# *Canadian Biotechnology Advisory Committee*

# *Program Plan 2000*

## Biotechnology Ministerial Coordinating Committee

## February 17, 2000

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***Preamble***

In preparing its Program Plan, the Canadian Biotechnology Advisory Committee (CBAC) identified aspects of biotechnology that are of interest to various sectors of Canadian society and that are considered to be different strategies for addressing its mandate in these areas of interest. The process involved:

- review of documentation developed by, or on behalf of, the Canadian Biotechnology Task Force;
- review of reports and "issues" summaries prepared by, or on behalf of, the Canadian Biotechnology Secretariat;
- briefings by representatives of the federal government departments, whose ministers comprise the Biotechnology Ministerial Coordinating Committee (BMCC), and by related agencies;
- briefings from representatives of other bodies and from consultants concerning methods of soliciting citizen engagement;
- idea generation through "brainstorming" sessions among CBAC members themselves.

This document is CBAC's initial Program Plan (the "Plan"). The Plan is subject to ongoing refinement and change as appropriate.

## *Operation of CBAC*

### 1. *Ongoing Mandate*

CBAC is distinguished from some other federal advisory bodies (e.g., the National Forum on Health) charged with producing a single "deliverable" by having an indefinite life-span and by serving as an ongoing source of advice for the federal government over a wide range of biotechnology issues and sector. It will act as an ongoing vehicle for engaging Canadians in the process of determining what that advice should be.

This fundamental feature of CBAC is reflected in the manner in which it has organized itself, the principles that will guide its work and the kinds of activities it will undertake.

### 2. *Organization*

To facilitate its work, CBAC has organized itself in a manner that reflects the three main themes of the Canadian Biotechnology Strategy. These are stewardship, economic and social development, and citizen engagement. Three standing committees (see Appendix A for their Terms of Reference) have been established under these headings with the following mandates:[1]

- **Stewardship**: The committee shall concern itself with the social, ethical, legal, environmental and regulatory dimensions of the development and application of biotechnological innovations.

- **Economic and Social Development**: The committee shall concern itself with scientific developments leading to biotechnological innovations and their application to health, the environment and the economy.

- **Citizen Engagement** The Committee shall concern itself with engaging Canadians in discussion of the public policy implications of the development and application of biotechnological innovations for both present and future generations.

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[1] Terms of Reference for the Standing Committees are given in Appendix A.

3. ***Guiding Principles***

CBAC has adopted the following principles to guide its undertakings:

- primacy of the public interest
- independence
- knowledge-based deliberation
- integrity
- openness
- responsiveness
- breadth of perspective

4. ***Prioritization***

CBAC has adopted the following considerations as "criteria" to be used in the choice of specific activities to be included in its Program Plan.

**Primary**

- centrality to the CBAC mandate (e.g., matters referred by the BMCC to CBAC for advice)
- feasibility
- timeliness (current level of interest and concern – in government and in the public)
- complementarity (does not duplicate the work of other groups, fills a gap, adds value)
- alignment with special features of CBAC (multiple stakeholder and multi-dimensional perspective)
- potential policy impact

**Other**

- contribution to public education and awareness
- contribution to CBAC's effectiveness

5. ***Program Categories***

CBAC has identified two main categories of program activities to be included in its Plan: general activities and special projects.

**General Activities**

These are continuing activities of a general nature (e.g. monitoring developments in Canada and abroad; providing opportunities for raising public awareness; and maintaining a forum for a continuing "national conversation" on developments in biotechnology and their societal implications).

**Special Projects**

These are projects of a limited duration on particular topics (e.g. patenting of higher life forms). Each special project will be directed by a project steering committee (see Appendix B for their Terms of Reference) made up of representatives of each standing committee.[2]

6. ***Types of CBAC Involvement in Special Projects***

Given the limitations of time (CBAC members are volunteers) and resources, and the commitment of CBAC members to high standards, there is a tension between the desire of CBAC to be helpful and responsive in mounting special projects and the need to support longer-term activities. Accordingly, CBAC has identified the main types of involvement it will consider in undertaking special projects. The choice of a particular type of involvement will be influenced mainly by the desire to optimize the balance between responsiveness and the ability to establish a sustained deliberative approach to the main themes of CBAC's activities. The types of involvement are described in the following action statements:

- CBAC takes on the proposed project, includes it in its current activities, and acts as the organizer and the locus of responsibility for the execution and delivery of the results.

- CBAC takes on the proposed project but defers its implementation.

- CBAC agrees to participate in a joint project with appropriate government agencies or others, but reserves the right to incorporate the project results

[2] Terms of Reference for the Project Steering Committees are given in Appendix B.

into its own complementary activities that examine issues that may not have been addressed in the original project.

- CBAC chooses not to become involved in a given project. However, this does not preclude members of CBAC from participating in their personal capacities as experts should others mount the project. Nor does it mean that CBAC may not take the project on in the future. Here too, CBAC might incorporate the project results into complementary activities.

- CBAC decides that the project lies outside its mandate or that there is little opportunity for CBAC to add value.

7. ***Project Scope***

When designing special projects it has chosen to undertake, CBAC will deliberately set ambitious targets as to scope and completion date, recognizing that both may have to be modified or that considerations of timeliness may prompt CBAC to issue reports on parts of the project before the whole project is completed.

