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Profile of the
**Biotechnologies
Sector**

Prepared for the Expert Panel on Skills
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1999

Canada

**PROFILE OF
THE BIOTECHNOLOGIES SECTOR**

Advisory Council on Science and Technology
Expert Panel on Skills

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Abstract

Although the modern biotechnology industry is only in its infancy, the large market potential for health and agri-food products has created high expectations for rapid growth in industry and employment. The products of the industry, most involving new uses of genetic materials, show potential for medical breakthroughs and more environmentally friendly agriculture, aquaculture, forestry and mining. Consumer education as well as demonstration that the products of the industry are safe in the long term are significant challenges for the industry.

The industry currently employs a highly skilled work force, with about 50 percent of employment in research and development. However, the industry faces a critical shortage of skills associated with management and the commercialization of products under development.

The skills most needed are those of managers with a science background and with expertise in business development, domestic and international regulatory requirements, technology transfer, strategic alliance development, production scale-up, and investor relations. Shortages also exist for quality control/quality assurance managers, clinical trial managers and managers with expertise in intellectual property issues. Managers with these skills are in short supply worldwide, and competition for qualified people is intense.

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INDUSTRY SECTOR CHARACTERISTICS

The Challenge of the Future

Industry Potential

Canada currently has about 5 percent of the world biotechnology market, with global sales of biotechnology products estimated at US\$22 billion in 1997. The global biotechnology market is forecast to grow to US\$50 billion by 2005. Almost 75 percent of sales are expected to come from bio-pharmaceutical products and about 24 percent from agricultural biotechnological products. The Canadian industry is expected at least to maintain its market share, which implies growth at the forecast global rate of 10 percent per year.¹

The large number of new products developed through biotechnology reinforces the expectations for high growth rates in this sector. Areas of product development include new diagnostic and therapeutic agents in the medical field, disease-resistant plants in agriculture, chemicals and enzymes to promote efficiency in industrial processes, and pesticide and tree treatments that improve the health and growth rate of trees.

Bio-pharmaceuticals

Over the past decade, the bio-pharmaceutical segment of the sector, the largest segment of the biotechnology sector, grew at an annual rate of 10 percent. The health segment in Quebec has been growing at a much faster rate, with employment increasing at about 25 percent per year since 1991.²

Currently there are fewer than 20 bio-drugs on the market, with six accounting for about 80 percent of sales. However, there are some 300 bio-therapeutic products in the development pipeline, representing 30 percent of all drugs under development. More than 40 percent of the new drugs currently in clinical trials are products of biotechnology.³

¹ National Biotechnology Advisory Committee, *Sixth Report 1998: Leading into the Next Millennium*, "Industry Canada, 1998

² Biotech Québec 1997 - Portrait de l'industrie, MICST, Direction des industries de la santé.

³ Factsheet - Biotechnology: The Benefits, Bio-industries Branch, Industry Canada, August 1998.

Industrial Enzymes

The worldwide demand for industrial enzymes is estimated at US\$2.3 billion, and growing at 5 percent per year. The most important applications are detergents, which account for 40 percent of demand, food (35 percent) and textiles (14 percent). There are also important applications developing in the area of mineral leaching, pulp and paper processing, and mill effluent treatment. Currently 50 percent of industrial enzymes are produced through genetic engineering.⁴

Agriculture

The strongest growth is projected for the agri-food sector, particularly for transgenic plants and products for animal health care. However, public acceptance of the products of biotechnology is a major concern. European countries have refused to buy unlabeled engineered food from Canada, though some commentators believe that this is more of an attempt to erect trade barriers than to ensure food safety.

Aquaculture

Products related to fish cultivation currently represent only a small segment of the world biotechnology market, but aquaculture is expected to play a major role in food supply throughout the next century. The Food and Agriculture Organization of the United Nations (FAO) calculates that the annual demand for seafood will outstrip the capacity of the wild fishery by 55 million tonnes by 2025.⁵ The balance will need to be provided by fish farming operations. This is an area where biotechnology is expected to play a major role in enhancing the health and the feeding efficiency of the fish stock, through the development of genetically engineered fish, and diagnostics and treatment of infectious diseases.⁶

Forestry

Biotechnology also plays a role in the forestry sector. It is a particularly important enabling technology for this sector enhancing the growth rates of trees, and producing products and tree stocks that help increase resistance to disease and insect damage, and enhance forest biodiversity. Products of biotechnology are also used in environmentally friendly pulp production and in the treatment of mill effluents.

