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# The 1998 Canadian Biotechnology Strategy: An Ongoing Renewal Process

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Cat. No. C21-22/5-1998  
ISBN 0-662-63917-0  
52467B



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## FOREWORD

**B**iototechnology is one of the world's fastest-growing technologies. It offers significant economic benefits, particularly in exports and job creation, as well as important health, safety and environmental benefits.

Like many countries that started investing in biotechnology research in the 1980s, Canada is in a position to build on its strengths. In this context, the Minister of Industry was asked in March 1997 to launch a process to renew the country's strategy for biotechnology. The result of this renewal process is the 1998 Canadian Biotechnology Strategy (CBS). The CBS builds on its predecessor, the 1983 National Biotechnology Strategy (NBS). The centrepiece of the renewal process was a series of intensive, broad-based stakeholder consultations held in the spring of 1998.

This report summarizes the current status of the CBS, which was announced in August 1998. The document illustrates that while the renewal and

approval of the CBS are important milestones, they represent just one stage in an ongoing process. The process began in 1983 when the National Biotechnology Strategy was first established, and will continue as the CBS evolves over the coming years to address new opportunities and challenges. Canadians are invited to use this document in their reflections and discussions regarding biotechnology, and to make their views known to the CBS Secretariat.

Throughout the renewal process, the federal government met frequently with provincial officials, industry stakeholders, non-government organizations (NGOs), scientific and academic communities and other partners, and will continue to do so as the strategy is implemented. Such partnerships are an important aspect of the strategy and a crucial component in building a distinctively Canadian approach to biotechnology.

# INTRODUCTION

## WHAT IS BIOTECHNOLOGY?

Biotechnology is an umbrella term covering a broad spectrum of scientific applications used in many sectors. It involves the use of living organisms, or parts of living organisms, to provide new methods of production, make new products and find new ways to improve our quality of life. Biotechnology can enhance our health and well-being, create jobs and economic growth and support environmental sustainability.

Biotechnology has been with us for centuries. For example, we have long used yeast, a living organism, to make beer, bread and wine, bacteria to make yogurt, and bacteria and fungi to make cheese. More complex applications involve the production of antibiotics, vaccines and enzymes. As well, farmers have traditionally used plant and animal-breeding techniques to create improved fruits and vegetables, special varieties of flowers and healthier livestock.

### SOME WAYS BIOTECHNOLOGY HAS IMPROVED OUR QUALITY OF LIFE

*Earlier, more reliable disease diagnosis*

*New drug therapies and formulations*

*Crops with higher yields and greater pest resistance*

*Foods with health benefits*

*Innovative tree production and biological pest-control methods*

*New forms of bio-remediation for ecologically sound clean-ups*

*Renewable fuels to reduce greenhouse gases*

*Gene probes to monitor and track the genetic diversity of fish*

*Cleaner bio-processes, which are expected to replace more polluting chemical processes within 10-15 years*

Biotechnology is a powerful “enabling technology” with applications in many industrial sectors and holding much promise for the future. It has great potential to add to industrial efficiency, output and jobs, enhance the productivity and competitiveness of Canada’s important natural resource sectors, safeguard the environment and enhance our quality of life through improved pharmaceuticals, diagnostic medicine and food production. Many people see biotechnology as the next important “change maker” after the convergence of information, computer and telecommunications technologies, which have transformed our lives. All Canadians — producers and consumers across the country, including people in smaller communities and rural areas — will benefit from the new transformation.

## CANADIANS’ VIEWS — WHAT THE RESEARCH TELLS US

While biotechnology makes significant contributions to our lives, new techniques such as genetic engineering or DNA-based technology generate considerable discussion and some controversy over health, the environment, social issues and ethical matters. It is important for consumers to understand and be confident in and comfortable with the new DNA-based technologies.

We know through research that, for the most part, Canadians appreciate the potential benefits of biotechnology. But the research also tells us that there are concerns and information gaps. Some of these concerns go beyond traditional questions regarding price, quality and product choice to include broader ethical, social and environmental matters. Also, while Canadians have confidence in their national regulatory system, they often do not know how it applies to biotechnology products and services.

Research also points to gaps in consumer awareness and understanding. The public opinion research indicates that only 6 percent of Canadians consider themselves "very familiar" with biotechnology. Some people want better, more detailed information so that they can make more informed contributions to policy development and more informed decisions in the marketplace. For example, 58 percent of respondents said they would use labels to learn more about the use of biotechnology in particular food products.

Public awareness of biotechnology, its applications and the issues surrounding it often depends on the ebb and flow of public events and the media coverage of new developments. A complicating factor is that people often do not know about or do not understand the benefits to them of various biotechnology applications. As well, many people do not have the time, resources or interest to seek out information, particularly if they think that biotechnology products offer few benefits. Research suggests that people are more likely to accept applications such as new drug therapies that clearly address health needs, and are less likely to accept applications that offer less obvious benefits.

## RENEWING THE STRATEGY

The Minister of Industry was asked in March 1997 to coordinate a federal effort to revise the policy framework and institutional structures created for the 1983 National Biotechnology Strategy (NBS), now called the Canadian Biotechnology Strategy (CBS).

The CBS Task Force was formed to coordinate the renewal efforts of the departments of Industry, Health, Environment, Agriculture and Agri-Food (and the Canadian Food Inspection Agency), Natural Resources, Fisheries and Oceans, and Foreign Affairs and International Trade. Fifteen other federal departments and agencies also took part.

