OPPORTUNITIES FOR

BIOTECHNOLOGY-BASED BUSINESS

IN ATLANTIC CANADA

Prepared by

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for the

Atlantic Agri-Products Competitiveness Council

and the

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SUMMARY

BIOTECHNOLOGY IN ATLANTIC CANADA

This study was conducted by BICON Consulting Associates under contract to the Atlantic Agri-Products Competitiveness Council. The Atlantic Canada Opportunities Agency contributed the funding for the study. Consultations were undertaken with 28 biotechnology firms and 43 public sector agencies engaged in bioscience activities. The study reports on the views and opinions of the private and public sector stakeholders consulted. While surveys have been undertaken in the past to characterize Canada's biotechnology industry, this is the first time that individual biotechnology entrepreneurs in the region have been consulted directly on the future of their industry.

Biotechnology business has emerged more slowly in Canada and in the Atlantic region than in the United States (U.S.). Biotechnology businesses in the region are primarily small individual entrepreneur-driven companies. Fifteen of the 28 companies consulted, primarily those in the medical, aquaculture and environmental areas, reported annual sales in excess of $500,000. The businesses with sales of less than $500,000 tend to be in the process of commercializing science developed and/or modified by public institutions. It is estimated that there are more than 100 private sector bioscience businesses in Atlantic Canada, generating gross revenues of more than $50 million and employing more than 1500 people.

Biotechnology is defined as the application of scientific and biological principles for the alteration of substances by biological agents with the aim of providing goods and services.

The majority of biotechnology firms in the Atlantic region are clustered near universities, public research and development laboratories and teaching hospitals located in: St. John's, Newfoundland; Halifax, Nova Scotia; Charlottetown, Prince Edward Island; and Fredericton, New Brunswick. Many of the biotechnology firms consulted were founded by university scientists who recognized the economic potential of a technology and moved to commercialize it. Health and aquaculture-related biotechnology businesses account for the largest number of firms. Agricultural and environmental applications are well established; industrial applications of forest biotechnologies, however, have been slow to happen.

A well developed network of universities and government laboratories supply science to entrepreneurs in the region. The Dalhousie and Memorial University medical faculties are productive sources of medical science and the Atlantic Veterinary College (AVC) is an important source of aquacultural technologies. Government laboratories such as the N.B. Research and Productivity Council (RPC), the P.E.I. Food Technology Centre and the Nova Scotia Agriculture College (NSAC) provide important technology development support as does the university-owned Huntsman Marine Sciences Centre. Federal departmental laboratories include the Canadian Forest Service (CFS) laboratory in Fredericton, the Fisheries and Oceans Canada (DFO) research station in St. Andrews, the National Research Council (NRC) Institute for Marine Biosciences in Halifax, and Agriculture and Agri-Food Canada (AAFC) research centres across the region.

OPPORTUNITIES FOR NEW BUSINESS FORMATION

The study identified a number of private sector business formation opportunities and new biotechnologies awaiting commercialization. Three general types of commercial bioscience opportunities were identified.

1. ***Adoption of new technologies by existing business:*** Existing businesses can benefit from bioscience technologies by integrating them with existing operations to: improve efficiency of production; improve product quality; and diversify product lines.

2. ***New business operations, based exclusively upon biotechnologies*:** The commercialization of research and development work done in the Atlantic region, or elsewhere, offers a second type of business formation opportunity. Intellectual capital developed here can be put to work to produce new commercial products.

3. ***The development, sale and provision of biotechnology service:*** This knowledge-based activity offers job creation and business formation and income-generation opportunities for the region. A number of institutions and firms are now involved in the business of creating and selling biology-based technologies on the world market.

Opportunities for each of the three types of business noted above were identified in the health sciences, aquaculture, environment, agri-food and forestry sectors.

The health sciences offer significant opportunities for commercialization of bioscience technologies. The world class medical research facilities of Dalhousie and Memorial and the excellent research and commercialization thrust at these universities provides a fertile environment for future product and business growth. Opportunities exist to increase market share in pharmaceutical clinical trials, diagnostic test kits, and in blood fractionation processes. Similar opportunities exist in the animal health sector and in the use of genetically altered animals for human health purposes.

The aquaculture sector is comparatively new and its current rate of growth is indeed remarkable. Solid biotechnology business growth has taken place in fish health, toxin analysis, development of antifreeze proteins and forensic services. Additional opportunities will become available in species diversification as problems related to genetically engineered species are overcome and as regulatory hurdles are cleared; for example, in transgenic salmon, domesticated halibut and triploid Arctic Char.

The environment industry offers bright prospects for commercialization of biotechnology applications. Established firms are capitalizing on opportunities in sewage and water treatment, soil remediation,

household and industrial waste treatment and composting. The market opportunities are international, based on the intellectual capital and process skills in the region. The microorganisms which are the workhorses of many potential environmental applications can be readily reproduced in Atlantic Canada.

There are significant business opportunities in veterinary products, cattle semen and embryos, clonal production of virus-free potato stocks, strawberry and raspberry nursery stock, and selected ornamentals. The development and production of improved plant and animal species and the recovery of byproducts from the red meat processing industry offer business potential in the human health sector. Integrated biological processes, such as the addition of "de-odorase" to animal feeds, can be used to reduce odours, resolve animal waste disposal problems, improve production efficiency and also offer business opportunities.

Forestry opportunities are limited at this time. Businesses in the sector are moving from a dependence on traditional chemical technologies to biologically-based alternatives for forest pest control. Reforestation, based on genetically superior, disease and pest-resistant tree forms, such as those developed by the CFS and currently being tested by a major forestry company in New Brunswick, offer private sector industrial development potentials.

Challenges and Key Recommendations

CHALLENGE ONE

Strategic Focus and Coordination: A viable world-class biotechnology industry is emerging in Atlantic Canada. If this new industry is to succeed, it must develop a shared private and public sector vision of its capabilities, potential and collective needs.

Recommendation: The private and public sector should work together to establish a region-wide biotechnology alliance similar to that which currently exists for the geomatics sector.

CHALLENGE TWO

Clustering: Proximity to major research facilities is important to the establishment and expansion of biotechnology-based firms. As well, a critical mass of firms in one location encourages the formation of additional bioscience firms. Opportunities exist in Atlantic Canada to encourage the formation of biotechnology clusters in the medical sciences, aquaculture (marine biotechnology), agri-food and environment sectors.

Recommendation: Investigate the characteristics of successful biotechnology cluster models elsewhere in Canada and worldwide, identify those which are most appropriate to Atlantic Canada and propose measures which would encourage formation of clusters in Atlantic Canada.

CHALLENGE THREE

Availability of Management and Professional Staff: The bioscience industry is very young and there is a shortage of entrepreneurial science managers with the ability to raise capital, put together a business plan and build a viable company.

Recommendations:

1. ***The cost of providing a qualified Chief Executive Officer or business manager be an eligible expense under public financial assistance programs.***
2. ***Examine the feasibility of establishing a specialized business management training program for bioscience entrepreneurs.***

CHALLENGE FOUR

Research and Development (R&D): Bioindustry will flourish only if fed a continuous supply of science. There are two sources of marketable science — local researchers and sources external to the region. The current budgetary cutbacks in public sector scientific research will increasingly force the industry to look externally to fill its science needs.

Recommendation: Federal departments with research operations in Atlantic Canada should not further erode their existing research capabilities.

CHALLENGE FIVE

Partnering: **A partner with "deep pockets" is an important ally in validating the undertaking in the eyes of both the business and the investment community. Partnering with established Canadian and foreign companies offers an effective way of bringing in new capital, accessing technical capabilities and facilities not resident in the particular company and establishing markets outside Canada.**

Recommendation: ***ACOA and Industry Canada consider taking a brokerage role in assisting bioindustry entrepreneurs to establish partnerships with companies external to Atlantic Canada as a means of obtaining financing, accessing technical assistance and overcoming foreign trade and licensing barriers.***

CHALLENGE SIX

Trade Development: **The operators of established regional biotechnology firms indicated that they are well positioned and can be successful in accessing world markets. Several entrepreneurs suggested that they prefer to deal in the larger markets of the United States, Europe, the Middle East and Asia, rather than compete on the limited Canadian market. They are optimistic about global opportunities and feel Eastern Canada is a good place to do business in the "new economy".**

Recommendations:

1. ***Industry Canada and ACOA implement a trade and investment promotion initiative directed at the major global markets for biotechnology products.***

2. ***ACOA undertake a study to identify new products, new market opportunities and a strategic approach to further development of the biotechnology sector.***

CHALLENGE SEVEN

Public Funding Assistance: Financing is the major constraint to new biotechnology business formation in Atlantic Canada. Unlike traditional manufacturing industries that depend upon engineering solutions, biology involves life processes. Bioscience technologies are commercialized at a much slower pace than physical and engineering processes. Venture capitalists are reluctant to invest their money until they can be shown that the researcher has a product that will sell at a profit.

Recommendation: The appropriate federal and provincial business development agencies examine their policies and programs with the objective of improving their effectiveness in the biotechnology sector.

CHALLENGE EIGHT

Program Delivery: Scientist entrepreneurs find it difficult to communicate with non-science trained government officials. The level of scientific knowledge demonstrated by project evaluators in the various federal and provincial funding agencies was found wanting by science entrepreneurs.

Recommendation: Every federal and provincial business funding agency should include or have easy access to a qualified biological scientist with responsibility for coordinating the scientific review of biotechnology project proposals.

I. THE STUDY

INTRODUCTION

The potential for significant new business formation based on the application of existing and emerging biotechnologies was the focus of this study. Biotechnology-based businesses, utilizing technologies from the health sciences, aquaculture, environment, agriculture, forestry and fishery sectors, offer business formation and job creation potential in Atlantic Canada.

Biotechnology, as a specific field of economic endeavour is not yet recognized as an industry with its own standard industrial classification (SIC). As a consequence, it is difficult to obtain accurate data on sales, employment, investment and other economic activity. Indeed, data on many of the new applications of biotechnology are to be found embedded within the Statistics Canada data on traditional industry sectors.

Biotechnology in Canada is being driven by private sector interests in the pharmaceutical, medical and human health areas, in plant breeding and the related seed trade, and in veterinary medicine. Ontario and Quebec lead in collective biotechnology activities, but Saskatoon is home to the largest concentration of Canadian bioscience research.

FOCUS OF THE STUDY

Three bio-technology issues provide the focus of this study:

1. ***Current trends in private sector R&D activities.*** The impact of these trends on the potential for continued and/or increased biotechnology R&D in the Atlantic region was examined.

2. ***The current and future role of government as a regulator, broker and facilitator for the biotechnology sector in Atlantic Canada was studied.*** The policy issues surrounding both roles in Atlantic Canada were examined and challenges for action are offered.

3. ***The most effective focus for action to increase biotechnology-based business formation in Atlantic Canada.*** Biotechnology can be used as an engine for value-added development, but to what extent does the Atlantic region offer opportunities for its development? This issue and the related public policy issues were examined in this study and biotechnologies that offer real opportunities for new or expanded businesses were identified.

STUDY OBJECTIVES

The study's objectives were to:

1. Provide a list of opportunities for new biotechnology-based business formation in the region;

2. Describe the business activities, issues and the future plans of current business operators in the sector;
3. Assess future prospects for new biotechnology-based business formation within the region; and
4. Recommend policy actions which could be pursued by ACOA and other public sector organizations in Atlantic Canada.

STUDY SPONSORS

The study was contracted by the Atlantic Agri-Products Competitiveness Council (AAPCC), a private sector group with membership from of a wide range of Atlantic entrepreneurs and businesses. The Council was established to identify ways and means of strengthening the economic impact of agri-products on the Atlantic economy. The AAPCC is interested in obtaining information and proposals that strengthen the competitiveness of the Region's business community.

BICON Consulting Associates (BICON) carried out the work for the Council and relied upon its good offices in contacts with the private sector.

