Renewal of the Canadian Biotechnology Strategy

Roundtable Consultation Document

Government of Canada Gouvernement du Canada

Canada

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Roundtable Consultation Document

Prepared by:
Canadian Biotechnology
Strategy Task Force
February 1998

Comments must be submitted to the Canadian Biotechnology Strategy Task Force by April 30, 1998, to be taken into account in the Canadian Biotechnology Strategy's renewal process.

Renewal of the Canadian Biotechnology Strategy Roundtable Consultation Document is available electronically on the Industry Canada *Strategis* web site at: **http://strategis.ic.gc.ca/cbs**

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Erratum

Re: *Renewal of the Canadian Biotechnology Strategy Roundtable Consultation Document*

Page 16, Annex A under "Other Related Activities," please note the two additional subsections:

1.7 CODEX Committee on Food Labelling

1.8 Safety of Xenotransplantation

Objet : *Renouvellement de la Stratégie canadienne en matière de biotechnologie : Document pour les consultations en table ronde*

À la page 19, Annexe A, rubrique « Activités connexes », prière d'ajouter les deux sections suivantes :

1.7 Comité du Codex sur l'étiquetage des denrées alimentaires préemballées

1.8 Sécurité de la xénotransplantation.

CONTENTS

INTRODUCTION

Biotechnology makes significant contributions to our lives. It enhances our health and well-being, creates jobs and economic growth, and supports environmental sustainability. But some of biotechnology's newer techniques (such as cloning), despite their potential benefits, raise certain questions about possible risks to health and the environment, and give rise to social and ethical issues. These questions and issues require careful consideration and discussion. They also involve finding new — or refining existing — national strategies, policies and partnerships, international agreements and other mechanisms to ensure that biotechnology products enhance our health, quality of life and environment as they generate jobs and economic growth.

The Government of Canada is working with partners to determine the best ways and means to realize the potential benefits of biotechnology for Canadians. These partners include industry, universities, consumer groups, non-governmental organizations, provincial governments and others. The challenge is to develop a shared vision as to how biotechnology can best contribute to improving our quality of life and maximize economic and social benefits in a way that is ethically and environmentally responsible. This consultation paper is one means of providing Canadians with an opportunity to express their views. The results of these consultations will be an important step in the ongoing process of renewing the Canadian Biotechnology Strategy.

Like many countries that started investing in biotechnology research in the 1980s, Canada is in a position to build on its strengths. More nations are recognizing the benefits of biotechnology and have started to target it as a strategic enabling technology to support growth and international competitiveness. This focussed attention changes the global biotechnology landscape in terms of faster-paced developments in knowledge and applications, stiffer competition and shifting world markets. At the same time, several countries are increasingly examining biotechnology-related ethical and social issues.

To maintain its position as a global biotechnology leader and to address public concerns, Canada must act now. Renewing our biotechnology strategy is an important early step. The federal government is examining its activities in several key areas. These areas include research and development (R&D) and other related scientific activities, intellectual property, technology transfer, commercialization, human resources, regulation of biotechnology products and ways to address social and ethical questions. This renewal process is critical to ensure that Canadians' well-being in terms of health, safety and the environment are safeguarded, that jobs, economic growth and international competitiveness are enhanced, and that biotechnology is developed responsibly for the maximum benefit of Canadians, both now and in the future.

Since the inception of Canada's first National Biotechnology Strategy in 1983, federal initiatives in biotechnology have concentrated on strengthening Canada's R&D, human resources, regulatory and economic capacities. The renewed strategy will recognize the government's role in protecting the health of humans, animals, plants and the environment, and addressing social and ethical concerns and sustainable development. Building on the current strategy, it will also encompass such matters as public awareness, involvement and confidence, and will work to position Canada as a responsible leader in providing and using biotechnology products and services.

To ensure that the strategy addresses stakeholder and public priorities, the government will conduct two sets of cross-country consultations. The first will be five roundtable consultations with key stakeholders to be held in Halifax, Montreal, Toronto, Saskatoon and Vancouver in March and April 1998.

The purpose of the Roundtable Consultations is to garner input on the strategy's general directions. Three key areas are the broad policy framework (that is, the vision, objectives and principles of the renewed strategy), the advisory body on biotechnology, and public awareness and participation.

In addition, consultations will also take place in the sectors of health, agriculture, environment, forestry, aquaculture, mining, energy and research. Conducted by the responsible federal departments, these consultations will address matters specific to individual sectors.