⁴ Bio-Industries: Growth Prospects for the Industry, Sector Competitiveness Frameworks Series, Industry Canada, *Strategis* Web site, April 1998.

⁵ Aquatic Biotechnology: A Discussion Document for the Renewal of the Canadian Biotechnology Strategy, *Strategis* Web site, April 1998.

⁶ Factsheet – Biotechnology: The Benefits, *op. cit.*

Biotechnology as an Enabling Technology

Because biotechnology is an enabling technology, it has an increasingly important role to play in enhancing competitiveness, growth and environmental sustainability in many sectors of the economy. Biotechnology will play a role in the development of new products and production processes in the pharmaceutical, pulp and paper, and agri-food industries, and in many other sectors.

Financing Issues

The biotechnology industry is a science-driven sector and is characterized by major investments in research and development (R&D), and long lead times to commercialization. For example, to bring a new diagnostic product to market takes three to five years and costs between \$1 million

between \$150 million and \$250 million.⁷ In a recent Statistics Canada survey of the industry, it was reported that over half of the companies in the industry spend more than 50 percent of their revenues on R&D.⁸ With these industry characteristics, financing becomes a major concern for new start-ups and for continuing R&D programs.

Although there are prospects for high returns, sales and payback have not lived up to expectations, and this appears to have resulted in a downturn in investor confidence. The flow of venture capital has slowed, and the weak equity markets of the past year have made it difficult to raise start-up capital. In the Statistics Canada survey, 64 percent of the firms cited access to capital as their "most pressing hurdle" to commercialization.⁹

Strategic Alliances

The financing issue has meant that strategic alliances with large multinational companies have become common in order to share high R&D costs. This also allows the smaller companies to obtain managerial and regulatory expertise, and the marketing know-how of the multinationals. Because of these factors, the large multinational pharmaceutical companies are now the principal source of funding for biotechnology firms in the United States.

Multinational drug companies have also entered into alliances with Canadian bio-pharmaceutical companies, and in exchange receive worldwide marketing and manufacturing rights to Canadian developed products. In agricultural biotechnology, there is also a trend toward consolidations and

⁷ Industry Canada, *Bio-Industries Part 1: Overview and Prospects*, Sector Competitiveness Framework Series, Bio-Industries Branch, 1997.

⁸ Survey results are reported in *Canadian Biotechnology 98 - Success, Excellence*, BIOTECanada, 1999.

⁹ BIOTECanada, *Ibid.*

acquisitions by the large multinational chemical and agricultural companies.¹⁰ Results from the Statistics Canada survey show that 69 percent of biotechnology firms have R&D partnerships in place, 49 percent have marketing alliances and 29 percent were involved in manufacturing alliances.¹¹

Government Support and Research Collaboration

Government support for the industry is very important. Because of the high R&D costs, Canada's R&D tax credits are a key factor for continued industry growth. There are also high levels of government funding for basic biomedical research. Governments also provide a considerable amount of the research infrastructure. In the agri-food sector, much of the R&D activity is undertaken in government laboratories and universities.

There has been a greater focus on research collaboration between the public sector and industry in recent years. For example, the collaboration between the National Research Council Canada (NRC), Agriculture and Agri-Food Canada, and AgroEvo (a German company) led to the development of Innovator Canola, the first major crop developed through agricultural biotechnology to be commercially used.

Industry observers believe that Canada has a cost advantage in comparison with the United States undertaking biotechnology R&D. This cost advantage, along with reported first-class R&D facilities and an apparent above-average capability in conducting clinical trials, has attracted some international companies to set up operations in Canada.¹²

Regulatory Issues

The regulatory environment is a critical factor in industry success. Biotechnology products fall into several regulated categories: foods, medicine, diagnostics and environmental agents. They are regulated under a range of laws administered and enforced by a number of federal and provincial departments and agencies. Canada's complex regulatory process is seen as a major challenge facing biotechnology companies, as delays in the regulatory process have an effect on market access and a direct impact on the rate of return on investment. The regulatory process, therefore, is a major concern for the industry.

There is some support within the industry for deregulation, following the trend in the United States. Consumer groups, however, are urging more stringent legislation and controls on biotechnology. The industry also sees the need to assure the public safety of biotechnology products via a thorough, transparent and efficient approval process.