### STEPS IN CBS RENEWAL: 1997-98

1. *Set up the CBS Task Force.*
2. *Reviewed and integrated the work and accomplishments of the NBS<sup>a</sup> and the reports of other groups.<sup>b</sup>*
3. *Consulted with stakeholders and others concerning the strategy's vision, goals and principles, specific industrial sectors, and research and development.*
4. *Met with provincial representatives (provincial governments also attended the sector and roundtable consultations).*
5. *Learned Canadians' views regarding biotechnology through a poll of 1 500 individuals, 10 regional focus group sessions, and written and e-mail communications.*

<sup>a</sup> *The sixth report of the National Biotechnology Advisory Committee (NBAC), titled Leading into the Next Millennium, was an important contribution to the renewal process in terms of its considered advice on building Canadian competitiveness in biotechnology. (The full NBAC report may be viewed on Strategis at <http://strategis.ic.gc.ca/bio> or may be obtained by writing Distribution Services, Communications Branch, Industry Canada, Room 205D, West Tower, 235 Queen Street, Ottawa ON K1A 0H5, Tel.: (613) 947-7466, Fax: (613) 954-6436.)*

<sup>b</sup> *One example is the third report of the Standing Committee on the Environment and Sustainable Development, titled Biotechnology Regulation in Canada: A Matter of Public Confidence.*

The centrepiece of the renewal process was a series of intensive, broad-based stakeholder consultations that took place across the country from March to May 1998. The first set of consultations involved roundtable discussions in five cities concerning the strategy's policy framework, a proposed broad-based body to advise federal Ministers, and public perceptions and participation. The second set of consultations focussed on matters pertinent to Canada's main biotechnology sectors — health, agriculture and agri-food, environment, aquaculture, forestry, mining and energy — and biotechnology research and development (R&D).

Including web site "hits," more than 5 000 Canadian organizations and individuals participated in the CBS consultation process. In addition, during this period, federal departments and agencies maintained regular contact with industry stakeholders, the provinces, NGOs, and the scientific and academic communities.

# BACKGROUND AND CONTEXT

## GOVERNMENT COMMITMENT

Canadian governments have been supporting biotechnology for about two decades. In 1983, the federal government launched the National Biotechnology Strategy (NBS), which focussed on R&D and human resources development. In the late 1980s, the NBS was broadened to address the regulatory framework for biotechnology. The National Biotechnology Advisory Committee was formed to advise the Minister of Industry on issues related to industry growth and competitiveness. In the 1990s, as the number of biotechnology applications entering the marketplace increased, attention turned to consumer, social, ethical and other public interest issues.

The Government of Canada has consistently expressed its support for biotechnology as a priority. It is evident in the federal *Science and Technology Strategy* and the *Jobs and Growth Strategy*, as well as in federal investments in biotechnology projects available to industry through Technology Partnerships Canada (TPC) and the Industrial Research Assistance Program (IRAP). As well, in its 1997 Speech from the Throne, the government identified biotechnology as one of the important knowledge-intensive sectors targeted for future jobs and growth. The federal government currently spends approximately \$314 million a year on biotechnology R&D (this figure does not include any R&D in support of regulations), while industry invests in the order of \$341 million, and not-for-profit institutes invest about \$115 million.

Provincial governments also have made biotechnology a priority. Some provinces, such as Saskatchewan, have had well-defined biotechnology development strategies, and have been making significant financial and other commitments over an extended period. Others, such as Newfoundland, Nova Scotia, Prince Edward Island, New Brunswick, Ontario, Manitoba and Alberta, either have biotechnology strategies in place or are in the process of developing them.

Quebec and British Columbia address biotechnology in the context of their innovation or science and technology strategies. All provinces recognize the economic development potential of biotechnology and, like the federal government, recognize the need to balance economic and stewardship objectives in order to position Canada as a responsible, innovative world leader.

## DOMESTIC CONTEXT

Biotechnology is one of the world's fastest-growing technologies. The global market for biotechnology products and services is expected to more than double from \$20 billion in 1995 to \$50 billion in 2005. This and other factors, such as the growth in national and international industries and markets, growing competition from other countries and the attention given to biotechnology in several international negotiations, are shaping the CBS renewal process.

*More than 100 bio-pharmaceutical products were under development in Canada as of June 1996. More than 800 field trials to use genetically modified plants were approved in 1997, up from 200 in 1992. Most of the field trials involved canola and potatoes. In 1995, biotechnology R&D expenditures by industry centred on health (78 percent), agriculture (11 percent) and natural resources (3.1 percent).*

Like many countries that started investing in biotechnology research in the 1980s, Canada is in a position to build on its strengths. Biotechnology is changing the basis for innovation and productivity in sectors as diverse as agriculture, health care, aquaculture, forestry, mining, energy and environmental services. Together, these sectors as a whole account for more than 25 percent of Canada's gross domestic product (GDP).

The dramatic growth in biotechnology activity in Canada — from a small core of health care companies, to a community of more than 500 firms employing more than 25 000 Canadians — underscores the success of the National Biotechnology Strategy over



the past 15 years. Biotechnology-related industrial activities in Canada now generate revenues of nearly \$2 billion and exports of more than \$750 million.

*Canada ranks third after the United States and the United Kingdom in the global biotechnology market. With more than 500 firms, mostly small companies, Canada now has more biotechnology companies per capita than any other country.*

Canada and the world are at the threshold of rapid growth in the development and commercialization of new biotechnology applications. Many biopharmaceuticals and other health care applications are already available in the marketplace. Crops such as canola, corn and soybean that have been genetically enhanced to improve productivity while better protecting the environment are now being cultivated on a commercial basis. These applications may be only the tip of the iceberg as the pace of commercialization accelerates. It is anticipated that functional foods (e.g. lower or zero cholesterol oil), nutraceuticals (e.g. edible vaccines), cures for over 4 000 genetic diseases, and reductions in pesticides and chemicals in agriculture and manufacturing will rapidly impact on our quality of life.

Biotechnology is a key component of the knowledge-based economy that directly generates many new jobs and business opportunities, and supports the competitiveness of some of Canada's most important economic sectors. Biotechnology has the potential to increase Canada's international competitiveness and promote sustainable development in key economic sectors.

*The use of technology is integral to increasing the world's food production capacity in the face of environmental concerns, limited arable land and continuing population growth. Biotechnology therefore plays an increasingly important role in agriculture and agri-food. For example, by using crops genetically engineered to be insect resistant or herbicide tolerant, farmers can manage their crops more effectively and improve yields while applying fewer chemical pesticides and herbicides.*

All regions of Canada have benefited from the growth of biotechnology. Science-based organizations and core biotechnology companies are distributed broadly across the country. Quebec, Ontario, Alberta and British Columbia have strong bio-health care sectors. In Quebec, the provincial government has made a concerted effort to develop biotechnology and pharmaceuticals as a key knowledge-based part of the Quebec economy. British Columbia's strong bio-health care sector is due in part to significant university spinoff activities and favourable listing procedures with respect to venture capital and the Vancouver Stock Exchange.