The Task Force will produce a Summary Discussion Report after each of the five roundtable consultations and these will be posted on its web site. Summary Reports of the sector consultations will also be made available and posted on the web site. The Task Force will also produce a Final Consultation Report on the various consultations, including comments received from Canadians writing to the Task Force. All reports will be available from the Task Force at the address above and on the web site (**http://strategis.ic.gc.ca/cbs**). The views expressed in the Final Consultation Report will inform the renewal of the Canadian Biotechnology Strategy and it will be passed on to the new advisory body.

Individuals or organizations wishing to comment on this report are invited to write to:

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A Quick Overview of Biotechnology

> Biotechnology is "the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms."
>
> — *Canadian Environmental Protection Act*

Biotechnology is an umbrella term that covers a broad spectrum of scientific tools. Biotechnology uses living organisms, or parts of living organisms, to make new products or provide new methods of production.

Biotechnology is not a new discipline. People 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 activities such as the production of antibiotics, vaccines and enzymes have also been used for many years. Farmers have traditionally used selective plant and animal breeding techniques to create improved fruits and vegetables and special varieties of flowers and animals. However, biotechnology's newer techniques, such as genetic engineering or DNA-based technology, have generated much discussion. Some applications of DNA-based technology involve the modification or duplication of genetic information or its transfer from one organism to another.

Biotechnology's greatest impact both in Canada and worldwide has been in the health field. More than 90 percent of the advanced biotechnology products on the world market are related to health. In Canada, 59 percent of the core biotechnology companies are in the health care sector.

Biotechnology is less an industry *per se* than a family of tools, with applications across several industries. Its real impact is its enabling effect; that is, the scope of benefits made possible by applying new and innovative scientific techniques in many sectors, from traditional to advanced.

The potential benefits of biotechnology encompass improved health and well-being, environmental protection, and jobs and economic growth. In health care, for example, biotechnology is leading to earlier, more reliable health surveillance, disease diagnoses and therapies. In other areas, benefits include improved plant yields, a cleaner environment, more pest-resistant trees and crops, enhanced fish stock management and more environmentally friendly biological pesticides.

The Canadian government regulates products, including biotechnology products, to protect health, safety and the environment. The regulatory system uses science-based risk assessments and takes into account the characteristics of the product and any potential risks throughout its life cycle. Canada's risk assessment process is considered to be among the best in the world. In addition to its regulatory functions, the federal government also serves as a policy maker, researcher and service provider to foster biotechnology's potential benefits for Canadians.

A key question at the heart of biotechnology discussions is the matter of consumer confidence and comfort with the new DNA-based technologies. Research shows that while Canadians have heard of biotechnology, their understanding of it is limited. Citizens want to know that the potential risks associated with such technologies are being adequately addressed. This means that governments and stakeholders must go beyond scientific reassurance; they must also ensure that Canadians get the information they need from a source and in a form that they find useful and credible.

CONTEXT

Canada has a growing biotechnology sector. It includes companies in industries such as health, agriculture and agri-food, environment, aquaculture, forestry, mining and energy. A strong R&D capacity is fundamental to bring forward new biotechnology products and services.

The renewal of the biotechnology strategy is in recognition of the pace and magnitude of new product and process development. It also addresses the requirement to reflect current needs and strategic priorities and to more fully address social and ethical issues. In addition, as Canadians increasingly seek to be involved in decisions that affect their lives, the new strategy takes into account the issues of public trust and confidence in our regulatory institutions — essential elements in realizing the potential of biotechnology.

The economic potential of biotechnology is impressive. According to Industry Canada's Sector Competitiveness Framework on *Bio-Industries* (Ottawa, 1998), the worldwide market for biotechnology products and services is expected to more than double in 10 years from $20 billion in 1995 to $50 billion in 2005. In Canada, the overall bio-industry, including firms that develop and apply biotechnology as well as suppliers and service providers, consists of almost 500 companies employing 25 000 people, typically in high-quality jobs. These firms generate almost $2 billion a year in revenues and some $750 million in exports. Employment, sales and exports are growing by more than 10 percent a year. Industrial R&D expenditures in biotechnology currently are approximately $350 million a year, while universities, government and non-profit institutes together spend another $400 million on biotechnology R&D.

Within the overall industry, some 224 companies focus primarily on biotechnology. (Data are taken from a study by Ernst & Young, "Fourth Report on the Canadian Biotechnology Industry, Canadian Biotech '97," Ottawa: 1997). These core companies employ about 11 000 people and generate revenues of more than $1 billion. Strong centres exist which apply technologies, particularly health and agriculture.

Biotechnology has the potential to increase Canada's international competitiveness and promote sustainable development in key economic sectors. It is also an important component of Canada's knowledge-based economy. In the 1997 Speech from the Throne, the federal government acknowledged it as an important sector for future jobs and economic growth.