The Atlantic Canada Opportunities Agency (ACOA) funded the project under its mandate for the economic development of the Atlantic region. Recently, the Agency has increased its interest and program focus on the creation of business activity through science and technology innovation. Part of this focus includes the examination of new opportunities for economic activity based on the biosciences. This study was sponsored by ACOA under the Economic Cooperation and Integration Initiative; it is evidence of ACOA's interest in determining the business formation potential of bioscience technologies to the Atlantic economy.

STUDY METHODOLOGY

1. The global and Canadian context for the study was obtained by reviewing selected documentation on the sector in Canada and worldwide.

2. The nature and extent of the biotechnology sector in Atlantic Canada were determined by consulting with private and public sector stakeholders in the sector. A consultation list of 28 private sector firms and 43 public sector stakeholders was developed jointly by the AAPCC, ACOA and BICON Associates.

3. Structured interviews were conducted with corporate executives and senior staff from 28 Atlantic region firms involved with the development and commercialization of biotechnology applications.

4. Senior policy spokespersons from federal departments and agencies, both in Ottawa and Atlantic Canada, were consulted on federal policies and programs for the biotechnology sector, including: Agriculture and Agri-Food Canada; Industry Canada; Natural Resources Canada (Canadian Forest Service); Fisheries and Oceans Canada; Health Canada; Environment Canada; and the National Research Council (NRC).

5. Senior officials from provincial departments were consulted on their respective Province's policies and programs for the bioscience sector, including: the departments of Agriculture in Nova Scotia, Prince Edward Island and New Brunswick; Fisheries in Newfoundland and New Brunswick, and Health and Industry, Trade and Technology in Newfoundland

6. Deans or other responsible senior officials from throughout the region were interviewed on their respective institution's activities in biotechnology, including: Dalhousie University, the University of Prince Edward Island (U.P.E.I.) - Atlantic Veterinary College, the Université de Moncton (UdeM), the Nova Scotia Agriculture College (NSAC), the Seabright Corporation at Memorial University, the Research and Productivity Council (RPC), the Huntsman Marine Sciences Centre and the Food Technology Centre (FTC) in Prince Edward Island, and the InNOVAcorp in Nova Scotia.

7. The data and information gathered above were then analyzed, and the report and policy recommendations were prepared.

ACKNOWLEDGMENTS

Consultations held with representatives from private business, research institutions and government provided the data and information for this study. The response and interest of those individuals and firms contacted were greatly appreciated by the contractor. The success of the study is in large measure a result of the positive and helpful responses from these bioscience stakeholders.

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II. OVERVIEW OF BIOTECHNOLOGY

BIOTECHNOLOGY DEFINED

Biotechnology has been defined[1] as "the application of science and engineering to the direct or indirect use of living organisms, or parts or products of living organisms, in their natural or modified forms". The Organization for Economic Cooperation and Development (OECD) describes biotechnology as "the application of scientific and biological principles for the alteration of substances by biological agents with the aim of providing goods and services".[2] Biotechnologies can be viewed as the tangible technologies emerging from *bioscience*, the collective biological research activity involving living organisms. The growth in private sector industrial capability to exploit the commercial opportunity associated with biotechnologies is now of sufficient scope to group them as a common *bioindustry* sector.

Historically, biotechnology has been characterized by three stages of development. The first generation employed fermentation techniques to produce drinks, food and fuel; large-scale fermentation techniques were used around the time of the First World War to manufacture solvents. The second-generation technology emerged after the Second World War from the integration of microbiology, biochemistry, and chemical engineering. They were employed in large-scale fermentation for brewing, sewage treatment, and in the chemical and pharmaceutical industries. The third-generation technology grew out of advances in genetic engineering or recombinant DNA technology. The first genetic experiments were successfully performed in 1973 with the results first emerging in the marketplace in the 1980s.

It is this new area of genetic engineering that has caused all the public controversy with biotechnology. The terms can be confusing; some writers use the word biotechnology when referring to genetic engineering applications only, while others use it to imply both traditional and new uses of living organisms. Media reports of biotechnology breakthroughs in health and agriculture are intermingled with those focusing on concerns about biotechnology itself. While Canadians have heard about biotechnology, their understanding of what it is about is limited.

GLOBAL CONTEXT

Biotechnology is still in the early stages of development, similar to where the software or telecommunications industries were 15 to 20 years ago. Its influence and socioeconomic impact are expected to be at least as pervasive.

Approximately $15 billion to $20 billion worth of biotechnology products were sold worldwide in 1994. It is estimated that global sales of biotechnology products will grow rapidly in the next few years to reach $75 billion to $100 billion by the year 2000. Achievement of this potential will depend on how well

[1] Agriculture and Agri-Food Canada. *Regulation of Agricultural Products of Biotechnology*, August 31, 1993.
[2] In *Ciba-Geigy Informs: Biotechnology*, January, 1988.

biotechnology regulations are implemented and harmonized internationally, as well as upon public acceptance of biotechnology products.

The Canadian bioindustry's main international competitors are found in the United States, Japan and Europe. The U.S. has by far the most developed and diversified bioindustry, with over 1,300 core biotechnology firms employing more than 100,000 people. Statistics for Japan are difficult to compare with those for other countries, since biotechnology in that country is mostly developed within large corporations where biotechnology is not usually the prime focus. Even though the industrial paradigm is different, Japan is second only to the U.S. in the development of its bioindustries and is positioning itself for the future through continued commitment to research and technology development or acquisition on both the domestic and international fronts. The European bioindustry began to develop later than its U.S. and Canadian counterparts, but now has over 400 core biotechnology firms. The United Kingdom has the largest biotechnology industry in the European Economic Union.

Bioindustry is developing in other regions of the world. Australia has an emerging bioindustry (approximately 30 core firms employing approximately 600 people). Israel has over 60 active biotechnology firms. In both countries, the driving force is provided by small companies growing out of a strong foundation of basic life sciences in academia and government. Southeast Asia has a number of major corporations in the resource and agri-food sectors that are beginning to focus on biotechnology as a tool for producing value-added products. A number of core biotechnology firms are beginning to develop in the region, especially in Singapore, that are making significant worldwide investments in small, promising companies that have the potential for entering into collaboration with domestic and foreign companies. Latin America has similar developments, with large agri-food companies such as breweries, diversifying into value-added products through biotechnology.

Today, over 50% of new drugs in North American clinical trials are products of biotechnology. In the agri-food sector, it is predicted that by the year 2005, 50% of the crops grown in developed countries will be transgenic. The market in the U.S. and Western Europe for bioremediation of toxic waste sites is expected to increase five-fold, between 1993 and the year 2000.

THE CANADIAN EXPERIENCE

In Canada, commercial applications of biotechnology are predominantly in three main areas: *health care*; *natural resources*; and *environmental protection*. Bioindustries in all of these sectors are distinguished from their non-biosciences counterparts by their relatively high level of research and commitment to ongoing innovation. Biotechnology has been expanding most rapidly in the health care sector, where it is an integral part of the new drug discovery process.

The Canadian biotechnology effort is small when compared with that of the U.S. and Japan, but on a per capita basis, it compares favourably with that of other countries. The Canadian sector is made up of approximately 700 companies employing more than 23,000 people across Canada. The majority of firms are small companies with less than 50 employees. Over the next 10 years, the agri-food sector should capture the largest share of the Canadian biotechnology market. A growth rate of over 25% per year is

forecast for the sector as a whole, leading to sales of $20.4 billion by the year 2003. These estimates are based on greater than expected world demand for food and for bioremediation, and other environmental biotechnology applications, according to Haynes.[3]

Health-Care: Canada has a world-class bioclinical research base in its medical schools and teaching hospitals. As a result, over 50% of Canadian biotechnology firms are oriented to the health care sector. In 1993, these firms exported products worth approximately $300 million. Exports of health care biotechnologies grew 20% per year over the 1989-93 period. This rate of growth is expected to continue, since a growing number of Canadian-developed therapeutic and diagnostic products are now in clinical trials. The bulk of the products, some of which represent billion-dollar-a-year markets, have yet to reach the marketplace. Canadian strengths are in research relating to genetic diseases, vaccine development and therapies for cancer and certain neurodegenerative diseases. On the services side, a related Canadian strength is in providing clinical trial services to pharmaceutical companies.

Agri-food: Canada has developed a strong competitive position in animal husbandry. Embryo transplants, high-quality bovine semen, animal protection (veterinary vaccines), plant breeding and biological pest control have all been growth areas. About 28 per cent of the Canadian bioindustry is in the agriculture sector. In 1993, agriculture biotechnology exports were approximately $400 million. Canada's agricultural biotechnology sector is distinguished from that of the U.S. by its relatively greater size. In the U.S., ag-biotech companies make up 9% of the industry compared to 28% in Canada.

Companies in the Canadian ag-biotech sector are located in almost every province. In Atlantic Canada, the focus is on plant and animal health, whereas the focus shifts to animal health in Ontario and Quebec. On the west coast, advances are taking place in micropropogation, as well as biological pest control products. The greatest concentration of Canada's ag-biotech companies is found in the Prairie provinces, particularly Saskatchewan, where the work centres on genetic engineering in crops and animals. Over 30% of Canada's core ag-biotech companies are found in Saskatoon. The reasons for this are two-fold: first the emphasis on agriculture in the provincial economy; and second, the infrastructure for supporting the commercialization of technology is in place.

Aquaculture: Aquaculture includes both controlled production of fish species with its concerns for fish health and brood stock optimization, and bioprocessing, with its potential to obtain valuable compounds such as those used in cosmetics from marine organisms. The short and medium-term export opportunities are primarily in aquaculture biotechnology, since world production, currently valued at $40 billion, is expected to increase seven-fold over the next 30 years to help meet the protein needs of a growing population.

The Canadian aquaculture industry[4] is essentially a new sector, grossing in excess of $289 million, or 6% of Canada's total fishery output. Atlantic Canada represented $109.7 million of this output ($96 million salmon; $5.4 million trout and steelhead; $5.7 million mussels and $2.6 million oysters). With increasing global competitiveness, industry must ensure: competitively priced broodstock, seedstock, feed and

[3]Haynes, F. 1996. Canadian Biotechnology 1996 Directory
[4]DFO Federal Aquaculture Development Strategy

equipment; high quality, clean and productive growing sites; safe and effective therapeutics; and technological leadership for improved husbandry, new species development, innovative products and enhanced productivity.

Canadian capabilities in aquaculture biotechnology have developed because of the availability of marine science expertise and because of bio-environmental constraints that have resulted in unique domestication difficulties (i.e., slower growth rates and enhanced stress). Although Canada accounts for less than 1% of world aquaculture production, companies in this field, which represent about 5% of the total bioindustry in Canada, have a disproportionately high percentage of the global market for their products and services. Canadian strengths include diagnostics and vaccines for fish and shellfish diseases, as well as genetic characterization to support brood stock optimization.

Forestry: Key sectoral issues in forestry include:[5] increasing the productivity of Canada's forests through advanced genetics and biotechnology, improving the level of protection against insects and diseases through advanced genetics and biotechnology; genetic conservation; and regulations to make genetically altered organisms safe and acceptable. Species emphasis is on Douglas Fir, White Pine, Black Spruce and Jack Pine.

Partnerships, as with the New Brunswick Tree Improvement Council, the Quebec Ministry of Natural Resources and the B.C. Ministry of Forests, are seen as important means of transferring CFS-developed biotechnologies to industry clients. International collaboration, particularly in research with countries such as Sweden, France, New Zealand and the United States, is also seen to be particularly important in advancing biotechnologies in the forest sector.

***Environment Industry*:** Increasingly, biological systems are being used to diagnose and solve environmental problems in air, water and soil. Research is intensifying in areas such as: selecting naturally occurring organisms that break down specific toxic substances; improving the understanding of the conditions that make these organisms work more effectively; and developing genetically-modified organisms specifically designed to break down certain persistent toxic chemicals.