Saskatchewan, which has a strong infrastructure of government, university and federal departments, is attracting agricultural-based biotechnology firms. Ontario also has developed strong clusters of health and agriculture-based activity. Alberta and Manitoba are seeking to develop health-related biotechnology industries. Atlantic Canada is undertaking initiatives in aquaculture, health and forestry.

## INTERNATIONAL CONTEXT

Around the world, especially in other G-7 countries such as the United States, the United Kingdom, Germany and Japan, national governments are targeting biotechnology as a strategic enabling technology to support growth and international competitiveness. As a result, the Canadian biotechnology industry faces formidable competition from American, German and other companies that have benefited from major biotechnology and related government initiatives in their countries. The downstream impacts may also have significant effect on the relative competitiveness of the industries that use biotechnology products and services (e.g. agriculture, health, environmental, forestry, pulp and paper and fisheries).

Biotechnology issues are front and centre in many international fora. For instance, Canada joins several other nations in working on the United Nations' Biosafety Protocol. The purpose of the protocol is to protect biological diversity from potential adverse effects resulting from the transboundary movement of living modified organisms, including those made through biotechnology. It will also address the needs of developing countries to develop the capacity to assess and manage potential risks. Canada is also a member of the CODEX Alimentarius Commission and is working with the CODEX Committee on Food Labelling to arrive at a common international position on labelling.

In the context of the renewal of the Canadian Biotechnology Strategy and the World Trade Organization's review of the Trade-Related Aspects of Intellectual Property (TRIPs) Agreement, the government will be conducting consultations to develop a Canadian policy on the patenting of higher life forms. Biotechnology patent issues include, among others,

whether and to what extent patent claims covering plants, animals and human body parts should be allowed, what exemptions and safeguards are needed to protect the public interest and whether or not ethical and moral aspects should be considered in granting patents.

In 1997, the United Nations Educational, Social and Cultural Organization (UNESCO) adopted the Universal Declaration on the Human Genome and Human Rights. Canada is playing an active role in ensuring domestic and international implementation of the declaration and in addressing unresolved concerns shared by many countries.

Having a well-articulated national strategy not only will help Canada realize biotechnology's full benefits in terms of jobs, economic growth and quality of life, but also will allow it to participate responsibly and effectively in international negotiations and promote the country's position on these matters.

# ELEMENTS OF THE 1998 CANADIAN BIOTECHNOLOGY STRATEGY

## CANADIAN BIOTECHNOLOGY ADVISORY COMMITTEE

An important element of the renewed CBS is the creation of an expert, arm's-length committee to advise Ministers on biotechnology issues, raise public awareness and engage Canadians in discussions on biotechnology matters.

### SOME PROMINENT GUIDING ETHICAL PRINCIPLES AND VALUES IDENTIFIED IN OTHER COUNTRIES

*Human Dignity: respect for human dignity as a primary principle of decision making*

*Beneficence: recognition that the purpose of biotechnology should be to enhance the quality of life*

*Biological Diversity: a commitment to safeguard biological diversity*

*Human Health and Safety: protection of human health and safety as a guiding principle*

*Individual Autonomy: recognition of each individual's right to make informed decisions about his or her use of biotechnology*

*Protection of the Vulnerable: a commitment to protect those who cannot act for themselves*

*Respect for Animals: a commitment to the ethical use of animals in research*

*Sustainable Development: a commitment to consider the needs of both present and future generations*

Advisory committees are increasingly the way of the future in biotechnology, and Canada joins other forward-thinking countries such as the U.S., the U.K. and the European Union in adopting this approach. In the U.S., for example, the President's National Bioethics Advisory Commission addresses socio-ethical issues,

provides high-level, broadly based public advice to the government and acts as an intermediary in receiving and assessing input from the public. In the U.K., the Human Genetics Advisory Commission reports publicly on issues arising from advances in human genetics that could have social, ethical and economic consequences. In the European Union, the Group of Advisers on the Ethical Implications of Biotechnology expanded its mandate in 1998 and became the European Group on Ethics in Science and New Technologies, providing confidential advice to the European Union and its member governments. Other nations such as the Netherlands and Denmark have conducted consultative conferences and other ambitious public consultation initiatives to better inform and involve their citizens in decisions about biotechnology and genetic engineering.

### POSSIBLE ROLES OF THE ADVISORY BODY

*Is the advisory body an appropriate mechanism to facilitate a dialogue among Canadians and with the government, or should the body concentrate on receiving public input and providing advice and recommendations to Ministers?* – Question in the Roundtable Consultation Document.

*The participants' responses to this question were interesting and helpful. They felt that the advisory body should perform both roles, and developed and described models that would use dialogue as a key source of input. They suggested that several interactive processes could be used, including consultative conferences, citizen juries, science courts, traditional public opinion research, secondary research, deliberative polling, science shops and affinity networks.*

*Participants also stressed the importance of providing the results of these activities to the public, using a variety of channels such as the Internet, print media and 1-800 telephone numbers. In general, they urged a more creative approach to communicating with the public, particularly young Canadians.*

A common task undertaken by several of these bodies is to help build consensus toward broad ethics frameworks, which are then used to arrive at socially acceptable national policy positions on biotechnology. These frameworks help to guide legislation, regulation, patent law and the deliberations of the advisory bodies themselves. Some countries have effectively used public consultation and dialogue to identify the “core values” that make up an ethics framework. International experience shows that public involvement in identifying these values is important in giving the subsequent framework legitimacy.

CBS consultation participants analyzed some of these international models, as well as selected domestic successes such as the Information Highway Advisory Council. They agreed that a new advisory body was essential in helping to address biotechnology’s opportunities and challenges and the unpredictable events that will continue to test the limits of our current systems. Participants stressed that the body’s members should be experts able to transcend narrowly defined stakeholder interests in order to reflect and respond to the wider concerns of Canadians. Support for creation of an external advisory body was expressed by nine out of 10 Canadians in the public opinion research.

The government will establish a new advisory body — named the Canadian Biotechnology Advisory Committee — to provide government with independent, impartial advice on crucial policy issues associated with the ethical, social, regulatory, economic, scientific, environmental and health aspects of biotechnology. The focus will generally be on horizontal issues that cut across sectors. It may advise on policy directions concerning regulatory matters, but will not arbitrate regulatory decisions.