◆ 1997 Speech from the Throne ◆

"Canada is well positioned to be a world leader in the global knowledge-based economy of the 21st century. We have the talent, we have the resources, we have the technology, and we have the institutions. By rising to the challenge of mobilizing our resources well, we can enable our citizens to succeed in the global knowledge-based economy. With targeted growth strategies, we will build those knowledge-intensive sectors where we are strong and where the opportunities for growth and global leadership are highest. Examples are aerospace; bio-pharmaceuticals; biotechnology in agriculture and fisheries; and the environmental, information and telecommunications technologies. Governments have a crucial role to play in supporting science, technology and the creation of knowledge."

Around the world, especially in countries such as the United States, the United Kingdom, Germany and Japan, national governments are targeting biotechnology as a key enabling technology of the future and a priority for support. Canada, already established in developing safe, effective uses of biotechnology, is well positioned to assume a greater leadership role in this field.

The Government of Canada first identified biotechnology as an important economic sector in the late 1970s. In 1983, it introduced the first National Biotechnology Strategy. The strategy contributed to the development of key scientific capabilities, as well as the regulatory systems and commercial environment that the fledgling sector needed to grow and prosper. The government also undertook several reviews to update and improve its biotechnology framework. In 1993, it adopted the Principles of the Federal Regulatory Framework for Biotechnology. The framework strengthens the regulatory system by building on existing legislation and institutions.

◆ Ministerial Portfolios and their Involvement in Biotechnology ◆

Minister	**Department, Agency, Council**
Industry	Industry Canada
	Atlantic Canada Opportunities Agency
	Western Economic Diversification Canada
	Federal Office of Regional Development (Quebec)
	National Research Council
	Natural Sciences and Engineering Research Council
	Office of Consumer Affairs
	Social Sciences and Humanities Research Council
	Statistics Canada
Health	Health Canada
	Medical Research Council
	Pest Management Regulatory Agency
Agriculture	Agriculture and Agri-Food Canada
	Canadian Food Inspection Agency
Natural Resources	Natural Resources Canada
Environment	Environment Canada
	Canadian Environmental Assessment Agency
Fisheries and Oceans	Department of Fisheries and Oceans
Foreign Affairs and	Department of Foreign Affairs and International Trade
International Trade	International Development Research Centre
	Canadian International Development Agency
Human Resources	Human Resources Canada
Development	

THE ROLE OF THE FEDERAL GOVERNMENT

With regard to biotechnology, the Government of Canada:

- evaluates potential new and modified products to protect health, safety and the environment
- supports the development and application of the scientific knowledge base that underpins the government's stewardship functions and the creation of jobs and growth in an innovative, knowledge-based economy
- advances the principle of sustainable development
- provides ways for Canadians to voice their views and participate in discussions on relevant issues, including social and ethical matters related to biotechnology
- develops framework policies to support the responsible development, application and export (including access to foreign markets) of biotechnology and its products and services
- facilitates Canadians' access to accurate, understandable information regarding biotechnology, its applications and its regulation
- advances Canada's regulatory approach internationally regarding the protection of health, safety and the environment.

The government is committed to building a systematic approach to supporting innovation; that is, developing a strong R&D, science and technology transfer base, commercialization tools and intellectual property management, as well as maintaining, enforcing and enhancing the Canadian regulatory system. An evolving, dynamic innovation system needs to nurture new research areas and be linked to quality of life, environmental protection, job creation opportunities and the advancement of knowledge. Support for R&D is vital in the generation of knowledge leading to innovation and technology transfer.

◆ Advances in Health Care ◆

Health biotechnology is achieving important advances. These advances will significantly improve our quality of life and economic future. Health Canada's Laboratory Centre for Disease Control, for example, is working on candidate vaccines against human acute meningitis and pneumonia, and both vaccine prototypes will soon be commercially developed. As well, projects initially funded by the National Biotechnology Strategy have led to the creation of new immunodiagnostic assays for the early detection of breast tumors and influenza. These initiatives are at early stages of technology transfer and commercialization.

The federal government is uniquely positioned to work with its partners in knowledge-intensive sectors where Canada is strong and has opportunities for growth and global leadership. It can foster and strengthen partnerships and strategic investments, support and develop a skilled work force, and improve access to international markets. The government can also improve the country's access to international technology, standards and scientific information. Long-term R&D and technology planning and forecasting capabilities can continue to be improved so that individuals and institutions can better anticipate opportunities, align their resources and plan for maximum effectiveness and commercialization.

