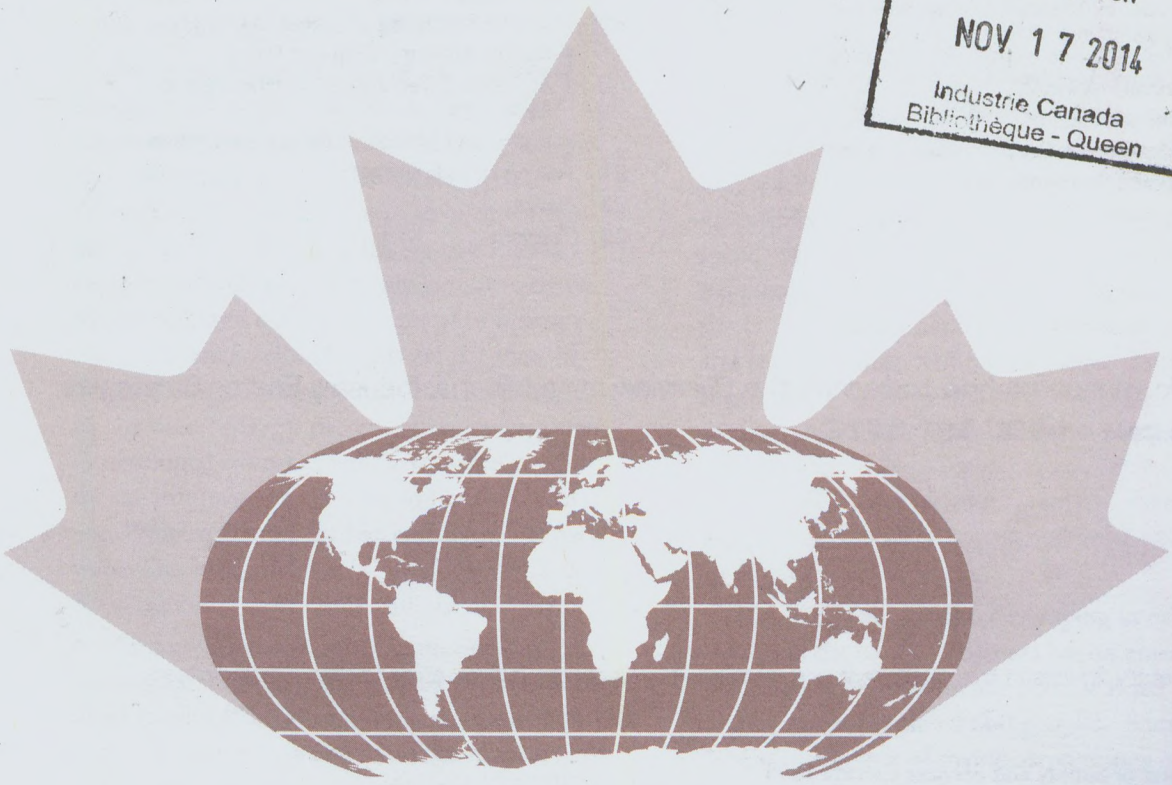
5 BIOTECHNOLOGIES

CANADA'S EXPORT STRATEGY

The International Trade Business Plan

1995/96



An Integrated Plan for Trade, Investment and Technology Development

The International Trade Business Plan is made up of an **Overview** highlighting Canada's international business development priorities, and a series of **Industry Sector Strategies**, which include lists of planned international activities. The following documents are available:

Overview

1. Advanced Manufacturing Technologies
2. Agriculture and Food Products
3. Aircraft and Parts
4. Automotive
5. Biotechnologies
6. Business, Professional and Educational Services
7. Chemicals, Plastics and Advanced Materials
8. Construction Products
9. Consumer Products
   - Apparel and Fur
   - Textiles
   - Footwear
   - Sporting Goods (including recreational watercraft)
   - Tools, Hardware and Housewares
   - Residential Furniture
   - Business and Institutional Furniture
10. Cultural Industries
11. Defence Products
12. Environmental Equipment and Services
13. Fish and Sea Products
14. Forest Industries
15. Information Technologies and Telecommunications
    - Sector Overview
    - Computers and Peripheral Equipment
    - Electronic Components
    - Geomatics
    - Instrumentation
    - Software Products and Computer Services
    - Telecommunications
16. Medical and Health-Care Products and Services
    - Medical Devices
    - Pharmaceuticals
    - Health-Care Services
17. Minerals and Metals
18. Oil and Gas Products and Energy Equipment
19. Power Equipment
20. Primary/Secondary Industrial Machinery
    - Mining, Forestry, Pulp and Paper
    - Agricultural Technology, Machinery and Equipment
    - Ocean and Marine Shipboard Technology
21. Rail and Bus Equipment
22. Space
23. Tourism

For information on how to receive the Overview, or additional Industry Sector Strategies, please call: **1-800-267-8376**

All monetary figures in this document are expressed in Canadian dollars unless otherwise indicated.

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Biotechnologies

Biotechnologies involve the use of either naturally occurring or engineered biological systems in the production of goods and services. Commercial applications of biotechnology occur in a wide range of sectors, but primarily in the health-care, agri-food and, to a lesser extent, environmental sectors. Thus far, biotechnology has had the greatest impact in the health-care sector, and is in the early stages in the agri-food and environmental sectors. Bio-industries in all three sectors are distinguished from their non-biotechnology counterparts by their relatively high level of research and commitment to innovation, and are therefore discussed together in this section of the International Trade Business Plan.

International Environment

Worldwide, it is estimated that between 3000 and 4000 companies, employing about 250 000 people, represent the more broadly defined bio-industries, which use biotechnology in some aspect of their products and services. The number of companies whose core business involves biotechnology is smaller, at approximately 2000 to 2500, employing approximately 150 000 people.

Biotechnology is still in the early stages of development, somewhat like the software or telecommunications industries were 15 to 20 years ago. Nevertheless, its influence and socio-economic impact are expected to be at least as pervasive. The impact in health care is already evident, as biopharmaceuticals are currently on the market, and over 50 percent of new drugs in North American clinical trials are products of biotechnology. In agriculture, it is predicted that by the year 2005, 50 percent of the crops grown in developed countries will be transgenic. As for the environment, the market in the United States and Western Europe for bioremediation of toxic waste sites is expected to increase fivefold, from $200 million in 1993 to $1 billion in 2000.

Around the world, most biotechnology companies are heavily committed to research and development (R&D) programs, and only relatively few have sufficient products on the market to be considered profitable. An estimated $15-billion worth of biotechnology products was sold worldwide in 1993. Depending on how well biotechnology regulations are implemented and harmonized internationally, and how well public opinion accepts products of biotechnology, it is estimated that total sales will grow rapidly over the next few years to reach $75 billion to $150 billion by the year 2000.

The major international competitors for Canadian bio-industries are found in the United States, Japan and Europe. The U.S. has by far the most developed and diversified bio-industry, with 1270 core biotechnology firms employing 97 000. Statistics for Japan are difficult to compare with those for other countries, since biotechnology in that country is mostly carried out within large corporations where it is not usually the prime focus. Nevertheless, even though the industrial paradigm is different, Japan is second only to the U.S. in the development of its bio-industries, and is positioning itself for the future through continued commitment to technological R&D, or through domestic and international acquisitions. The European bio-industry began to develop later than its U.S. and Canadian counterparts, and now has an estimated 370 core biotechnology firms employing about 15 000.

Bio-industries are also developing in other regions of the world. Australia has an emerging bio-industry (approximately 30 core firms employing an estimated 600 people). 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 also developing in the region, especially in Singapore. Latin America has similar developments, with large agri-food companies such as breweries diversifying into value-added products through biotechnology, but also with a few core firms such as BioSidus, a biopharmaceutical manufacturer in Argentina.

Canadian Position

The Canadian biotechnology effort is small when compared to that of the U.S. and Japan, but compares favourably with that of other countries. Approximately 300 companies employing 13 000 form the broadly defined bio-industry in Canada. Some 120 firms employing 6500 have biotechnology as their core business. In 1993, the core biotechnology firms invested approximately $250 million in R&D.