The Advisory Committee will also provide Canadians with an ongoing forum to voice their views and participate in a “national conversation” on biotechnology issues. It will engage Canadians on a broad range of biotechnology issues from stewardship and ethics to economic development. This emphasis on public participation is a key component of the strategy.

Reflecting the views of consultation participants, the advisory committee will consist of 12 to 20 individuals from various fields, appointed on the basis of individual merit rather than as representatives of interest groups. As required, the committee should be free to strike ad hoc working groups that include interested groups and individuals. It will report to the new Biotechnology Ministerial Coordinating Committee, which is representative of the key biotechnology sectors.

## **POLICY FRAMEWORK**

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At the core of the renewed CBS is a policy framework. The framework includes a vision, guiding principles and strategic goals. Consultation participants concurred that the vision should emphasize quality of life and position Canada as a responsible world leader, that the guiding principles must be based on Canadian values, and that the strategy’s objectives form the basis for implementing the strategy.

The policy framework is designed to integrate social, ethical, health, economic, environmental and regulatory considerations; strike an appropriate balance between social and economic matters; promote Canadian values and interests; provide the basis for effective intergovernmental relationships; foster partnerships with stakeholders; establish open, transparent processes; and increase public understanding and confidence.

The CBS **vision** is:

*To enhance the quality of life of Canadians in terms of health, safety, the environment and social and economic development by positioning Canada as a responsible world leader in biotechnology.*

The **guiding principles** centre on reflecting Canadian values; engaging Canadians in open, ongoing, transparent dialogue; promoting sustainable development, competitiveness, public health, scientific excellence and an innovative economy; and ensuring responsible action and cooperation domestically and internationally.

The strategy's goals are to:

- ◆ ensure that Canadians have access to, confidence in and benefit from safe and effective biotechnology-based products and services
- ◆ ensure an effective scientific base and make strategic investments in R&D to support biotechnology innovation, the regulatory framework and economic development
- ◆ position Canada as an ethically and socially responsible world leader in the development, commercialization, sale and use of biotechnology products and services
- ◆ be sensitive to the need for developing countries to build indigenous capacity to assess and manage the risks of biotechnology
- ◆ improve public awareness and understanding of biotechnology through open, transparent communications and dialogue
- ◆ solicit broadly based advice to the government on biotechnology
- ◆ promote awareness of, and maintain excellence in, Canada's regulatory system, based on the Federal Regulatory Framework for Biotechnology (1993), to ensure the country's continued high standards for protecting health, safety and the environment (see Annex C)

- ◆ support the development of a Canadian biotechnology human resources strategy to ensure an adequate supply of highly qualified personnel
- ◆ work with the provinces, territories, business, academia, and consumer and other interest groups to develop and implement action plans addressing stewardship issues (for example, health, safety, environment, and social and ethical matters), sectoral opportunities and horizontal challenges (for instance, R&D, regulations, human resources, investment, innovation, technology transfer and market access).

*Many important partnerships are already in place. For example, with respect to federal-provincial interactions at the working level, significant biotechnology-related collaborations exist between federal departments/agencies and provincial/regional organizations, and many include industry and universities. Examples include co-locations for research in agriculture, health and forestry and, in the environmental area, cooperative programs for test sites related to hazardous waste clean-up are being established in several locations.*

## ROLES, RESPONSIBILITIES AND PARTNERSHIPS

The consultations and policy framework benefited from a consensus on the roles and responsibilities of government and the importance of partnerships in advancing Canada's biotechnology capability.

The federal government has wide-ranging responsibilities for biotechnology. It evaluates potential new and modified products to protect health, safety and the environment; supports the development and application of the scientific knowledge base; advances the principle of sustainable development; provides ways for Canadians to voice their views; develops framework policies to support the responsible development, application and export of biotechnology products and services; facilitates Canadians' access to accurate, understandable information; and promotes Canada's regulatory approach internationally.

Many consultation participants underlined that the federal government should continue to play a leadership role by working with its partners in knowledge-intensive sectors such as biotechnology where Canada is strong and has opportunities for growth and global leadership. It can foster strategic investments, create and strengthen partnerships, support the development of a skilled work force and improve access to international markets. The federal government can also improve Canadians' access to information regarding international technology and science, technical standards and biotechnology-related products and markets. Access to this information — for all Canadians and

companies of all sizes — is being supported by related federal initiatives to support electronic commerce, connectedness and the Information Highway.

The consultations and resulting policy framework also recognize the important contributions of others. Many provincial governments actively promote the competitiveness of specific biotechnology sectors, applications and companies, and inform the public regarding the benefits and possible risks of this technology. Existing arrangements with the provinces focus largely on ways to pool human and financial resources to capitalize on and expand regional clusters of biotechnology-related activity, particularly in the food and health care sectors. Consumer and environmental groups and other NGOs are active and effective in providing information to the general public, in working with industry to promote shared interests and in contributing to government policies.

Perhaps most importantly, as the technology matures and as more biotechnology applications are ready for market, the private sector has the lead responsibility for commercialization, securing financing, promoting its products in national and international markets, and meeting its customers' information and product needs. Industry is also responsible for ensuring that its decisions and practices are consistent with Canadian laws, social values, ethical norms and international obligations.

## TEN KEY THEMES IN THE CBS WORKPLAN

Consultation participants provided a rich harvest of ideas regarding possible actions to be considered for implementation. Over the coming months and years, the federal government will work with its partners to identify which of these actions are priorities for achieving the strategy's vision, principles and goals, and how to begin implementing them in partnership.

The proposed actions divide into 10 key themes — public confidence, communication and awareness; R&D; regulation to protect health, safety and the environment; biotechnology for public health

advantage; intellectual property; commercialization; international issues; human resources; policy relevant data collection and analysis; and sector-specific strategies. The National Biotechnology Advisory Committee's sixth report, titled *Leading into the Next Millennium*, which was published in the spring of 1998, was also helpful in determining the themes.

In the months ahead, the federal government, working with its partners, will flesh out a concrete action plan in each of the 10 areas.

(See Annex A for details on the 10 themes and proposed actions.)