The government plays an important role in facilitating the creation of partnerships, strategic alliances and networks. These collaborations embrace the provinces, industry, academia and others. Collaboration with the provinces is essential given the common goals and potential for complementary roles in several areas. These areas include health, agriculture, forestry, aquaculture, mining, energy and the environment, as well as human resources, science and technology (S&T), trade and economic development.

Innovation

Innovation is the process by which new or improved products and processes are developed and introduced to the marketplace. It is the connection between research, science and technology, and the creation of wealth and social improvements. Canada's innovation system is composed of the networks of universities and colleges, federal and provincial laboratories, industry/university consortia, and entrepreneurs. Financial institutions support the system by providing venture and other types of capital. Canadian firms and laboratories are also involved in numerous strategic alliances with international partners, linking the Canadian system and the global economy.

The provinces are diverse in terms of their biotechnology strengths, levels of investment and stages of government involvement and expertise. Existing partnerships with the provinces tend to focus on ways to pool human and financial resources to capitalize on and enhance regional clusters. As well, federal and provincial governments working with industry and academia to build on existing strengths allow them to achieve their shared objectives of improved quality of life, jobs and economic growth faster and with better results.

The provinces and industry also have important responsibilities. Many provincial governments actively foster the competitiveness of specific biotechnology sectors, applications and companies, and inform the public regarding the benefits and risks of this technology. Consumer and environmental groups and other non-governmental organizations provide information and work with industry to promote shared interests and contribute to government policies.

As the technology matures and 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 ensuring that its customers' information and product needs are satisfied. The industry also has a responsibility to ensure that its decisions and practices are consistent with Canadian laws, social values and ethical norms.

Issues for Roundtable Consultations

The issues presented on the following pages reflect the basic elements of the government's approach to renewing the Canadian Biotechnology Strategy. The three key issues are the policy framework, the advisory body for biotechnology, and public awareness and participation. Each topic is presented here in broad terms with a brief context plus some suggested discussion points. It is up to consultation participants to further develop and fine tune these and other suggestions that might come forward.

POLICY FRAMEWORK: VISION, OBJECTIVES AND PRINCIPLES

One of the first tasks in renewing the strategy is to establish its vision, objectives and principles. These matters represent the essence of the strategy and will guide its creation and implementation over the next decade. To initiate the talks, the following ideas are presented for consideration.

Proposed Vision

For Canada to be a world leader in biotechnology and, through it, to enhance the quality of life of Canadians in terms of health, safety, the environment and economic development.

Proposed Objectives

- To ensure that Canadians have access to, confidence in and benefit from, safe and effective biotechnology-based products and services.
- To position Canada as a responsible world leader in the development and sale of biotechnology products and services, domestically and internationally.
- To develop suitable mechanisms to support Canada's economic and stewardship objectives (that is, health, safety, the environment and social and ethical matters) and to be a leader in promoting such mechanisms in the world arena.

Proposed Principles

- Respect Canadian values.
- Hold ongoing, transparent and open dialogue with Canadians.
- Support sustainable development.
- Maintain a sound scientific base and make strategic investments in R&D to support innovation, the regulatory framework and economic development.
- Establish collaborative links, nationally and internationally, with governments, businesses, academia, consumer and interest groups, provinces and territories.
- Promote an export orientation for the benefit of Canadians in a competitive global environment.

Suggested Question for Discussion on Vision, Objectives and Principles:

1. ***Are the proposed vision, objectives and principles appropriate?***

ADVISORY BODY FOR BIOTECHNOLOGY

Biotechnology is a critical emerging technology for Canada in terms of potential economic and societal value. However, the field is evolving rapidly and new concerns have arisen, especially pertaining to risk, ethics and public confidence. To deal with these and other related matters, the government has proposed that a broad-based body be created to advise federal ministers.

In its response to the *Third Report of the Standing Committee on the Environment and Sustainable Development* (April 7, 1997), the government made the following statements.

> "The government . . . agrees with the Standing Committee on the need for a more broadly based body to provide advice to a group of ministers on the ethical, social and regulatory aspects as

well as the economic, scientific, environmental and health aspects related to biotechnology consistent with the principles of sustainable development. . . . It is the government's intent that the advisory body could examine potential benefits and risks of this emerging technology and the public's understanding and confidence in biotechnology. It is not the government's intent that the advisory body would arbitrate regulatory decisions but rather would advise on larger policy directions. . . . The government is in agreement with the Standing Committee that addressing ethical considerations is critical for the public good and the development of a vibrant Canadian biotechnology industry, and that priority be placed on advice to government in this area."