¹⁰ Industry Canada, *op. cit.*

¹¹ BIOTEC Canada, *op. cit.*

¹² Industry Canada, *op. cit.*

Other Factors Affecting Growth

The principal techniques at the core of this sector involve the industrial use of recombinant DNA, cell fusion and novel bioprocessing techniques. At present, there is an international cooperative effort under way to catalogue the entire 100 000-gene human genetic code. This work is expected to be completed by 2004, and will lay the foundation for an acceleration of the development of biomedical products.

There are factors in place that provide the Canadian industry with the opportunity for continued growth. Canada is considered to have a strong research infrastructure base, high calibre technical personnel, and a relatively low cost per researcher. There is a research tax advantage compared with the United States, and an above average capability in conducting clinical trials.¹³

There are also some uncertainties and factors that can slow the growth rate. The availability of capital, along with industry concerns about the regulatory environment, issues of intellectual property protection, and the availability of highly qualified human resources are important in this regard.¹⁴

Public interest groups have raised a number of questions about the merits and risks of genetically engineered foods and drugs in comparison with conventional products. Consumer concern about the environmental impact of introducing biotechnology-derived products is also pointing out that the ecological consequences are largely unstudied and unknown. Ethical and social questions with respect to some applications of biotechnology have also been raised.

The federal government's biotechnology strategy, the Canadian Biotechnology Strategy, is currently under review. While the new initiatives that result from the strategy are likely to provide enhanced support for biotechnology, the new strategy is also likely to address rising consumer concerns about the technology.

Current Situation

Industry Definition

Although often referred to as an industry, "biotechnology, broadly defined is the applied use of living organisms or their components to make or modify products, to improve plants or animals and to develop micro-organisms for specific uses.... A narrower definition (often called 'new' or second-generation biotechnology) restricts the term to the use of recombinant DNA, monoclonal

¹³ Industry Canada, *Ibid.*

¹⁴ National Biotechnology Advisory Committee, *op. cit.*

antibody and other modern techniques arising from applications of molecular biology."¹⁵ This narrower definition is the one assumed in this profile.

Because it is an enabling technology used in different sectors, the products derived from biotechnology are not differentiated within the Standard Industrial Classification code. This means that data on sales, trade and employment have not been available from Statistics Canada. However, the recent Statistics Canada survey of the industry helps fill in some of the gaps.¹⁶ Applications of biotechnology in various sectors of the economy include the development of disease- and insect-resistant plants, herbicide- and frost-tolerant plants, diagnostic and therapeutic agents, chemicals and enzymes to promote efficiency in industrial process, and environmental remediation technologies.

Industry Characteristics

Statistics Canada's survey of the biotechnology industry conducted in 1998 estimated that there were 282 companies whose core business was biotechnology. Most of these companies were small companies, with almost 72 percent of them employing only 50 or fewer employees. Only 12 percent of the companies employed more than 150 employees. Revenues for 1998 were estimated at around \$1.1 billion. Canada has 5 percent of the global market. The health care sector accounts for 50 percent of biotechnology sales, while agricultural biotechnology products account for 44 percent of sales.¹⁷

Regional Distribution

Some 31 percent of the biotechnology companies in Canada are located in Quebec, 25 percent are located in Ontario, 20 percent in British Columbia, 18 percent in the Prairies, and 6 percent in the Atlantic region.

Quebec is the 10th largest centre for biotechnology in North America, and leads Canada's commercialization and production of biotechnology products. Ontario is the 13th largest biotechnology region in North America. Saskatoon has an advanced agricultural biotechnology sector centred around the University of Saskatchewan and the NRC's biotechnology institute. Vancouver has a strong health biotechnology cluster. Both Vancouver and the Atlantic provinces have significant core research capability in aquatic biotechnology.

¹⁵ Industry Canada, *op. cit.*

¹⁶ BIOTECanada, *op. cit.*

¹⁷ *Ibid.*

Unionization and Professional and Industry Associations

Up to this point in the development of the industry, with the focus having been on research, the majority of employees are scientific personnel. Currently R&D personnel make up 41 percent of total employment and are mainly PhDs and lab technicians.¹⁸ Many of the scientific personnel are members of the relevant professional societies.