The overall bio-industry in Canada is growing rapidly. A recent survey of the more broadly defined bio-industry indicated that from 1989 to 1993, sales grew at an average annual rate of 24 percent, exports at 19 percent and employment at 14 percent. In 1993, estimated total sales were almost $2 billion, and exports were approximately $750 million.

Regulation

On the domestic front, the regulatory environment is a major issue affecting international competitiveness. Countries that have set up more stringent or less responsive regulatory regimes for biotechnology products have experienced a loss of investment, as well as the movement of R&D and manufacturing activities to countries with more favourable regulatory systems. Canada is currently developing its biotechnology regulations, and a top priority for the federal government is the early finalization and promulgation of these regulations, ensuring that its regulatory practices are harmonized with those of its major trading partners, especially the United States. The objective is to develop a system that effectively manages risk, while ensuring that regulatory requirements for bringing biotechnology products to market in Canada are not more onerous or time consuming than those of our major trading partners.

Investment

The Canadian bio-industry, like its counterparts in the U.S. and Europe, is experiencing increasing difficulty in raising capital, at a time when its capital requirements are rapidly expanding. While alliances with multinational pharmaceutical companies may address the needs of health-related bio-industries to a large extent, other sources are needed to address capital requirements in the agri-food and environmental bio-industries.

On the domestic front, efforts continue to encourage the private sector to place more resources in venture capital for promoting the start up and development of early-stage bio-industries. In some cases, tax incentives (such as those for labour-sponsored venture capital funds) are being used to help achieve this objective. In other cases, key private-sector institutions are taking the initiative. One such venture is Neuroscience Partners LP, which was formed by the Royal Bank, the Caisse de dépôt et placement du Québec, MDS Health Ventures, Manufacturers Life Insurance Company and several pension funds.

On the international front, an information package highlighting the Canadian investment climate for biotechnology, including Canadian tax incentives, government programs and research capabilities, is being developed by the Department of Foreign Affairs and International Trade (DFAIT) for use by Canadian missions abroad to promote Canada as a place to invest in biotechnology. Another initiative by DFAIT focusses on using contacts with international investors to raise capital for early stage firms in the agri-food and environmental biotechnology sectors. They have traditionally received less attention from investors than the health-care biotechnology sector.

Human Resources

Canada appears to have an adequate supply of highly skilled researchers in the science and engineering disciplines related to biotechnology, although skill shortages are evident in the scale-up and production process and in business management.

A comprehensive survey of future human resource needs by the Canadian bio-industry will be carried out by Human Resources Development Canada, and the results will be made available to educational institutions so that curriculums may be revised as necessary. To upgrade Canadian biotechnology firms' international business skills, Industry Canada (IC) will include issues relating to biotechnology companies in sectoral training programs being developed by the Forum for International Trade Training (FITT). The feasibility of including biotechnology in a pilot course directed at the agri-food industry is being investigated by FITT.

Intellectual Property Protection

Changes to the Canadian Patent Act to increase the length of patent coverage for pharmaceuticals have already enhanced Canada's attractiveness as a place to develop and manufacture biopharmaceuticals. Other changes, to be phased in over the next year, deal with the handling of sequencing data and the deposit of biological material. Beginning in 1996, the Canadian Patent Office will have the capacity to process sequencing data in electronic form for nucleotides and peptides. This will lead to more efficient processing of patent applications, and will provide a more accessible database for the public. In the short term, Canada will become a signatory of the Budapest Treaty, so that by 1996, the deposit of biological material in any of the collections of the international depository authorities may be considered as part of a patent disclosure in Canada.