"The government will identify its priorities to the advisory body for consideration, but will not restrict the advisory body in its deliberations."

"The government . . . believes the existing regulatory framework for biotechnology provides the necessary safeguards to protect human health and the environment. As such the government is of the view that the current approach of product based sectoral regulation is an appropriate regulatory structure. The government does, however, remain committed to continuous improvement of the regulatory system within the context of the existing regulatory framework, and as such will attach importance to the advice of the advisory body on the current application of the regulatory system to transgenic organisms."

Current Range of Advisory Bodies

The Advisory Council on Science and Technology provides advice to the Prime Minister on national S&T goals and policies and their application to the Canadian economy. This advice, and that of a federal committee of senior officials (the ADMs' Committee on S&T) deals with broad S&T policy issues and coordination. However, there is no single, comprehensive body that advises a collection of ministers on all aspects of biotechnology. Individual departments have advisory bodies that report either to ministers or departments, with direct or indirect impact on biotechnology. These groups include the Department of Agriculture and Agri-Food Canada's Canadian Agri-Food Marketing Council, the Department of Natural Resources' National Advisory Body on Forestry Research, Industry Canada's National Biotechnology Advisory Committee and its National Sector Teams, Health Canada's Advisory Committee on Reproductive and Genetic Technologies, and the Department of Foreign Affairs and International Trade's Sector Advisory Groups on International Trade (SAGIT) and the International Trade Advisory Committee (ITAC). These groups have been formed to address specific matters as opposed to the full range of issues raised by biotechnology. As well, no advisory mechanism exists to connect their advice to the formulation of government policy. Federal and provincial governments both have bodies addressing the ethical aspects of research and medical practices. The result is a lack of a coherent advisory structure on biotechnology matters.

◆ National Biotechnology Advisory Committee ◆

In 1983, Cabinet established both the National Biotechnology Strategy and the National Biotechnology Advisory Committee (NBAC). The NBAC's mandate is to provide advice to the Minister of Industry on matters related to the creation and maintenance of an internationally competitive Canadian position in the development and application of biotechnology, and on matters referred to it by the Minister. The committee has 19 members — 12 from industry, mainly at the level of company president or chief executive officer, three from academia, three from public research organizations, and one from a non-governmental organization. Members are drawn from every region in Canada. The committee normally meets twice yearly. It is served by an Industry Canada secretariat. The NBAC has issued five reports. The sixth report will be issued in March 1998 (see Annex A, 3.6).

Information Highway Advisory Council

One model of a broad-based federal advisory body in Canada was the Information Highway Advisory Council (1994–97). Reporting to the Minister of Industry, the 29-member council represented industry, academia, the research community and other interested constituencies. The IHAC responded to key questions posed by Ministers, organized working groups, held press conferences, and released periodic reports to the public on issues of interest. The IHAC proved to be a flexible and responsive body for government, capable of timely briefings and commentaries as issues arose. More generally, the Council operated as a visible forum for public discussion on issues related to the impacts of the Information Highway on Canadian society. Their 1995 report to government "Connection Community Content" and their 1997 final report "Preparing Canada for a Digital World" have assisted the government in preparing Canada to be a world leader on the Information Highway by the year 2000.

Several examples of biotechnology advisory bodies can be found in other countries and the international community. They range from broad-based entities that advise on a spectrum of biotechnology matters, to those that concentrate on a specific aspect. The British model, for instance, involves a network of advisory bodies and regulatory agencies which together guide developments in biotechnology and genetics. The United Nations Educational, Scientific and Cultural Organization (UNESCO), the World Health Organization, the European Union and the U.S. have bodies that provide advice specifically on ethical matters.

Discussion Points Regarding the Advisory Body

Terms of Reference: It is proposed that the advisory body address the ethical, social, regulatory, economic, scientific, environmental and health aspects of biotechnology consistent with the principles of sustainable development. During the consultations, participants may wish to make recommendations regarding priorities within these broad topics and/or additional matters on which the body could advise. The advisory body could examine potential benefits and risks of biotechnology and the public's understanding and confidence in biotechnology. It is not the government's intent for the advisory body to arbitrate regulatory decisions but rather to advise on larger policy directions.