The following are most important industry associations and government agencies serving Canada's biotechnology industry:

- Ag-West Biotech Inc.
- Agriculture and Agri-Food Canada
- B.C. Biotechnology Alliance
- BIOTECCanada
- Biotechnology Human Resources Council
- Canadian Agri-Food Research Council
- Canadian Biotechnology Advisory Committee
- Canadian Forest Service
- Department of Fisheries and Ocean
- Forest Engineering Research Institute of Canada
- Forest Renewal B.C.
- Forintek
- Medical Research Council of Canada
- National Research Council Canada
- Natural Resources Canada
- Networks of Centres of Excellence
- Nova Scotia Biotech Working Group
- Pharmaceutical Manufacturers of Canada
- Pulp and Paper Research Institute of Canada
- Quebec Association of Bio-Industries
- Toronto Biotechnology Initiative

¹⁸ *Ibid*

CHARACTERISTICS OF EMPLOYMENT

Because of the lack of official statistics, estimates of total employment in the industry have varied, ranging from 8000 to 20 000. (For example, 8000 was cited in Paget, 1996;¹⁹ just under 10 000 in the recent Statistics Canada survey²⁰; 11 000 in the Ernst and Young study cited in the National Biotechnology Advisory Committee Sixth Report 1998;²¹ and 20 000 was cited by an industry representative in a November 1996 newspaper article.²²) Much of the differences in estimates are likely due to differing definitions of the sector.

The lower estimates of employment levels do not include the employment of personnel in universities, hospitals and research centres who are focussing on extramural biotechnology research investment placed by both global and domestic private sector companies. The employment of biotechnology researchers in government laboratories is also excluded.

Generally, the work force is highly educated and highly skilled, with the majority of personnel in the sector having university degrees. Many of the scientific and technical employees in the biotechnology industry have postgraduate degrees in a variety of disciplines, including biology, chemistry, physics and engineering. Degree-holding individuals are concentrated in sales, marketing, and R&D occupations. Manufacturing workers are generally less highly educated.

Comparative data to determine whether or not pay rates are competitive with similarly qualified workers employed in other sectors, and whether or not pay rates are rising (the market signal for emerging shortages) are not currently available. Indications from an on-line survey administered by personnel systems indicate that pay increases in this industry have been close to the economy-wide average.

¹⁹ The Paget Consulting Group, *Building Long-Term Capability Now Canadian Human Resources Study in Biotechnology*, 1996.

²⁰ BIOTEC Canada, *op cit*

²¹ National Biotechnology Advisory Committee, *op cit*

²² "Patents vital, biotech leader says," *The Globe and Mail*, November 28, 1996

CRITICAL SKILL NEEDS AND GAPS

Skill Needs

The 1996 Paget Human Resources study examined the human resource requirements of firms at each stage of development: early start-up, pre-clinical or field trials, clinical/field trials and full commercialization. In general, biotechnology integrates disciplines such as biology, genetics, microbiology, biophysics, biochemistry, chemical engineering and computer science.

Not only are individuals with multidisciplinary backgrounds sought, but within the research team itself there is a need for researchers with a range of different backgrounds.²³ Product development teams tend to involve specialists in a number of areas. At the University of Alberta, for example, a research team working on an agri-food project involves a physiologist, a nutritionist, a biochemist and a molecular biologist.

The Paget study forecast that industry growth will create 4000 new jobs by the end of the decade, including 1300 in research, technical and support activities, 2000 in commercialization, and 700 in management.²⁴ Companies surveyed in the Statistics Canada study anticipated employment growth of 10 percent per year.²⁵

Without ready access to skilled people and the facilities in which the commercial products will ultimately be produced, successful development and production scale-up is difficult to achieve. Cross-degree scientists are increasingly being sought. An example of this multidisciplinary approach would be represented by a person with chemistry, plus a divergent post-doctoral degree such as cell biology and computer skills.

An MBA with a science background is also desirable, as there is a strong need for managers who understand both the research side and the business side of running a biotechnology company.

Skill Gaps

Staff requirements differ at each stage in a product or service life cycle. Shortages are expected to be driven over the next five years by the move from technology research to commercialization. There is a critical need for managers with a background in science and business, with expertise in

²³ Paget Consulting Group, *op cit*

²⁴ Paget Consulting Group, *op cit*

²⁵ BIOTECCanada, *op cit*

both domestic and international regulations, investor relations, international business development, and strategic alliance development.

It is unlikely that the Canadian industry has achieved the critical mass to find managers with the skills needed, and companies are going abroad to recruit managers with the necessary expertise. The industry has stressed the importance of salary and income tax harmonization, and an expedited immigration process to recruit the highly qualified key personnel needed for the successful commercialization of products currently in the development pipeline.²⁶

Computer-based competencies such as bio-informatics and molecular modelling are also becoming more important as companies and researchers deal with the integration of traditional and information sciences.