Approximately 10% of the Canadian bioindustry is in the environmental sector. About 15 to 20 Canadian firms have developed the biological/microbiological expertise to form the core of an emerging environmental bioindustry. The much larger group of consulting engineering firms that are active in site remediation, wastewater treatment, etc., but that have little or no in-house biological expertise, should be encouraged to use biotechnology as an environmental problem-solving tool. In 1993, Canadian sales of environmental biotechnology services were estimated to be about $25-50 million and exports estimated to be about $10-20 million.

[5] CFS, Science and Technology Networks 1996 Consultations

III. BIOSCIENCE IN ATLANTIC CANADA

INTRODUCTION

Atlantic Canada is being impacted by the global transition of economies. The region is experiencing a paradigm shift from traditional manufactured products to products that can take advantage of the region's intellectual capital, information technology resources and quality of life opportunities. Products based on biotechnology applications fall into the latter category and represent a significant business formation opportunity for Atlantic Canada's business community.

Paget[6] described the biotechnology industry in Atlantic Canada as consisting primarily of smaller, specialized companies (fewer than 50 employees). Many highly innovative, niche market products and services are being spun off core technologies by small "start up" companies. Most of these companies are clustered in medical products, diagnostics and biochemicals, with others in the marine/aquaculture, agriculture and forestry sectors. The region's biotechnology sector also includes a few larger pharmaceuticals and biochemical companies. Natural resource or food-based businesses responsible for some degree of biotechnical innovation may be included in the group. BICON found that Paget's conclusions were supported by the current study, although a significant number of environment-related businesses were identified across the region.

THE ATLANTIC BIOTECHNOLOGY SECTOR

Industry Size and Employment: Statistics on the bioscience portion of the Atlantic Canada economy are scarce to nonexistent because many of the activities are included by Statistics Canada in their traditional industry classifications that do not include a specific category for "bioindustry". BICON estimates that between 60 and 100 firms are involved in activities that may be defined as bioindustry or relying primarily on biotechnology for the production of consumer products. These firms generate an estimated $50 million in annual sales and employ about 1,500 people. The average annual wage is in the order of $25,000 - 30,000 per worker, providing a total estimated wage and salary contribution of at least $40 million per year. Conservative projections indicate these numbers will double in seven years. [7]

Estimating the number of people employed in the region's bioindustry is very difficult. Data categories overlap with the traditional sectors and other high technology industries. The 28 private sector firms contacted for this study reported employment of approximately 800 person year equivalents (PYEs). Twenty-one of the firms reported employment of less than 25 PYEs, but one firm consulted employs 350 PYEs. Despite an increased level of activity in the private and public sectors, the Atlantic region has a very small part of Canada's biotechnology-based economic activity. As with other parts of Canada and

[6] *The Paget Consulting Group Inc.*, 1996, Canadian Human Resources Study in Biotechnology
[7] The funds allocated to this study were not sufficient to permit verification of these numbers.

other countries, firms tend to be small elite-type operations and often in the Canadian context, branches of very large multi-national chemical and pharmaceutical producers.

Research Facilities: There are 14 public research facilities in the Atlantic region that are engaged in some form of biotechnology research and development. These institutions reported that they employ about 560 people and have an annual combined budget of over $66 million devoted to bioscience projects.

The infrastructure of universities and public sector laboratories in the Fredericton, St. Andrews, Moncton, Halifax, Truro, Charlottetown and St. John's areas form the focal points for biotechnology research and development activity. Many of these research facilities are devoting a high proportion of their capacity and budget toward the discovery and development of new technological applications based on biology. For example, virtually all of the R&D activities at the Dalhousie Medical School and at Memorial University are of a bioscience nature. The relatively new aquaculture industry is already benefiting from biotechnology advances developed in regional research facilities at St. Andrews, Charlottetown, and St. John's. Managers of these institutions see biotechnology R&D as an important part of their future research activities, both from the standpoint of staff motivation and private sector funding support for the discovery of new "marketable" research results.

Health Sciences: Biotechnology applications in the human health field dominate the bioindustry activities in the Atlantic region. These include the development, testing and sales of pharmaceutical products and processes; other medical applications include diagnostic products and procedures, less-invasive treatments, modified essential nutrients and forensic medical procedures. Bioscience facilities and business operations are clustered in Halifax and St. John's, close to the medical science and biochemistry facilities at both Dalhousie and Memorial universities.

The biotechnology emphasis at Dalhousie is in several areas of health science including: pharmaceutical development and related clinical trials; development of genetic markers; neuro-sciences; foetal transplants for Parkinson's disease; cardio-vascular research; transplant immunology; population health; and environmental illness. The Medical School has formal business relations with other universities, plus many bioscience industry contracts. Dalhousie has spun off a number of companies, including Medallion and Technology Knowledge, a for-profit company designed to sell telemedicines, and a joint investment in Clinical Trials Atlantic, together with Memorial, AVC and a number of regional hospitals.

Memorial University has also established a not-for-profit corporation, Seabright Corporation, which focuses on new technologies, processes, services and products emerging from the medical sciences and biochemistry areas of the University. The Corporation utilizes existing university labs and support facilities to help scientists and others at the university bring their technology to commercial production. Seabright is presently dealing with 37 biotechnology and/or medically related patented processes and 14 separate biotechnology and/or medical projects that are linked to the University. To date, Seabright has spun off four biotechnology companies: Terra Nova Biotechnology; Bio ID; PA Pure Additions; and A/F Protein Canada.

Agri-Food: Modern agriculture is rooted in innovations based on what may be considered "classical" biology; however, agricultural research is increasingly based on biotechnologies. Research is being

carried out at the seven research establishments of Agriculture and Agri-Food Canada and at NSAC. Food-related technology development and testing is conducted or sponsored by the U de M, the PEI Food Technology Centre, the New Brunswick RPC and the Technical University of Nova Scotia (TUNS). Private sector activity in agriculture and food-related biotechnology is primarily limited to "off-the-shelf" technologies that are brought into the region and adapted to specific needs of the agriculture and food sectors.

The majority of biotechnology work is directed to enhancing productivity and to pest and disease control. Examples of productivity-enhancing technologies are embryo transplants for dairy cattle, meristem culture in the production of ornamental and strawberry plants, and advances in composting technology. The development of environmentally friendly pest and disease control technologies is a second important area of biotechnology. Selection of disease resistant crop varieties, new applications of biology and the use of transgenic technology to produce genetically altered strains of animals and crops resistant to specific pests and diseases are additional examples of this technology.

Aquaculture: Driven by the rapidly growing sector in the region, the development of bioscience aimed at fish (shell and fin) farming has seen a rapid acceleration. Aquaculture-related bioscience is centred at the AVC in Charlottetown, the DFO Biological Research Station and the Huntsman Marine Science Centre in St. Andrews and the NRC Institute for Marine Biosciences in Halifax. New aquaculture producers face many startup problems related to fish husbandry, disease treatment and pest control. Aquaculture operators and private sector bioscience companies involved in aquaculture rely on the facilities at these locations and at RPC in Fredericton, UdeM and the Fisheries and Marine Institute at Memorial University for the development and adaptation of technology.

The four research establishments have a multi-disciplinary, scientific capability in aquaculture and fisheries management issues. Research projects are ongoing and are designed to: identify new species; discover new techniques for disease and pest management; develop new vaccines and feed additives; control temperature as a means of increasing sea urchin production; model movement of pesticides; use transgenic techniques to increase the growth rate of Atlantic Salmon; develop bioengineering techniques related to the development and or modification of fishing gear; improve brood stock management; improve scallop-rearing technology; and improve management and control of phytotoxins in scallops. Two of the facilities are also involved in non-research activities. The Atlantic Aquaculture Institute at AVC provides training in aquaculture management skills and the Huntsman Marine facilities are used by both university and private sector researchers to conduct contract research on various biotechnologies.

Forestry: Forestry-related biotechnology work in the region is concentrated at the CFS Research Centre and at the University of New Brunswick (UNB) in Fredericton. The CFS Atlantic Station has been conducting genetics research since the 1950s. Over the past 40 years the Station has forged close links with private sector foresters. Initial work focused upon identifying and testing native and non-native trees that performed well in the region and upon a cooperative tree improvement program with private sector firms.

Biotechnology research is underway in four areas of concentration at CFS; somatic embryogenesis involving cloning superior white and black spruce individual trees; physiology and genetics of tree

reproduction; disease and insect control; and the physiology of triggers for wood fiber formation. CFS, in collaboration with J.D. Irving, the B.C. Research Council and the former N.S. Research Foundation, is carrying out a national research effort on somatic embryogenesis. The physiology work is being done in collaboration with UNB, The University of Maine and J.D. Irving and the wood fiber formation work in cooperation with the Swedish Institute of Agricultural Sciences.

Viral protein-transmitted viruses utilizing the "anti-sense gene" and baculovirus has been developed at CFS and UNB and has been patented by UNB. The process for manufacture of this product and its application to trees awaits development and piloting. The insect diseases work with the viral protein transmitted anti-sense gene is being conducted in collaboration with Ciba-Geigy.

Environmental Industry: Bacteria and fungi are important tools for wastewater treatment, water quality improvement, composting waste products and remediation of hydrocarbon and chemically contaminated soils. The processes used involve conditioning and adapting bacteria so that they then work to transform wastes into beneficial biomass and organisms. There is little or no public bioscience research into these environmental applications. Private firms in Fredericton, Halifax and Moncton have developed world class bioremediation techniques.

The majority of the waste water treatment involves anaerobic processes for wastewater treatment using sequencing batch reactors, for example. A Fredericton engineering consulting company, ADI, has a number of portable pilot reactors that they take on site worldwide. The company runs effluent through these reactors and determines whether the process works or requires modification. If it works, they build a full-scale facility for the purchaser. ADI has its own patents and licenses its process to companies in Korea, India and Australia.

GEOBAC, a second Fredericton company, sells remediation services and bacterial products based upon bacteria imported from the U.S. GEOBAC does not sell bacteria, rather it contracts to do the removal using its own technology. GEOBAC, in cooperation with CAMAR of the U.K., is now looking into bacterial methods of decontaminating soils containing PAHs and Phenols.

INDUSTRY ISSUES

Human Resources: The acquisition and training of personnel employed in biotechnology activities is an issue raised by most of the managers contacted. There are good training programs for laboratory technicians at NSAC, UdeM and community colleges. Graduates of these schools have the basic training for most requirements; however, additional in-house training is normally required to meet individual business needs. One firm suggested that about 75% of the first year's salary must be spent on training before new staff are considered a fully contributing resource.

Concern also was raised regarding the supply of professional personnel available for biotechnology positions. All firms hire staff with a minimum of BSc training and most hire staff at the MSc and PhD level. The higher the requirements, the more difficult it is to attract people to the industry or the region. Several firms stated this is a major constraint to future growth of biotechnology activities, with

microbiologists being a major gap in the professional pool. Firms rely on training resources outside the area for professional and specialized skill training, sending people to Ontario, B.C. the U.S. and even Europe.

There is an apparent shortage of scientists with a flair for business and entrepreneurship. One successful Nova Scotia scientist's comment illustrates this point quite well. "*I have found a lack of sufficient scientific people in the area trained in biotechnology. I am not looking for technical support people. Instead, I am looking for creative scientists ... idea people who understand science and are capable of conceiving of new, potentially marketable technologies which can in turn expand our product line. We have been looking nationwide without success*".

A fourth employment issue raised was the preparation of young people for a bioscience career. Some managers suggested that high school graduates lacked interest in biological sciences due to a low emphasis on this subject in the school curriculum. It was felt that some teachers may be anti-biotechnology due to the personal concerns for gene manipulation and animal-based research. In addition, some felt that universities may not be devoting sufficient attention to the sector.