*General Activities*

1. ***Communications***

- develop a CBAC communications strategy
- establish a web site and implement an online "Open Forum" on biotechnology
- develop educational activities, as required, to raise public awareness of specific or general biotechnology issues
- prepare media releases
- organize media conferences
- develop a contact list for stakeholder groups and interested individual Canadians
- post minutes of CBAC meetings on the web site

2. ***Monitoring and Reporting on Developments***

- establish linkages with counterpart bodies or agencies in other countries or in multinational organizations to facilitate the monitoring function
- review and comment on selected reports produced by federal departments or by interdepartmental groups that bear on CBAC's interests or work in progress
- publish an annual report that describes developments in Canada and abroad and summarizes the activities of CBAC. Each of the three standing committees will guide the preparation of a section of the annual report describing developments in Canada and abroad in their respective areas of focus.

3. ***Conferences, Workshops, Roundtables and Focus Groups***

CBAC may decide to sponsor major ("national") conferences on biotechnology. In planning these conferences, special attention will be paid to the possibility of "piggy-backing" on related conferences where that might be advantageous. In addition, CBAC will organize workshops, focus groups and conferences on selected topics in various regions as part of the process of raising awareness, citizen engagement, eliciting expert opinion or to access cross-disciplinary input.

## Special Projects

In addition to its general activities, CBAC intends to focus on two special projects in 2000 (projects P1 and P2) and to initiate preparatory work on three others (projects P3, P4 and P5).

### Project P1: The Regulation of Genetically Modified Foods

#### P1.1 *Background*

The ability of science to introduce novel traits into plants has changed the way we grow food as well as the characteristics of the food we eat, and may also affect trade relations between nations. At this time, there is no public or scientific consensus on the implications of these new developments for people, animals, or the environment. The genetic modification of food remains one of the most controversial areas of biotechnology.

Since 1995, Canada and other countries have produced a variety of genetically modified food crops, textile crops and animal feeds. By the end of 1999, Canada had approved 42 genetic modifications. In addition, a wider variety of foods and food products are available to Canadians through international trade. Examples of genetically modified products currently available in this country include cheese, corn, soybeans, canola, tomatoes, potatoes, tobacco, squash, melons, sugar beets, flax and milk. Genetic modifications to these products include: herbicide, pesticide, viral and insect resistance, increased yields and enhanced shelf life.

Foods with new functional, nutraceutical or pharmaceutical attributes are also under development or are awaiting regulatory approval in many countries. These foods are designed to enhance human health by providing certain nutrients or delivering vaccines when the food is ingested. Examples include rice with increased vitamin A and iron content, potatoes modified to produce hepatitis B vaccine and genetically altered tobacco plants that produce proteins that can be used to treat diabetes.

The introduction of genetically modified food and textile crops has generated significant debate in almost all countries. This controversy has resulted in a lack of public acceptance of this technology in the European Community. The GM foods have also been the focus of much attention at trade and regulatory harmonization negotiations such at the World Trade Organization meeting in Seattle in December 1999, and the Biosafety Protocol meetings in Montreal in January 2000.

The public debate has focussed on two major areas: the safety of GM foods, and their possible negative effect on the environment. The effect of these foods on the developing world has also been identified as a concern.

Proponents claim that GM foods will aid farmers by increasing yield and quality and by reducing fertilizer and water use, length of the growing season, and their reliance on herbicides and pesticides. They say these developments in turn will decrease the extent of environmental degradation and the exposure of humans, animals and other plant life to dangerous chemicals. Proponents claim that farmers in the developing world will also benefit from these advantages, and that the world's food supply will eventually increase. They also claim that genetically modified food will improve the health of people in developing nations by increasing the nutrient content of food and providing a simple method of administering vaccines. In short, they believe that GM foods are safe for humans, animals and the environment, will improve human health and will help maintain the family farm in both developed and developing countries.

Critics claim that GM crops will in fact hurt farmers in the developing world, as large multinational corporations come to control the international seed market, and poor farmers can no longer save seed to use in the next growing season. Some Canadian farmers have expressed concern that they will not be able to find international markets for their genetically modified crops due to the current controversy. Some people also question the ethics of manipulating plant life in this way. There is also concern that the long-term effects of these foods on human health have not been properly examined, and that problems may emerge in the future. Environmental concerns include fear that transgenes from modified crops will "drift" into neighbouring environments and affect other plant life, that biodiversity will decrease and that animals and insects who eat these plants will be negatively affected.

Underlying these concerns is an expressed lack of public confidence in the regulatory capacity of governments to deal effectively with this new technology. Some have expressed concern that regulatory capacity may be compromised in countries where governments also promote GM foods and crops as part of their economic growth agenda.

These concerns, taken together, have led to calls for the labelling of genetically modified foods so that consumers can decide whether or not they wish to purchase and consume these products. Disclosure and consumer choice are only one facet of this complex issue.

On September 17, 1999, the Canadian government announced its support for a project to develop a Canadian standard for the voluntary labelling of GM foods. This project is being undertaken by the Canadian General Standards Board and the Canadian Council of Grocery Distributors.

The controversy over GM food has led several governments and international organizations to undertake scientific studies and public consultations on the safety and regulation of these products. In June 1999, the G8 Heads of State, meeting in Cologne, Germany, invited the member countries of the Organisation for Economic Co-operation and Development to undertake a study of the implications of biotechnology and other aspects of food safety. In December 1999, the U.S. Food and Drug Administration (FDA) held three public forums on food biotechnology to hear public concerns and describe how the FDA regulates GM food.