## FEDERAL STRUCTURE FOR MANAGING THE CBS

A new Biotechnology Ministerial Coordinating Committee will oversee the implementation of the strategy, address issues that cut across the mandates of various federal departments and agencies, and give direction to and receive advice from the Canadian Biotechnology Advisory Committee and the government's internal coordinating structures. The Coordinating Committee is comprised of the seven federal ministers whose portfolios most closely touch on biotechnology matters: Industry, Agriculture and Agri-Food, Health, Environment, Fisheries and Oceans, Natural Resources, and International Trade.

The Ministerial Committee's work will be supported by an eight-member coordinating committee of Biotechnology Deputy Ministers and Agency Heads, a nine-member coordinating committee of Assistant Deputy Ministers and a small secretariat headed by an Executive Director. Working groups may be struck as required to address specific issues.

## NEXT STEPS

CBS consultation participants stressed the need to move quickly to address some short-term priorities to achieve the strategy's vision, principles and goals, and many, including provincial representatives, emphasized that they looked forward to participating in the next stages. Consistent with these views, the federal government has proceeded on several fronts. Key milestones for the remainder of 1998 and early 1999 include:

- ◆ establishment of Canadian Biotechnology Advisory Committee in early 1999
- ◆ outreach and further consultations by the CBS Secretariat and the federal departments and agencies engaged in biotechnology to build understanding and support for a CBS workplan built on partnerships
- ◆ discussions with partners to identify immediate priorities and develop action items based on the CBS 10 priority themes
- ◆ continued work by sectoral departments and agencies with stakeholders and others to refine sector strategies and action plans
- ◆ ongoing negotiations by departments and agencies in the international arena regarding biotechnology-related matters such as the Biosafety Protocol and the development of a common international position on food labelling
- ◆ maintaining an up-to-date CBS web site and e-mail links to the CBS Secretariat.

Just as biotechnology continually evolves, so too must the strategy respond to changing opportunities and conditions. This will help to ensure that biotechnology continues to serve Canadians, including industry and consumers, and reflect Canadian values. The Government of Canada is committed to working in close partnership with the provinces and territories, other national governments, businesses, academia, consumer groups and other NGOs to develop and implement a uniquely Canadian approach to biotechnology in the coming years.



## CONCLUSION

**W**e have made important strides in setting the stage for the future development of biotechnology so that it continues to enhance the quality of life of Canadians, promote Canadian values and interests, and balance social and economic objectives. At the same time, in many respects, our work has just begun. In the coming months, the federal government looks forward to working with its partners and learning the views of Canadians on how to implement the Canadian Biotechnology Strategy.

In the short intervening period before the Canadian Biotechnology Advisory Committee and the other consultation and information tools are fully operational, Canadians are invited to reflect on and talk about their own priorities and concerns regarding biotechnology.

It is hoped that this summary document will contribute to these reflections and discussions. We welcome your written views on the CBS and future directions.

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# ANNEX A: TEN KEY THEMES IN THE CBS WORKPLAN

## 1. BUILDING PUBLIC CONFIDENCE AND AWARENESS, AND COMMUNICATING ACCURATE, BALANCED, EASY-TO-UNDERSTAND INFORMATION TO CANADIANS

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Public opinion surveys and focus group tests suggest that, relative to people in other industrialized countries, Canadians have a comparatively high level of interest in and acceptance of biotechnology. However, Canadians' detailed knowledge of biotechnology is limited. Most important, the public wants assurance that biotechnology products and services are safe for humans, animals and the environment.

Consultation participants stressed:

- ◆ using credible sources such as government, health care professionals, scientists, educators and NGOs to convey information
- ◆ recognizing the difficulties of conveying science-based information in a thoughtful, understandable manner to reduce the potential for misinformation
- ◆ increasing the visibility of regulatory processes, providing support for the communication of regulatory matters, including risks and benefits, to the public to "de-mystify" regulatory operations, and better explaining of how they function and protect the public interest
- ◆ explaining more proactively the issues surrounding food labelling and Canada's current policy.

Possible actions:

- ◆ work with public and private sector partners to coordinate and enhance respective information and public education functions
- ◆ develop a comprehensive, coordinated communications strategy to inform Canadians about the regulatory system and other biotechnology-related activity

- ◆ articulate and promote the CBS vision in Canada and abroad
- ◆ encourage biotechnology companies and/or industry associations to work with customers and stakeholders to develop voluntary codes of practice for use in Canada and abroad
- ◆ promote research in and awareness of the ethical, legal and social issues associated with biotechnology
- ◆ celebrate Canadian achievements in biotechnology science and commercial applications.

## 2. FURTHER EXPANDING CANADA'S R&D AND SCIENCE BASE TO SUPPORT CANADIAN COMPETITIVENESS IN BIOTECHNOLOGY AS WELL AS THE REGULATORY SYSTEM

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Canada undertakes 3-4 percent of the world's R&D, based on patents and publications. However, a recent citation index review (1992-97) by the National Research Council showed that Canadians have strong citation ratings of 6 percent or more in many biotechnology-related fields. Consistent with this, biotechnology accounts for almost 10 percent of overall Canadian expenditures on R&D. These strengths have not gone unnoticed internationally. Several American and European organizations have located in Canada to take advantage of our excellent research base and infrastructure. This theme is designed to build and capitalize on these strengths.

Possible actions:

- ◆ identify key strategic choices in biotechnology platforms/domains in basic research, research to support the regulatory framework and the public good, and research related to wealth creation, innovation and commercialization (see accompanying box)
- ◆ examine the effectiveness of the R&D tax-credit policy as the technology matures and commercializes

- ◆ develop proposals for effective biotechnology foresight functions
- ◆ identify key activities and partnerships to support the formation of biotechnology clusters
- ◆ explore ways to encourage industry to develop, diffuse and adopt biotechnology for cleaner industrial products and processes.

### POSSIBLE R&D PRIORITIES IDENTIFIED IN CBS R&D CONSULTATIONS

*Genomics — including bio-informatics, sequencing amplification and functional genomics*

*Genetic engineering*

*Peptide and protein engineering*

*Antigens/vaccines/immunology*

*Bio-diagnostics*

*Bio-remediation*

*Other research areas noted in the R&D consultations included microbiology, molecular drug design, drug delivery, fermentation/bio-processing/bio-transformation and molecular signalling/molecular interactions.*

A fundamental conclusion from the R&D consultations was that, to be globally competitive, Canada must make strategic choices among possible science platforms and invest in those areas.

