Renewal of the Canadian Biotechnology Strategy

Resource Document

2

Sector Overviews

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Canada

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Resource Document

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The following material provides additional details on six sectors that make use of biotechnology. These sectors are actively participating in the renewal of the Canadian Biotechnology Strategy. Individuals or organizations wishing more information on these sectoral initiatives are invited to follow up with the listed contact point.

2.1 Agriculture and Agri-food

Agriculture and agri-food is one of Canada's top five industries. It accounts for 14.7 percent of employment and 8 percent of the gross domestic product.

Biotechnology plays an increasingly important role in agriculture and agri-food. Already the planted acreage of crops with novel traits has increased dramatically. For example, planting of genetically modified canola has increased from 141 600 hectares in 1996 and 1 619 000 hectares in 1997 to a projected 2 630 000 hectares for 1998, according to the Plant Biotechnology Institute of the National Research Council. Similar growth in acreage has been found in other transgenic crops such as corn, flax and potato.

The use of technology is key to increasing the world's food production capacity in the face of environmental concerns, limited arable land and population increases. Of Canada's core biotechnology companies, 26 percent focus on the development of agriculture and agri-food products. Industry groups expect Canada to double current exports of agricultural products to $40 billion by 2005. Biotechnology will have a significant role to play in achieving these export goals, if the policy framework is well structured today.

KEY ISSUES

Public Participation: Input, Information and Communication

As with other technologies, public confidence will determine the future of biotechnology. The public has a stake, and has played a key role, in policy development. Canadians have had significant opportunity to comment on and debate the regulatory process. These fora have included consultation documents, regulations published in the *Canada Gazette*, parliamentary committees, government-led consultations, public opinion surveys, conferences, workshops and presentations. Still more work with the public needs to be undertaken to determine information needs and the role that all stakeholders can play in more efficiently and effectively satisfying those needs.

Regulatory Framework

The Canadian Food Inspection Agency (CFIA) conducts safety and environmental assessments of fertilizers, seeds, plants, plant products, animals, vaccines, animal disease diagnostic kits and feeds. It also enforces portions of the *Food and Drugs Act*. Health Canada is responsible for assessing the safety of novel foods that include biotechnology products. Health Canada also develops, in conjunction with the CFIA and other government departments, regulations concerning food labelling. The Pest Management Regulatory Agency (PMRA) of Health Canada has the mandate under the *Pest Control Products Act* to conduct safety and environmental assessments of pest control products, including those derived from the use of biotechnology.

Clear and timely information on regulatory processes, decisions and enforcement activities have been suggested as important factors in public confidence of the government's regulatory role. Public input into regulatory policy development is also important and needs greater visibility amongst all stakeholders.

Research and Development

The successes of biotechnology have been largely due to dedicated research activity, which has provided the foundation for Canadian agriculture. There has been greater focus on research collaboration between the public sector and industry in recent years.

One of the most visible commercial outcomes of this collaborative effort is the development of canola. Canadian research will continue to focus on increasing the overall economic value of crops, and making improvements in livestock production, animal health care and husbandry.

Commercialization and Competitiveness

Canada's agriculture sector faces many challenges in the coming years. The fundamental strength of the country's research community can help the sector meet those challenges and maintain a strong international presence. Canada must continue to foster the alignment of the private sector with the research community and identify key areas for commercialization.

Many countries and organizations are rushing to sequence the genomes of commercially valuable crop species. As these discoveries will be protected by patents, Canadian researchers have indicated that Canada will face a difficult period if it does not take similar steps. It is important therefore to ensure that Canada has a prominent role in the emerging science of genomics, which includes genome mapping and gene sequence technologies. Along with genomics, it is vital that the identification of new traits or the modification of existing traits be accompanied by the preservation of wild and novel germplasms.

International

Canada is a trading nation with considerable dependence on agricultural exports. Access to foreign markets could present a barrier to Canadian biotechnology products, particularly in the absence of internationally harmonized standards. Canada has actively supported the development of internationally harmonized standards for regulatory regimes and risk assessments to facilitate international trade in biotechnology products. In addition, Canada has advocated that any international standards be based on scientific principles and procedures to protect health, safety and the environment.

The federal government and stakeholders are currently working in several international fora to harmonize biotechnology standards and thereby facilitate the flow of international trade in agricultural biotechnology products. These fora include the World Trade Organization, Codex Alimentarius Commission, the Biotechnology Experts Group and the Pesticides Forum of the Organisation for Economic Co-operation and Development, proposed Biosafety Protocol negotiations under the United Nations Convention on Biological Diversity, North American Plant Protection Organization, etc.

Federal-Provincial Collaboration

To facilitate trade, federal and provincial governments are coordinating and cooperating with each other and with industry to develop marketing strategies. Many provinces already have strategies to facilitate the use of biotechnology to advance their economic competitiveness and others are in the process of developing strategies. The opportunity will exist for the Canadian Biotechnology Strategy and the provincial policy frameworks to be mutually supportive.