At its inaugural meeting in October 1999, CBAC identified the robustness of Canada's systems for assessing and regulating the application of biotechnological innovations as an issue requiring study and evaluation. It specifically cited the topic of genetically modified foods as being of intensifying interest. The government's interest in the topic was emphasized in briefings by deputy ministers and other officials. On the basis of its discussions and consultations CBAC identified three areas of study in relation to biotechnological innovations in general, and genetically modified foods in particular. These are the **Science Base** underpinning the regulatory processes involved in the assessment of current and emerging innovations; the **Governance and Organization** of regulatory systems and their efficacy in maintaining a balance between potential benefits and harms in exploiting biotechnological innovations; and, the **Social, Ethical and Legal Dimensions** of the introduction and use of genetically modified foods as seen by various expert and non-expert sectors of Canadian society.

On December 17, 1999, following consultation with CBAC, Health Minister Allan Rock, Agriculture and Agri-Food Minister Lyle Vanclief, and Environment Minister David Anderson announced their intention to establish an Expert Scientific Panel on the Future of Food Biotechnology. Its mandate is to provide Health Canada, the Canadian Food Inspection Agency and Environment Canada with advice on Canada's regulatory system and the scientific capacity that the federal government requires into the 21st century to ensure that safety of new food products being developed through biotechnology.

Given the proposed establishment of an Expert Scientific Panel focussed on the science base, CBAC will concentrate on the governance and organization of regulatory regimes and on the social, ethical, legal, economic and environmental aspects of food biotechnology.[3]

Following the completion of the work of the Expert Scientific Panel and its own work, CBAC will then produce an overarching report with recommendations that will be informed by work of the Expert Scientific Panel and results from the Canadian General Standard Board project on voluntary labelling standards.

### P1.2 *Objectives*

- To identify the issues that require examination in the public debate on GM food in the broader context of agriculture and food production in general;
- To examine issues related to the governance and organization of the food regulatory system for GM foods not examined by the Scientific Expert Scientific Panel;
- To examine other issues related to GM food, including social, ethical, legal, economic and environmental issues;
- To make recommendations concerning policy options for Canada;
- To maintain liaison with the Expert Scientific Panel on the Future of Food Biotechnology and to relate its findings to the outcome of the work of CBAC on governance and organization and on social, ethical, legal, economic and environmental issues;
- To raise public awareness and engage Canadians in an unbiased manner.

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[3] Questions surrounding the robustness of Canada's systems for assessing and regulating the application of biotechnological innovations arise not only in relation to food biotechnology, but also in relation to a wide variety of other applications in areas of human health and the environment. The commercial exploitation and regulation of innovations in therapeutics applied to humans and animals and in environmental bioremediation have special features, as well as features in common with applications of food biotechnology. Thus the work outlined in the present program plan should be seen as part of a larger program of study that will generate a series of projects in relevant areas. These projects will benefit considerably from the experience gained in addressing the topic of food biotechnology.

Research Topics

1) Examination of the **governance and regulation** of the food regulatory system.

- What is the rationale for a state-operated regulatory system for food? Do GM foods alter that rationale?
- How does the Canadian regulatory system for GM food (as it relates to human and animal health and the environment) compare with the systems in other leading industrial countries with respect to governance and organization, including:
  - the accountability structures to the government and the public;
  - performance standards and measurements for effectiveness and efficiency;
  - the openness and transparency of the current system;
  - the separation between the regulators and the promoters of GM food within the government;
  - public input into the development of regulatory policy and individual regulatory decisions;
  - pre- and post-release monitoring systems;
  - the approval process for GM food;
  - the monitoring of food consumption by Canadians;
  - the mechanism for regulatory enforcement;
  - roles for the regulator vis-à-vis the various stakeholders, [such as scientists, suppliers, farmers, the general public].
- What is the appropriate position for Canada with respect to international harmonization and specialization of various elements of the regulatory system?

- What changes in the regulatory system are needed to increase effectiveness and public confidence?

2) Examination of the **social, ethical, legal, economic and environmental** aspects of GM food

- What are the current and anticipated benefits of GM foods (economic, health, legal, environmental, etc.)? Do these differ according to gender, race, ethnicity, social class, region, etc? In what way?

- What ethical and justice issues (including distributive, social and global justice) are raised by GM foods? Are they different for different aspects of GM food (food consumption, industrial development, pharmaceuticals/nutraceuticals)?

- Do GM foods present unique concerns in the area of research ethics?

- How, when and by whom are non-science issues identified and addressed in the current regulatory and policy system? Should this change?

- What are the rationales and methods used (including labelling) to make information available to the public and consumers to support citizens and consumers decisions? What are the alternatives? What is the likely effectiveness, cost and benefit of each method?

**P1.3** ***Methodology***

CBAC will form a project steering committee to undertake its work on GM food. This committee will have representation from each of the standing committees.

This work will be done in two phases. The first phase will involve the clarification of research questions and research studies to identify current international norms and future trends and to assess the current Canadian situation.

The resulting research studies, the report of the Expert Scientific Panel, and any results from the Canadian General Standards Board voluntary labelling standards project will provide the basis for the development of public consultation documents. The outcome of the public consultations together with all research studies will then be integrated by CBAC into a final, overarching report with recommendations.

**P1.4** ***Timeline***

Expert Scientific Panel: Final report to be completed in the fall of 2000.
CBAC reports on research topics 1 and 2 to be completed by end of summer 2000.
CBAC public consultations to be held in the fall/early winter 2000.
Final CBAC report to be prepared by spring 2001.

**Project P2: Protection and Exploitation of Biotechnological Intellectual Property**

## P2.1 *Background*

In the 21st century, biotechnology is expected to become a major driver of economic growth. It has the potential to improve the quality of life and to enhance job creation and promote economic growth in a variety of industrial sectors. If Canada is to participate to its full potential in the "biotechnology revolution," it must have a sound and effective infrastructure of policies in the area of intellectual property rights. The ultimate goal is to devise policies that reflect Canadian values, support the growth of biotechnology in an ethical and sustainable manner, and maximize the benefits of biotechnology for Canadians.