### 3. REGULATING TO PROTECT HEALTH AND THE ENVIRONMENT

The federal government remains committed to maintaining Canada's high regulatory standards and international leadership for the protection of health and the environment. This will require the continuous improvement of the regulatory system — within the context of the existing federal regulatory framework — to accommodate the growing demands that new biotechnology applications will place on it.

Possible actions:

- ◆ greater emphasis on generating the scientific knowledge and information needed to support biotechnology regulatory decisions
- ◆ identify options to make the regulatory system more efficient, effective, responsive and predictable, using tools such as international benchmarking, performance standards and monitoring
- ◆ improve international and domestic regulatory cooperation, harmonization and related R&D programs (for example, through mutual recognition agreements)
- ◆ provide the general public with clear, timely information on regulatory processes, decisions and enforcement activities.

### 4. PROMOTING THE USE OF BIOTECHNOLOGY FOR PUBLIC HEALTH AND SAFETY

Building on current efforts, this theme involves applying the federal government's resources and considerable expertise in areas such as research, health and disease surveillance, prevention and treatment to improve public health. Possible areas for further work include disease diagnosis and treatment, and safer, more nutritious and healthful foods.

*Biotechnology's greatest impact, both in Canada and globally, is in human health. Some 90 percent of all biotechnology products on the global market are health related. More than 40 percent of the new drugs in clinical trials are products of biotechnology. In Canada, nearly 60 percent of Canadian biotechnology companies focus directly on health care.*

## 5. MODERNIZING CANADA'S INTELLECTUAL PROPERTY LAWS

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Modernizing Canada's intellectual property laws and ensuring their effective administration would significantly improve the domestic investment climate in knowledge-based sectors such as biotechnology. This point was stressed in many of the consultation sessions.

Possible actions:

- ◆ review Canada's intellectual property laws and policies in relation to the vision, principles and goals of the renewed CBS
- ◆ use international benchmarking, stakeholder consultations and the new CBS structures to help develop a Canadian position regarding the World Trade Organization review of the patenting of higher life forms
- ◆ analyze the implications of amending the *Plant Breeders' Rights Act* consistent with the 1991 UPOV Convention (International Union for the Protection of New Varieties of Plants)
- ◆ ensure that the Canadian Intellectual Property Office's patent review process meets or surpasses international performance standards.

## 6. FACILITATING MEASURES TO HELP ACCELERATE THE APPLICATION AND COMMERCIALIZATION OF NEW TECHNOLOGIES

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Possible actions:

- ◆ identify options for removing possible financing gaps facing the biotechnology sector
- ◆ improve technology transfer from government laboratories, universities and research institutes to the private sector.

## 7. DEMONSTRATING RESPONSIBLE WORLD LEADERSHIP TO IMPROVE MARKET ACCESS AND ACCEPTANCE AS WELL AS STEWARDSHIP IN DEVELOPED AND DEVELOPING COUNTRIES

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The public opinion research showed strong support among Canadians to position the country as an international leader in biotechnology in terms of the quality of research and products as well as the stringency of standards and regulations. Respondents underlined that the CBS should build on our national tradition of responsible global leadership.

Possible actions:

- ◆ develop a comprehensive strategy for improving market access including an international communications strategy, technical support to exporters and better coordination of federal and provincial market access and export promotion activities
- ◆ promote Canada as a preferred location for investment in biotechnology
- ◆ review Canada's international development assistance policies and programs in relation to the CBS vision and goals, particularly with regard to the developing countries to which Canada exports or is likely to export, and work with Canadian and local industry and other stakeholders to build indigenous capacity in these countries to capture the benefits of biotechnology and assess and manage the risks. This would help lesser developed countries to enhance their quality of life, ensure environmental sustainability and improve their risk management systems.

These and other actions, including Canada's contributions to international negotiations, will help to ensure that the international harmonization of regulatory systems reflects Canadian values and high standards for stewardship.

## 8. DEVELOPING HUMAN RESOURCES

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The availability of technology and management skills is becoming a limiting factor to biotechnology development, both for the private sector and for government.

Possible actions:

- ◆ examine immigration procedures and other impediments to the international recruitment of highly qualified personnel and experienced managers
- ◆ develop innovative strategies to meet the human resources needs of regulatory departments
- ◆ work with the provinces and other partners, particularly the Biotechnology Human Resources Council (BHRC), to increase the availability and skill sets of technical and managerial personnel
- ◆ work with the BHRC, provinces and other partners to further integrate ethical, legal and social issues into educational programs and the standards of professional associations.

## 9. IMPROVING POLICY-RELEVANT DATA COLLECTION AND ANALYSIS

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Few data are collected domestically or internationally on biotechnology-related industry activities or biotechnology-related R&D. Database development — for example, on industry structure, expenditures, revenues and market trends, government policies, programs and

spending, technology and product diffusion and use, and international benchmarks — is needed to support policy development and to monitor and assess the impacts of the CBS in the future.

Possible actions:

- ◆ assess federal data needs and work with Statistics Canada to develop best collections and monitoring tools
- ◆ work with partners to design, implement and maintain a national biotechnology database
- ◆ develop international benchmarking tools.

## 10. BUILDING SECTOR STRATEGIES AND ACTION PLANS

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Because biotechnology is an enabling technology with many different applications, efforts to promote its responsible development centre on delivery at the sectoral level. Sectoral overviews are presented in Annex B.

Possible actions:

- ◆ direct sector departments to work with their stakeholder community and other interested parties to develop and refine sector strategies and plans.

## ANNEX B: SECTOR OVERVIEWS

This annex presents brief overviews of biotechnology's influence and effects in six key sectors. These overviews are based for the most part on the CBS sector consultations and the consultation documents. They focus primarily on the issues and challenges unique to the individual sector; the more generic issues that are common to many sectors are addressed earlier in the document as part of the overall CBS.

### HEALTH AND HEALTH INDUSTRIES

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

Nearly 60 percent of Canadian biotechnology companies focus directly on health care. Canada's health care segment consists largely of small and medium-sized enterprises with a few large companies. It employs more than 8 000 people, primarily in knowledge-based positions, and its market capitalization has increased fivefold in just five years to reach \$10 billion. Revenue growth over the same period was 45 percent. Canada's health biotechnology industry is small by world standards, but is growing rapidly.

