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No.

**14000**

**FOLDER ID: 69532**

**Interdepartmental Relations**

Canadian Biotechnology Strategy ( CBS ) -  
Biotechnology ADM Coordinating Committee  
(BACC)

Opened: 1999/04/01

Closed: 2000/12/31

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Nofra → Bart  
copied &  
binder in  
my office

**From:** <Atkinson.Roy@ic.gc.ca>  
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**Date:** Thu, Dec 7, 2000 9:05 AM  
**Subject:** Biotechnology Transition Package and BACC meeting notes

As a follow up to the BACC meeting of November 23, please find attached a biotechnology transition package for your use as well as BACC meeting notes from the two last meetings. At the current time, we have no additional information on confirmation of a date for a biotechnology deputies meeting in December.

1) The first set of documents are BACC meeting notes from November 23 for review and comment, and meeting notes from October 19 incorporating changes from Health and Environment.

<<BACC Meeting Notes October 19 2000 amended FINAL.doc>> <<BACC Meeting Notes November 23 2000.doc>>

2) The second is a revised biotechnology overview note for transition which incorporates comments received by various departments.

<<LSE & biotechnology overview.doc>>

3) Lastly, you will also find attached a full set of sector/horizontal strategy summaries and strategies including the new piece on international from DFAIT and the R&D piece from NRC, for transition purposes.

- 3a) Agriculture summary & strategy
- 3b) Economic Development summary & strategy
- 3c) Environment summary & strategy
- 3d) Fisheries summary & strategy
- 3e) Forestry summary & strategy
- 3f) Health Strategy
- 3g) International Strategy
- 3h) Mining summary & strategy
- 3i) Research and development summary and strategy
- 3j) NSERC strategy
- 3k) CIHR strategy

<<November 20 Agriculture summary.wpd>> <<November 20 Agriculture strategy.wpd>>

<<November 21 economic summary.wpd>> <<October 30 Economic Development of Biotechnology.wpd>>

<<November 20 fisheries summary.doc>> <<November 20 Environment strategy.doc>>

<<November 20 fisheries summary.doc>> <<October 27 Fisheries strategy.doc>>

<<November 20 Forestry summary.wpd>> <<October 17 Forestry strategy.wpd>>

<<November 5 Health strategy.wpd>>

<<November 23 DFAIT strategy.wpd>>

<<November 20 Mining Summary.wpd>> <<October 18 Mining strategy.wpd>>

<<November 20 R&D summary.doc>> <<November 20 R&D strategy.doc>>

<<October 17 NSERC strategy.doc>>

<<October 27 CIHR.wpd>>



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## DRAFT MEETING NOTES

### Meeting of the Biotechnology ADM Coordinating Committee (BACC)

October 19, 2000 by conference call

4:30 p.m. - 6:00 p.m.

#### Participants:

##### Member or Delegate

Diane Gorman (HC) co-chair  
Robert Slater (EC)  
Peter Hackett (NRC)  
Jan Dyer (AAFC)  
André Gravel (CFIA)  
Iola Price (DFO)  
Claudio Vallé (DFAIT)  
Gordon Miller (NRCan)  
John Banigan - Regrets (IC)

##### Observer

Karen Dodds (HC)  
Neil MacIntosh (IC)  
Michael Vandergrift (CIHR)  
Mitch Davies (PCO)  
Nora Nishikawa (CFIA)

##### Secretariat

Roy Atkinson (CBSec)  
Norma Burlington (CBSec)  
Stella Deacon (CBSec)  
Kimberly Empey (CBSec)

Eugene Lang Regrets (FIN)

Agenda Item	Action
<p><b>1.0 Opening remarks</b></p> <p>BACC members opened the meeting by proposing to postpone the deputies (BDMCC) meeting planned for October 24, 2000. The likely deferment of a Ministerial meeting in early November would allow for additional effort to enhance the quality of material that would go forward on transition planning.</p> <p>The agenda was amended to focus discussion on only two items: a re-scheduling of the BDMCC meeting, and the CBS fund.</p>	

## 2.0 Re-scheduling the BDMCC Meeting

BACC members reaffirmed that the goal of the federal biotechnology community would remain to articulate an integrated federal biotechnology vision for the next mandate that can be used across departments. However, the timeline for preparation would be realigned recognizing recent events.

Material would be developed over the coming weeks to provide common direction on biotechnology for departmental transition briefings. This integrated approach for developing horizontal biotechnology policy priorities could, in turn, provide important direction for the new mandate including the Speech from the Throne, Budget 2001, and/or a ministerial meeting early in the new year.

BACC recognized the importance of maintaining the present forward momentum in the development of sector strategies and priorities. Accordingly, they directed biotechnology DG's (BDGCC) to finalize sector strategies, and elaborate horizontal issues by no later than October 26. BACC will meet prior to the next BDMCC to review and refine material for deputies.