With the growth of the industry, government regulatory agencies are also expected to require more staff and more expertise to handle the additional demand for new product approval. The National Biotechnology Advisory Committee placed top priority on the availability of highly qualified human resources, along with the development of competitive policies on intellectual property protection and regulatory approvals as the key ingredients for industry success.²⁷ The Paget Report also pointed out that growth in the industry is likely to be curtailed by a shortage of suitably qualified people.²⁸ The human resource issue is regarded as one of the most important challenges facing the industry.

The Statistics Canada survey of biotechnology firms in Canada, conducted in 1998, reported 1900 unfilled positions (20 percent of current employment) in core biotechnology firms. More than half of these vacancies were in small companies. Problems were reported in recruiting technical, production, scientific and R&D staff.²⁹

²⁶ National Biotechnology Advisory Committee, *op cit*

²⁷ National Biotechnology Advisory Committee, *op cit*

²⁸ The Paget Consulting Group, *op cit*

²⁹ BIOTEC Canada, *op cit*

RECRUITMENT, TRAINING AND DEVELOPMENT PATTERNS

Human Resource Strategies

Because the bulk of the industry is composed of firms with only a few employees, the development of a formal human resource strategy generally lags behind the development of other aspects of business strategy. The larger companies have formalized their human resource policies, but with the smaller companies (fewer than 35 employees) more informal approaches are used.

Specialization is the norm in the biotechnology industry. Because the Canadian industry is small, there is a relatively small pool of people with the required skills on which companies can draw. This leads to foreign recruitment of people with the type of expertise the industry needs. Even the international pool of skilled people is limited, and the competition for qualified people is expected to intensify.

Using co-op programs is a preferred approach for many companies recruiting university and college students. Companies seek graduates who are at the forefront of emerging fields, such as molecular medicine, gene therapy, signal transduction, combinatorial library and genomics.

The Biotechnology Human Resource Council has recently set up a job bank for the industry. It maintains a data bank of the résumés of skilled biotechnology employees and potential employees, as well as available biotechnology positions. Although it is presently operating only on a small scale, it has the potential to become a valuable placement tool for the industry and people with the relevant skills seeking employment in the industry.

Emigration Issues

Although the demand for skilled people is growing in the biotechnology industry, there is a considerable loss of skilled workers to other countries. This appears to be happening at two levels. Despite the fact that the industry is continually seeking to recruit researchers with particular specialties, the absorption rate of newly graduated PhDs and post-doctoral students is reputed to be low. The reasons for this are unclear.

The reduction in government spending over the past few years no doubt has played a role in the decrease in recruitment by government research facilities and universities. A relatively low absorption rate may also be attributed to the possible mismatch between the specialties of people with PhDs and the particular specialty companies require. Because the industry in the United States is so much larger, the people with PhDs find it easier to obtain positions there.

At another level, there has been a loss, to the United States especially, of people the industry calls their "stars" — the highly skilled people who companies can ill afford to lose. The industry has blamed the loss of people and the difficulty in recruitment abroad to the higher personal income taxes in Canada compared with the United States.

According to one report, in 1996 Canada lost 30 percent of its bio-pharmacy workers to countries such as the United States.¹⁰ An initiative to upgrade the country's research laboratories may help mitigate this situation. The Canada Foundation for Innovation has received \$800 million in federal government funding to help reduce the brain drain through the upgrading of facilities in hospitals, colleges and universities.

Educational Requirements

A career in biotechnology can be pursued with education from a technical or vocational school, community college, or university, depending on the level of training desired (i.e. a university degree is not required if career aspirations do not include conducting original research).

Most biotechnology employers consider a B.Sc. to be the required entry level for a research career. There are then good opportunities for advancement to supervisory jobs or for using the basic training as a foundation for moving into other areas such as marketing or regulatory affairs.

Job opportunities for those who have completed a M.Sc. are mid-level positions often involving supervision. There may be opportunities for original research. A doctorate is usually the prerequisite for planning and conducting original research.

At the university level, the study of biology, chemistry and physics is important for entry into the biotechnology field. Agriculture, veterinary science, microbiology or engineering also make good choices, depending on where interests lie.

At a community college level, courses should give a good grounding in basic animal, plant, chemical and microbial science. Graduates are trained to work in laboratories and research facilities in a variety of different areas. Opportunities for advancement are generally confined to technical and production areas of operations.