Canada's private and public sectors are both making important contributions to stimulating the growth of the health-bio sector. Canadian companies have developed world-class therapeutic products for infectious agents such as HIV (human immuno-deficiency virus), hepatitis and influenza. Other Canadian companies are at the leading edge of diagnosing life-threatening diseases such as heart disease. In bio-pharmaceuticals, Canada has significant strengths in molecular biology, cancer treatments, neuro-degenerative diseases,

bone disease and viral infections. Canada has several world-class companies including BioChem Pharma and Allelix Biopharmaceuticals.

Scientists at Health Canada's Health Protection Branch have developed biotechnology products such as monoclonal anti-bodies (MABs) and recombinant proteins, and then have transferred the technology — including the know-how, trade secrets and patent rights — to the private sector to develop vaccines and diagnostic kits. The National Research Council's Institute for Biological Sciences has also made significant contributions to vaccine development.

Key challenges facing the health sector include:

- ◆ continual improvements to the regulatory system to keep pace with product growth (speed to market is a critical success factor for producers and users)
- ◆ maintaining a strong science base in the face of declining public investment in basic science
- ◆ continued improvements in technology transfer and commercialization of Canadian R&D
- ◆ access to capital for start-up companies and for the establishment of pilot and full-scale production facilities
- ◆ improved and more certain access to international and domestic markets (the latter, for biopharmaceuticals, involves differences in provincial formulary requirements, drug-listing strategies and pricing formulas).

Participants at the sectoral consultations urged that the CBS recognize and foster geographical strengths, and promote the open communication and core competencies that are so important to creating regional clusters of biotechnology firms, research and training facilities, and other capabilities. As well, industry and the science community recognized the importance of socio-ethical considerations, underlining that these are already being addressed in their day-to-day work.

## AGRICULTURE AND AGRI-FOOD

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Agriculture and agri-food is one of Canada's top five industries, accounting for 14.7 percent of employment and 8 percent of GDP. The use of technology is integral to increasing the world's food production capacity in the face of environmental concerns, limited arable land and population growth, especially in the developing world. Biotechnology therefore plays an increasingly important role in agriculture and agri-food, with global sales of ag-biotech products now estimated at \$5 billion.

The planted acreage of crops with novel traits — for example, canola, corn, flax and potatoes — has increased dramatically in a short time. For instance, planting of genetically modified canola increased from 141 600 hectares in 1996 to 1.6 million hectares in 1997 and to a projected 2.6 million hectares in 1998.

The use of crops with modified traits contributes to environmental sustainability by reducing the need for chemical weed and pest control, enabling the practice of "no-till" agriculture and encouraging higher crop yields. For example, by using crops genetically engineered to be insect resistant or herbicide tolerant, farmers can manage their crops more effectively and improve yields while applying fewer chemical pesticides and herbicides.

Biotechnology allows the Canadian Food Inspection Agency and Canadian food-processing companies to develop new, more effective disease-detection tools to protect Canada's food supply (including the more effective detection and elimination of food pathogens such as "hamburger" disease). It also promotes more efficient food processing through the use of enzymes (for example, the removal of lactose from milk for lactose-intolerant consumers).

Some 26 percent of Canada's core biotechnology companies focus on agriculture and agri-food. Industry experts expect Canada to double its current exports of agricultural products to \$40 billion by 2005. Biotechnology will play a significant part in achieving these export goals. The successes of biotechnology in agriculture and agri-food have been due largely to dedicated research activity, which traditionally has

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

However, several challenges need to be addressed by industry and government working together. One involves building public confidence, including determining the public's information needs and the role that industry and other stakeholders can play in satisfying those needs, and providing clear, timely information on regulatory processes, decisions, enforcement activities and other matters.

As well, Canada must continue to foster the alignment of the private sector with the research community and identify priority areas for commercialization. Many countries and organizations are rushing to sequence the genomes of commercially valuable crop species, and are expected to file patents on inventions created using this genomic information. It is important that Canada have a prominent role in the emerging science of genomics, including genome mapping and gene sequence technologies.

The final challenge is to ensure access to foreign markets despite the absence of internationally harmonized standards. At the same time, the federal government and various stakeholders will continue to work in several international fora to harmonize biotechnology standards, which in turn will facilitate international trade in agricultural biotechnology products.

## ENVIRONMENT AND THE ENVIRONMENTAL INDUSTRIES

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One aspect of biotechnology that has received considerable attention in recent years is the multifaceted role that its environmental applications could play in meeting national goals for innovation, environmental protection and sustainable development. The environmental industries market is large and growing, currently worth an estimated \$16 billion in Canada.

Environmental biotechnology products and processes are poised to capture a significant share of the environmental industries market. Domestically and internationally, demands for environmental applications of biotechnology are increasing in areas such as processes to detoxify and reduce traditional waste streams and convert them into valuable new products; new biomaterials based on renewable resources; less labour- and energy-intensive inputs to improved bio-process engineering and systems design; innovative environmental solutions to the removal, reduction or stabilization of recalcitrant pollutants; restoration ecology; and the next generation of pollution prevention, detection and biological monitoring techniques.

Biotechnology can also help to address climate change through the use of enzymes to produce cleaner burning fuels and by improving the capacity of forests to sequester carbon dioxide. More generally, environmental processes can be significantly cleaner and require less energy than their conventional counterparts. In the future, clean industrial bio-products and bio-processes will increase the productivity, competitiveness and sustainability of Canada's resource industries.

Many of the environmental benefits of biotechnology are related to the dramatic changes now taking place in the chemicals industry. Worldwide sales of chemicals using biotechnology — excluding biopharmaceuticals — total \$6-8 billion. Increasing numbers of commodity and fine chemicals are produced through biotechnology processes. Biotechnology enables the development of chemical processes that consume less energy and produce less toxic waste. As well, biomass is beginning to replace petroleum as a chemical feedstock, thus reducing net greenhouse gas emissions.