It was noted that the optimal timing for having integrated material on biotechnology ready for transition packages was the week prior to the election (expected on November 27, 2000). The secretariat was asked to check availability of deputies and schedule a BDMCC meeting the week prior to the election in order to meet this deadline, if at all possible.

Once availability of members has been determined, notices for BDMCC, BACC, and BDGCC will be forwarded to all relevant members from the Secretariat.

Cancel BMCC of  
November 9, 2000  
(CBSec)

Re-schedule  
BDMCC (CBSec)

BDGCC scheduled  
for October 30  
(done)

Refine and circulate  
strategies for  
BDGCC meeting  
(sector leads)



**2.0 CBS Fund - Norma Burlington**

A memorandum from the Chair of the Interdepartmental Coordinating Committee (ICC) was circulated to BACC outlining background and the following recommendations for re-distribution of potentially lapsing funds from the CBS Fund in the amount of \$303,122.50:

**CBS Infrastructure**

CBS Accountability/Evaluation Framework                      \$ 35,000

**Strategic Horizontal Projects**

Technology Foresight: scoping proposal                      \$160,000 (00-01)  
and \$40,000 (next fiscal year)

Biosafety Protocol: National Office                      \$ 58,122.50

Genetic Privacy: issues scoping and action plan                      \$ 50,000.00

It was noted that the additional \$40,000 allocated for the technology foresight project for next fiscal year (2001-02) were to come from a cancelled Health Canada project which will return \$43,200 to the CBS Fund in 2001-02. After discussion and clarification of certain projects, members agreed to approve unconditionally the first three projects. Approval for the project on genetic privacy is conditional upon assurance of the absence of duplication between this project and work in Health Canada.

It was agreed that if there were any additional lapsed funds found by CBSec, it would be directed first to the National focal point for the biosafety protocol then to the existing list developed by the Interdepartmental Coordinating Committee for the CBS. The projects on genetic privacy, the accountability framework, and the Technology Foresight project are considered fully funded.

Review genetic privacy project for duplication and advise BACC (CBSec & Health Canada) DONE

**UPCOMING MEETINGS**

BDGCC October 30, 2000 (12-4)  
BACC November 23, 2000 (TBC)  
BDMCC January 2001 (TBC)  
BMCC January/early February 2001 (TBC)

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BACC Meeting Notes October 19, 2000 amended FINAL.doc

**DRAFT MEETING NOTES****Meeting of the Biotechnology ADM Coordinating Committee (BACC)****November 23, 2000****1:00 p.m. - 3:30 p.m.****Participants:****Member or Delegate**

Diane Gorman (HC) co-chair  
 Barry Sternshorn (EC)  
 Peter Hackett (NRC)  
 Yvan Hardy (NRCan)  
 André Gravel (CFIA)  
 John Davis (DFO)  
 John Gero (DFAIT)  
 Y. Baltacioglu - regrets (AAFC)  
 John Banigan - regrets (IC)

**Observer**

Mitch Davies (PCO)  
 Laura Ouellette (IC)  
 Emmy Verdun (IC)  
 Heather Gluckow (OCA)  
 Bart Bilmer (CFIA)  
 Iola Price (DFO)  
 Christine Moran (DFAIT)

**Secretariat**

Roy Atkinson (CBSec)  
 Kimberly Empey (CBSec)

<b>Agenda Item</b>	<b>Action</b>
<b>1.0 Opening remarks</b>  The agenda was approved. Changes to meeting notes FROM October 19 were proposed by Health and Environment.	CBSec to edit and re-circulate final notes to members
<b>2.0 Public Opinion Research - Earnscliffe Research &amp; Communications</b>  The draft results from the most recent CBS sponsored public opinion research (POR) were presented.	CBSec to circulate POR presentation to BACC members

**3.0 Update on Deputies Exercise – Diane Gorman**

(CCDM Deck circulated for information)

A dinner meeting of biotechnology deputies was held in early November. PCO proposed that a small group of deputies develop a federal overview for life sciences and biotechnology. This group "Steering Committee" would be composed of deputies from Health, Agriculture and Industry (chair).

A group of Director Generals from the three departments and the CBSec have been working on a deck that endeavours to capture this overview. On November 22, the DM Steering Committee met to assess progress. They concluded that a presentation to the broader CCDM community on November 29 would not be deferred to a date immediately prior to Christmas. Each of the three DM's committed their departments to develop materials for the strategic overview. Work on the deck under construction by DG's was to be put on hold.

The Steering Committee also decided that policy pieces would be developed involving departmental policy communities for discussion by deputies at their December meeting.

Develop contribution for the Strategic Overview (HC, IC, AAFC)

Deputies Meeting to be scheduled before Christmas (Industry)



**4.0 Common Transition Material - All**

The BDGCC committee has been preparing a number of documents for use in transition briefings by departments. This was requested by biotechnology deputies in October and later reiterated at a biotechnology ADM dinner. This package includes two components. Firstly, a three-page overview notes to describe the federal life science and biotechnology context. The second component is a series of one-page summaries of sector and horizontal strategies that have been crafted from more detailed sector strategies that have been refined over recent weeks by the BDGCC community.