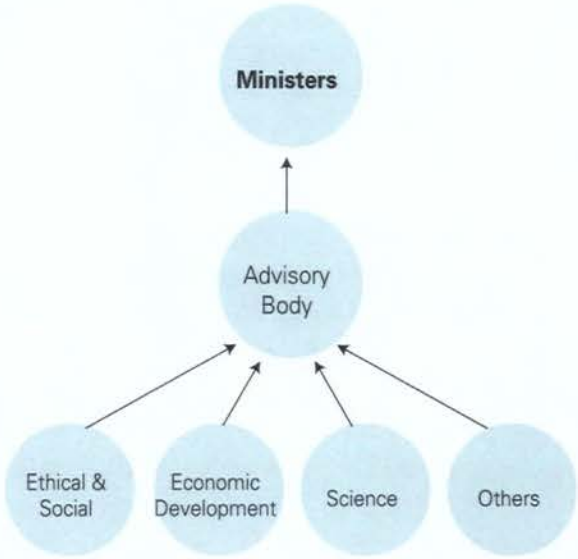
Reporting: Discussion is sought on the structure of the new body, its reporting linkages to federal ministers, and how it will relate to existing advisory bodies.

Membership: Roundtable consultation participants should address the number of representatives required, the criteria on which selection will be based and length of terms.

Possible Options: Two options regarding the structure and reporting linkages of the new body are presented here to stimulate discussion. Participants may wish to consider these and/or other options.

Possible Option 1: A single main body with broad-based membership would be created with subcommittees to provide input and new subcommittees added as required. Each subcommittee would be

OPTION 1



represented on the main advisory body. Depending on possible overlaps of mandate, some existing advisory bodies may be terminated.

Possible Option 2: A single broad-based body would be created to address all biotechnology issues. There would be no subcommittees, and existing external advisory bodies on biotechnology could continue to advise individual ministers on matters such as regulations and economic, scientific, environmental and health matters.

OPTION 2

Further Discussion

The government has indicated that an Advisory Body is needed to provide advice on a range of important topics, including ethical, social and regulatory aspects as well as economic, scientific, environmental and health aspects related to biotechnology consistent with the principles of sustainable development. To assist the roundtable participants additional material is provided below on ethical and social, economic and regulatory aspects (see also Annex A).

Ethical and Social Aspects: Canadian society has values that underpin its ethical and social perspectives. These values are often expressed in legal, regulatory and policy instruments. For example, our beliefs regarding freedom, human dignity and non-discrimination are articulated in documents such as the *Canadian Constitution* and the *Canadian Charter of Rights and Freedoms*. Our values for human health and safety are embedded in a range of laws and regulations, including regulatory systems dealing with food and health protection, labour laws and highway speed limits. Other values such as sustainable development are reflected in environmental protection laws and regulations, the sustainable development strategies of federal departments and Canada's signing of the *United Nations Convention on Biodiversity*.

Canada already has specific examples of ethical guidelines and related tools that have implications for biotechnology. For instance, codes of ethics are in place dealing with the delivery of medical practices and research involving humans and animals (see Annex A). As well, various laws and policies cover privacy and the confidentiality of personal information. In addition, several professions and industries have voluntary codes of conduct.

Certain aspects of biotechnology, such as those related to the potential cloning of humans and the patenting of higher life forms, have caused some Canadians to ask if we need a more complete articulation of our values as they apply to biotechnology. For example, the Royal Commission on New Reproductive Technologies more precisely articulated its values when it adopted an "Ethic of Care" to explore the potential ramifications of new reproductive technologies and to make policy recommendations.

Some social and ethical issues may best be addressed by adapting existing approaches. For instance, concerns about the privacy of personal genetic information might best be dealt with through new privacy legislation (see Annex 1.5). One priority for the new advisory body might be to provide advice on matters identified during the consultations or to facilitate discussion among Canadians on some of these issues.

Internationally, some governments and organizations have established processes that, because they are socially inclusive, are generally seen as ethically acceptable for dealing with biotechnology. Consensus conferences and broad-based advisory bodies are two such mechanisms.

Consensus conferences have been used by Denmark, the Netherlands and the United Kingdom. Small groups of ordinary citizens, stakeholder representatives and experts meet for a short time to arrive at a "consensus" on public policy in a given area (for example, food irradiation, transgenic animals and plants, and human genetics research).

Independent, broad-based advisory bodies are another prominent model. Typically, governments establish advisory bodies made up of a range of social and scientific interests, and solicit their advice on biotechnology-related issues. These groups often seek to determine public opinion on a given issue as part of their mandate. For example, the European Commission has established a Group of Advisors on the Ethical Implications of Biotechnology. The United Kingdom has a comprehensive network of advisory bodies on both the scientific and ethical aspects of biotechnology. Although the U.S. government is not especially active in seeking broad-based advice on biotechnology, its Bioethics Advisory Committee's mandate is sufficiently extensive to include human biotechnology issues. For instance, it recently advised President Clinton to support a five-year moratorium on human cloning. Other advisory groups have examined questions related to the patenting of higher life forms and the use of gene therapy.