Health Biotechnology

Canada has a world-class bioclinical research base in its medical schools and teaching hospitals. As a result, companies focussed on biotechnology as it applies to human health form the largest single group in the Canadian bio-industry, accounting for nearly 48 percent of all companies and 71 percent of the core industry. This group includes developers and manufacturers of diagnostics and therapeutics, as well as suppliers of biologicals (antibodies, antigens, fine biochemicals). It has also received more direct investment by the private sector (an estimated $150 million in 1993) than any other bio-industry group. Over the period 1989-93, the annual average growth rates of sales, exports and employment were well above the industry average, at 27 percent, over 50 percent and 17 percent respectively. In 1993, Canadian health biotechnology sales were approximately $1 billion, exports were approximately $300 million and employment approximately 8000.

Companies in the diagnostics segment of this sector are challenged by the fast pace of technological change in this field, as well as by the cost-containment demands on health-care systems worldwide. These companies need to identify technology to advance their product lines, investment capital to support their R&D, and marketing partners.

Companies in the therapeutic segment of this sector, especially biopharmaceutical firms, are heavily committed to R&D, product development and increasingly, clinical trials. The bulk of the products, some of which represent billion-dollar-a-year markets, have yet to reach the marketplace. The impact of health-care cost-containment pressures has been to reduce the flow of investment from public equity markets. As a result, biotherapeutics companies need to identify alternative international sources of investment capital to bring their products to market. They also need to identify alliance partners who can help them with regulatory approvals and penetration of foreign markets.

Agri-food Biotechnology

Canada has developed a strong competitive position in animal husbandry (embryo transplants, high-quality bovine semen), animal protection (veterinary and aquaculture vaccines), plant breeding, biological fertilizers, biological pest control and aquaculture. Almost 20 percent of the core Canadian bio-industry is in the agri-food sector, forming the second-largest industry grouping. Over the period 1989-93, the annual average rates of growth for sales, exports and employment were 17 percent, 7 percent and 4 percent respectively. In 1993, agri-food biotechnology sales were almost $600 million, exports approximately $400 million and employment about 4000. The lower growth rates for this sector, as compared to health biotechnology, reflect two related factors:

- private-sector investors have tended to neglect this sector in favour of the perceived higher-profit potential in other sectors such as health care; and
- development of a responsive regulatory regime in Canada for agri-food biotechnology products has experienced significant delays when compared with the United States.

Aquaculture is an increasingly important segment of the agri-food bio-industry worldwide. The global annual catch of fish from the wild has increased to 100 million tonnes, a level that is not likely sustainable. Currently, worldwide production from aquaculture is about 20 percent of the wild catch, but by the year 2010, it is estimated that the aquaculture catch will exceed that from the wild. Although Asia remains the largest aquaculture producer with over 80 percent of the world output, Canada's aquaculture output has increased substantially from sales of $7 million in 1984 to almost $300 million in 1993. Salmon farming forms the largest segment of the Canadian industry, with sales of about $200 million in 1993. Since 1992, Canada has sold more farmed salmon than wild salmon. Farming of trout, arctic char, mussels, scallops and other species is also in various stages of development. Aquaculture feeds form a $150-million business for a number of Canadian companies. A fish health and husbandry industry has developed on both coasts, and is actively pursuing market opportunities with fish and shellfish farming operations in Latin America and the Asia-Pacific region. Biotechnology is playing an increasingly important role both in brood stock development and in identifying and preventing diseases that can drastically affect commercial production.

Agri-food biotechnology companies need help to identify niche market opportunities and potential joint-venture partnerships to successfully penetrate export markets. This is especially true in the emerging market countries of the Asia-Pacific region and Latin America, which have focussed on biotechnology as a means of increasing agricultural productivity while potentially decreasing the use of chemical fertilizers and pesticides.

Environmental Biotechnology

Biological systems to deal with environmental problems in air, water and soil are currently being developed. Traditional methods that consider the biological component as a "black box" still predominate. However, research is intensifying worldwide on selecting naturally occurring organisms that break down specific toxic substances; improving the understanding of the conditions that make these organisms work more effectively; and, more recently, developing genetically modified organisms specifically designed to break down certain persistent toxic chemicals.