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2.2 AQUACULTURE

Canada's aquaculture sector has benefited significantly from various enabling technologies that improve fish health and broodstocks. Biotechnology is emerging as an important subset of these enabling aquaculture technologies and its application promises important economic returns as well as social and ethical challenges.

Among the strengths of Canada's aquaculture industry are its technical and aquaculture management expertise and a geographical setting that affords easy access to the huge North American and Pacific Rim fish and seafood markets.

The Food and Agriculture Organization (FAO) calculates that the annual demand for seafood will outstrip the capacity of the wild fishery by some 55 million tonnes by the year 2025. To compensate for the shortfall, aquaculture production will have to increase by 350 percent. This represents a major opportunity for both the Canadian aquaculture sector, which is currently only 0.3 percent of global production, and the aquaculture biotechnology industry.

KEY ISSUES

Public Participation: Input, Information and Communication

Governments and the public are increasingly aware of the potential of aquatic biotechnology to generate new scientific knowledge and produce useful products and processes for the aquaculture industry. Biotechnology-derived vaccines and diagnostics for use in the aquaculture industry receive as wide a public acceptance as they do in the terrestrial animal and human health sectors. However, consumable aquatic biotechnology products may face the same public perception problems as other genetically modified food products. The use of transgenic aquatic organisms poses environmental safety issues related to the potential spread of "new" genes to wild fish populations. Canadians need to be informed about both the risks and benefits of aquatic biotechnology.

Regulatory Framework

The federal government regulates aquaculture biotechnology products under several acts. Recombinant fish vaccines are regulated under the *Health of Animals Act* and Regulations; transgenic organisms for human consumption under the Novel Food Guidelines. To ensure no ecological harm results, 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 applies equally to transgenic and non-transgenic organisms. This requirement will enhance the current powers being drafted and will provide for the gathering of information on transgenic aquatic organisms, containment procedures and environmental assessment.

As the aquaculture biotechnology sector grows, the number of products for which regulatory approval is sought will increase — so too will the demands on the regulating agencies. To remain effective and maintain public confidence, federal regulatory departments must ensure that they have enough skilled people and regulatory resources.

Research and Development

Research in aquaculture biotechnology is limited — only some universities and government institutions, and a few private firms, have active programs. Although impressive success stories exist, the aquatic biotechnology industry is at an earlier stage of development than those in the health or agriculture sectors, and scientists still have much to learn about aquatic organisms.

Commercialization and Competitiveness

Aquaculture biotechnology is now at the stage where practical applications are being identified and commercialized. The rising number of R&D initiatives around the world points to an increasingly competitive aquatic biotechnology sector. Countries such as Australia, France, Germany, Italy, Japan, Norway, Sweden, the United Kingdom and the United States have significant research and development programs. Among developing countries, China and India are making considerable investments in aquatic biotechnology.

The United States was the first country to establish a specific program in aquatic biotechnology (Center for Marine Biotechnology, University of Maryland). It is the largest aquatic biotechnology institute in North America and second largest in the world (Japan has the largest). While Japan and the U.S. are leaders in the bioprocessing aspects of aquatic biotechnology, Canada is strong in aquaculture biotechnology. The Canadian knowledge base in aquaculture biotechnology is solid and is viewed by many as a competitive strength. Nevertheless, aquatic biotechnological research in Canada continues to occur in relatively small teams with specialized expertise.

The issue of public confidence and acceptance, not only of the product but of the way in which it is produced, is increasingly important in aquaculture and will be even more so with the application of biotechnology. Public concern regarding the aquatic environment could well exceed that for terrestrial plant products. A major concern is that fish will escape captivity and create changes in the genetic make-up of wild stocks. For fish, the environmentally safe commercialization of transgenic broodstock is the biggest biotechnology issue (although maintaining such fish in secure facilities is possible).

International

Because Canada exports more than 70 percent of its aquaculture biotechnology products and services, foreign markets are vital for a competitive Canadian aquaculture biotechnology industry. International harmonization of regulations and public acceptance are key issues in accessing global markets. International business development initiatives have focussed on developed country markets (for example, the United States, Chile and Norway). Current initiatives centre on marketing vaccines and gene probes to developing countries in some of the largest aquaculture-producing areas of the world (Asia Pacific and Latin America).

◆ Gene Probes for Stock Identification ◆

Scientists at the Department of Fisheries and Oceans have developed gene probes that permit the identification of different stocks of Pacific salmon. The probes allow fisheries managers to identify the origins of wild fish caught at sea and, eventually, to track migration paths more precisely. This will help the department better manage the harvesting of stocks on an individual basis. The same technology is being used by the aquaculture industry to select for superior lines of fish using pedigree broodstocks. A line of selectively bred coho salmon has been transferred to industry. Eggs from this strain have found a ready export market (United States, Japan, Chile and Korea).