Suppliers and Services: The growth of a bioindustry business in an area will have impacts in the service and supply sectors. Private sector firms and research institutions will make expenditures on construction, renovation and expansion of facilities and on supplies and raw materials. Bioscience firms will require special services of a professional and technical nature such as packaging, printing, marketing and facility maintenance. Specialized skills in equipment repair and financial services are critical to the success of the bioscience entrepreneur. In many instances, the level of these services required is higher than for traditional manufacturing — expectations are high for security, quality standards, precision tolerances and on-time delivery. In some cases live organisms are involved and this demands a special level of service performance.

The often unique requirements of biotechnology-based firms can be a problem for the small service industry base found in the Atlantic region. Specialized services may not be available locally until a critical mass develops which warrants the location of the services in the region. A number of the biotechnology-based business managers consulted indicated that servicing of specialized equipment is difficult in the region.

CLUSTERING OF BIOTECHNOLOGY ACTIVITIES

Proximity to major research facilities and other biotechnology firms is important to the establishment and expansion of business in the sector. A "critical" mass of firms in one location can encourage the formation of additional firms and increases R&D activities. As linkages are formed among commercial companies, research facilities and a specialized service sector, a concentration of skilled workers and a common technology base for all aspects of economic development is developed. "*An industrial cluster allows for joint venturing, sharing of expertise, a larger skilled labour pool, and better access to technical*

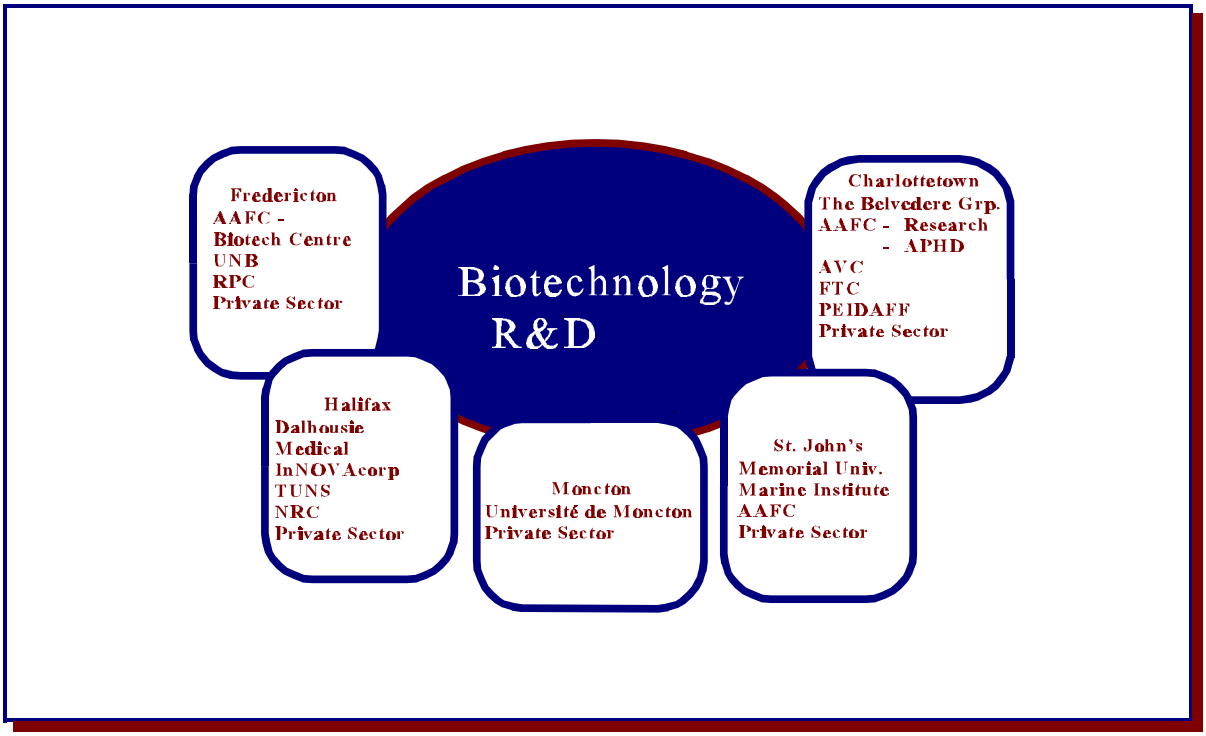
knowledge. The ability to form both formal and informal networks between large and small businesses, particularly international ones ,is critical for bioindustry success."[8]

The potential synergy of public and private operations suggests that regional bioscience and information technology facilities can be a major incentive for the growth of a commercial bio-industry. Since startup biotechnology companies are usually the result of commercializing a biotechnology application, they tend to locate in physical or at least easy electronic proximity to facilities that can offer skilled professional assistance in the start-up phase of the new operation.

Emerging Atlantic Region Clusters: There appears to be an emerging geographic clustering of biotechnology activities around five centres in the region; namely, Fredericton, Moncton, Charlottetown, Halifax and St. John's (Figure 1). A second type (Figure 2) of clustering by sector is also evident in the region. These subject matter clusters each tend to have their own network and linkages, often based on the extensive use of information technology. In effect, the second type of cluster can be viewed as a "virtual science park" in comparison to the more traditional geography-based approach to industry location.

[8]Koehler

Figure I
EMERGING BIOTECHNOLOGY CLUSTERS
ATLANTIC CANADA



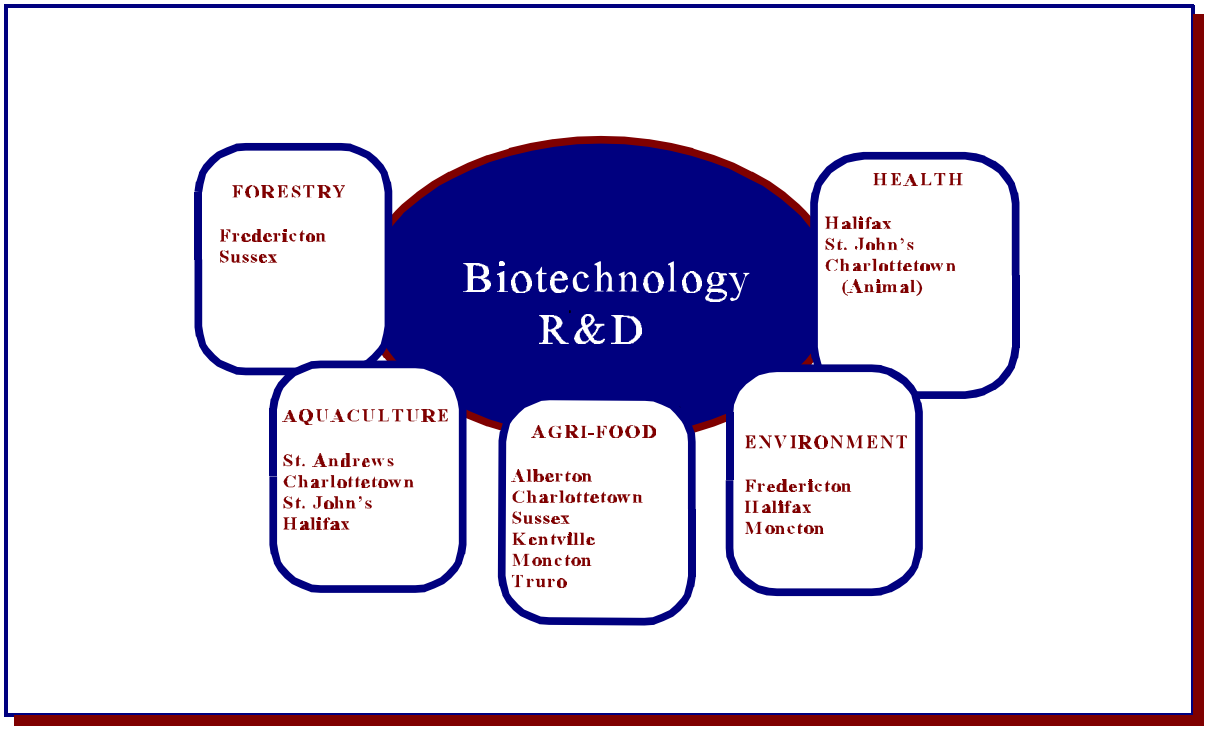


Figure 2

THE VIRTUAL SCIENCE PARK

IV. STRENGTHS AND OPPORTUNITIES FOR NEW BUSINESS FORMATION

REGIONAL STRENGTHS

Biotechnology business activities are well suited to the Atlantic region. Bioscience businesses tend to be small, niche, high valued, knowledge-based and paying higher than average salaries. Small communities like St. Andrews and Charlottetown, for example, have been successful in attracting bioscience firms. The availability of world class communications technology permits scientists in any part of the region to locate in small communities and be in constant touch with the world.

Regional biotechnology firms tend to locate in clusters supported by R&D facilities and specialized services. For new firms wishing to consider the Atlantic region as a possible location for a biotechnology business, there are a number of positive factors that will influence the decision:

Emerging Clusters of Biotechnology Centres and Activities: The clustering of public education and research facilities with bioindustrial enterprises is viewed by Koehler[9] as the most important factor influencing new biotechnology business location.

Public R&D Facilities: Well equipped and favourably disposed to serve the needs of the bioindustry. All contacted indicated a growing percentage of budget and activity being dedicated to bioscience industry collaboration.

Intellectual Capital Resources: A growing number of public and private sector sources as evidenced by university teaching and research trends, government support and private R&D levels.

Communications: Electronic infrastructures that are world class and globally connected contribute to the encouragement of knowledge-based businesses such as bioindustry firms.

Transportation: World class air, land and sea transport services that link the region to global markets.

Global Orientation of Atlantic Business: The mindset of existing business is focused on global market opportunities.

Quality of Life: Lifestyle, cost of living and other social factors are conducive to the location of small to medium-sized business in the region.

Favourable Climate for Cottage Style Business: A compact region with well-serviced urban and rural communities.

[9] Koehler

Successful Biotechnology Business Base Upon Which to Build: All of the businesses contacted were generally positive about their start-up experiences and optimistic about the development potential of the region.

OPPORTUNITIES

Business Formation Opportunities

There are three general types of commercial application of biotechnologies adaptable to the Atlantic region:

1. ***Adoption of new technologies by existing business:*** Existing businesses can benefit from bioscience technologies by adopting or modifying them to an existing operation, to improve efficiency of production, improve product quality or to diversify product lines. New biotechnologies enable existing business operators to improve incrementally their performance in existing markets and to benefit from sales into new markets. The value of these incremental sales can be the important expansion opportunity needed by smaller business in order to expand volume, keep cost competitive and ensure a degree of profit during the early years of the business.

2. ***New business operations based exclusively upon biotechnologies:*** The results of research and development work done in the Atlantic region offers a second type of business formation opportunity. Intellectual capital developed in the region can be put to work to produce products that are based on biotechnology applications. Scientist entrepreneurs can be given an opportunity to carry their idea through to commercial production, creating more jobs in the region. Their option is to sell their ideas to a U.S. or other foreign company and see the jobs created elsewhere.

3. ***The development, sale and provision of biotechnology services:*** This has become an important part of the Atlantic economy, offering job creation and business formation opportunities based on highly paid jobs. A number of institutions and firms are now involved in the business of creating and selling biology-based technologies on the world market. This knowledge-based activity, is a growing area of income generation in the region. Many of the research institutions visited for this study have established for-profit commercial operations that assist staff with patenting, selling and servicing the results of their research projects. The private sector also is taking advantage of the demand for biotechnology applications; in the environment industry, for example, ADI and Jacques Whitford and Associates are successfully selling technology and service to a world market.

Sectoral Opportunities

BICON identified a number of private sector opportunities as well as a list of technologies currently under development, which are highlighted in Table I and Table II. The following summarizes some of the most promising opportunities:

Health: The health sciences sector offers significant opportunities for commercialization of bioscience technologies in Atlantic Canada. The world class medical research facilities of Dalhousie University and

the excellent research and commercialization thrust of Memorial University offer fertile environments for future product and business growth. Currently, opportunities exist to increase our market share in pharmaceutical clinical trials, diagnostic test kits, and in blood fractionation processing. Similar opportunities exist in the animal health sector and the use of genetically altered animals for human health purposes.