Less than 10 percent of the Canadian bio-industry is in the environmental sector. About 20 to 30 Canadian firms have developed the biological/microbiological expertise to form the core of an emerging environmental bio-industry. A much larger number of consulting engineering firms are active in site remediation, wastewater treatment, etc., but have little or no in-house biological expertise. In 1993, Canadian sales of environmental biotechnology products and services were estimated to be about $25 million

to $50 million, exports about $10 million to $20 million and employment about 500 to 1000.

Canada needs to promote the upgrading of technical capabilities in its bio-environmental companies through stronger linkages with researchers in this field. Efforts will continue to build more company participation in existing research networks in the bio-environmental field. These augmented networks will promote the flow of information not only on new technology developments but also on markets and new international business opportunities in this field. This will encourage the development of Canadian strategic alliances for export market penetration. Formation of strategic alliances is especially important, since most of the Canadian environmental firms with biological/microbiological expertise are small and focussed on niche markets, and will only be able to compete in international markets by forming partnerships to provide the full-service capabilities offered by their multinational competitors. Several consulting engineering consortia have recently been formed in Canada to address this issue, and have begun to focus on penetrating export markets in North America and the Asia-Pacific region. Since these consortia currently have relatively little in-house biotechnology expertise, attempts are being made to promote links with internationally active biotechnology firms.

Strategic Direction

Upgrading Canadian Trade Promotion Capabilities

Biotechnology products often differ from their non-biotechnology counterparts. For example, biological fertilizers are specific to certain types of plants and soils, and function in quite a different manner than their chemical counterparts. Trade promotion initiatives need to take this into consideration.

Trade commissioners and commercial officers in Canadian missions abroad will receive information and orientation to better promote the rapidly expanding stream of Canadian biotechnology products and services. It is important to do this now, since a significant number of Canadian biotechnology products are already on the market, and a much larger number will soon enter the marketplace. Industry Canada will collaborate with the private sector to put information on the Canadian industry and its capabilities into an easily accessible electronic format, using IC's INSIGHT information system. IC will work with DFAIT to make this information system available to trade promotion personnel. Also, IC will develop orientation sessions in collaboration with the National Research Council (NRC), to profile specific segments of the Canadian bio-industry to groups of trade commissioners during their periodic visits to Canada. As electronic information capabilities develop, better tools will be available to promote Canadian products and services abroad. The first prototype multimedia marketing systems based on CD-ROM technology have already been demonstrated (profiling companies in the Canadian telecommunications sector), and application of this medium to promote Canadian biotechnology firms will be explored over the next few years.

Intelligence on Business Climate and Market Opportunities

Access to timely market intelligence is a key factor for success in international business. As trade commissioners and commercial officers in Canadian missions abroad increase their awareness of Canada's bio-industries, it will be possible to improve the quality of the business and market intelligence that they gather on behalf of the small- and medium-sized firms that form the bulk of this industry grouping. These firms need information from abroad on the business climate (e.g. biotechnology regulations, intellectual property protection for biotechnology inventions), business opportunities, and key business and government contacts. In some cases this intelligence is already available in the form of published documents, but special studies may be required in other cases, especially for emerging markets.