One task undertaken by several of these bodies is to help build consensus toward broad ethics frameworks that are then used to arrive at national policy positions on biotechnology. These values then 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. The public needs to be involved in identifying these values to enhance their legitimacy.

◆ Some Prominent Guiding Ethical Principles and Values Identified in Other Countries for Biotechnology ◆

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

Economic Aspects: Canada's biotechnology sector is emerging in the context of the knowledge-based economy. This economy is part of an international shift toward economic strength that is based on the generation, collection, manipulation, transmission and use of information. Because biotechnology centres on innovation, R&D and the use of knowledge in manufacturing and other processes, it constitutes a key component of the new economy.

The September 1997 Speech from the Throne set out priorities for the country based on seizing the opportunities presented by the new knowledge-based economy to create jobs and growth. The framework for the knowledge-based economy provides for strengthening the R&D base, enhancing trade and investment, and creating an amenable marketplace climate.

The federal government is working with the private sector and others to build the national knowledge infrastructure, accelerate the transformation of knowledge into commercial products and services, target high-potential knowledge-based sectors (such as biotechnology) and fully connect the national economy to the rest of the world.

The international regulatory environment is a major factor in international competitiveness because it affects market access, costs, investment decisions and the ability to raise capital.

Regulatory Aspects: The federal government protects health, safety and the environment largely by means of its comprehensive science-based regulatory system, considered one of the best in the world. Health Canada, Environment Canada, the Canadian Food Inspection Agency and the Department of Fisheries and Oceans are the principle federal organizations involved in regulating biotechnology products. Federal regulatory organizations must continue to work with provincial partners and other stakeholders to ensure an efficient, effective and transparent Canadian regulatory system.

Several factors are now providing challenges to Canada's science-based regulatory system. These include the accelerating volume of new developments, growing public awareness of and concern about some biotechnology applications, scarcity of financial and skilled human resources despite increases in demand, and the increasing globalization of the regulatory context. The ongoing work of maintaining an efficient, effective regulatory system must take into account that the development, regulation and sale of biotechnology products, whether domestic or imported, occur in the context of the increasing globalization of markets, trade and regulatory activity.

This provides opportunities for enhanced cooperation with our trading partners, allowing Canada access to the best scientific knowledge in the world. Globalization of trade and environmental concerns have increased worldwide efforts to harmonize regulations, standards and risk assessments, leading to increased effectiveness and efficiencies.

Suggested Questions for Discussion Regarding the Advisory Body:

2. ***What should be the terms of reference and structure of the new federal advisory body?***
3. ***Regarding membership, what should be the composition, membership criteria, qualifications and length of terms?***
4. ***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?***
5. ***On what priorities should the advisory body focus?***

PUBLIC AWARENESS AND PARTICIPATION: INFORMATION, COMMUNICATION AND CONFIDENCE

Research funded in part by the National Biotechnology Strategy indicates that Canadians appreciate the potential benefits of biotechnology. For example, they strongly support bio-pharmaceutical products that have been on the market for many years. In eastern Canada, a genetically modified potato that resists insects and therefore requires less chemical pesticide — which was advertised as such — has sold well in supermarkets. The research also reveals, however, that some information gaps exist that need to be filled.

Some consumers and their representatives have questions not only about traditional concerns such as price, quality and product choice but also about the broader ethical, social and environmental matters associated with biotechnology products. Several issues give rise to these questions. While Canada's regulatory system for food, drugs, the environment and other public interests continues to be well respected among Canadians, there are questions about how the system is applied to biotechnology. Research points to gaps in consumer awareness and understanding of biotechnology. Some people want access to more detailed information so that they can make more informed decisions in the marketplace and more informed contributions to policy development.

Public awareness of biotechnology in general, as well as of specific applications and issues, can vary greatly depending on the ebb and flow of public events and media reports surrounding particular related events. For example, the possible future applications of biotechnology affect how some Canadians feel about biotechnology.

The attributes of biotechnology applications often are not directly evident to citizens. More work is needed to determine the best way to inform them about such technologies. Not all citizens have the time, resources or interest to seek out information, particularly if they believe that the potential benefits of biotechnology products are low. Research suggests that acceptance is highest for applications such as new drug therapies that meet clearly identified personal and social needs. Applications that offer less obvious benefits are less likely to receive market acceptance.

Finally, anecdotal evidence indicates that public knowledge, concern and support vary somewhat according to region. This diversity of views poses special challenges for government, industry and public interest groups.