However, policies on granting or extending intellectual property rights in the field of biotechnology, including exemptions and exceptions, must be framed within the general context of the balance of their potential benefits and disadvantages. This context must include the public's concern about access to new developments, and Canada's international treaty obligations.

Concerns from several quarters suggest that there is a growing need for Canada to review its policies on intellectual property, including the *Patent Act,* to address issues raised by the rapid pace of biotechnological innovation. Four examples of areas of concern are cited below.

- The Patent Office and the courts do not appear to have the tools or the capacity under current legislation and policy to deal with the unique characteristics of biotechnology. For example, in a recent Federal Court of Canada ruling, Mr. Justice Nadon of the Trial Division ruled that the Harvard Onco-mouse (a transgenic mouse) was not patentable subject matter under the *Patent Act.* He suggested that Parliament, if it so wishes, could change the law to allow for the patenting of higher life forms. The appeal of this decision was heard on December 9, 1999.

- The biotechnology industry has identified the lack of certainty in Canada's patent environment as one of the key impediments to commercialization of biotechnological products and processes developed in Canada. The 1998 National Biotechnology Advisory Committee report identified several priority patenting issues to be addressed by Canadian policy makers including the need to ensure that Canadian biotechnology "start-ups" have sufficient access to patent protection to attract venture capital investment.

- Recent polling indicate that the application of genetic engineering to plants, animals and humans raises a range of potential ethical issues of concern to the general public that must be factored into the design of marketplace laws, including the Patent Act.

- Patents granted on plant and animal genes and cells have raised questions in Canada's agricultural sector in respect of public researchers' "freedom to operate" and the practice, in some instances, of sowing harvested seed.

- There is some concern that, in the current environment, patent law may be failing to achieve its assumed objectives of facilitating innovation, commercialization and the dissemination of useful technologies.

It would appear that Canada is lagging behind other Organization for Economic Cooperation and Development countries in considering these issues. The United States has been implementing a biotechnology patent framework over the past ten years and the European Union has had Community legislation in force since July 1998.[4]

**P2.2** ***Objective***

To provide advice to the government on policy initiatives that will enhance the ability of Canadians to protect and exploit intellectual property developed through biotechnology.

This project will focus on five main areas of inquiry:

- How does the Canadian system of intellectual property protection compare with the systems in other leading industrialized nations (i.e. the G8)?

- If the parameters of Canada's intellectual property system are markedly different from those of other countries, what implications will this have for Canada?

- How does the current Canadian system of intellectual property protection affect the development and exploitation of biotechnological innovations?

- What changes in the system are desirable from a scientific and economic perspective?

[4] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the *Legal Protection of Biotechnological Inventions*

➢ What social and ethical considerations should be integrated into the design and implementation of a Canadian system of intellectual property protection?

### P2.3 *Methodology*

CBAC will form a project steering committee to undertake its work in the area of intellectual property. Project 2 will proceed in a phased manner. The first two questions above will be addressed by reviewing existing work undertaken by government and other bodies. Significant gaps in the information available will be identified and studies will be commissioned to fill in the gaps. With the information assembled in phase 1 as background, the second phase will proceed and will involve consultation with stakeholder groups and the public generally. Phases 1 and 2 will not be strictly sequential in that work on certain elements of phase 2 will likely begin before phase 1 is completed.

### P2.4 *Timeline*

Review of existing work to be completed by May 2000
Subsequent steps to be decided by the project steering committee

## Project P2a: Patenting of Higher Life Forms

### P2a.1 *Background*

There are certain aspects of intellectual property that, on the grounds of timeliness and currency, require and/or lend themselves to special consideration. In this connection government officials have identified the issue of patenting of higher life forms as being of particular interest. Accordingly, CBAC has identified a specific sub-project in the area of intellectual property on this topic.

The government seeks to reassess its existing intellectual property framework regarding the patenting of higher life forms. Given the complex economic and stewardship concerns surrounding this issue, the government wishes to consult with the principal stakeholders on the patentability of higher life forms; advice from CBAC on building consensus.

Biotechnology patenting issues will be considered during the coming years in international negotiations. The next round of multilateral trade negotiations is expected to commence in the year 2000. The World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) addresses the question of patentability of higher life forms in Article 27.3(b). The operation of this section allows WTO member countries to exclude from patentability plants and animals and essentially biological processes for the production of plants and animals. Some member countries are advocating for the Article's expansion, while others (for example, the United States) are advocating a narrowing of the Article and possibly its elimination. Canada will be better able to contribute to this debate by developing a domestic policy prior to the commencement of these negotiations.

There are a number of domestic and international developments suggesting that there is a growing need for Canada to review its *Patent Act* to address the new issues raised by biotechnology. As noted earlier, the patentability of a specific higher life form, the Harvard Onco-mouse, is currently before the courts. At this time this animal is not patentable under the existing *Patent Act,* based on a 1997 appeal hearing in the Trial Division of the Federal Court; however, an appeal to the Appeals Division of the Federal Court was heard on December 9, 1999.

Regardless of the legal patentability of any higher life form, the question of whether such patents ought to be permitted in Canada remains open and extremely complex, since it reflects social and ethical values.

**P2a.2** ***Objective***

To provide advice to the government on whether the patenting of higher life forms should be permitted in Canada.

Research Topics

1) What should be included in the term "higher life forms"? This definition could include animals, plants, transgenic entities, the human body and human organs and body elements.

2) What biological entities should be included or excluded as patentable subject matter in the *Patent Act*?