Members decided that no further work would be done on sector strategies or summaries unless a department chose to do so. They were to be distributed to all departments. The three-page overview would be revised for use by departments.

NRC in its role as Chair of the CBS R&D Committee presented a piece on research and development which was distributed interdepartmentally for the first time. NRC undertook to consult with federal ADMs within two weeks to seek further input to this work.

A suggestion was made to prepare a similar stewardship piece that encompasses a section on regulatory oversight and science for regulatory oversight and ethics. The CBS Stewardship Chairperson will work with an ADM level subcommittee from Environment, Health and the Canadian Food Inspection Agency to develop the piece.

An international piece was also tabled for the first time to the interdepartmental community by DFAIT.

Provide comments on 3-pager by November 29 to CBSec (All)

Distribute revised 3-pager and existing pieces to Biotech community (CBSec)

Develop strategy for Steering Committee (NRC).

Develop strategy for Steering Committee (Health).

**5.0 Round Table**

No round table items were tabled.

<p><b>6.0 Summary and Next Steps</b></p> <p>BACC's Stewardship and R&amp;D committees will develop input for the Steering Committee on R&amp;D and Stewardship.</p> <p>The three-page overview piece will be revised and used to inform deputies. No further work will be done on sector strategies at this point. However the most up to date copies will be distributed to departments.</p>	
<p><b>UPCOMING MEETINGS</b></p> <p>CCDM Late December, 2000 (TBC) BACC Early January (TBD/TBC) BMCC January/early February 2001 (TBD/TBC)</p>	

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## **LIFE SCIENCES AND BIOTECHNOLOGY FOR THE NEXT MANDATE**

### **Vision**

To be a world leader and a responsible innovator in life sciences and biotechnology, deriving benefits in health, the environment and the economy. This will be done in a way that enhances the quality of life of Canadians in terms of health, safety, the environment, and social and economic development.

### **Context**

In the life science economy of the 21<sup>st</sup> century, a new transformative and enabling body of knowledge arising from modern biotechnology has the potential - if it is developed with care - to result in significant benefits to the quality of life of Canadians and their environment. In the next thirty years, modern biotechnology has the potential to be as transformative for Canada and the world as information technology has been over the last thirty years. This knowledge will transform our understanding of human health, diseases and potential cures; production and manufacturing processes; and environmental improvements. The biotechnology revolution is inevitable. Government must take strong steps now to optimize benefits for Canadians while taking necessary steps to ensure that human health and the environment are protected.

In Canada and around the world, most biotechnology activity relates to the health sector, followed by the agri-food sector. Together they account for 95% of the biotechnology research and industry. Biotechnology discovery will radically change the health sector in prevention, diagnosis, treatment, cure, and the development of drugs. It will change the way crop improvements are targeted and diversify production into high-value molecular "pharming", nutraceuticals, functional foods and industrial feedstocks. In other areas, applications are being explored to: protect our environment; develop bio-fuels and bio-products from renewable resources; conserve wild fish stock and improve aquaculture; support our efforts on forest regeneration and protection; manage mining and metallurgy; promote cleaner industrial processes; and mitigate effects of global climate change.

At the level of the cell, there are only small differences between the functioning of many plants, animals and bacteria. Genetic scientific discovery in one organism can translate into new understandings in others. Combined with developments in the use of information technology, such discoveries will profoundly impact the knowledge base that underpins a range of traditional sectors. In the life science economy, knowledge arising from biotechnology will have pervasive horizontal impacts and will challenge framework laws, regulatory regimes, and Canadian institutions over the coming decades.

Science and knowledge has a profound role for discovery and innovation in a life science economy - both for protecting Canadian health and safety, and capturing benefits. Around the world, investment in research and development (R&D) is largely provided through public sector financing and is accelerating. Industrialized nations are investing heavily in biotechnology R&D and its commercialization for the life science economy. Although Canada has been investing more in biotechnology R&D, such as the genomics investment in Genome Canada, we are still falling behind. Furthermore, this investment needs complimentary investments in commercialization, framework policy development, business finance, and a human resource plan to assure



knowledge-based jobs and economic benefit for Canadians well into this century.

In terms of investments in research for example, 1997 OECD data indicate that Canada spent \$12 per capita on public health research expenditures, compared to the United States (\$62), Japan (\$41), France (\$27) and Britain (\$23). While Canada has increased its investments in research since 1997, other countries have also accelerated their pace of investment. As examples, the United States has added over US\$5 billion to the research budget of the National Institutes of Health since 1997, and both presidential candidates have promised to further double the National Institute's budget, which would bring it to well over \$30 billion.