◆ Accurate, Credible Information ◆

Research reveals no consensus among Canadians on a single, accurate and credible source of information. Some people question the credibility of industry and other profit-oriented organizations. Some consider that governments and universities are the most credible sources of information but others express scepticism about government and the ability of universities to be objective when their research is funded by industry. Some respondents view non-governmental organizations as potentially credible, while others see some public-interest groups as being too extreme or one-sided.

It is important that more Canadians have access to complete, accurate information about biotechnology, that the information emanates from reliable, truthful and credible sources and that people are aware of and have the opportunity to provide input into the formulation of key policies and regulatory processes. Feedback mechanisms are also required to show Canadians how their input has been channelled into advisory processes and their views taken into account.

While the government has instituted several such mechanisms, some groups argue that more must be done to create greater access and openness in policy formulation. Among the government's current mechanisms are consultations on regulations and policy development, department-sponsored workshops to solicit opinions on specific matters, a network of government advisory bodies in which various segments of society are represented, special processes such as royal commissions and consultations on major issues as they arise, and reviews by parliamentary committees, which have venues for public input and deliberation on all matters requiring legislation.

A key issue in renewing the strategy is to determine ways to facilitate a transparent, open dialogue between the government and the public. While consensus on many issues may be difficult, the process of dialogue itself will generate greater understanding and awareness of the issues involved and the decisions that must be made.

Suggested Questions for Discussion Regarding Public Awareness and Participation:

6. *What kinds of information does the public need, and how do these needs differ by sector and application?*
7. *What are the best ways to make information to the public available?*
8. *What are the roles of industry, academia, non-governmental organizations and governments in providing information?*
9. *What mechanisms should the federal government implement or facilitate to increase public awareness and understanding of biotechnology products and processes?*
10. *Should ongoing consultation mechanisms be established to increase the two-way flow of information between government and the public and, if so, what form should they take? Is the new advisory body an appropriate vehicle?*

Annex A: Listing of Related Activities and Resource Documents

The documents listed below provide additional detail on selected subjects discussed in this consultation document and on other matters related to the renewal of the Canadian Biotechnology Strategy. Many of the related activities have their own consultative process, which is noted in the resource document. The documents are available on the Task Force's web page **http://strategis.ic.gc.ca/cbs** and are also available, on request, from the Canadian Biotechnology Strategy Task Force, Room 799B, East Tower, 235 Queen Street, 7th Floor, Ottawa ON K1A 0H5 (Tel.: (613) 946-2848; Fax: (613) 946-2847; E-mail: cbstf@ic.gc.ca).

1. OTHER RELATED ACTIVITIES

- 1.1 Renewal of the *Canadian Environmental Protection Act*
- 1.2 Biosafety Protocol
- 1.3 Reproductive and Genetic Technologies
- 1.4 World Trade Organization Patent Review
- 1.5 Privacy Legislation
- 1.6 Human Genome Declaration

2. SECTOR OVERVIEWS

- 2.1 Agriculture and Agri-Food Canada
- 2.2 Aquaculture
- 2.3 Environment and Environmental Industry
- 2.4 Forestry
- 2.5 Health and Health Industries
- 2.6 Mining and Energy

3. RELATED RESOURCE DOCUMENTS

- 3.1 Biotechnology Human Resources Council
- 3.2 Research and Development
  - 3.2.1 Research and Development in Biotechnology
  - 3.2.2 Biotechnology: Technology Transfer and Commercialization
- 3.3 Regulatory System
  - 3.3.1 The Federal Regulatory System
  - 3.3.2 Labelling of Novel Foods Derived Through Genetic Engineering
- 3.4 Ethics
  - 3.4.1 Background Research Papers
  - 3.4.2 Ethics in Research: Tri-council Ethics Policy
- 3.5 International Issues Report
- 3.6 1983 National Biotechnology Strategy

Annex B: Suggested Questions for Discussion

Policy Framework

1. Are the proposed vision, objectives and principles appropriate?

Advisory Body for Biotechnology

2. What should be the terms of reference and structure of the new federal advisory body?
3. Regarding membership, what should be the composition, membership criteria, qualifications and length of terms?
4. 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?
5. On what priorities should the advisory body focus?

Public Awareness and Participation

6. What kinds of information does the public need, and how do these needs differ by sector and application?
7. What are the best ways to make information to the public available?
8. What are the roles of industry, academia, non-governmental organizations and governments in providing information?
9. What mechanisms should the federal government implement or facilitate to increase public awareness and understanding of biotechnology products and processes?
10. Should ongoing consultation mechanisms be established to increase the two-way flow of information between government and the public and, if so, what form should they take? Is the new advisory body an appropriate vehicle?