Protecting Human and Animal Health, and the Environment

The Department of Fisheries and Oceans (DFO) is responsible under the *Fisheries Act* for the conservation of the marine resource and its habitat. DFO's mission is to manage Canada's oceans so that they are clean, safe, productive and accessible, and to ensure the sustainable use of wild fishery resources. DFO is also the lead federal agency for aquaculture and, through the Federal Aquaculture Development Strategy, is committed to ecologically and environmentally sound aquaculture development.

Federally funded biotechnology research programs promote research that supports industry competitiveness and the generation of information necessary for fulfilling government responsibilities regarding health, safety and the environment.

Federal-Provincial Collaboration

No formal federal-provincial aquatic biotechnology agreements exist. DFO has memoranda of understanding (MOUs) with several provinces relating to the regulation of aquaculture and performance of R&D — biotechnology is not a subject of the MOUs. Most provincial environmental and natural resource agencies have experienced budget cuts in recent years and many lack the resources and expertise to tackle the issues associated with aquatic biotechnology.

Aside from DFO and the National Research Council, most biotechnology related to aquaculture will emerge from universities, which are under provincial jurisdiction and supported through federal institutions such as the Natural Sciences and Engineering Research Council. University-based research programs in aquaculture biotechnology need to be coordinated for maximum effectiveness. The federal and provincial governments could work together to create a climate of biotechnology innovation that would include, but not be limited to, aquaculture.

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2.3 Environment and Environmental Industry

One aspect of biotechnology that continues to garner wide-scale attention is the multifaceted role that its environmental applications could play in fulfilling national priorities regarding innovation, environmental protection and sustainable development.

Environmental biotechnology products and processes are poised to capture a significant share of the environmental industries market, both in Canada (worth an estimated $16 billion) and worldwide (expected to reach $600 billion by 2000, according to OECD figures). After health care and agriculture, the environmental industries sector is estimated to be the third largest creator of biotechnology jobs, with an annual average growth rate for 1989–93 of 25 percent.

Major strengths of the Canadian environmental industry sector are its technical expertise in specific and broad-based bioremediation (the biological clean-up of effluents) of soil and wastewater treatment applications, and the sector's flexibility to accommodate innovation and entrepreneurship. Domestically and internationally, demand for environmental applications of biotechnology are increasing in areas such as processes to detoxify and reduce traditional waste streams and convert them into valuable new products; new biomaterials based on renewable resources; less labour- and energy-intensive inputs to improved bioprocess engineering and systems design; innovative environmental solutions to the removal, reduction or stabilization of recalcitrant pollutants; restoration ecology; and the next generation of pollution prevention, detection and biological monitoring techniques.

Biotechnology developments in Canada and elsewhere suggest that enhanced environmental applications of biotechnology will be important contributors to Canada's future economic growth and prosperity. Despite the significant potential of environmental biotechnology to capture larger shares of the environmental technology markets, it faces serious challenges that require innovative, timely, viable and publicly acceptable solutions. The challenge is to present a clear vision for the future of environmental biotechnology development that addresses, in a realistic and consultative manner, key issues.

KEY ISSUES

Public Participation: Input, Information and Communication

We have only recently started to recognize the scope and level of understanding of issues that will work together to create public confidence in environmental applications of biotechnology.

Focus groups sponsored by Environment Canada and Industry Canada in 1996 revealed that a high degree of public support exists for a range of specific environmental applications across Canada. Such groups have also identified issues and concerns about potential adverse effects of biotechnology on the environment and the extent of public involvement and available information on these matters. This input has been an important input to the work program of Environment Canada as well as other government departments and regulators. In addition, many of these matters are being addressed by the current renewal of the Canadian Biotechnology Strategy, including public participation and information.

Regulatory Framework

As discussed more fully in Resource Document 3, Related Resource Documents, Canada has a comprehensive regulatory system for the protection of human and animal health and the environment. The federal regulatory framework includes several acts, including the *Canadian Environmental Protection Act* (CEPA), and regulatory agencies. As a result, the intentional introduction of organisms into Canada is regulated. The specific set of regulations that applies depends on the use of the organism, for example, in an animal feed, to produce a drug, or as a biopesticide. Many organisms are regulated by the New Substances Notification Regulations of the *Canadian Environmental Protection Act* (CEPA). These regulations are set in motion when someone wishes to produce the organism in Canada or bring it into Canada through importation. CEPA plays a "safety net" role by ensuring that all new biotechnology products that are organisms or products of micro-organisms (such as enzymes) are assessed for environmental and human health effects before they are introduced into Canada either under the New Substances Notification Regulations or under other appropriate regulations.

There may also be provincial and municipal regulations that must be met in order for an environmental application of a biotechnology product to occur. However, the federal government is actively involved in reducing duplication and enhancing harmonization with the provinces through the Canadian Council of Ministers of the Environment and through direct dialogue with provincial government officials. In addition, municipalities may have by-laws that will effect environmental applications of organisms, for example, waste water treatment organisms and bioremediation organisms.