¹⁰ *The Globe and Mail*, February 16, 1998

Sources of Personnel Supply

Most of Canada's 66 universities offer various programs in biosciences. The Biotechnology Human Resource Council released a report, *An Inventory of Biotechnology Education in Canada*, in November 1998, which sets out an "inventory of biotechnology education at all Canadian colleges and universities. . . . The course content and program material from 128 colleges and 66 universities across Canada was reviewed" to identify "those programs offering education and training applicable to the biotechnology industry."³¹

The Paget study notes that "universities and community colleges should be able to handle the demand for post-doctoral fellows, postgraduates, university graduates and technicians." The capability gap will relate more to the specialized requirements of emerging fields in biotechnology, and in the area of intellectual property and regulatory requirements.³²

Personnel Supply Issues

Canadian companies have indicated that experienced scientific and management personnel are in short supply.³³ According to Industry Canada, the country seriously lacks programs to nurture management skills pertaining to product development, strategic alliance management, international regulation and technology transfer, all of which are required by Canada's strong core of established R&D-driven companies.³⁴

Companies also point out that new science graduates lack the skills related to the business aspects of the sector. The success of a firm in this industry often requires that research personnel have entrepreneurial skills. In addition, employers often find that new graduates are usually quite knowledgeable in their discipline of study but that they often lack the "real world" workplace skills, such as working to deadlines, understanding the practical needs of the firm's clients, total quality management, and so on.³⁵

The National Biotechnology Advisory Committee recommended that undergraduate programs should be developed along with an apprenticeship/internship program at the postgraduate level to

³¹ Biotechnology Human Resource Council, *An Inventory of Biotechnology Education in Canada*, November 1998.

³² Paget Consulting Group, *op. cit.*

³³ Paget Consulting Group, *op. cit.*, and National Biotechnology Advisory Committee, *op. cit.*

³⁴ Industry Canada, *op. cit.*

³⁵ Task Force on Labour Market Issues, *Sectoral Skill Needs and the Role of Universities*, Office for Partnerships for Advanced Skills, Council of Ontario Universities, Ontario Ministry of Education and Training, March 1998.

give science students vital business experience. The training and development of skilled managers through new programs in universities and business schools is a long-term solution to skill shortages, while adjusted immigration rules can help to address the situation in the short term.¹⁶

Because specialization is very focussed in scientific fields, it is likely that companies will need to broaden and intensify their internal training efforts. However, the biotechnology sector is also a relatively new sector, and companies in the early stages of development need to focus on technical and scientific issues. In addition, the majority of firms employ fewer than 10 employees. The result is that companies in the biotechnology sector are not as advanced in developing human resource strategies as those in more mature industries with greater proportions of large firms. The establishment of the Biotechnology Human Resource Council has become very important to assist the industry in the development of comprehensive human resource strategies.¹⁷

The research departments of some universities have links to biotechnology companies, which can provide important exposure to the field and to the industry as a whole. Co-op education and internship programs provide practical experience and valuable opportunities for future employment.

Interviews conducted with biotechnology firms in Saskatchewan and the Atlantic provinces on behalf of the Expert Panel on Skills indicated that recruitment issues had eased somewhat in the past two years, but that recruitment difficulties in Saskatchewan had worsened in recent years.

¹⁶ National Biotechnology Advisory Committee, *op. cit.*

¹⁷ Task Force on Labour Market Issues, *op. cit.*

OVERVIEW: KEYS AND OBSTACLES TO SUCCESS

The huge potential market in health and agri-food for the products of biotechnology has created very high expectations for the industry. Furthermore, the ongoing increase in the basic knowledge base on which the industry relies, such as the cataloguing of the genetic code, points to the provision of a foundation for an explosive increase in the rate of product development.

With its strong research infrastructure, high quality technical personnel, above average capability in conducting clinical trials, and relatively low cost per researcher, Canada is well positioned in many respects to take advantage of increasing market growth.

However, there are public concerns about the technology, especially regarding its application in agri-food. Consumer acceptance is becoming a major issue, particularly in European markets, where public opinion seems to have shifted against genetically modified foods.

The National Biotechnology Advisory Committee placed top priority on the availability of highly qualified human resources, along with the development of competitive policies on the protection of intellectual property and on regulatory approvals, as key elements of the industry's success.³⁸ The Paget Report also pointed out that growth in the industry is likely to be curtailed by a shortage of suitably qualified people.³⁹ The human resource issue is regarded as one of the most important challenges facing the industry.