Biotechnologies

Activity	Date	Location	Dept.	Contact
Asia-Pacific South				
Business Financing for Emerging Biotech Firms: Promo	TBD	Various	DFAIT	613-992-5339
Incoming Mission from Australia	30-Jun-95	Montréal	IC	514-283-8813
Canada				
Market Profile (Mexico)	TBD	Canada	DFAIT	613-996-8625
Pharmaceutical Strategic Alliance Mission from Texas	Oct-95	Montréal, Québec City	DFAIT	613-944-9482
East Asia				
Outgoing Mission to Promote Canadian R&D	Sep-95	Seoul	DFAIT	613-996-2807
United States				
Strategic Alliance Facilitation Program	TBD	Canada/Various	DFAIT	613-944-9482
Venture Capital Roundtable on Biotech	TBD	Philadelphia	DFAIT	613-944-9482
Biomedical Study: Update	TBD	Chicago	DFAIT	613-944-9482
Breakfast Seminars: Strategic Alliances	TBD	U.S./Various	DFAIT	613-944-9482
Baylor College of Medicine (Houston) Technology Transfer	05-May-95	Montréal, Vancouver	DFAIT	613-944-9482
BIO '95: Info Booth	20-May-95	San Francisco	DFAIT	613-944-9482
Midwest Regional Strategic Alliances Mission	Jun-95	Evanston	DFAIT	613-944-9482
Midwest Biotech: Industry Guide	Jun-95	Chicago	DFAIT	613-944-9482
Mission to Michigan Biotech Association	Jun-95	Ann Arbor	DFAIT	613-944-9482
Pharmaceutical Purchasing Organizations Strategies	Aug-95	Dallas, Houston	DFAIT	613-944-9482
Biomedical Mission from Atlanta	Sep-95	Toronto, Montréal	DFAIT	613-944-9482
Environmental Biotech Partnering Event	Sep-95	Boston	DFAIT	613-944-9482
Biotech Technology Transfer: Guide	Sep-95	Minneapolis	DFAIT	613-944-9482
Incoming Strategic Alliance Mission	Oct-95	Quebec	DFAIT	613-944-9482
Connect San Diego: Presentation	Oct-95	San Diego	DFAIT	613-944-9482
St. Louis Biotech Forum: Investment Roundtable	Oct-95	St. Louis	DFAIT	613-944-9482
Cross-Canada Biotech Industry Seminars: Strategic Alliances	Nov-95	Canada/Various	DFAIT	613-944-9482
NEBS Mission from Eastern Canada	Nov-95	Boston, Baltimore	DFAIT	613-944-9482
Bio-pharm Investment Mission from Minneapolis	Jan-96	Ontario, B.C.	DFAIT	613-944-9482
Biotech Forum: Strategic Alliances	Feb-96	Milwaukee	DFAIT	613-944-9482

Note: Dates and locations are subject to change.

Acronyms and Initialisms Used in The International Trade Business Plan

(This list does not include sector-specific references)

ACOA	Atlantic Canada Opportunities Agency
AG Can	Agriculture and Agri-Food Canada
ASEAN	Association of Southeast Asian Nations
BBS	electronic bulletin board system
BOSS	Business Opportunities Sourcing System
CCC	Canadian Commercial Corporation
CIDA	Canadian International Development Agency
CIS	Commonwealth of Independent States
CSA	Canadian Standards Association
DFAIT	Department of Foreign Affairs and International Trade
DFO	Department of Fisheries and Oceans
DND	Department of National Defence
EC	Environment Canada
EDC	Export Development Corporation
EU	European Union
FITT	Forum for International Trade Training
FORDQ	Federal Office of Regional Development - Quebec
FSU	former Soviet Union
FTA	Canada-U.S. Free Trade Agreement
GATT	General Agreement on Tariffs and Trade
GDP	gross domestic product
GNP	gross national product
HRDC	Human Resources Development Canada
IC	Industry Canada
IDRC	International Development Research Centre
IFI	international financial institution
ISO	International Standards Organization
ITBP	International Trade Business Plan
ITC	International Trade Centre
MAPAQ	Ministry of Agriculture, Fisheries and Food of Quebec
MDB	multilateral development bank
NAFTA	North American Free Trade Agreement
NATO	North Atlantic Treaty Organization
NRC	National Research Council
NRCan	Natural Resources Canada
NRCan-CFS	Natural Resources Canada - Canadian Forest Service
OECD	Organization for Economic Co-operation and Development
PEMD	Program for Export Marketing Development
R&D	research and development
SMEs	small- and medium-sized enterprises
UNEP	United Nations Environmental Program
WED	Western Economic Diversification
WTO	World Trade Organization

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GNP	gross national product
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IDRC	International Development Research Centre
IFI	international financial institution
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MDB	multilateral development bank
NAFTA	North American Free Trade Agreement
NATO	North Atlantic Treaty Organization
NRC	National Research Council
NRCan	Natural Resources Canada
NRCan-CFS	Natural Resources Canada - Canadian Forest Service
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