Aquaculture: The aquaculture sector is comparatively new and its current rate of growth is indeed remarkable. Solid bio-industrial growth has taken place based in fish health, toxin analysis, antifreeze proteins and forensic services. Additional opportunities will arise as the industry taps into the regional competence in universities, government laboratories and the private sector. Opportunities related to the species diversification area will emerge as scientific problems related to genetically engineered species are overcome and as regulatory hurdles are cleared; for example, in transgenic salmon, domesticated halibut and triploid Arctic Char.

Environment: The environment industry offers particularly bright prospects for development of biotechnology applications. The opportunities exist in sewage and water treatment, soil remediation, household and industrial waste treatment and composting. The market opportunities are international, based on the intellectual capital and process skills in the region, exemplified by enterprises such as ADI and Jacques-Whitford. Surprisingly, there is little in the way of an endemic academic R&D base to kick-start and catalyze such a development. Regional firms are relying on the considerable global research activity in the environmental sciences and the related process technologies. The bacteria and fungi used in the environmental applications can be readily transformed and reproduced in Atlantic Canada. An opportunity exists to overcome the stringent barriers limiting the importation and exportation of these high-performance cultures, by producing them in Canada.

Agri-Food: There are significant enterprises and market opportunities relating to veterinary products, cattle semen and embryos, clonal production of virus-free potato stocks, strawberry and raspberry nursery stock and selected ornamentals. The development and production of improved plant and animal species and the recovery of byproducts from the red meat processing industry offers potential for use in the human health sector. Integrated biological processes such as the addition of "de-odorase" to animal feeds can be used to reduce odours, resolve animal waste disposal problems and improve production efficiency. Opportunities also exist for Atlantic regional firms to perform contract research for the development of biopesticides, genetically altered fruits and vegetables.

Forestry: Businesses in the sector are moving from the traditional chemical technologies to biologically-based alternatives for forest pest control. The newer protocols are likely to be adaptations of agricultural applications and, as with agriculture, opportunities exist for contract research focussed upon developing pest control protocols. Reforestation, based on genetically superior, disease and pest-resistant tree forms such as those developed by the CFS and currently being tested by the J.D. Irving operation in New Brunswick, offer private sector industrial development potentials.

TABLE I

Industrial Biotechnology Opportunities in or Nearing Commercial Production in Atlantic Canada

SECTOR	DESCRIPTION	ENTERPRISE	MARKET POTENTIAL
Health	Needle-less injectors	Adv. Med.	International
	Forensic nucleotide sequencing	Bio-ID	Regional
	Diagnostic strip test for diabetic marker	Diag. Chem.	U.S.
	Nutritional supplements	Efamol	International
	Private blood and blood product banking	Futurac	Regional
	Dry chemical test kits	Octopus	International
	Diagnostic tests/bone marrow transplanting	Terra Nova	International
Aquaculture	Antifreeze proteins and transgenic salmon	A/F Protein	International
	Fish vaccines	Aqua Health	International
	Diagnostics and pharmaceutical testing	Atl. Fish Hlth.	Regional
	Cryogenic milt storage; Species diversification	Atl. Sea Smolt	National
	Shellfish toxin test	MDS	International
	Bacteria as immuno-stimulators	Aqua Health	International
	Species diversification - Halibut	Mar. Mariculture	International
Environment	Drinking water/waste water treatment	ADI	International
	Soil remediation	Geobac	International
	Chemically-clean composted soils	Envirosoil	Regional
Agriculture	Feed additives	Coburn's	National
	Virus-tested nurserystock	Keddy	Cda. and U.S.
	Cured Meat Pigment	P.A. Pure Additions	International
Forestry	Clonally-produced forest tree nursery stock	J.D. Irving	N.B.

TABLE II

Biotechnologies Currently Under Development in Universities, Federal and Provincial Laboratories in Atlantic Canada

SECTOR	BIOTECHNOLOGY	INSTITUTION
Health	Linking of genomes with specific genetic traits	Dalhousie Medical School, Halifax
	Foetal transplants for Parkinson's control	Dalhousie Medical School, Halifax
	Long-lived mice	N.S.A.C., Truro
	Emu Oil/anti-inflamatory	P.E.I. Food Tech. Centre, Charlottetown
	Artificial bone	P.E.I. Food Tech. Centre, Charlottetown
	Woodchuck Test Animals for Hepatitis B	Memorial University, St. John's
	Cardio myopathy - animal/human health models	Atlantic Veterinary College, Charlottetown
	Organ transplant	Dalhousie Medical School, Halifax
Aquaculture	IBR antivirus	Atlantic Veterinary College, Charlottetown
	Genetically engineered insulin producers	Dalhousie Medical School, Halifax
	Genome sequencing and related bioinformatics	NRC Inst. Marine Biosciences, Halifax
	Lipid encapsulation vaccine delivery system	Memorial University
	Transgenic salmon	Huntsman Marine Sciences Centre
	Scallop rearing technology	DFO, St. Andrews
	Arctic Char / salt water adapted	Huntsman Marine Sciences Centre
	Carotenoid Yeast	Seabright Corporation
Agriculture	Maedi Visna virus test	AAFC, Charlottetown
	Biocontrols for clubroot and red mites	AAFC, Kentville
	Hardy transgenic forages	Nova Scotia Agriculture College
	Genetic markers/economic potential in cattle	Nova Scotia Agriculture College
	DNA fingerprinting of brewers' yeast	Research and Productivity Council, Fredericton
	Pharmaceutical products from blueberies	Université de Moncton
Forestry	Somatic embryogenesis/white & black spruce	Canadian Forest Service, Fredericton
	Baculovirus for forest insect control	University of New Brunswick, Fredericton
Environment	Hydrocarbon degrading bacteria	Research and Productivity Council, Fredericton
	Waste water filters from peat moss	Université de Moncton

V. GOVERNMENT BIOTECHNOLOGY POLICIES AND PROGRAMS IN ATLANTIC CANADA

FEDERAL POLICY AND PROGRAM INITIATIVES

Biotechnology is a long-term economic development priority of the Government of Canada; a National Biotechnology Strategy (NBS) is in place and being implemented by Industry Canada. The strategic objectives are to:

1. focus biotechnology activity in a few areas chosen on the basis of their importance to future economic development of Canada;
2. encourage effective communication and collaboration amongst all sectors (federal and provincial governments, industry and universities);
3. to ensure an adequate supply of trained human resources; and
4. to create a climate conducive to investment by industry in biotechnology.

The "tool" to implement the Strategy has been the NBS Fund, in existence since 1983 through which funds are allocated to federal departments and agencies active in some facet of biotechnology development. In the period 1992-95, the annual allocation has been in the order of $11.9 million. For the years 1995-98, the allocations are $10.1 million, $9.5 million and $9.5 million, respectively.

Federal government activities in the biotechnology sector in Atlantic Canada are extensions of national programs, guided in the region by the particular department's business plan. There is no comprehensive regional federal strategy or business plan aimed at assisting the private sector take advantage of business formation opportunities in the Atlantic region. Each federal department and agency deals with biotechnology development on an independent basis. The NRC, through the Industrial Research Assistance Program (IRAP) is a major source for private sector R&D funding. ACOA, through the Business Development Program (BDP) and the Innovation Element of that Program, assists entrepreneurs produce and market biotechnology products.

***Agriculture and Agri-Food Canada (AAFC)*:** Agriculture and Agri-Food Canada maintains a network of research centres each specializing in a national responsibility. Fredericton is the national potato breeding centre; Kentville is the centre for berries and food science; Charlottetown specializes in livestock feed crops and potato management; and St. John's specializes in cold climate agriculture.

AAFC intends to carry out higher-risk, long-term research that industry will not undertake on its own. In addition, it will be supporting research on food safety and security issues as well as environmental stewardship. Future programming is expected to be heavily influenced by the private sector, given the federal government's emphasis on joint industry collaboration (partnering). AAFC's role is to ensure that the expertise and research and development infrastructure are in place.

Federal government budget restraint is having an impact on the Atlantic region. Continued cutbacks in staff and budgets are reducing the volume of work that can be done in the region. It was noted by departmental representatives that the Atlantic region of the AAFC Research Branch sustained much larger reductions than most other establishments across Canada. Partnering of research with the private sector in Atlantic Canada is difficult, as the business funding available for matching is modest.

Fisheries and Oceans Canada (DFO): DFO is primarily a regulatory body concerned with the conservation of wild species. While it currently conducts some biotechnology research, this involvement is expected to decrease. In the view of DFO Ottawa, universities, including foreign universities, will be the major source of new biotechnologies. In the future, the private sector will also be relied upon to do more of the R&D. Aquaculture is expected to be the focal point for new biotechnology development. However, for the most part, DFO will continue to be preoccupied with conservation of the wild fishery. Atlantic region aquaculture research is consolidated at St. Andrews.

Public good research will be the DFO orientation, with fish health and species diversification the priorities. Aquaculture science within DFO is budgeted at about $5 million per year and it is shrinking fast. DFO plans to retain its expertise in fish diseases, however, its main thrust will be on the removal of impediments to development, rather than on research. DFO will be most interested in bringing new species to the point where they can be produced commercially. Genetic improvement work at the St. Andrews and Toronto will include emphasis on transgenics, growth factors and disease resistance. Feed companies will be expected to do the nutritional work and other aquaculture/fish industries expected to do the product development. DFO is also very concerned with developing regulations for new genetically engineered fish.

***Canadian Forest Service (CFS)*:** The provinces own the majority of the Canadian forestry resource and are responsible for its management. Science is the major focus of the CFS. The organization is based on two pillars: knowledge generation; and technology transfer. The CFS has 10 research networks in place, each with a national orientation. The priority is research with a strong biotechnology emphasis in pest management in Sault Ste. Marie and tree biology in Quebec City and Fredericton. Growth rate and tree formation are the key interests in tree biology work. Pest management research is closely linked to industry needs. Research emphasis is being placed on developing new strains of bacillus thuringiensis (Bt) and developing action protocols for targeted approaches to biological forms of pest management. Insect pheromones and insect viruses are important pest control tools and an important component of the CFS biotechnology portfolio.

The CFS has spawned a separate network of Crown agencies such as Forintek (Vancouver) to link with industry and the provinces in transferring innovative forest technologies. Unfortunately, industry take-up of forest technologies is abnormally slow. This is attributed, in part, to the prevailing provincial rather than private ownership of the forest resources.

Health Canada (HC): HC has two primary roles: regulatory, with emphasis on medical devices and food; and research, wholly in support of HC's regulatory function. Biotechnology activities are represented in the Drug, Food, Environmental Health, Laboratories, and Blood Secretariat Directorates.

The Environmental Health Directorate regulates products of biotechnology and formulates standards and work procedures to reduce the threat to human health. Health Canada is also engaged in research through its Laboratory Centre for Disease Control (LCDC), a national public health institute with well-developed investigative abilities in microbiology and epidemiology. The LCDC is a leader in the use of molecular genetics for diagnostic tests. Once the LCDC develops a new biotechnology process, it is transferred to the public health laboratories or the private sector. Atlantic region operations of Health Canada include a research unit, the National Centre for Enteroviruses in Halifax and the regional operations of the Health Protection Branch (Dartmouth).

The Canadian Medical Research Council (CMRC) funded by Health Canada will provide $2 for every $1 Newfoundland or Nova Scotia invests in health research. Funding from this source is diminishing, however, and is tending to be largely captured by Central Canada. The CMRC has created a regional fund that earmarks $2 million each for Nova Scotia and Newfoundland, to be matched by provincial and/or private sector partners. Government funding from the CMRC will continue to be the major health technology funding source in Atlantic Canada.

Industry Canada (IC): IC sees its role as setting an appropriate business climate, including a supportive regulatory and investment environment. IC has the federal policy lead on issues surrounding patenting of higher life forms (ISSUE). The National Biotechnology Strategy is currently under review by IC with a national conference planned for January. IC maintains close ties with the OECD on the harmonization of biotechnology regulations and with External Affairs on international trade linkage and intelligence on emerging technologies.