Research and Development

Environmental biotechnology R&D requires enhanced support, particularly in the following areas: resolution of life form patent issues; strategic research outside the domain of a single environmental industry entity; reluctance to utilize unproven technologies; public uncertainty and anxiety regarding genetically modified products; venture capital to support applications of biotechnology; and skilled human resources.

Commercialization and Competitiveness

Environmental applications of biotechnology offer a suite of promising, green, labour-efficient, low-energy-usage solutions applicable to several areas of environmental concern in Canada. However, the sector is largely project driven, which results in insufficient strategic-alliance activity, expertise scattered across the country and limited integration into the broader Canadian environmental industry sector. Although poised to contribute substantially to national economic growth and prosperity, the environmental biotechnology sector has been unable to compete with the more "glamorous" applications in agriculture and human health. It is also perceived as being a vast, extremely complex field that cuts across many industries. Also, as with other biotechnology sectors, it needs public acceptance and support to succeed commercially.

International

As biotechnology develops, the international community has addressed, or is addressing, many important biotechnology related issues. In the environmental area, Canada signed the United Nations Convention on Biological Diversity in 1992 and is the seat of the international secretariat of the Convention on Biological Diversity. In order to protect local biodiversity, Canada and other nations are engaged in the process of

negotiating a Bio-safety Protocol that will govern the transborder shipment of genetically modified living organisms. Canada is also active in the development of effective international environmental regulatory standards and procedures through organizations such as the OECD.

Several of Canada's major trading partners and environmental industry competitors (notably, the United States, Germany, Japan and the Netherlands) are accelerating research and development in environmental biotechnology. In the United States and the Netherlands, for example, four major initiatives (worth more than $20 million each) were recently launched focussing on biology-based restoration ecology technologies. On the international scene, Canadian scientific capabilities are rapidly becoming recognized in areas such as bioremediation of contaminated soils, oil spill bioremediation, phytoremediation, biomonitoring and biosensors. While some successes have been achieved, the potential benefits of the more innovative and attractive environmental applications of biotechnology in Canada are far from being realized for both domestic and international markets.

Federal-Provincial Collaboration

The Canadian Council of Ministers of the Environment — with the exception of Quebec — recently signed an accord designed to lead to improved cooperation and better environmental protection across Canada.

The Canada-wide Accord on Environmental Harmonization envisions governments working in partnership to achieve the highest level of environmental quality for all Canadians. Under the Accord, each government will retain its existing authorities but will use them in a coordinated manner to achieve enhanced environmental results. Each government will undertake clearly defined responsibility for environmental performance and will report publicly on its results.

At the promotional level, a number of federal/provincial strategic alliances and a number of federal-provincial strategic alliances and biotechnology projects have been undertaken in such areas as bioremediation, biological gas cleaning, phytoremediation, regulatory clarification, test-method development and ecotoxicology. Many provinces (notably British Columbia, Saskatchewan, Ontario, Quebec, Nova Scotia and Newfoundland) have expressed interest and willingness to sustain these collaborative projects and to initiate new endeavours. Mechanisms to realize and advance these ongoing and promising future collaborative projects need to be fully explored.

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2.4 Forestry

The forest sector is a cornerstone of Canada's economy. It employs close to one million people and is consistently the single highest contributor to Canada's positive trade balance ($33 billion in 1996), outpacing all other manufacturing sectors combined. Exports in 1996 reached $38 billion (72 percent of the sector's shipments).

Sustainable development is a major issue, both domestically and globally. With the emergence of international conventions, Canada's domestic coordination efforts are directed by international forces. Forest biotechnology provides tools that could reduce the exploitation pressure on forests, thus contributing to sustainable development, and knowledge of forest ecosystems that can contribute to conservation. The productivity of intensively managed forests can be improved through the use of biotechnology-derived products such as genetically enhanced trees or environmentally sound biological pest management products and strategies. Enzymes from microorganisms are commonly used in the pulp and paper industry for enhancing pulp and fibre properties, de-inking and mill effluent treatment.

Canada's prominence in forest science and as a forest producer gives it the opportunity to become a world leader in forest biotechnology. However, only a few biotechnology-derived products and processes have been commercialized, mostly in the area of pest management, forest regeneration, pulp and paper processing and mill effluent treatment.

KEY ISSUES

Public Participation: Input, Information and Communication

Despite ongoing efforts by the Canadian Forest Service, stakeholders in the forestry sector and the public in general remain largely unaware of forest biotechnology developments. An urgent need exists to inform Canadians of the benefits and risks of biotechnology to ensure that people understand the methodologies for improving forest productivity. At present, the public is concerned about health and environmental degradation in general and, more specifically, about the conservation of old-growth forests and natural ecosystems.