There is a federal structure in place to implement the Government's vision under the Canadian Biotechnology Strategy through a Biotechnology Ministerial Co-ordinating Committee (BMCC). It is mandated to ensure a consistent and coherent Government of Canada approach that encourages the responsible development and application of biotechnology in Canada. The BMCC comprises the Ministers responsible for Agriculture and Agri-Food, Health, Environment, Fisheries and Oceans, Natural Resources, International Trade, and Industry. The Minister of Industry is the committee chairperson. This ministerial committee is supported by inter-departmental mirror committees to ensure the timely and effective implementation of BMCC direction at the level of deputies, assistant deputies, and directors general. This structure is supported by a small Secretariat whose annual budget is \$725,000.

The Canadian Biotechnology Advisory Committee (CBAC) was established in September 1999 by the Government of Canada to provide comprehensive, independent expert advice on policy issues related to biotechnology. CBAC is also tasked with raising public awareness and engaging Canadians in a national dialogue on biotechnology. The 21 members of CBAC have been drawn from a range of disciplines including science, business, nutrition, law, environment, philosophy, ethics, public advocacy, and members of the public. CBAC members serve on a part-time, volunteer basis. It is supported by a small Secretariat with a budget of \$2.25 million.

In recent public opinion research, Canadians have told government to be both a vigilant regulator and a responsible promoter in managing biotechnology. In other words, Canadians have given a cautious "yellow light" to proceed responsibly with biotechnology. The enormous potential benefits of biotechnology will not be realized without consumer confidence. An effective stewardship and regulatory agenda is essential to maintain public confidence. Capturing health and environmental benefits are of high interest to Canadians. This is the backdrop on which new priorities for the next mandate should be developed and strategic investments made.

Accordingly, the government should consider three priorities for biotechnology and the life science economy in a matrix management approach that has both a horizontal and a sector focus across departments. Priorities include: 1. A Stewardship agenda to ensure that the development, application, and use of biotechnology-derived products and services are safe for Canadians and their environment, and to manage the social, legal and ethical aspects of biotechnology in a way that is consistent with the values and belief systems of Canadians; 2. Realizing the health, environmental and economic benefits of biotechnology for Canadians; and 3. Engaging Citizens in ongoing dialogue and discussion about the role of these new technologies and the issues they raise in the context of implementing the Canadian Biotechnology Strategy.

**Stewardship**

The broad responsibility of Government creates public expectations for a wide stewardship role that protects the health and safety of Canadians. Ethical issues range from patenting of higher life forms, to genetic testing and research. The Government of Canada has a direct role in the regulation of many life science products of biotechnology, including genetically modified foods and therapeutic products. The Government must ensure that a strong, efficient, and scientifically sound regulatory system is in place for the protection of human health and the environment and must assure its capacity to address social, ethical and legal issues relating to biotechnology. It must also assure an adequate investment in regulatory science in order to keep pace with the growing number of increasingly complex products being submitted for review to regulators.

The high growth rate of biotechnology is challenging the Government's capacity to keep up with advances and their impact on human health and the environment. Our regulatory system is generally seen as strong and the public has consistently supported it. However, Canada and other international partners such as the United States and the European Union need to invest in R&D to generate knowledge to understand and predict potential long-term impacts of biotechnology on human health and the environment.

International considerations are also critical for life sciences and biotechnology. A strong regulatory system is an asset in maintaining international trade and in developing markets, since it earns confidence in our products and technology. World-class stewardship of biotechnology is an enabler for positioning Canada to capture benefits from biotechnology. Canada has played a significant role in a number of international fora - in determining international standards in food safety, and in biotechnology policies. Canadians expect the government to take a leadership role in stewardship of the environment through signing and implementing the Biosafety Protocol.

**Benefits**

Potential benefits to Canadians from biotechnology in a life science context are enormous in terms of quality of life for health from new therapeutics for treatment of diseases, new vaccines for prevention, new tests for diagnosis and new genetic testing for surveillance of susceptibilities. Biotechnology offers significant benefits to the environment through reduction in greenhouse gases, recycling of organic wastes, remediation of contaminated sites, improved waste management, conservation of endangered species, and production of fuels and products from renewable resources. Environmental biotechnology also has substantial secondary benefits in lower costs and improved productivity.

Capturing these benefits presents an important economic opportunity for Canada. Worldwide markets in biotechnology are expected to be \$50 billion by 2005. Growth is anticipated to be over 10% annually - more than five times higher than the average for the economy. In 1997, Canada's biotechnology industry ranked second in the world in terms of number of companies, had \$1.1 billion in revenues, \$400 million in exports with 10,000 knowledge-based jobs. The health and agri-food sectors represented 95% of Canadian biotechnology sales and 75% of companies. Biotechnology R&D in Canada is dominated by the health sector (87%). World sales of biopharmaceuticals have grown more than seven-fold over the past decade and should exceed

\$18US billion by 2003. Canadian firms have developed three of the 24 biopharmaceuticals approved for sale on the world market. Public R&D investment is a key engine for the biotechnology revolution. In 1998 Canada spent \$2.5 per capita, versus \$7 in Japan, \$9 in France, \$14 in Britain and \$15 in the United States. Although we have invested \$160 million in Genome Canada since this point, it still only brings Canada to \$7.8 per capita in biotechnology R&D.