3) Should the *Patent Act* include a "public policy" exception such as the "ordre public" or "morality" provision found in the European Patent Convention Article 53(a)? If so, what should be the scope of this exception?

4) Should the *Patent Act* contain specific exemptions such as a "methods of medical treatment" or "research/experimental use" exemption affirming the common law developed to date?

5) Should an opposition procedure to a particular patent be created? If so, what should be the preferred form and grounds for opposition? Who should be responsible for the operation of the procedure?

**P2a.3** ***Methodology***

CBAC will strike a project steering committee with members from all standing committees to examine this issue by reviewing current information and commissioning special studies if required. A discussion document will be prepared as the basis for consultations with stakeholders and the public, followed by a final report with recommendations.

**P2a.4** ***Timelines***

Discussion document to be completed by October 2000
Consultations to be completed by April 2001.
Final report to be completed by September 2001.

**P2a.5** ***Existing Work and Studies***

Schrecker, T. and A. Wellington. "Patenting of Biotechnological Innovations concerning Animals and Human Beings." Ottawa: March 1, 1999.

Schrecker, T. and A. Wellington. "Patenting of Higher Life Forms and Human Biological Materials." Ottawa January, 2000.

## Project P3: Incorporating Social and Ethical Considerations into Biotechnology

### P3.1 *Background*

Many biotechnology applications have profound social and ethical implications. The federal government is committed to developing biotechnology in a way that reflects the social and ethical values of Canadians. How can this be done in a pluralistic society? One suggestion is to establish an ethics framework for biotechnology within the federal government. Such a framework can encourage ethical deliberation, identify value conflicts, and encourage public participation in the policy-making process.

An ethics framework has been defined as having three interactive and complementary elements:

1) a substantive element (the values that will be reflected in policy making)
2) a procedural element (how the framework will be implemented)
3) a structural element (what body or bodies will be responsible for implementing all or part of the framework)

France, Norway, the United States, the United Kingdom, the European Union, and UNESCO have included all or some of the above elements of a formal ethics framework in their biotechnology, bio-ethics or science policy processes. The establishment of CBAC can be seen as one element of such a framework for Canada (a body that provides advice on ethical aspects of biotechnology).

Other stakeholders such as industry groups and non-governmental organizations also have roles to play. For example, international biotechnology organizations are working together to develop a code of ethics for their industry. Many churches and public interest groups have also undertaken studies and have made recommendations in this area.

### P3.2 *Objective*

To facilitate the integration of the social and ethical dimensions of biotechnology into public policy decision making and administration.

Research Topics

1) How can we identify the values that Canadians wish to see reflected in public policy on biotechnology?

2) What procedures and/or structures need to be established to implement these values?

3) How can the effectiveness of these procedures and/or structures be monitored and assessed?

### P3.3 *Methodology*

CBAC will strike a project steering committee to further examine the above questions, and to undertake public consultations.

### P3.4 *Timelines*

To be decided.

### P3.5 *Existing Work and Studies*

Papers 1 to 3, on ethics and biotechnology, were published as part of the consultations for the renewed Canadian Biotechnology Strategy. All three recommended the establishment of an ethics framework. The Interdepartmental Working Group on Ethics and Public Confidence in Biotechnology commissioned paper 4.

1) Jones, Derek J. "Ethics and Biotechnology: The Role of the Government of Canada." Ottawa, 1998.
2) Jones, Derek J. "Towards a Coherent Ethics Framework for Biotechnology in Canada." Ottawa, 1999.
3) Schrecker, Ted and Margaret A. Somerville. "Making Ethically Acceptable Policy Decisions: Challenges Facing the Federal Government." Ottawa, 1998.
4) Schrecker, Ted, Barry Hoffmaster, Margaret A. Somerville and Alex Wellington. "Biotechnology, Ethics and Government: Report to the Interdepartmental Working Group on Ethics." Ottawa, 1998.

## Project P4: The Use of Novel Genetically Based Interventions

### P4.1 *Background*

Biotechnology research has led to the development of a broad range of genetically based interventions in humans that raise a host of scientific, social, ethical and economic issues. Examples include, but are not limited to, stem cell research and therapy, gene therapy and enhancement, cloning and xenotransplantation.

There have recently been a number of extraordinary advances in research on human stem cells - immature cells that have the potential to develop into a variety of human tissues. These advances have led stem cell research to be labelled the "breakthrough of the year" by the journal *Science*. Stem cells can come from several sources: adult humans, aborted human fetuses, human embryos created through in vitro fertilization (IVF), and cloned human embryos. The use of adult stem cells is generally considered non-controversial, but the use of other stem cells raises a number of profound social, ethical and policy questions. The U.S. National Bioethics Advisory Commission recently concluded that embryonic stem cell research should be eligible for funding because of its potential scientific and therapeutic benefits. However, it put strict conditions on the sources of stem cells used in research. The Nuffield Council in the United Kingdom may adopt a similar position. What is an appropriate policy in Canada?

Although gene therapy is currently in the research phase and does not exist as an established therapy, researchers believe it has enormous potential to treat a variety of genetic diseases. Concerns have been raised in a number of areas. These areas include the use of germ-line gene therapy (therapy that will result in genetic modifications to future generations) and the patentability of such therapies. Somatic cell therapy (therapy that does not affect future generations) has also been subject to regulation in some countries on ethical grounds. In 1990, the Medical Research Council of Canada published Guidelines for Research on Somatic Cell Therapy in Humans in which it recommended against germ-line gene therapy. Proposed federal legislation on human reproductive and genetic technologies would also prohibit this intervention. However, as our knowledge of the human genome and our understanding of biological functions has increased, so too has the desire of some to manipulate the genome in ways that they see as beneficial. Some even argue that there is an obligation to develop and use gene therapy.