Regulatory Framework

At the federal level, forest biotechnology-derived products are regulated under several acts for safety and efficacy: the *Seeds Act* for genetically modified trees, the *Plant Protection Act* for imports, the *Fertilizers Act* for biofertilizers and mycorrhizae, the *Pest Control Products Act* for microbial pest control agents and the *Canadian Environmental Protection Act* for microorganisms used in the pulp and paper industry. The *Seeds Act*, *Plant Protection Act* and *Fertilizers Act* are administered by the Canadian Food Inspection Agency; the *Pest Control Products Act* by the Pest Management Regulatory Agency; and the *Canadian Environmental Protection Act* by Environment Canada.

Clarification of the interactions between the federal and provincial governments in the regulation of genetically modified organisms for forestry application is required. Existing scientific expertise available to regulatory agencies for safety assessments should be strengthened. Legal mechanisms to protect improved tree seeds as intellectual property must be explored.

Research and Development

The capacity for research and development in forest biotechnology is low outside the federal government. The private sector and provinces do not invest significantly even though they are major trustees of the country's forests. The need for scientific knowledge continues to expand, while resources for scientific research and the number of qualified scientists remain inadequate. A need exists to pursue basic research to understand trees, forest pests and potential biological control agents at the molecular and cellular levels. The state of this understanding is far from

◆ Biopesticide to Fight Spruce Budworm ◆

The Canadian Forest Service (CFS) conducted the basic research to acquire the appropriate knowledge of the insect virus (baculovirus) to utilize it in its natural form as a biopesticide or to genetically engineer it for more efficient use. In the first case, the company Bio-Sag (Québec) is involved in its commercialization; in the latter, a licensing agreement with Rhom and Haas has been established to commercialize the product. The CFS also performed environmental impact assessment research to ensure the environmentally sound use and evaluation of this new class of biopesticide.

what has been achieved in the agriculture field, in part because of the long life cycle of tree species. Private industry is reluctant to invest in forest biotechnology because it takes a long time to see a return on the investment. Studies on the environmental fate and effects of genetically modified organisms to be used in forestry are required to provide scientific data for safety assessments. Also, more research needs to be conducted on the use of microbes and their products for pulp and paper processing and mill effluent treatment.

An important thrust of Canadian R&D activity over the next five years would be the development of economical methods for mass production of biotechnology-derived products leading to commercial-scale operations.

Commercialization and Competitiveness

Globally, Canada's major competitors are the Scandinavian countries, the United States, New Zealand and Australia. New competition is emerging in the former Soviet Union and South America. Although Canada is a leader in the development of forest biotechnology, it lags behind the United States and New Zealand in application. Support for basic research in biotechnology is excellent in Sweden, Finland and Norway, although commercialization is hindered by stringent regulatory structures. In contrast, regulatory requirements are permissive in Chile, Brazil and Argentina, and several multinational forest companies plan to use biotechnology-derived products extensively in these countries (starting with tissue culture and breeding, and moving toward genetic engineering).

The rate of commercial development and use of forest biotechnology in Canada is influenced by land tenure (mostly owned by provincial governments). It is also influenced by the regulatory framework for environmental assessment and by intellectual property issues related to genetically improved or modified organisms.

The forest sector is conservative and slow to pick up new technologies for resource management. However, significant potential exists for technology transfer and commercialization as responsibility for forest management is transferred to industry. There is thus an urgent need to develop mechanisms for encouraging private industry involvement and investment in research and biotechnology applications.

International

Because demonstrating environmentally responsible forest practices is becoming a factor in market access, Canada must ensure international leadership in this regard. In 1995, the Canadian Council of Forest Ministers (CCFM) established a set of criteria and indicators for sustainable forest management. The development of certification processes for forest products will also encourage exporting countries to adopt the forestry practices that will best integrate strong principles of sustainable development.

Canada must develop a unified position among its stakeholders on international policy issues in forest biotechnology for presentation at international fora (for example, negotiations toward the international Biosafety Protocol; OECD Biotechnology Expert Groups). Key business and partnership opportunities for international cooperation also need to be discussed.

The international competitiveness of Canadian biotechnology-derived products will depend on public acceptance and the international harmonization of standards and regulations.

Stewardship

As the largest Canadian organization involved in forest biotechnology, Natural Resources Canada plays a key role in defining strategic research orientations, developing regulations, training personnel to a highly qualified level, building infrastructures, increasing public awareness of forest biotechnology, and coordinating activities with industry, academia and other government departments and agencies. Other stakeholders such as universities concentrate on the training of highly qualified personnel and on shorter-term research. Industry has been primarily involved in the use of the technology.

The federal government must work closely with provincial governments, industry, universities and environmental groups to ensure a common understanding of goals in all biotechnology applications. Biotechnology-related considerations should be integrated into developing national forestry frameworks such as the Science and Technology initiative and the National Forest Strategy.