Canada's positioning in the biotechnology sector will continue to rely on government support for innovation in a number of areas. These include: major funding for research and development; favorable taxation policies; excellent scientific research base and strategic partnerships; predictable framework policies such as patenting; an adequate supply of knowledge workers in the domestic labor force; internationally recognized regulatory system that ensures safe products are approved; a first-rate business environment; a stable investment climate; business finance; cluster development; and market access within North America. In Canada, most biotechnology companies show promise and are maturing rapidly, but have not yet reached the commercial product stage. Additional investments in these areas along with an early commitment in other aspects of biotechnology will be essential to secure further economic benefits for Canada well into this century.

### **Citizen Engagement**

Engaging citizens and earning the confidence of Canadian consumers to move forward on issues related to biotechnology will be critical in achieving the goals of our common vision to become a responsible world leader in the life science economy. Although Canadians are currently expressing guarded comfort with the application of modern biotechnology in the health and environment sectors, issues such as genetically modified foods and long-term health and environmental impacts have caused citizens to be wary of biotechnology.

The nature of biotechnology - its novelty, pace of innovation, breadth of application, the financial stakes involved, potential global impact, differences in opinions - means that isolated events may snowball and raise broad-ranging concerns. These issues will need to be addressed if citizens are to have confidence in biotechnology and the Government's ability to manage the responsibilities of a life science economy. CBAC is an important vehicle to engage citizens in issues such as genetically modified foods and patenting of higher life forms.

First and foremost, Canadians want to be able to rely on an effective regulatory system. They also want to know that reliable information related to biotechnology is available on potential risks to health and the environment, and they want that information from a reputable source, and in a way that they can understand. There is a need to develop and articulate a consistent, government-wide integrated management plan for biotechnology and life sciences that covers: stewardship; benefits of biotechnology in health, environment and for the economy; and, on engaging Canadians in meaningful dialogue. A low-key, "pull" communications effort is being developed that will allow Canadians to access information on biotechnology and to engage on key issues as desired. This will allow the Government to better demonstrate that the health and safety of all Canadians, environmental protection, maintenance of ethical standards and respect for informed choice, are paramount issues for the Government of Canada.



## **Agriculture and Agri-Food Sector Biotechnology Within the Life Science Economy Strategy Summary**

**Vision:** Canada's agriculture and agri-food sector as a responsible world leader and innovator in the Life Science Economy.

**Role of Biotechnology:** The Life Science Economy is about pursuing growth opportunities by developing and enhancing products across many industries in a sustainable fashion by applying our growing knowledge of living things, and the techniques and processes of biotechnology.

### **Policy Objectives:**

- **For the Food System and the Environment:** world leader in the safety and security of the food system and environmentally responsible agriculture.
- **For the Non-Food System:** to capture the benefits of the emerging Life Science Economy.
- **For Governance:** timely and adaptive policy-making as well as an effective and efficient regulatory system
- **For Biotechnology:** the application of biotechnology to enhance the quality of life in terms of health, safety, the environment, and social and economic development.

### **Goals:**

- A rigorous regulatory system that protects humans and the environment and sets the standard by which other nations judge themselves in the Life Science Economy; and
- A business and policy climate that supports the attraction and retention of investment and human resources needed to establish Canada as a world leader in the Life Science Economy.

### **Critical Sector Priorities:**

- Engaging the public in the biotechnology debate; building science capacity, knowledge and tools for innovation, regulation, policy and governance; and embracing / supporting multidisciplinary solutions and innovation that will build the Life Science Economy

### **Incremental Initiatives:**

- Sector support of the three pillars of the CBS: Benefits (science capacity and genomic research); Citizen engagement (discussions/ consultations on key sector and public issues); and Stewardship (strengthening the regulatory system and international capacity building).

### **Visionary Initiatives:**

- Eco-system science led by Environment Canada; investments in building new partnerships e.g., a proposed bio-mass institute and cluster; and a world class technology foresight program that will aid regulators, focus investment, and target commercialization.
- Tracking and tracing and testing mechanisms and procedures will be required to maintain the identity of products as they move through the marketing channels.

### **Horizontal Issues:**

- Taxation and investment policies and programs; Canada's regulatory system; S&T capacity issues; participation in international fora dealing with life sciences and the products of biotechnology e.g., research and regulatory capacity building, harmonization with trading partners, and the development of international, science-based standards are key elements needed to a Life Science Economy.

## **Agriculture and Agri-Food Sector for Biotechnology within the Life Science Economy Strategy**

### **Vision**

Canada's agriculture and agri-food sector as a responsible world leader and innovator in the Life Science Economy – an economy that focuses on the safe and environmentally responsible production, processing, distribution and marketing of bio-based products including traditional food and feed products, as well as innovative products including pharmaceutical, health, energy, industrial, and medical applications.