IC works closely with regional and national associations and other government departments with respect to its roles related to development and distribution of: information products; sectoral policy; and industrial services in technology transfer, trade promotion and investment, and human resource development. IC initiatives take a variety of forms, ranging from commissioning reports on trade opportunities, to leading the National Biotechnology Strategy.

IC promotes Technology Partnerships Canada. This program provides repayable contributions up to 30% of approved project costs for biotechnology projects. IC also allocates $4 million annually to biotechnology through the IRAP program.

National Research Council (NRC): NRC is Canada's foremost R&D agency with a unique multi-sectoral capability, a national presence through its network of laboratories and an international reputation for excellence. It is committed to innovation in a knowledge-based economy and has a well-established record of partnering with industry, universities and other government agencies. It has three principal tools at its disposal: its network of 23 research institutes and Technology Centres; its IRAP program and the Canada Institute for Scientific and Technical Information (CISTI).

The NRC's institutes have recently been realigned into five technology groups. One of these groups is identified with biotechnology, a clear indication of the importance which NRC attaches to this aspect of science. The NRC intends to maintain its nation-wide network of technology advisors and bring a more proactive approach to its information technology vehicle, CISTI.

Biotechnology research is centred in five laboratories: the Plant Biotechnology Institute (Saskatoon); the Institute for Biodiagnostics (Winnipeg); the Institute for Biological Sciences (Ottawa); the Biotechnology Research Institute (Montreal); and the Institute for Marine Biosciences (Halifax). The latter centre is oriented primarily to aquaculture research with strong competencies in genome analysis, organic analytical chemistry, advanced mass spectrometry and bioinformatics.

PROVINCIAL POLICIES AND PROGRAMS

Each of the four Atlantic provincial governments has policies and programs designed to encourage bioscience and the application of biotechnology. BICON consulted with one or two provincial departments or agencies in each province in order to obtain a cross-section of provincial opinion on the sector. Consequently, the following discussion does not include all provincial policies or programs that may exist or may be planned in each of the provinces.

All four provincial governments have recognized the significance of the sector, but the investigators found no evidence of a pan-Atlantic biotechnology industry strategy. Atlantic governments, federal and provincial, have not shown the level of financial, technical and coordinating support for the effective development and commercialization of biotechnology, as is seen in provinces like Saskatchewan. Atlantic governments have not taken a leadership role in the creation of private sector alliances to promote bioindustry, as they have with the Atlantic Geomatics Alliance, for example. However, the four governments have begun to emphasize biotechnology as an important element in their economic development strategies.

NEWFOUNDLAND AND LABRADOR

The Province places a priority on using the intellectual capital built up at Memorial Medical School for economic development purposes. The Province's objective is to build upon and strengthen the Memorial facility as an economic development generator for the province and a way of keeping intellectual capital in and attracting it to the province.

The technology being commercialized will be both locally developed and imported, but the Province intends to work in those areas that are Memorial's strengths. The departments of Industry Trade and Technology and Health, are working together to market the intellectual capital and world class research at Memorial. The two departments are succeeding in increasing the quantity of clinical and diagnostic testing being done at Memorial for pharmaceutical companies.

***Department of Health*:** The Newfoundland and Labrador Medical Research Foundation is proposed as the means of taking advantage of the strengths at the Memorial Medical School complex. These include: clinical trials and diagnostic tests for pharmaceutical companies; telemedicines; and other technologies under development at the University such as woodchucks as a test medium for Hepatitis-B, AIDS-related retro virus work and forensic identification. The Department of Health has set aside 1% of its budget for

research through the Foundation; half of this will go to biotechnology. The Foundation will be a designated charity that should encourage donations from the private sector.

***Department of Fisheries*:** The department does not appear to have a specific strategy on biotechnology. It does have a full species utilization policy that stresses finding alternate uses for a wide range of fish and seal byproducts. Imported technology and technology developed in Newfoundland will form the base of biotechnology work in the fisheries sector.

The department is now sponsoring work on seal oil, shark cartilage, seaweed, fish compost, health supplements, protein concentrates, fish feed, fish silage and fish oil. A cod hatchery and scallop hatchery are under development by Seabright Corporation scientists. Research work on these technologies is being done in cooperation with Aqua Health and the Atlantic Veterinary College, DFO and Huntsman Marine Sciences.

PRINCE EDWARD ISLAND

The Province has no formal policy on biotechnology. The Belvedere Avenue Group (Atlantic Veterinary College, Agriculture and Agri-Food Canada's Research Station and Animal and Plant Pathology Laboratory, the P.E.I. Department of Agriculture and Fisheries and the P.E.I. Food Technology Centre) is seen as a strong knowledge base to which the province can look for development of technology tailored to the needs of agriculture, fisheries and forestry.

Department of Agriculture, Fisheries and Forestry (PEIAFF): The PEIAFF sees biotechnology as the basis for its future. The department has a business plan that shifts emphasis from traditional roles of extension and services to that supporting technology commercialization. The Department is now moving funds from subsidies and extension toward funding for research and the encouragement of technology commercialization. The movement in funds recognizes the need for more coordination and co-operation among agencies; and that industry service is doing the best job of technology transfer to the primary producer.

Food Technology Centre (FTC Enterprises Ltd): The FTC is a provincial Crown corporation created to provide innovation, applied research and development, technical support and technical partnering to the P.E.I. food sector. The Centre has a staff of about 30, of which 15 are professionals representing several disciplines. The annual budget is slightly over $2 million, about 50% of which comes from contracts. The services offered clients by the FTC include global scanning for technology and assistance with product modification and customizing. The FTC has the mandate and means to enter joint ventures for the commercialization of biotechnology applications and to provide retrofitting services to foreign clients.

NOVA SCOTIA

Nova Scotia has recognized the biotechnology, health and medical device manufacturers as a key development sector. Provincial government support has been supportive to the Dalhousie Medical School

and associated business activity in the health sector. The new Red Cross blood fractionation plant and its anticipated spin-off of new businesses will provide an additional focal point for provincial biotechnology development. Planning is now underway in Nova Scotia to develop an Agri-Tech Business park in Bible Hill as a centre of excellence in agri-food biotechnology.

***Department of Agriculture and Marketing (NSDAM)*:** The NSDAM does not have any specific policies or programs for biotechnology. NSAC is the research arm of the NSDAM with a research budget just less than $1 million per year, out of a total departmental budget of $32 million. The majority of the research underway at NSAC can be considered biotechnology.

***InNOVAcorp*:** InNOVAcorp is a provincial Crown corporation with a private sector board of directors. The Corporation contracts research capability in plant biotechnology (synthetic seeds, bioprocess mechanization and Mycorrhizae) and provides research facilities under its "Campusing Program" for selected biotechnical industries, i.e., Jellett Bioteck Ltd. (Aquaculture/shellfish toxin R&D). Otherwise, it plays a technology brokerage role and carries out recruiting of scientific and technical staff as required to meet the needs of its contracts.

NEW BRUNSWICK

New Brunswick has recently introduced a new biotechnology strategy. The main objective of the strategy is to strengthen New Brunswick's rural and resource-based economy through the development, application and commercialization of biotechnology and biotechnological innovations. The Province believes that this will enable the New Brunswick agri-food sector and other resource-based sectors to take advantage of new technologies, thereby improving their competitive position in the global marketplace.

The strategy includes: the creation of a New Brunswick Biotechnology Centre; University Chairs in Biotechnology at UNB and UdeM; and refocusing of existing government adaptive research and technology transfer programs. The new Biotechnology Centre is to be a "virtual centre" or a "centre without walls". The Executive Director of the Centre will work with industry to facilitate research and partnerships and act as a clearing house and a brokerage for biotechnology in the province.

Department of Agriculture and Rural Development (NBDARD): The NBDARD has the lead provincial role in implementing the New Brunswick Biotechnology Strategy. The department is aware of the need for additional applied research and the conducting of field trials with private sector companies and AAFC. The department wishes to focus on promoting partnerships between existing laboratories and private sector companies, not on funding large numbers of researchers. It expects biotechnology to be introduced to the province, primarily by companies with the resources and capability to develop and test new technologies.

Department of Fisheries and Aquaculture (NBDFA): The NBDFA will be involved in implementing the new provincial Biotechnology Strategy. The department places considerable emphasis on the biotechnology aspects of aquaculture. Effort is being dedicated to identifying and selecting new fin-fish species, including the domestication of fish such as halibut, and the expansion of shellfish production.

Biotechnology work, particularly research, is coordinated by a special committee that brings together the private sector aquaculture operators, universities and government to discuss development needs.

The NBDFA and federal and provincial funding agencies respond to private sector proposals and assemble a parcel of assistance fitted to the entrepreneurs' needs. The funding package may include a wide range of programs, including ACOA programs, DFO programs and provincial programs. Assistance is available to commercialize a technology, to do site selection and to acquire a licence. The Province is not highly supportive of proposals that include the cost of licensing and the franchising of processes. However, proposals to bring in technology from other countries are encouraged.

Research and Productivity Council (RPC): This Crown corporation's mission is to assist industry and other clients involved in technological innovation, by providing fee-for-service technical expertise that is supported by modern and comprehensive facilities. RPC offers a wide range of professional and technical services to help industry develop new products and innovative solutions to operating problems.

The RPC has a total staff of 100, of whom 12 are assigned to biotechnology work, which accounts for about 15% of the $8 million recovered annually in fees for service. RPC laboratories and pilot plants dedicated to biotechnology work include: a fish health and forensics facility; fish quarantine lab; extensive pilot plant; a test kitchen; microbiological test equipment, etc. Current biotechnology work at the RPC includes: DNA fingerprinting of brewery yeast; detection of pathogens for quality assurance; diagnostic tools for fish disease pathogens; hydro-carbon degrading bacteria; bacterial separation of sulphides in base metals; forensic detection methods for wildlife protection; and quality assurance methods for Bt-based insecticides. The RPC maintains close links with UdeM and the P.E.I. FTC. The RPC has also worked closely with Aqua Health of P.E.I. on the development and patenting of fish vaccines.

VI. POLICY PERSPECTIVES

THE UNIVERSITIES

Representatives of Memorial University, Dalhousie University, Nova Scotia Agriculture College, University of Prince Edward Island, University of New Brunswick, Université de Moncton, the Huntsman Marine Sciences Centre and the Seabright Corporation in Newfoundland were asked for their perspective on policies and programs for biotechnology in Atlantic Canada. The following summarizes the responses BICON received from the people representing each of these institutions.

A Strategic Focus: A strategic focus is required across the Atlantic region. The present attitude of competing instead of collaboration is untenable in a time of scarce resources. A viable biotechnology community is emerging in Atlantic Canada that can be world class, but for it to succeed, government, academics and industry must share a vision. The first requirement is the need for a philosophical commitment of the type that exists in Saskatchewan. Research priorities should be established for each research institution in Atlantic Canada. The priority should be applied research and the modification, enhancement and adaptation of products to the specific needs of industries in Atlantic Canada. The region will continue to rely upon basic research done elsewhere. Biotechnology offers significant low volume, high value, employment creating opportunities in Atlantic Canada.

Coordination: Biotechnology policies, programs and activities across the region must be coordinated. Unfortunately, there is a limited history of successful private or institutional or interprovincial coordination. A region-wide strategic focus is required to facilitate collaboration, rather than competition, if the region is to benefit from this new science. To do this, a structure will be required to develop linkages and alliances or partnerships in biotechnology among universities in Atlantic Canada and between universities and research institutes in Atlantic Canada and elsewhere wherever the expertise resides.

Multiplicity Of Agencies: Dealing with multiple agencies in government slows the process of R&D and commercialization of new technology. The broad concepts stated by government departments are well meaning, but have not been transferred into business plans. University spokespersons commented that the difficulties they sometimes experienced in explaining their projects to government agencies constrained their ability to work through the various bureaucratic levels.