Cloning technology can be used for reproductive and non-reproductive purposes. The main benefit of human reproductive cloning would be for infertile persons and couples at risk of

having a child with a genetic disorder who could not otherwise have a child that would be genetically related to one of the partners. Other benefits, from the perspective of some, would be the ability of parents to clone a dying or deceased child, and the ability to create a homologous tissue or organ donor. The benefits of non-reproductive cloning include the ability to replace damaged or diseased tissue and organs, and the possible development of a better vehicle for the delivery of gene therapy. The Canadian government plans to prohibit human cloning for reproductive purposes in its proposed legislation on reproductive and genetic technologies. At present in the U.S., there is a five-year moratorium on federal funding for research on reproductive cloning. When this moratorium ends in 2002, the debate will no doubt be renewed.

Xenotransplantation is the transplantation of cells, tissues or whole organs from one species to another. Heart valves from pigs have been used in humans for several years, and animal organs are sometimes used for short periods to keep a patient alive until a human organ becomes available. Research is currently under way in several countries that may eventually result in the permanent transplantation of genetically modified pig organs into human beings suffering from organ failure. Researchers believe that xenotransplantation may eventually help to alleviate the existing shortage of human organs for transplant. However, many social, ethical, scientific and economic questions must be answered before whole-organ xenotransplantation can become a reality. The feasibility and acceptability of this type of xenotransplantation is currently being examined by several countries, including Canada.

While these genetically based interventions have been described separately, it is important to recognize that they may eventually be combined in ways that will generate even more complex questions. CBAC recognizes the importance of these developments, and will monitor their development.

### P4.2 *Objectives*

To review the social, ethical, legal, economic, regulatory, health and environmental policy implications of new developments in biotechnology related to novel genetically based interventions.

<u>Research Topics Applicable to Any Novel Genetically-Based Intervention</u>

1) Which genetically based interventions are ethically acceptable?

2) Do our obligations to present and future generations require the development and use of any genetically based intervention technologies?

3) What are the current and anticipated benefits of these technologies (economic, health, legal, environmental, etc.)? Do these differ according to gender, race, ethnicity, social class, region, etc.? In what way?

4) What are the current and anticipated harms of these technologies (economic, health, legal, environmental, etc)? Do these differ according to gender, race, ethnicity, social class, region, etc.? In what way?

5) What equality and justice issues (including distributive, social and global justice) are raised by the use of these technologies? Are they different for different technologies?

6) What new concerns need to be addressed in the area of research ethics?

7) If a technology is acceptable, are special oversight or regulatory mechanisms needed?

8) Are there unique intellectual property or property law issues that should be considered?

### P4.3 *Methodology*

CBAC will establish a project steering committee with members from all Standing committees to examine this issue and consult with the public.

### P4.4 *Timelines*

To be decided.

## Project P5: Genetic Privacy

### P5.1 *Background*

Advances in genetics promise many health benefits, but they also give rise to concerns about possible violations of the privacy of genetic information. Should genetic information be treated like other medical information, or does it have characteristics that make it unique? Should it be protected in some circumstances, but made available in others? The inappropriate release or use of genetic information can lead to genetic discrimination, which might take the form of rejection for employment, loss of credit, insurance, eligibility for pensions, or even discriminatory treatment in the application of government social policy. The unwanted sharing of genetic information can also disrupt family relationships. Above all, the promise of genetic research for improved health may be jeopardized unless privacy and discrimination issues are addressed.

In western countries there is little legislation dealing specifically with genetic privacy and discrimination at this time. However, the move toward specific legislation is growing, especially in the U.S. The issue continues to be debated and examined internationally.

In Canada, most provisions that deal with genetic privacy and discrimination appear in more general legislation - including the Canadian Charter of Rights and Freedoms, laws governing professional confidentiality, data protection (privacy) and human rights laws, etc. Many of these were drafted before genetic information became an issue. An important overriding issue is whether genetic information is somehow different from other medical information, and therefore requires more protection. This issue has not been resolved.

### P5.2 *Objective*

To examine the adequacy of the existing mechanisms that protect the privacy of genetic information.

Research Topics

1) What are current international practices in this area? How does Canada compare?

2) Does Canada need to take additional steps to address the issue of genetic privacy? Are existing safeguards of medical information adequate?

3) If additional steps are needed, what would they be?

### P5.3 *Methodology*

CBAC will establish a project steering committee to examine existing research, undertake new research as needed, and undertake appropriate consultations.

### *P5.4 Timeline*

To be decided.

### P5.5 *Existing Work and Studies*

1) Oscapella, Eugene. "Genetics, Privacy and Discrimination" Paper commissioned by the Interdepartmental Working Group on Ethics and Public Confidence. Ottawa, 1999.

2) The Department of Justice is currently undertaking a review of the *Canadian Human Rights Act*. The Department recognizes that genetic privacy and discrimination may be one of the issues that to be incorporated into a revised Act. However, it is not clear at this time to what extent the department will be examining this issue.

Appendix A

# Terms of Reference - CBAC Standing Committees

**Names and Purpose**

- The Standing Committee on Stewardship facilitates the work of CBAC by providing focused attention on the social, legal and ethical, environmental and regulatory dimensions of the development and application of biotechnological innovations

- The Standing Committee on Economic and Social Development facilitates the work of CBAC by providing focused attention on scientific developments leading to biotechnological innovations and their application to health, the environment and the economy.