Federal-Provincial Collaboration

The federal and some provincial governments have developed forest strategies. There is no federal-provincial forest biotechnology strategy, although provincial and federal activities are closely linked (especially in the Maritimes, Quebec, Manitoba and Saskatchewan). Forestry activities are coordinated under the Canadian Council of Forest Ministers (CCFM) and through the provincial forestry research councils. The CCFM is also working toward a new National Forest Strategy that should include all relevant technologies that could be used in this sector.

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2.5 Health Sector Overview

The greatest impact of biotechnology, both globally and in Canada, is in human health: 90 percent of all biotechnology products on the worldwide market are health related.

Biotechnology is used for disease surveillance, diagnosis, treatment and prevention. It permits the identification of disease agents where conventional means do not succeed, allows better tracking of pathogens, facilitates earlier detection of disease and provides therapeutic products and processes. Biotechnology is also used as a product base in the health industrial sector, and as an enabling technology in health sciences.

In Canada, nearly 60 percent of Canadian biotechnology companies focus directly on health care. The industry is quite successful: it employs over 8 000 people, most in knowledge-based positions; in recent years, its market capitalization has increased fivefold to $10 billion; and its revenues have grown by over 45 percent in the same period. Three of Canada's biotechnology clusters (in British Columbia, Ontario and Quebec) rank among North America's top 20 centres by revenue and number of businesses.

Knowledge resources are one of Canada's recognized strengths. Biotechnology is a major part of the activities of a health research community that includes 30 000 investigators and technical personnel in 16 medical schools, 30 university departments, 75 research institutes and numerous industrial firms producing pharmaceuticals, medical devices, fine chemicals and novel foods.

In addition, there is a network of federal laboratories under the direction of the National Research Council (NRC) and Health Canada (HC). Three federal agencies ("granting councils") provide significant financial support for research and development in biotechnology and biotechnology-related areas: the Medical Research Council (MRC), the Natural Sciences and Engineering Research Council (NSERC) and the Social Sciences and Humanities Research Council (SSHRC).

Some aspects of the link between biotechnology and health have been part of the public debate in Canada over the past five years. For example, the Royal Commission on New Reproductive Technologies, the Krever Commission, the parliamentary review of the *Patent Act Amendment Act, 1992* (Bill C-91) and the reports of the National Biotechnology Advisory Committee have all touched on biotechnology issues in future health policy.

For the health sector, three central questions revolve around application, development and research: (1) How can the potential of biotechnology be best managed for the public health advantage of Canadians? (2) How can a globally competitive Canadian-based industry in health biotechnology be best built and sustained? (3) How can health biotechnology research be supported and focussed to most effectively contribute to health protection and industrial development?

KEY ISSUES

Public Participation: Input, Information and Communication

Stewardship of our growing capabilities in health-related biotechnology requires the full and continuing participation of all stakeholders: the public, consumers and providers of health care products and services, health researchers, health industries, health-related regulators and policy makers at all levels.

In health protection, stewardship entails measures to provide, safeguard and coordinate information that makes Canadians aware of both the advantages and risks associated with biotechnology products and processes and of the social-ethical and health safety considerations. In industry, stewardship means provision of innovative and high-quality products that respond to the health needs of Canadians, and that are developed, manufactured and sold in accordance with self-imposed guidelines, ranging from research ethics review, to marketing rules, to codes of conduct

for international business. In research, stewardship involves responsiveness to social values and sensitivities about science, and preserving its capacity to serve humanity.

Regulatory Framework

The Federal Regulatory Framework for Biotechnology is intended to ensure that the benefits of biotechnology products and processes are realized in a way that protects health, safety and the environment. Through its Health Protection Branch and Pest Management Regulatory Agency, Health Canada is responsible for identifying and managing risks to health posed by biotechnology-based products and processes.

The continued growth in the number and range of these products and processes means that ongoing improvements to the regulatory system are required. Among other things, this entails aligning resources to needs, providing the requisite scientific and regulatory capacity, and reconciling the need for cost and time efficiencies with the primary goal of protecting health and safety. An effective, efficient and predictable regulatory environment achieves this protection and creates confidence among the public, regulated industries and the international community.

Research and Development

Canada currently spends about $1.6 billion on all aspects of health research, but public investment in the basic science fundamental to biotechnology has lost competitive ground internationally in recent years. Of the G-7 countries, only Italy invests less. The United States, Germany, the United Kingdom, Japan, France, Singapore and Taiwan have all expanded their biotechnology R&D efforts in the health arena.

Both the federal and provincial governments have been reducing spending in order to reduce their deficits. At the federal level, this has had an impact on government laboratories and the budgets of the granting councils. However, the recently announced Canada Foundation for Innovation program will support renewal of research infrastructure in hospitals and universities. Restructuring of provincial health and education programs has also impacted research resources. There are growing concerns that the changes could lead to shortages in highly qualified personnel in this sector.

International intelligence can be used to better forecast biotechnology needs and opportunities, and thereby provide a sharper focus for health biotechnology R&D in Canada. A long-term development plan, or strategy, would improve coordination and concentration of R & D efforts.