### **Role of Biotechnology:**

The Life Science Economy is about pursuing growth opportunities using renewable resources by safely and responsibly applying our growing knowledge of living things and the tools, techniques and processes of biotechnology to develop and enhance products across many industries. And it is about creating new products and services that can lead to the establishment and growth of new industries. The biotechnology industry is about developing these enabling tools, techniques and processes.

Responsible development of biotechnology and its applications in the Life Science Economy holds the potential to:

- provide safer, healthier and higher quality food;
- maintain and enhance the productivity of our renewable resource base;
- improve the environmental sustainability of the agriculture and agri-food sector, and enhance its economic viability and vitality; and
- create sustainable new growth opportunities in non-food markets for renewable resource-based bio-products by identifying, designing, and extracting specific components of renewable resources, and combining these components into new and innovative consumer products that help to meet increasingly sophisticated and differentiated needs of global consumers.

**Policy Objectives:****1. *For the Food System and the Environment***

- To position Canadian agriculture as the world leader in the safety and security of the food system and environmentally responsible agriculture.

**2. *For the Non-Food System***

- To position Canadian agriculture to capture the benefits of growth opportunities in the emerging global Life Science Economy.

**3. *For Governance***

- Timely and adaptive policy-making and an effective and efficient regulatory response in the face of an accelerating pace of change.

**4. *For Biotechnology***

- Tools, techniques and processes of biotechnology responsibly developed and applied within a policy and regulatory framework where the health and safety of Canadians and the environment comes first and at the same time accelerates the ability of the Canadian agriculture and food sector to safely produce, process and market biotechnology-based products to capture benefits from the growth opportunities offered by food and non-food uses of renewable agricultural resources in the emerging global Life Science Economy – a nation of innovators not imitators.

**Goals:**

- A rigorous regulatory system that protects humans and the environment and sets the standard by which other nations judge themselves in the Life Science Economy;
- International recognition as a reliable producer, processor, distributor and marketer of safe, high quality food;
- World leadership in environmentally responsible agriculture;
- A business climate that supports the attraction and retention of investment and skilled human resources needed to establish Canada as a world leader in the Life Science Economy;
- World-class science and knowledge capacity in support of regulation, innovation and governance; and
- Improved horizontal collaboration across federal, provincial and industry stakeholders involved in the Life Science Economy.

## Context

### Key Trends:

- Recognition of the finite nature of non-renewable resources and global concerns about climate change and the environment are exerting pressure to do more with our renewable resources in an environmentally sustainable manner.
- Rapid progress in life sciences and informatics is advancing our knowledge and understanding of living things. New discoveries are leading to convergence across scientific disciplines, changing our concepts of what the life sciences are, and what they can contribute to society, and broadening our perspective of the opportunities for the use of renewable resources. This revolution in science and technology is accelerating the pace of change. We can't run. We can't hide. And we can't stand still.
- Our trading partners are already investing to enable their agriculture and agri-food sectors to participate in the emerging Life Science Economy by exploiting new applications in fields such as pharmaceuticals (drugs), health (functional foods and nutraceuticals), energy (ethanol, bio-diesel), industrial products such as chemicals, oils, enzymes, proteins and a wide range of substitutes for petrochemical products (plastic).
- Public concerns, both domestically and globally, over bio-diversity, bio-safety and food safety are resulting in increased scrutiny of the policies, procedures and regulations surrounding the development and application of biotechnology, particularly in the food system. In a number of countries, pressures for tougher regulation and non-tariff barriers to trade are increasing with respect to the use of genetically modified organisms (GMOs).
- The escalation of issues associated with the globalization of the marketplace including market access and non-tariff trade barrier issues. Recent international attention to the StarLink® corn issue, a voluntary industry recall of US food products where a genetically modified corn unapproved for food use, was used as a food ingredient. The incident has led to questions about i) the industry approaches to tracking, tracing and identification of products in the marketing channels; ii) the potential for the loss of public confidence in the regulatory system; and iii) the ability of industry and governments to manage the introduction of products derived through new technologies.

### Competing Initiatives of Other Countries:

- In 1998, Canada spent \$2.50 per capita on R&D, versus \$7 in Japan, \$9 in France, \$14 in U.K. and \$15 in U.S.
- Canada is not alone in recognizing the potential of biotechnology and the Life Science Economy. The U.S. has announced plans to triple bio-energy and bio-product production from renewable resources by 2010. The E.U. has announced plans to double its bio-energy production by 2010.

- Some countries are moving to limit the use of genetically modified organisms in their agriculture system in an effort to differentiate themselves in the global marketplace.