After health care and agriculture, the environmental industries sector is estimated to be the third largest creator of biotechnology-related jobs, with an annual average growth rate of 25 percent from 1983 to 1993. Major Canadian strengths include our technical

expertise in specific and broad-based bio-remediation (the biological clean-up of effluents) involving soil and wastewater treatment applications, and the sector's flexibility to accommodate innovation and entrepreneurship.

However, while environmental applications of biotechnology offer considerable promise for the future, the sector is largely driven by individual projects. The result is insufficient development of strategic alliances and partnerships, expertise scattered across the country, and limited integration into the broader Canadian environmental industry. As well, similar to other biotechnology sectors, it needs public acceptance and support to succeed commercially.

Participants at the sectoral consultation stressed the need for predictable, transparent regulatory processes, including greater clarification of the regulatory oversight responsibilities among federal, provincial and municipal governments. Some called for changes in the *Canadian Environmental Protection Act's* New Substance Notification Regulations for biotechnology products with respect to the notification of naturally occurring organisms, cost of notification, ecozones, harmonization and enforcement. However, others noted the eight-year public consultative process that led to their development and the Industry Consultative Group struck to provide feedback on the regulations. In addition, the regulations are consistent in approach with other federal framework regulations.

Participants also believed there was a continuing need for centrally located and controlled-access biotechnology demonstration sites across Canada to allow for hands-on training, determination of proof of concept, validation of product claims under field conditions, opportunities for public education and development of responsible-use protocols. As well, several participants expressed the need for a national environmental biotechnology industry association in Canada.



## AQUACULTURE

The Canadian aquaculture harvest is valued at approximately \$400 million annually.

*Canada's aquaculture sector has benefited significantly from various enabling technologies that improve fish health and broodstocks. Biotechnology is emerging as an important subset of these enabling aquaculture technologies, and its application promises important economic returns. For example, biotechnology is used to evaluate the genetic diversity of wild fish stocks and to identify potential threats from disease. It is also used to support restocking and aquaculture programs by ensuring the quality of the broodstock and freedom from parasites and disease.*

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

Among the strengths of Canada's aquaculture industry are its technical and aquaculture management expertise, and a geographical setting that provides easy access to the huge North American and Pacific Rim fish and seafood markets. Major challenges include consumer acceptance, environmental concerns related to the possible spread of "new" genes to wild fish populations, limited research and the early stage of development of aquaculture applications compared to other industries.

Aquaculture biotechnology has reached the stage where practical applications are being identified and commercialized, and the sector is becoming increasingly competitive on a global basis. Because Canada exports more than 70 percent of its aquaculture biotechnology products and services, access to foreign markets and foreign consumer acceptance are essential to a competitive Canadian industry.

## FORESTRY

The forest sector is a cornerstone of Canada's economy. It employs almost one million people and is consistently the single most important contributor to Canada's positive trade balance.

*Forest biotechnology provides tools that could reduce exploitation pressures on forests. This would contribute to sustainable development and our knowledge of forest ecosystems, which in turn would contribute to conservation.*

Exports in 1996 reached \$38 billion, representing 72 percent of sector shipments. Intensively managed forests can be made more productive through the use of biotechnology-derived products such as genetically enhanced trees or environmentally sound biological pest-management products and strategies. For example, plantations of genetically improved trees will increase fibre availability and reduce wood costs, thus strengthening the forest sector's competitiveness relative to substitute materials, which are often more energy-intensive and entail greater environmental risks. As well, the pulp and paper industry uses enzymes from micro-organisms to enhance pulp and fibre properties, de-ink and treat mill effluent. These new enzymes provide significant energy savings and can reduce by 50 percent the use of chlorine-based bleaching agents used in pulp and paper production. The greatest growth in industrial enzyme use is in the pulp and paper sector, with worldwide sales of about \$50 million annually.

Canada's prominence in forest science and as a forest producer gives us the opportunity to become a world leader in forest biotechnology. However, only a few biotechnology-derived products and processes have been commercialized, mostly in the areas of pest management, forest regeneration, pulp and paper processing, and mill effluent treatment. It is necessary to increase industry and public awareness of forest biotechnology developments, expand R&D spending by parties outside the federal government, and accelerate technology transfer and the commercial development and use of forest biotechnology in Canada.

In particular, an urgent need exists to develop mechanisms for encouraging greater private sector involvement and investment in R&D and the commercialization of biotechnology applications.

## MINING AND ENERGY

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Canada's mining and energy sectors together contribute more than \$70 billion to Canada's GDP. Biotechnology development in these important sectors is primarily at the "science base" stage in universities.

Principal areas of current and potential application in these sectors include:

- ◆ resource extraction and quality improvement (including bio-oxidation/leaching of gold and base metal ores, microbially enhanced oil recovery, the removal of sulphur from petroleum and bio-upgrading of bitumen/heavy oils)
- ◆ environmental management (including metals recovery/immobilization, bio-remediation, phytoremediation and inhibition of natural biological activity in wastes)
- ◆ environmental monitoring (including bio-monitoring tools for toxicity testing and environmental quality evaluation).

In addition, bio-processes are used to produce fuel ethanol from biomass, and oil seed crops can be engineered to produce low-sulphur oil for diesel motors and for lubricating machinery.

Canada has few specialized biotechnology supply and development companies focussing on the mining and energy sectors. The scale-up of biotechnical processes tends to be performed by subgroups in the large mining and energy fields and processing companies.

Given the size of the mining and energy sectors, even small biotechnological applications can have major environmental and economic impacts. However, made-in-Canada biotechnologies have been used more extensively offshore than at home. Greater use in Canada requires that biotechnology applications be cost-effective under Canadian climatic and other conditions.

As with other sectors, public and industry acceptance and information exchange, environmental concerns, international harmonization of regulations, greater investment in R&D, and technology transfer and commercialization are all important to increasing biotechnology applications in Canada's mining and energy sectors. As noted at the sectoral consultation (and surfacing as a theme at many of the other consultations as well), for biotechnology to secure a stronger presence in the mining and energy sectors, biotechnological research should focus on problematic technical issues and applications with significant potential for cost reduction, emphasizing both the economic and environmental benefits of the proposed biotechnological solution.

# ANNEX C: FEDERAL REGULATORY FRAMEWORK FOR BIOTECHNOLOGY

## THE FEDERAL GOVERNMENT FRAMEWORK TO REGULATE BIOTECHNOLOGY

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

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