The National Biotechnology Advisory Committee has made a number of recommendations that it believes will provide a more solid base for the industry to achieve its potential. Continued and enhanced government support is necessary for basic research and improved research infrastructure. The committee also recommended that work is needed to make the regulatory process more efficient, and that a more effective intellectual property protection system is needed.

³⁸ National Biotechnology Advisory Committee, *op. cit.*

³⁹ Paget Consulting Group, *op. cit.*

Finance and Risk

Although there is great market potential, there also many risks and uncertainties. Long lead times are required between the research stage and commercialization. This involves major costs, and there are no guarantees for success when a potential product is moved into lengthy field or clinical trials.

There are more than 100 products in the product development pipeline, but the pipeline seems to be becoming longer, and that the expected high returns from successful commercial introductions are being pushed further into the future. With a downturn in investor confidence, financing has become more difficult.

Skill Requirements

A critical factor for the industry is a shortage of highly skilled human resources, particularly managers with a unique set of skills. For the successful commercialization of products, the industry needs managers with a science background and with expertise in domestic and international regulatory requirements, technology transfer, strategic alliance development, and investor relations.

The demand for the type of people with the range of skills required cannot be met quickly by the educational system. In the short term, the industry has recommended some changes in the immigration regulations that would allow such positions to be filled from abroad. For the long term, the industry is working with educational institutions to develop programs that will eventually meet the industry's needs.

BEST PRACTICES AND CASE STUDY PROFILES

Biotechnology Human Resource Council

The Biotechnology Human Resource Council (BHRC) was established on April 1, 1997, in response to a series of recommendations proposed by *Building Long-term Capability Now*, a joint industry-government study on the Canadian biotechnology human resources situation. In partnership with all stakeholders (industry, academia and government), the council helps to develop, train and retain a highly skilled work force to allow the sector to grow and increase its international competitiveness.

BHRC is developing and delivering a number of projects, including the following:

- **University and College Programs Review:** BHRC is collecting data on biotechnology and biotechnology-related programs offered by Canadian colleges and universities. This data will be used to compare current program offerings with the competency requirements of industry, in order to identify any gaps in post-secondary training. In addition, BHRC will prepare a status report for universities and colleges, with a view to having a long-term impact on the design and content of programs. This program review was completed in May 1998, and a report released in November 1998.
- **Biotechnology Skills Inventory:** BHRC has recently published an inventory of the skills required for a series of biotechnology job categories – after this Profile was completed.
- **Biotechnology Careers and Programs Reference Guide:** BHRC has developed a national guide to careers available in the biotechnology industry in Canada. This guide describes the career opportunities available, educational training requirements and the Canadian post-secondary institutions offering suitable training.
- **Canadian Biotechnology Job Bank:** BHRC currently maintains a data bank of résumés of skilled biotechnology employees and potential employees, as well as available biotechnology positions.
- **Training Program Series:** Select training programs under consideration include entrepreneurship/commercialization, scientific management, regulation and compliance, intellectual property strategies, biotechnology financing, and essential skills (e.g. communication).

- BHRC has initiated a Youth Internship Pilot program that offers young people work experience in biotechnology companies, assisted by wage subsidies provided by the federal government. The first phase calls for the creation of 25 to 50 positions, with subsequent expansion dependent on the success of the initial phase.
- BHRC has also established a number of task forces to focus on the specific training or knowledge requirements of different segments of the biotechnology community. The following task forces have been established: skills development, labour market research, standards/certification, career development and immigration strategies. Each task force will serve an advisory role to BHRC, evaluate data, and help coordinate the projects and activities targeted to their area communities.

Companies

Industry has contributed heavily to dealing with human resource issues through BHRC. Many firms are relatively small and unable to support large human resource departments, and the council offers opportunities to deal with many issues collectively, including communication between industry and academia on curriculum issues, career awareness and promotion, wage and salary benchmarking, and related initiatives.

Since 1994, the Connaught Student Biotechnology Exhibitions have provided high-school students with an opportunity to develop science projects in ways that emulate the "real world" of scientific research. Research proposals are reviewed by professionals, successful applicants are awarded small grants to pay for research costs, and projects are assigned mentors from the local biotechnology community. In partnership with a number of government, academic, and private sector sponsors, the founding company, Pasteur Marieux Connaught, is supporting the expansion of the program beyond its Toronto roots to communities across Canada. The exhibitions are intended to "raise awareness among students, educators and the public about biotechnology and its applications in such fields as health care, agriculture and the environment."⁴⁰

⁴⁰ Quoted from promotional materials at <http://www.connaughtbioexpo.com/>

Universities

Efforts in British Columbia universities include the development of a multi-institutional B.Sc. program in biotechnology that can be linked to graduate programs in law, business and science.