- The Standing Committee on Citizen Engagement facilitates the work of CBAC by providing focused attention on the engagement of Canadians in discussion of the public policy implications of the development and application of biotechnological innovations.

**Principles**

The standing committees will be guided by the principles outlined in the CBAC Statement of Guiding Principles.

- Primacy of the Public Interest
- Independence
- Objectivity
- Integrity
- Openness
- Responsiveness
- Comprehensiveness

**Composition**

(a) Membership

The standing committee shall be composed of:

- at least five members of the CBAC
- the Chair of CBAC (*ex officio)*
- additional *ad hoc* members as provided for in Section 5 hereof

(b) Chair/Vice-Chair/Secretary

- The CBAC Chair in consultation with the standing committee will appoint a Chair of the Standing Committee.
- A Vice-Chair will be appointed by the Standing Committee from among the members.
- A recording secretary will be designated to serve the Standing Committee.

**Mandate**

The standing committee shall:

- monitor developments in their respective fields related to biotechnology by maintaining a "watching brief"
- identify trends, emerging issues or other topics for CBAC to review and study
- keep up to date with the activities views, and advice of other bodies (domestic or foreign) involved in providing advice in regard to public policies related to biotechnology
- consider the findings arising from studies commissioned by CBAC or by the standing committee and make recommendations thereon to CBAC
- prepare a section of CBAC's annual report on developments within the standing committee's area of interest
- provide advice to CBAC on matters referred to it by CBAC or on matters that the standing committee deems to be appropriate and, without limitation, may recommend:
  - projects or programs of work for CBAC to undertake
  - the commissioning of research to support the members' deliberations
  - the selection of biotechnology related issues to be brought forward for review by the CBAC Committee of the Whole
- establish its own methods of work

The standing committee may recommend to CBAC the appointment of additional *ad hoc* members to the sub-committee to broaden its base of expertise in relation to specific matters.

**Reporting**

- The standing committee Chair will provide a copy to the CBAC Chair of minutes with all reports and other relevant materials available attached.
- The standing committee will report its analyses and recommendations concerning the work at regular Committee of the Whole meetings

**Frequency of Meetings**

- The standing committee will normally meet in conjunction with the regular CBAC meetings and at other times as may be required.

**Quorum**

A majority of the members of the standing committee shall constitute a quorum. Ordinarily decisions and recommendations of the committee will be achieved by consensus.

Where consensus cannot be achieved the main differences of opinion shall be reported and the balance of opinion shall be determined by means of a recorded vote or by such other means as are satisfactory to the standing committee.

**Minutes**

Minutes of standing committee meetings will be prepared by the recording secretary according to CBAC guidelines. The Chair of the standing committee will review and approve the draft prior to their distribution to members.

**Agenda**

An agenda for each meeting will be circulated to members of the committee in advance of the meeting.

**Accountability**

- The standing committees report to CBAC.

- The chair of the standing committee will report on the standing committee's activities during regular meeting of the CBAC; and will ensure that the standing committee functions within the terms of reference approved by CBAC.

**Committee Resources**

The following arrangements will be made by the Canadian Biotechnology Secretariat (CBSec).

- the provision of experts and other appropriate resources to aid in research and required for the formulation of recommendations;

- the designation of a member of the CBSec to assist the work of the standing committee;

- administrative support for the recording of minutes, word processing, photocopying, etc. as required;

- CBAC standing committees will have access to a secure Internet site, where documents may be posted for review. Other electronic work methods considered that would aid members in the carrying out of their functions independent of their geographic location will be considered.

