framework for a National Biotechnology Strategy (NBS). The strategy set out objectives, sectoral areas of strategic focus and various methods by which the objectives could be achieved.

Four central objectives for Canada's NBS were identified:

- to focus biotechnology research and development on areas of strategic importance to Canada
- to ensure an adequate supply of high-quality, trained human resources in biotechnology
- to encourage communication and collaboration between researchers in different disciplines and sectors
- to create a climate conducive to investment by industry in biotechnology.

To support the strategy objectives, the government undertook the following actions:

- A National Biotechnology Advisory Committee (NBAC) was established to advise the Minister of Industry on policies required to promote the development of biotechnology in Canada. Industry Canada provided the secretariat to the committee.
- An Interdepartmental Committee on Biotechnology (ICB) was established at the Assistant Deputy Minister level, chaired by Industry Canada, to review proposed government activities, take policy decisions and monitor the progress of the NBS.
- Federal government R&D capability in priority areas was strengthened.
- R&D networks were established in the priority areas to enhance collaboration and communication between the producers and users of research.
- Exchanges of personnel between federal, provincial and university research laboratories and industry were encouraged and financially supported.
- Cost-sharing programs for industry were established to develop collaborative research and development projects with universities and provincial research organizations.
- The Institute for Biotechnology Research was established in Montreal, under the auspices of the National Research Council.
- Existing and planned regulations were reviewed to ensure they did not unnecessarily impede developments in biotechnology.

Achievements under the 1983 National Biotechnology Strategy

Phase I: 1983–1986

- Five bio-networks were established.
- The NRC Program for Industry/Laboratory Projects supported 46 industry-led projects.
- Significant improvement in the level of biotechnology research activity in Energy, Mines and Resources (EMR) and Health Canada (HC) was achieved. Agriculture Canada was in the process of establishing a Food Research Institute to work on biotechnology applications.
- A program for Phase II was mapped out, with special emphasis on industrial development focussing on financing needs, regulations, human resources, communication and collaboration, and development of industry-university research collaborations.

- A system for monitoring progress in biotechnology was established using proxy measures such as increased economic benefits, measures of increased industrial activity such as new companies, increased number of jobs, in-house R&D, number of patent applications and increases in new products or processes. It was suggested that targets for biotechnology could be identified in niche areas for Canadian companies, i.e., canola, animal vaccines and bioinsecticides.

Phase II: 1989–1997

- A second NBS Review was undertaken in the early 1990s. It noted successes, including the development and strengthening of Canada's S&T infrastructure in biotechnology and important support to building human resources and biotechnology networks.
- The NBAC "Fifth Report" (1991) provided a "Business Strategy for Biotechnology in Canada" with an emphasis on a more effective and efficient regulatory system.
- Noting the NBAC "Fifth Report" business plan and recommendation regarding a strong regulatory framework, the second review urged that the NBS increase its focus on the regulatory issues affecting biotechnology, and the commercialization of technologies that would bring new products to market more rapidly.
- Federal departments involved in biotechnology regulation supported the elaboration of an internationally recognized, science-based regulatory framework placing emphasis on an efficient regulatory approval process to facilitate new product approvals.
- NBAC 1991 recommendations and inter-departmental biotechnology action supported the designation of the Patent Office as a "Special Operating Agency" (SOA); the *Patent Act* was amended to allow the deposition of unicellular life forms in internationally recognized depositories, and Canada signed the Budapest Treaty.
- NBS funded various studies into social, ethical and consumer issues.
- In 1997, the inter-departmental community, chaired by Industry Canada, organized Phase I of the biotechnology renewal process and submitted a Memorandum to Cabinet signed by six departments that set out the blueprint for a renewal process in 1997–98. At the same time, the Minister requested NBAC to contribute to the renewal process by preparing a "Sixth Report" to include forward-looking recommendations on socio-ethics, commercialization, options on a renewed advisory structure; and regulatory and infrastructure challenges for biotechnology into the next millennium. The Sixth Report will be released in March 1998 and will be available to the public. The web site for the NBAC Sixth Report is: **http://strategis.ic.gc.ca/ssg/bo01239e.html**

For further information, contact:

Bio-Industries Branch
Industry Canada
235 Queen Street
Ottawa ON K1A OH5
Tel.: (613) 954-3071
Fax: (613) 952-4209
E-mail: mcgregor.elizabeth@ic.gc.ca
or: michaliszyn.george@ic.gc.ca