The University of Saskatchewan is putting a "virtual" program in place that also emphasizes the multidisciplinary expertise that is needed by the industry.⁴¹

The Department of Chemical and Biochemical Engineering at the University of Western Ontario has developed a number of programs, effective September 1998, in B.E.Sc. And Honours Business Administration (five years), B.E.Sc. and B.A. in Economics (five years), B.E.Sc. and Law (six years), B.E.Sc. and B.Sc. in Environmental Science (five years), and B.E.Sc. and B.Sc. Scholars Electives Program in Genetics.

Queen's University has introduced a combined science and business program in which students can earn an M.B.A. in Science and Technology.

The University of Toronto has proposed a Master of Biotechnology Program that is designed to equip science and applied science graduates for a career in the biotechnology or pharmaceutical industries. The program provides students with a firm grounding in the science of biotechnology and an introduction to the management of biotechnology organizations.

⁴¹ CBS Sector Consultation: Summary Reports, Agriculture and Agri-food, p. 6.

APPENDIX I: SOURCE DATA

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Web Sites

Ag-West Biotech (Saskatoon) <http://www.agwest.sk.ca/>

B.C. Biotechnology Alliance <http://www.biotech.bc.ca/bcba/Default.htm>

BIOTEC Canada Human Resource Council <http://www.biotech.ca/>

Québec Biotechnology Innovation Centre <http://www.eqib.org/indexe.htm>

InfoBiotech Canada <http://www.ibr.nrc.ca/ibr>

Pharmaceutical Manufacturers Association of Canada <http://www.pmac-acim.org/>

Toronto Biotechnology Initiative <http://www.torontobiotech.org/>

APPENDIX II: SEGMENTS OF THE BIOTECHNOLOGY INDUSTRY (AS DESCRIBED IN STATISTICS CANADA'S BIOTECHNOLOGY FIRM SURVEY, 1997)

Human Health

- Diagnostics (e.g. immunodiagnostics, gene probes, bio-sensors)
- Therapeutics (e.g. vaccines, immune stimulants, bio-pharmaceuticals, rational drug design, drug delivery, combinatorial chemistry)
- Gene therapy (e.g. gene identification, gene constructs, gene delivery)

Bio-Informatics

- Genomics and molecular modelling (e.g. DNA/RNA protein sequencing and data bases for humans, plants, animals and micro-organisms)

Ag-Bio

- Plant biotechnology (e.g. tissue culture, embryogenesis, genetic markers, genetic engineering)
- Animal biotechnology (e.g. diagnostics, therapeutics, embryo transplantation, genetic markers, genetic engineering)
- Biofertilizers/biopesticides/bioherbicides/biological feed additives/microbial pest control (e.g. bacteria, fungi, yeasts)
- Applications of agricultural products (e.g. fuels, lubricants, commodity and fine chemical feedstocks, cosmetics)
- Bio-processing (e.g. using enzymes and bacteria culture)

Food Processing

- Functional foods/nutraceuticals (e.g. probiotics, unsaturated fatty acids)

Aquaculture

- Fish health (e.g. diagnostics, therapeutics)
- Broodstock genetics (e.g. tracking superior traits, genetic modification/engineering)
- Bio-extraction (e.g. carrageenan from seaweed, antifreeze proteins from fish, flavours)

Mining/Energy/Petroleum/Chemicals

- Microbiologically enhanced petroleum/mineral recovery
- Industrial bio-processing (e.g. biodesulphurization, bio-cracking, bio-recovery)

Forest Products

- Silviculture (e.g. ectomycorrhizae, tissue culture, somatic embryogenesis, genetic markers, genetic engineering)
- (Cleaner) Industrial bioprocessing (e.g. biopulping, biobleaching, biological prevention of sapstain)

Environment

- Biofiltration (e.g. treatment of organic emissions to air/water)
- Bioremediation and phytoremediation (e.g. clean-up of toxic waste sites using micro-organisms)
- Diagnostics (e.g. detection of toxic substances using bio-indicators, bio-sensors, immunodiagnostics)

Other

- Custom synthesis — chemical or biological (e.g. peptides, nucleotides, hormones, growth factors, biochemicals)

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