Commercialization and Competitiveness

Canada's health biotechnology industry is small by world standards, but it has been growing rapidly in the last five years. We have long been known for excellent research and poor commercialization, but this is turning around. Initiatives such as the Industrial Research Assistance Program (IRAP), the Networks of Centres of Excellence (NCE), Technology Partnerships Canada (TPC), the health-charity partnerships, and the new venture capital funds, for example, Canadian Medical Development Fund (CMDF), facilitate significant increases in innovation and new start-ups. Multinational companies are increasingly interested in supporting Canadian research efforts, in strategic partnering with Canadian firms, and in entering into international marketing arrangements with them.

Current competitiveness issues in this knowledge-based industry include: continued improvement in technology transfer from universities and government laboratories; human resource development, particularly in science and technology, entrepreneurial management, intellectual property management and regulatory affairs; stability in the intellectual property laws and regulations; a harmonized federal and provincial regulatory regime; growth in R&D commitments; access to capital for initial start-up and for establishment of pilot and full-scale production facilities; and market access.

International

Biotechnology is a global undertaking. Research successes are built on international collaboration. Industrial development successes require partnerships around the world and product successes ultimately demand global markets.

In an era of global markets, fewer resources and increasing demands, regulatory authorities in many countries are cooperating to ensure that their systems are as effective and efficient as possible. This entails collaboration in developing and implementing regulation and surveillance standards for health protection through arrangements to harmonize regulations and standards and by negotiation of mutual recognition agreements.

Federal-Provincial Collaboration

Provincial involvement in health biotechnology in Canada is extensive. Provinces have primary responsibility for the delivery of health care services, including the provision of biotechnology-based products and procedures. They are increasingly interested in technology assessments and pharmaco-economic studies that provide information on effectiveness and cost of biopharmaceuticals. They foster research through their support of universities and provide incentives and infrastructure to health biotechnology industries. Many provincial governments have seed money programs to support initial phases of industrial R&D. An increasing proportion is devoted to health biotechnology.

An effective Canadian Biotechnology Strategy requires close collaboration between federal and provincial government departments and agencies with health responsibilities, including coordinating their respective policies and programs to assure that the health advantage of all Canadians is protected and advanced and that research programs are focussed, efficient and well resourced; and that a Canadian health biotechnology industry grows on a world stage.

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2.6 Mining and Energy

The mining and metals sector contributes $24.4 billion to Canada's gross domestic product and generates more than 10 percent of Canada's merchandise trade surplus. It employs almost 350 000 Canadians and sustains 150 communities. The conventional energy sector, which includes oil and gas, electric utilities, refined petroleum and coal products, coal and uranium, contributes $52 billion and directly employs almost 200 000 people.

Biotechnology development is primarily at the "science base" stage within universities. Canada has few specialized biotechnology supply and development companies focussing on these resource sectors. The scale-up of biotechnical processes tends to be performed by subgroups within the large mining and energy field and processing companies. Given the size of these sectors, even small biotechnological applications can have major environmental and economic impacts. However, made-in-Canada biotechnologies have been used more extensively offshore than at home.

While acceptance and adoption of industrial biotechnology processes have been limited, naturally occurring microbial activities pose significant challenges for both the mining and energy sectors. Although in some cases natural organisms work to effect remediation through consumption of site contaminants, they also contribute to acid mine drainage at sulphidic mine sites. The liability associated with acid mine drainage in Canada ranges from $2 to 5 billion, and its prevention/control is perhaps the industry's greatest environmental challenge.

Principal areas of current and potential application of biotechnology in the mining and energy sectors include: resource extraction and quality improvement (including bio-oxidation/leaching of gold and base metal ores, microbially enhanced oil recovery and bio-upgrading of bitumen/heavy oils), environmental management (including metals recovery/immobilization, bioremediation, phytoremediation and inhibition of natural biological activity in wastes) and environmental monitoring (including biomonitoring tools for toxicity testing and environmental quality evaluation).

KEY ISSUES

Public Participation: Input, Information and Communication

At this stage, few people associate biotechnology with mining and energy. This creates an opportunity to take a proactive, considered approach to building industry and public confidence. In formulating such an approach, much can be learned from the health care and agri-food sectors as they grapple with issues such as ethics, public confidence and education, credible performance standards and effective communication strategies.

Regulatory Framework

Biotechnology products used or produced in mining and energy are subject to *Canadian Environmental Protection Act* (CEPA) biotechnology notification regulations, unless covered by other federal acts such as Agriculture and Agri-Food Canada's *Seeds Act*. As well, living modified organisms that cross international borders are expected to be subject to a biosafety protocol currently being negotiated under the United Nations biodiversity convention. The protocol is not expected to add extra steps to those required under CEPA or other federal regulations.

Continued dialogue and negotiation are needed among all levels of government, industry, the public and other stakeholders to ensure sound regulatory practices are developed and implemented. International harmonization of regulations would enhance the development and application of biotechnologies in Canada.