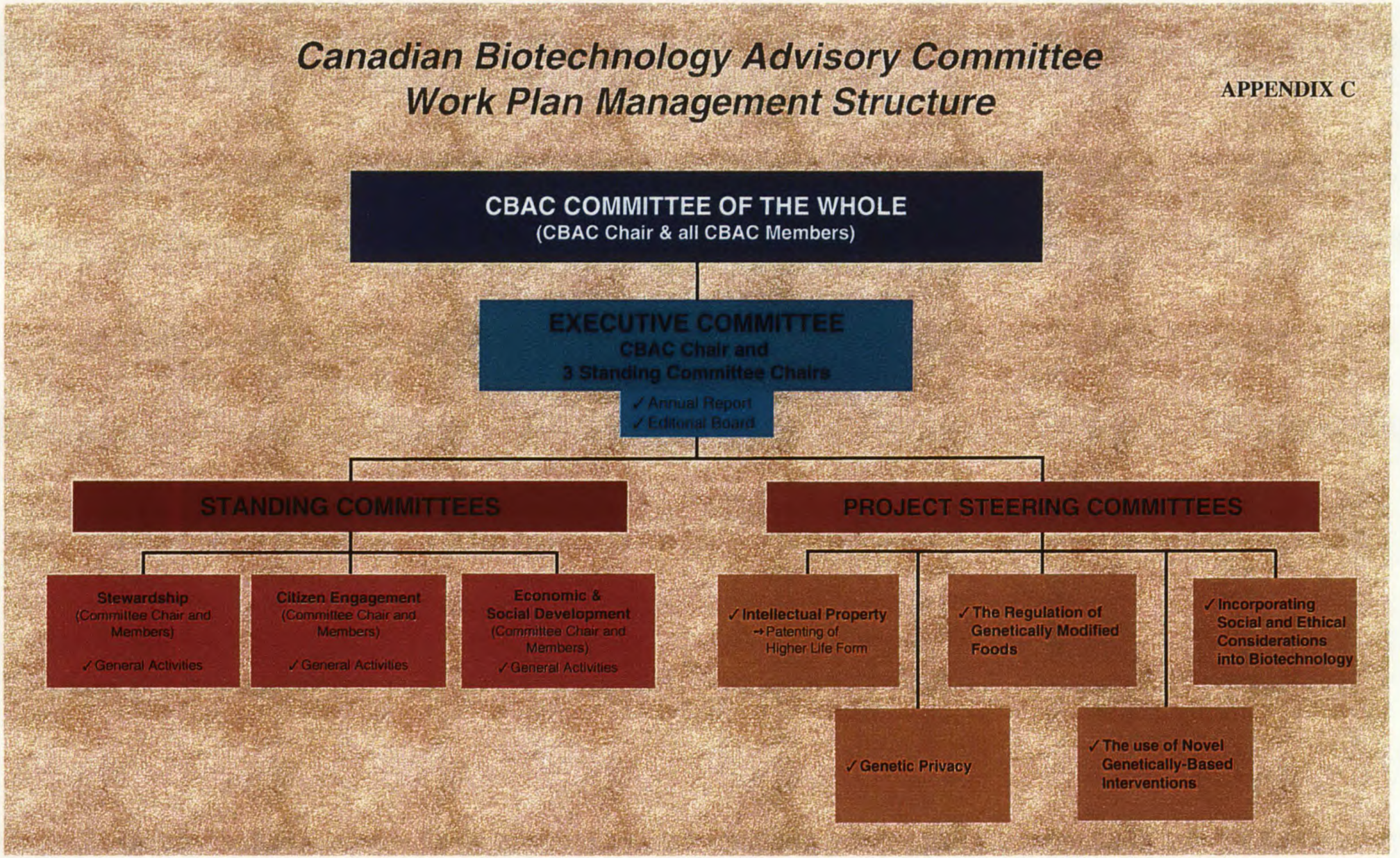
# Appendix B

## Terms of Reference - CBAC Project Steering Committees

- Provide overall direction and supervision to the project
- Recommend any changes in the scope of the project to the CBAC Committee of the Whole
- Identify necessary research studies; establish terms of reference for these studies; and assist in identifying contractors to carry out studies
- Monitor progress of research studies
- Review draft report and provide guidance to contractors
- Draft project steering committee conclusions and recommendations for consideration by the CBAC Committee of the Whole

# *Canadian Biotechnology Advisory Committee*
# *Work Plan Management Structure*

APPENDIX C



**Appendix D**

## MEMBERS OF THE CANADIAN BIOTECHNOLOGY ADVISORY COMMITTEE

| | |
|---|---|
| **Dr. Arnold Naimark** | *Chair, Canadian Biotechnology Advisory Committee*<br>Director, Centre for the Advancement of Medicine, University of Manitoba, Winnipeg, Manitoba |
| **Dr. Mary Alton Mackey** | President, Alton Mackey and Associates, Portugal Cove, Newfoundland |
| **Dr. Lorne Babiuk** | Director, Veterinary Infectious Disease Organization, Saskatoon, Saskatchewan |
| **Dr. Françoise Baylis** | Associate Professor in the Faculty of Medicine and the Department of Philosophy, Office of Bioethics Education and Research, Dalhousie University, Halifax, Nova Scotia |
| **Ms. Gloria Bishop** | Vice-President, Public Affairs and Communications, University Health Network, Toronto, Ontario |
| **Dr. Richard Black** | Head, Research & Development Nutrition, Novartis Consumer Health, Nyon, Switzerland and Assistant Professor, Department of Nutritional Sciences, University of Toronto, Toronto, Ontario |
| **Prof. Timothy Caulfield** | Associate Professor/Research Director, Health Law Institute, University of Alberta, Edmonton, Alberta |
| **Dr. Robert Church** | Professor Emeritus of Medical Biochemistry and Molecular Biology, University of Calgary; Owner, Lochend Luing Ranch, Airdrie, Alberta |
| **Dr. Pierre Coulombe** | President and CEO, Infectio Diagnostic Inc., Ste-Foy, Quebec |
| **Dr. Arthur Hanson** | Distinguished Fellow and Senior Scientist, The International Institute for Sustainable Development, Winnipeg, Manitoba |
| **Dr. Michael Hayden** | Director, Centre for Molecular Medicine and Therapeutics, Children's and Women's Hospital, University of British Columbia, Vancouver, British Columbia |
| **Mrs. Suzanne Hendricks** | Nutritionist, Ottawa, Ontario |
| **Dr. Thomas J. Hudson** | Director, Montréal Genome Centre, McGill University, Montréal General Hospital Research Institute, Montréal, Quebec |

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|---|---|
| **Dr. Bartha Maria Knoppers** | Law Professor and Senior Researcher, Centre for Public Law Research, Université de Montréal, Montréal, Quebec |
| **Dr. Murray McLaughlin** | President & CEO, Foragen Ventures Inc., Guelph, Ontario |
| **Ms. Anne Mitchell** | Executive Director, Canadian Institute for Environmental Law & Policy, Toronto, Ontario |
| **Dr. Peter W.B. Phillips** | Professor, University of Saskatchewan (College of Agriculture), Saskatoon, Saskatchewan |
| **Prof. Douglas Powell** | Assistant Professor, Plant Agriculture, University of Guelph, Guelph, Ontario |
| **Dr. René Simard** | Former Rector, Université de Montréal, Montréal, Quebec |
| **Mr. Jonathan Bjorn Syms** | Physiology Student, University of Winnipeg, Winnipeg, Manitoba |
| **Mrs. Denny Warner** | Manager, Vanderhoof Chamber of Commerce Vanderhoof, British Columbia |