#### **Public Opinion in Canada:**

- Public opinion surveys indicate that the public is cautiously optimistic about the use of biotechnology. Health and environmental applications receive the highest approval rating with Canadians expressing guarded comfort with the application of modern biotechnology to the agriculture and agri-food sector. The use of biotechnology in non-food applications is generally more palatable to Canadians than applications involving GMOs in the food chain.
- Although Canadians have confidence in the food safety system, there is a growing demand for improved information about biotechnology, its products, their benefits and risks.
  - A strong, efficient and effective regulatory system is key to addressing public concerns surrounding development and investment in the Life Science Economy.
- Canadians wish to participate in dialogue on social and ethical issues related to the development of biotechnology. The Canadian Biotechnology Advisory Committee has a mandate to engage Canadians in dialogue on a wide range of subjects related to biotechnology.
- Thus, the government has a "yellow light" to proceed with the responsible development of biotechnology but, the public expects government to be a vigilant regulator while seeking health and environmental benefits and other economic benefits for Canadians.

#### **Critical Sector Priorities**

- **Engaging the Public in the Biotechnology Debate**

Most biotechnology innovations are little more than extensions of traditional plant and animal breeding with limited and well understood risks. Advances in the emerging field of genomics (plant and animal genetics) enables far more precise and efficient breeding without recourse to transgenics (GMOs). Transgenic modifications represent a relatively small proportion of total biotechnology but at the same time represent an area where the risks and benefits need to be further explored. More sophisticated public understanding of the differences between traditional breeding, genetic modifications within species, and transgenics may be essential if we are to capture the benefits of the life science economy for Canada. Both government and industry have an interest in helping the public to understand the benefits and the risks.

- **Building science capacity, knowledge and tools for innovation, regulation, policy and governance**

Advances in science and technology are creating new opportunities for economic growth but

are at the same time raising new challenges for regulators and policy makers. We need to build our capacity for science not only to be able to capture new growth opportunities, but also to gain the knowledge and understanding of the technology, the risks, and the benefits as a basis for good policy decisions and effective regulation. This sound base will help the public be confident in agriculture, science, biotechnology and the government's ability to effect sustainable growth and maintain and enhance the safety and quality of the food supply.

- **Embracing multi-disciplinary solutions and innovations**

Cellular science is converging scientific disciplines -- small differences separate plants and animals, creating new opportunities for interdisciplinary science. Complex and multi-frontier issues, like climate change, bio-diversity, water quality, health and safety of the environment, and food safety require collaboration across disciplines. We need to find innovative ways and means of increasing collaboration and synergy within and across science, engineering and marketing and across federal and provincial governments, universities and the private sector. Coordinating and integrating federal science and collaborating with universities and the private sector will create the intellectual critical mass required to capture the benefits of the revolution in the life sciences for Canada.

- **Identifying the needs associated with diversification of growth**

International market access issues and the novel types of products emerging from the R&D pipeline will present new challenges to conventional approaches for the distribution, tracking, tracing, testing and marketing of food and non-food products from agriculture. Analysis is needed to identify the nature of any necessary adjustments in Canada's existing sector infrastructure.

**Incremental Initiatives:**

- **Benefits:** genomics research on cereals and oilseeds (intra-mural genomic funds from Budget 1999--\$55M); human resource development such as training and development for new scientists; commercially viable intellectual property; diagnostic tools in support of food safety; market access activities in international fora.
- **Citizen engagement:** public opinion surveys and participation in CBS surveys; Website development and other communications initiatives; support of a voluntary labelling initiative led by the Canadian Council of Grocery Distributors; and response to CBAC's proposed workplan and consultation work on intellectual property and gm-food regulation as they relate to the agriculture and agri-food sector. The CFIA has been active in providing increased consumer information about the regulatory system in place to protect humans and the environment.
- **Stewardship:** There are a number of initiatives that will involve the CFIA as the regulatory agency for agricultural products. They include:
  - Measures to strengthen the regulatory systems (funding in Budget 2000).

- Recommendations of the Expert Panel of the Royal Society will inform HC, CFIA and EC with their forecast of trends/innovations and identify the scientific capacity needed to keep pace with these developments. This may require additional resources to advance our knowledge base about potential long term environmental impacts and factors as innovative applications continue to advance.
- Implications of ratifying the Cartagena Protocol on Biosafety continue to be discussed/explored amongst federal departments and agencies. Managing the challenges associated with agricultural "living modified organisms" will require incremental initiatives. Environment Canada is leading a horizontal initiative to fund such initiatives.
- Under the National Implementation Strategy on Climate Change, the federal government recently announce a \$140 million expansion of the National Biomass Ethanol Program to enable tripling Canada's production of "green fuels" from biomass.

**Visionary Initiatives:**

- Eco-system science: this initiative led by Environment Canada is essential in the context of both the science needed to support regulatory decision-making, our stewardship role and the sustainability of the agricultural resource base. More support to the eco-system science field would also be an investment that will reflect a long term vision of having the Life Science Economy develop within a strengthened sustainable development framework.
- Work is underway to develop a framework for a major new initiative on bio-products and bio-energy. The key elements of this framework are substantial investments in building new partnerships and in a proposed bio-mass institute and cluster.
- A world class technology foresight program to aid regulators, to strategically position public investment in R&D, and to aid commercialization by Canadian innovators is needed to help position Canada as a world leader in the Life Science Economy of the 21<sup>st</sup> Century.
- Tracking and tracing and testing mechanisms and procedures will be required to maintain the identity of products as they move through marketing channels.