◆ Biotechnology Applications in Canada's Mining and Energy Sectors ◆

The only current biotechnology application practised on a commercial scale in Canada is in the bio-oxidation of copper sulphide ores for copper extraction. This bioprocess will continue well into the future and, depending on mineral reserves and prices, may include other metals such as uranium and gold. Other applications currently in the developmental stage include: bio-upgrading of oil, which would consume significantly less energy and lower greenhouse gas emission; an active biosulphide process that precipitates base metals through the microbial reduction of sulphate; a passive biofilter method for treating contaminated groundwater; an engineered wetlands system that treats acid mine drainage; inhibition of natural microbial activity for the prevention of acid mine drainage; phytoremediation, which includes the reduction, immobilization and/or recovery of contaminants from soil, ground and surface waters, sediments and sludges; and bioremediation of mining effluents or contaminated sites. Some of these applications are used commercially in other countries, and all show future potential in Canada.

Research and Development

The potential environmental and economic impacts of biotechnology in the mining and energy sectors are tremendous. However, to date, investment in R&D biotechnology in these sectors has been significantly less than in health care and agri-food in both the public and private sectors.

The environmental impacts of the mining and energy industries could be reduced by developing methods for enhancing bio-processes such as phytoremediation and bioremediation. These processes would allow the clean-up of sites contaminated with heavy metals or petroleum hydrocarbons. Research would allow the development of biological monitoring systems that not only would assess the state of contamination at the sites but also would aid in judging when a site is no longer contaminated. The environmental impact of the petroleum industry would also be reduced by the development of bio-upgrading processes for application at heavy-oil production sites. Bio-upgrading, under ambient conditions, would reduce the energy required for upgrading heavy oils to transportation fuels, and consequently reduce the carbon dioxide emissions from petroleum upgrading.

Applications of technologies such as bio-oxidation to metal extraction and bio-upgrading to heavy-oil production could also offer economical solutions to difficult processing problems.

For implementation of these bio-processes, research is needed from laboratory scale to pilot scale. In particular, work is required to address the specific difficulties resulting from Canada's climate and production site conditions. Research should focus, first, on enhancing the performance of endogenous organisms. However, in the longer term, it is likely that the use of genetically modified organisms will be necessary to extend biotechnology performance in the energy and mining sectors.

Commercialization and Competitiveness

Operators in the mining and energy sectors tend to purchase proven technology rather than undertake research. Consequently, industrial funding for biotechnology development has been, and will continue to be, limited to specific industrial issues where no proven, cost-effective, alternative technologies are known. As well, biotechnology must fit within the technology scheme and capital infrastructure currently used by the domestic industry.

For the biotechnology industry to secure a stronger presence in the mining and energy sectors, research should focus on problematic technical issues and applications that reduce costs. Both the economic and environmental benefits of the proposed solution should be emphasized.

International

The mining and energy sectors are driven by the quality and quantity of the resource reserves and access to the reserves found around the world. Benchmarking figures relating to tonnage produced are therefore more a measure of the resource quality/quantity than of the effectiveness of the technology. Further, applications of biotechnology to field operations tend to be site-specific due to climatic and geological variabilities.

Canada has gained much from academic networking and overseas experience. The strong presence of Canada's consulting engineering companies in other countries also stimulates export opportunities.

Continuing information exchange and collaborative projects with other cold-climate countries such as Sweden and high-altitude Andes countries with similar mineralogy could advance solutions to Canadian issues related to climate. As well, strong international scientific linkages are being developed to provide a common basis for worldwide policy and regulation development to help minimize downstream regulatory and trade barriers and other repercussions in foreign markets.

Stewardship

Natural Resources Canada plays a minor role in directing research, training highly qualified personnel, developing regulations and building infrastructures in biotechnology. A more significant role is its coordination of industry, academia and government through networks such as BIOMINET. A better network is required to coordinate the activities of industry, academia and all levels of government to advance biotechnology commercialization in Canada.

Federal-Provincial Collaboration

Existing federal-provincial policy dialogue (Mines Ministers Conference, Energy Ministers for Environment, etc.) could be used to address mining and energy biotechnological issues. Partnerships on technology development projects have proven effective in bringing together federal, provincial and industry stakeholders to address issues in a consultative and collegial fashion. Such partnerships include MEND (Mine Environment Neutral Drainage), AETE (Aquatic Effects Technology Evaluation), DEEP (Diesel Emissions Evaluation Program), CONRAD (Canadian Oil Sands Network for Research and Development) and PTAC (Petroleum Technology Alliance Canada). These collaborative efforts are an excellent model for achieving focussed, meaningful collaboration.

With respect to enhancing intergovernmental collaboration on biotechnology issues in mining and energy, no new provincial and federal discussion groups are required at this time. Federal and provincial participation in biotechnological consortia R&D programs should be encouraged.

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