Public Funding Assistance: The Atlantic region needs to keep up with the level of financial support for R&D provided by other countries to their comparable sector (i.e., Japan, which doubled its investment in the past year). Most Canadian government assistance programs are based upon the premise that a company will source and pay the development costs of a new technology. Most of the technologies are either still on the bench or just off the bench. The cost of commercializing this technology is too great for most private entrepreneurs. Consequently, the scientist entrepreneur is often forced to go to multinationals and when they do, Canadian ownership and control of the technology and the potential long-term economic spin-off is usually lost. Moreover, working with Canadian subsidiaries of multinational companies makes it difficult to get answers and commitments from the company's international headquarters. High-risk funding is required to get the technology off the bench to develop a commercial process to the point where

it can be patented and licensed and sold. Funds are not available for development of intellectual property, i.e., patents and process protocols.

Venture Capital: Private sector venture capital funds are averse to high risk biotechnology projects, and the current conservative approach of the public funding agencies further exacerbates the problem. The government repayability policy was designed for standard manufacturing processes, but the blanket application of repayability severely limits the technology development process. When a technology is successfully developed, the ACOA contribution, for example, must be repaid, the cost of repayment must be factored into the market cost of the process, and this can render it unsaleable to a commercial operator. The purchaser of a new technology must take a risk; adding the repayable contribution cost to his risk may render the process uneconomic for all but the multinationals. Provisional repayability for biotechnology-type projects, with projects dealt with on a case-by-case basis, should be the norm. Biotechnology is not at the same level of development as traditional manufacturing industries, especially in Atlantic Canada.

Intellectual Capital: Funding agencies could consider overcoming some of the funding problem by allocating a value to intellectual capital . The scientist may have invested many years of intellectual capital into the product or process subsequent to applying for assistance to bring it to commercial production. A way needs to be found to permit the scientific effort to be counted as equity in the new business (a version of sweat equity).

Business Skills: Scientists often do not have the business skills required to set up and manage a successful business. Current ACOA programs, for example, assist the scientist to formulate a marketing plan and hire a marketer but not a business head or CEO, which may be the critical missing link in getting the business off the ground.

Program Delivery: Government agencies need to ensure that the scientific expertise is included when they are assessing proposals for big projects that include aspects of biotechnology. All projects of this type should be referred to competent scientific authorities. In the opinion of the university spokesperson, the government officers reviewing proposals with a bioscience content usually do not have the training or experience to assess the science aspects of such projects.

Relevance: To be competitive on the world market the Atlantic region has to be relevant in the research and business development game. The region must be focused upon those aspects of research and business that it now does well.

THE PRIVATE SECTOR

Introduction

Biotechnology is a knowledge-based industry. Entrepreneurs in this sector typically identify a scientific idea and develop it in the hope that investors will come and help them bring their idea to fruition. The entrepreneurs we consulted felt that the primary challenge was in bringing bioscience from the university or research establishment to the market. The successful transfer of science from the laboratory bench to

the market involves a process of discovery, development, scale-up to manufacturing, commercial production and marketing.

The entrepreneur is not the only key person involved in the commercialization process. The scientist is also a key player. **Bioindustries will flourish only if fed a continuous supply of science.** There are two places to look for marketable science: from local researchers and from sources external to the region. Usually, it will be necessary to negotiate an agreement with the scientist or organization that owns the rights, patent and license to the particular scientific idea, whether it be a local idea or one imported, for example, from Norway.

BICON consulted with 28 private sector enterprises across Atlantic Canada. Their collective comments on current public sector policies and programs are organized into eight areas: Start-up Funding; Research Funding; Availability of Management and Staff; Partnering; the Project Review Process; Regulatory Process; and Consumer Resistance.

Start-up Funding

All twenty-eight private sector firms commented on the difficulties experienced in financing biotechnology from the discovery phase through to commercial production. Financing of biotechnology in Atlantic Canada was identified as the major constraint to new business formation in the sector. Unlike the traditional manufacturing sector, or sectors that depend upon engineering solutions, biology involves life processes. Characteristically, these technologies are commercialized at a much slower pace than physical and engineering processes.

As one entrepreneur commented, venture capitalists for the most part will not invest their money until they can be shown that the researcher has a product that will sell at a profit. To demonstrate the value of the product, the researcher must do development work. Money is needed for this step and it is unlikely to come from the venture capitalist. Most scientists do not have it, **so public funding is essential**. Atlantic entrepreneurs, in the absence of private risk capital, have three alternatives: to seek public assistance from the IRAP Program or from ACOA; to apply to other national and provincial assistance programs; to partner with or sell their idea to another company.

The current assistance programs require the scientist to put up 30-50% of the total cost. This requirement is often prohibitive unless the scientist has good backers or is independently wealthy. In addition, obtaining backing is usually very difficult until one has proof that a process or technology will work and be profitable. ACOA program funding for this purpose was said to be difficult to use within the current program rules. The requirement that money be spent up front and in a relatively short time makes it difficult for the scientist entrepreneur. It takes time to work out processes, purchase specialized equipment that cannot be ordered off the shelf, develop and test protocols and standard operating procedures, and get them approved by regulatory agencies.

Federal government assistance is now largely in the form of repayable loans. Repayable loans, with a short payback period (three years or less), are of little use in the piloting situation**.** If the pilot project is successful, the entrepreneur must recover the funds necessary to repay the loan. This means capitalizing

the cost of repaying the loan into the sale of a license or right to produce the product that can lead to a sale price too high for venture capitalists. The technology developer needs to be given the opportunity to succeed or fail on piloting an idea. The risk to government would not be that high. Small amounts in the $15,000-$20,000 range are often sufficient to pilot an idea. On the other hand, funding of pilot projects may not be a problem if the pilot is small and it can be funded from a company's cash flow from other aspects of its business. However, for a small company or a new and growing company, the level of available public assistance for piloting is inadequate.

Research Funding

The apparent decrease in available government research funding was of concern. Few companies are able to do R&D because of the high cost and high risk. R&D costs are reaching the point where, as one business owner said, "*we can't afford to do much other than product improvement. Probably the most important role for government is in helping to finance R&D and to support new business*".

The manner in which government allocates existing research funding was also raised. Feedback varied from highly complementary to very critical. Generally, the IRAP Program was given high marks. It was seen as useful, focused and in tune with the R&D needs of the various companies. The need for national project evaluation of IRAP projects over $200,000[10] was questioned, given the scientific intellectual resources in the region.

The current government drive to private sector partnering was received with some trepidation by smaller scientific firms. These firms are concerned that university and government scientists have direct access to their institutional infrastructures at unrealistically low costs and will compete unfairly. Moreover, as government scientists search for supplemental funding and partnering opportunities, some entrepreneurs expressed the fear that their attention will be diverted from the truly creative, longer term search for new biotechnologies.

Allocation of government research expenditures was a common target for criticism. More industry involvement is sought in establishing research priorities, as one entrepreneur said, "*A better inventory of industry needs is required if government is going to conduct research, it should be more in keeping with industry needs than with political needs. There is little opportunity for small entrepreneurs to make an input to the research selection process*". A second entrepreneur complained that "*Not enough research is evaluated for its potential commercial application. It is not transparent how research organizations strike a balance between knowledge generation and industry relevant research*".

Management and Professional Staff

An overriding concern of the expanding biotechnical industry is finding the right people to help companies advance along the path to commercial success. The bioscience industry in Atlantic Canada is very young and **there is a shortage of entrepreneurial bioscience managers with the ability to raise capital, put together a business plan and build up a company structure.** Too few scientists have the essential

[10]IRAP officials confirm that the threshold for referrals to Ottawa is $100,000.

business mindset. The industry needs innovative, open-minded people able to work well in a cooperative team setting.

BICON was told that many well-qualified scientist entrepreneurs do not understand the need for quality control, good process engineering and customer satisfaction. Although scientists are the people who come up with the ideas, they often do not have business management experience. They are the brains behind the concept, but they often need help from a business person; a person that can select a management team with the vision to sell, the ability to reach milestones, deal with patenting, regulatory, packaging and labelling issues, and get their product to market before the competition.

A number of the nonscientist business people consulted proposed that **the federal and provincial governments should play a much stronger brokerage and linkage role between business and the researcher. Scientific knowledge may be concentrated in the university, but business knowledge and entrepreneurial expertise are resident in the business community; both must come together if a biotechnology project is to succeed**. The brokerage role and emphasis on the transfer of intellectual property and knowledge to business should be given precedence over funding of capital expenditures for bricks and mortar.

Both business persons and scientists told BICON that funding agencies pay little if any attention to the special start-up problems encountered in transferring knowledge from the scientist to the businessman. Apparently, it is very difficult to get funding assistance to translate academic knowledge into a commercial operation. In addition, it was proposed that the cost of a CEO or business manager be included in the calculation of project funding assistance. Biotechnology should be commercialized by people that understand business plans, marketing and financial management.

Partnering

Partnering with established Canadian and foreign companies was one frequently mentioned way of bringing capital into the biotechnology development and commercialization process. Partnering can be in the form of strategic alliances, mergers and acquisitions, partial acquisitions and a host of other deals that may be negotiated. Many suggest that partnering is "*the way to go for Atlantic entrepreneurs"* using alliances with U.S. or other non-Canadian companies to provide funding and legitimacy to their project. **A partner "*with deep pockets*" is an important ally in validating the undertaking in the eyes of both the business and the investment community.**

Atlantic region entrepreneurs are experiencing difficulty in locating suitable business partners. One firm for example has experienced difficulty in finding good commercial partners to manufacture and market their new biotechnology based clinical test kit. The technology could be out in the marketplace within the next couple of years, if a suitable partner could be found to manufacture and package it properly. A second company has been much more successful. When it was confronted with a lack of indigenous venture capital it sought and obtained capital from outside the Province i.e., Toronto, Montreal and the U.S.).

The Project Review Process

The level of scientific knowledge demonstrated by project evaluators in the various government funding agencies was of major concern. The length of the control period and the program rules developed primarily for engineering and traditional manufacturing projects was an issue. Several entrepreneurs also commented that ACOA spending in bioscience should be directed to utilizing and capitalizing on intellectual capital and purchasing of specialized equipment, instead of bricks and mortar. The following summarizes comments on these issues.

1. There is a major need for bioscience knowledge in the funding agencies**.** Current program rules were said to be inappropriate for the assessment of biotechnology projects and in need of revision. It was proposed that the funding agencies should call upon scientific knowledge from outside government to review program rules and to assist in the assessment of biotechnology project proposals. Government project assessment people were said to be neither knowledgeable nor comfortable in science generally, and in biotechnology in particular.

2. An alternative solution to the perceived problem of understanding at the project assessment level was a proposal to have the funding agencies hire account managers that understand science and biotechnology. Poor communications between the science-oriented entrepreneur and the business-oriented account manager was said to be an important constraint to new business formation.

3. The practice followed by some scientists of hiring a consultant to assemble a business plan to satisfy funding agencies was criticized. Generally, it was felt that money should not be given in this situation unless the whole assessment and granting process be closely monitored by persons that understand both science and business issues. In addition, inclusion of both the science side and the business side in the monitoring process during the "control period" is essential to success.

Regulatory Environment

The regulatory environment is currently in transition as regulatory agencies are merged, downsized and retasked. The changes in the regulatory sector are exacerbated by the shortage of regulators versed in biotechnology. **The basis for the regulations is often poorly understood and the response time far too slow.**

Regulations were highlighted as a major constraint to marketing biotechnology world wide. BICON was informed by more than one entrepreneur that in their opinion, the European Economic Union, was using regulations as a non-tariff barrier, either to prevent the Canadian company from marketing in Europe or to force it to sell its technology to a European company.

Consumer Resistance

Generally, the Canadian consumer has a very limited understanding of biotechnology. The media tend to sensationalize biotechnology, dedicating their attention to those aspects that involve genetic manipulation. To date, public interest and consumer groups have raised concerns over novel foods such as genetically-engineered tomatoes and potatoes as well as milk from cows injected with bovine somatotrophin (BST). The public attitude to biotechnology tends to be very conservative, especially

toward genetic engineering. Recombinant DNA techniques, a major area of potential biotechnology products, is expected to be key to genetic improvement work in the aquaculture sector, as fish breeders access new strains by biotechnology means. Consumer education and involvement in these developments will be essential if there is to be widespread acceptance of this new technology.

VII. CHALLENGES AND RECOMMENDATIONS

A. STRATEGIC FOCUS AND COORDINATION

A viable biotechnology community is emerging in Atlantic Canada that can be world class, but if it is to succeed, government, academics and industry must share a vision**.** Currently, the federal and provincial governments, universities and private sector firms do not have a shared vision of the biotechnology sector in Atlantic Canada.

Recommendation 1*: The public sector take the lead role in developing a philosophical commitment and a strategic plan for the biotechnology sector in Atlantic Canada.*

The investigators found no evidence of a pan-Atlantic biotechnology industry strategy. All four provincial governments and the federal departments are following their own agendas. Atlantic governments, both at the federal and provincial levels, have not shown the same level of financial, technical and coordinated support for the biotechnology sector, as they have shown with the tourism and entrepreneurship initiatives, for example.

Recommendation 2: *A region-wide biotechnology alliance similar to that which currently exists in the Geomatics sector* be established.

B. CLUSTERING

Proximity to major research facilities is important to the establishment and expansion of biotechnology-based firms. As well, a "critical" mass of firms in one location encourages the formation of R&D and commercial clusters. Encouraged by linkages among commercial companies, research facilities and a specialized service sector, regional clustering can provide a concentration of skilled workers and a common technology base for all aspects of economic development. "An industrial cluster allows for joint venturing, sharing of expertise, a larger-skilled labour pool, and better access to technical knowledge. The ability to form both formal and informal networks between large and small businesses - particularly international ones - is critical for bioindustry success."[11]

Recommendation *3*: *ACOA investigate the characteristics of successful biotechnology cluster models elsewhere in Canada and world wide, identify those which are most appropriate in Atlantic Canada and propose measures which would encourage formation of clusters in Atlantic Canada.*

[11]Koehler

C. AVAILABILITY OF MANAGEMENT AND PROFESSIONAL STAFF

An overriding concern of the expanding biotechnical industry is finding the right people to help each company advance along its path to commercial success. The human resources available in Atlantic Canada to begin biotechnology businesses are limited. The bioscience industry is very young and there is a shortage of entrepreneurial science managers with the ability to raise capital, put together a business plan and build a viable company. Too few scientists have the essential business mindset. The industry needs innovative, open-minded people, able to work well in a cooperative team setting.

Scientists are the people who come up with the ideas. Unfortunately, they often do not have the business management experience. They are the brains behind the concept, but they often need help from a business person.

Recommendation 4: ***ACOA consider the provision of a qualified CEO or business manager as an eligible expense for assistance under the Business Development Program***

Recommendation *5*: ***The Maritime Provinces Higher Education Commission, in consultation with all Atlantic universities, evaluate the biological syllabus to determine the appropriateness of including business management course work as part of the requirement for the Bachelor of Science degree.***

Recommendation *6*: ***ACOA examine the feasibility of establishing a specialized business and commercialization training program for biological scientists.***

Recommendation *7*: ***Encourage departments of education to incorporate a higher level of biological science into the high school curriculum.***

Recommendation 8: ***Include a biotechnology category as a component of the annual Regional Entrepreneurship Awards Program.***

D. RESEARCH & DEVELOPMENT

Bioindustry will flourish only if it is fed a continuous supply of science. There are two places to look for marketable science: from local researchers, and from sources external to the region. The current budgetary scientific research cutbacks will increasingly force the industry to look externally to fill its science needs. Companies tend to locate close together in a location that has well-developed research facilities and well-trained scientists.

Recommendation 9: ***Federal departments with research operations in the region ensure that their existing research capability is not further eroded.***

A better inventory of industry research needs is required in Atlantic Canada. If government is going to conduct research it should be more in keeping with Atlantic region industry needs. Currently, it is not transparent how research organizations strike a balance between knowledge generation and industry relevant research.

Recommendation 10*: **Every publicly-funded research project undertaken in the region should have one or more private sector sponsors.***

E. PARTNERING

Partnering with established Canadian and foreign companies was frequently mentioned as a way of bringing capital into the biotechnology development and commercialization process. Partnering can be in the form of strategic alliances, mergers and acquisitions, partial acquisitions and a host of other arrangements. Many suggest that "partnering is the way to go for Atlantic entrepreneurs", forging alliances with U.S. or other non-Canadian companies. A partner "*with deep pockets*" is an important ally in validating the undertaking in the eyes of both the business and the investment community. Partnering with established Canadian and foreign companies offers an effective way of bringing in new capital, accessing technical capabilities and facilities not resident in the particular company and establishing markets outside Atlantic Canada.

Recommendation 11: *ACOA and Industry Canada consider taking on a brokerage role in assisting bioindustry entrepreneurs to establish partnerships with companies external to Atlantic Canada as a means of obtaining financing, accessing technical assistance and overcoming foreign trade and licensing barriers.*

F. TRADE DEVELOPMENT

The transition to a more knowledge-based economy from the traditional industrial economy is a world wide phenomena. Success for the Atlantic region will result from business activities that are efficient, innovative, market sensitive, and service oriented. Regional biotechnology business operators indicated that they are well positioned and can be successful in accessing world markets. Several suggested that they do not attempt to get a share of the Canadian market, but prefer to deal in the larger markets of the U.S., Europe, the Middle East and Asia. They are optimistic about global opportunities and feel the Eastern part of Canada is a good place to do business in the "new economy".

Efforts to promote Canadian bioindustry abroad have focused on helping Canadian firms find alliance partners and investment from the U.S. and Western Europe. In other important markets such as Asia-Pacific and Latin America, awareness of Canadian biotechnology capabilities is low. Japan, for example, is a difficult market to penetrate, but is a major market for certain products of biotechnology.

Recommendation 12: ***ACOA and Industry Canada implement a trade and investment promotion initiative directed at the major global markets for biotechnology products and services.***

Recommendation 13: ***ACOA undertake a study to identify new products, new market opportunities and a strategic approach to further development of the biotechnology sector.***

G. REGULATORY ENVIRONMENT

The regulatory environment is currently in transition as regulatory agencies are merged, down-sized and retasked. The changes in the regulatory sector are exacerbated by the shortage of regulators versed in biotechnology. The basis for the regulations is often poorly understood and the response time far too slow. The private sector also harbors the view that the regulations are unnecessarily stringent**.**

Recommendation 14: ***ACOA and Industry Canada examine the impact of the current regulatory regime on the Atlantic Canada biotechnology industry.***

H. CONSUMER RESISTANCE

Generally the Canadian consumer has a very limited understanding of biotechnology. The media tends to sensationalize it, dedicating its energies to those aspects of biotechnology that involve genetic manipulation. To date, public interest and consumer groups have raised concerns over novel foods such as genetically-engineered tomatoes and potatoes, as well as milk from cows injected with bovine somatotrophin (BST). The public attitude to biotechnology tends to be very conservative, especially toward genetic engineering. Recombinant DNA techniques, a major area of potential biotechnology products, is expected to be key to genetic improvement work in the aquaculture sector, as fish breeders access new strains by biotechnology means. Consumer education and involvement in these developments will be essential, if there is to be widespread acceptance of this new technology

Recommendation 15: ***Industry Canada implement its program to educate and promote a greater sense of awareness among Atlantic consumers as to emerging biotechnologies.***

I. PUBLIC FUNDING ASSISTANCE

Startup Funding

Financing of biotechnology in Atlantic Canada is the major constraint to new business formation in the sector**.** Unlike the traditional manufacturing sector that depends upon engineering solutions, biology involves life processes. Characteristically, the related technologies are commercialized at a much slower pace than physical and engineering processes. Venture capitalists, for the most part, will not invest their money until they can be shown that the researcher has a product that will sell at a profit. To demonstrate the value of the product, the researcher must do further development and scale-up work that consumes money. Most scientists do not have it, so access to public funding is essential.

Recommendation 16: ***The appropriate federal and provincial business development agencies examine their policies and programs with the objective of overcoming barriers to their effectiveness in the biotechnology sector.***

Project Review Process

There is a major need for bioscience knowledge in the funding agencies. The level of scientific knowledge demonstrated by project evaluators in the various federal and provincial funding agencies was criticized by science entrepreneurs. Scientists stated that they found it difficult to communicate with business-oriented account managers. A monitoring and review process that ensures that both the science side and the business side are included were said to be essential to project success.

Recommendation 17*:** ***Every biotechnology project submitted to a federal funding agency for funding assistance be subject to a scientific evaluation, prior to consideration for funding. Each funding agency should enter into a standing offer contract with individual Atlantic region biological scientists competent to carry out a peer review of project proposals.

Recommendation 18*:** ***Every federal and provincial funding agency should include a qualified biological scientist within its implementation staff, with responsibility for coordination of the scientific review of project proposals.

Program Rules

Atlantic entrepreneurs, in the absence of private risk capital, have three alternatives: to seek public assistance from the IRAP Program or from ACOA; application to other national and provincial assistance programs; or to partner with or sell their idea to another company. As noted above, entrepreneurs have difficulty obtaining private sector backing until they have proof that a process or technology will work or be profitable. ACOA program funding for this purpose was said to be difficult to use within the current repayability provisions and program rules. The requirement that money be spent up front and in a rather short time is particularly onerous. It takes time to work out processes, develop and test protocols and standard operating procedures, and get them approved by the regulatory authorities. In addition, very specialized equipment may be required which cannot be ordered off the shelf. (Note: during the course of this study ACOA modified its Business Development Program to take some of the biotechnology entrepreneurs' concerns into account.)

Recommendation 19: ***That ACOA program rules, particularly those relating to the length of the control period and the policy of repayability, be reviewed with representatives of the biotechnology industry in the region.***

STUDY CONTACTS

THE PRIVATE SECTOR

ADI Group Inc.	Andrew L. Steeves, Vice President
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REFERENCES

1. Atlantic Provinces Economic Council, 1989; Biotechnology in Atlantic Canada, p. 33.

2. Ernst & Young, 1994; Canadian Biotech '94: Capitalizing on Potential.

3. Canadian Forest Service, 1996; Science and Technology Networks: 1996 Consultations - Research Partnerships and Alliances, p. 18.

4. Fisheries and Oceans Canada, 1995; Federal Aquaculture Development Strategy, p.18.

5. Haynes, F, 1996; Canadian Biotechnology, 1996 Directory, p. 589.

6. Heller, J. 1996; Highlights from the recent background economic study of the Canadian biotechnology industry; Canadian Biotechnology, 1996 Directory: 9-12.

7. Industry Canada, 1996; Strategis: Research/technological strengths; Extensive Research and Development in Canada (Health).

8. Industry Canada, 1996; Strategis: R&D in Biotechnology.

9. KPMG Management Consultants, 1995; Improving Canadian biotechnology regulation - A study of the U.S. experience, p. 79.

10. Kimber, S. et al., 1996; InnovatioNS: Technology in Nova Scotia. p. 21.

11. Koehler, G.A., 1996; Bioindustry in the U.S., California and the World; Internet.

12. National Research Council, 1996; Vision to 2001, p. 25.

13. Office of Consumer Affairs, 1996; Biotechnology: What is it all about? Consumer Quarterly 1(3).

14. Paget Consulting Group, 1996; Building Long-term Capability Now; Canadian human resources study in biotechnology.

15. Tyler, The Honourable Doug, 1995; New Brunswick Biotechnology and Technological Innovations Strategy: Building the Bridge Between the Old and the New Economies, p. 28.

16. U.S. International Trade Administration, 1996; Biotechnology.