**Horizontal Issues:**

- Taxation and investment policies and programs will be one of the key engines of growth in development of the Life Science Economy.
- A linchpin of the federal biotechnology agenda – today and in the future – is the role of the Canada's regulatory system for products of biotechnology. In the past 2 years, through the collaborative efforts of the CBS Regulatory Working Group, regulatory departments and agencies worked to identify and address key priorities to prepare for emerging biotechnology innovations. The report of the Royal Society (commissioned by Health, Environment and



CFIA) on the future needs regulatory system is one element of preparing for tomorrow.

- In horizontal initiatives we are part of an inter-departmental proposal that will help address S&T capacity issues. Funds will be sought to fund national facilities/ strategic equipment, graduate opportunities strategy, and government sponsored research chairs. In support of the regulatory function, the CFIA is focussing on building human resources/capabilities through assistanceships, hiring new regulators, developing new training modules etc.
- "Science for Stewardship" will need more support to assure that the best available tools and information about factors such as long term ecosystem effects are either developed in Canada or accessible to Canadian regulators.
- On the international front, Canada has already played a significant role in a number of international fora -- where there have been broad discussions of standards (such as Codex) and food safety including the products derived through biotechnology (such as the G-8). Both research and regulatory capacity building, harmonization with trading partners, and the development of international, science-based standards are key elements needed to support diversifying and advancing a more sophisticated agricultural and agri-food biotechnology sector.

## Sector Strategy for the Economic Development of Biotechnology

### Context:

The G-7 countries and some major developing countries have targeted biotechnology as vital for the 21<sup>st</sup> century and are pouring major resources into R&D and financing. Canadian biotechnology companies show promise and are maturing rapidly, but most have not yet reached the commercial product stage. Public support of biotechnology is strongest in the health and medical applications.

### Strategic Economic Direction:

The current and medium-term benefits of biotechnology are in the health sector.

Bio-pharmaceuticals will continue to dominate biotechnology over the next twenty years both in Canada and abroad. Genomics research, particularly health genomics is critical to biotechnology in Canada.

Must address issues related to the policy and regulatory framework and the business climate that include: funding for public and private R&D; financing and access to capital (particularly for SMEs); skills development and human resources within government as well as the private sector; regulation and intellectual property; technology transfer and commercialization; and, foreign investment and trade.

### Critical Sector Priorities

- Develop a technology foresight program for the biotech industry and a technology roadmap for the biopharmaceutical sector.
- Begin work on commercialization and technology transfer. Policies for later-stage product development will be reviewed in preparation for a possible renewal of Technology Partnerships Canada (TPC). Consider revision of TPC to address the gaps identified by industry and to increase funding in response to financing difficulties within the industry.
- Begin an in-depth analysis of the financing issues of biotechnology. Alternative approaches will be developed to encourage venture capital investment in biotechnology.
- Develop proposals on tax policies (eg., SR&ED tax credits) for consideration by Finance.

### Visionary Initiatives

- Seek support for a second round of financing (comparable to the \$160M provided by Budget 2000) for large-scale program funding through Genome Canada to sustain Canada's anticipated leadership role in genomics, the discipline that is the basis of the vast majority of new biotechnology products and services in health, agriculture, aquaculture, forestry, environment, and informatics and software. Canada is behind and the initial funding was intended to "catch-up" with other countries.
- Begin a review about whether Canada's intellectual property regime, including the patenting of higher life forms, adequately supports biotechnology innovation and investment in Canada.
- Pro-active interdepartmental effort on public confidence, including the development of a federal policy on privacy, ownership and benefits of genetic data to sustain public support for biotechnology and to address the needs of research and development activities, and the commercialization of bioinformatics/genomics technologies.

### Horizontal Issues

- Address the skills gap both in the public and private sectors. Expand programs by the HRDC (ie. The Biotechnology HR Council), develop business skills through the cluster effect of Genome Canada, expand recruitment and retention of skilled employees for small start-up

companies through NRC biotechnology incubator expansions, and establish more specialized and technical resources for federal biotechnology regulation through the recent \$90M from Budget 2000.

## **Sector Strategy for the Economic Development of Biotechnology**

### **VISION**

Promote the responsible development of Canadian biotechnology that will be competitive and ensure world leadership in key areas in order to realize health and environmental benefits for Canadians.

### **CONTEXT**

Biotechnology is a transformative set of technologies. As a key technology enabler for other sectors, the impact of biotechnology may be as great as that of the information and communications industries in the last century.

#### **International Context:**

Canada must act now to ensure that it is not overwhelmed by the growing dominance of the American industry. As of August 2000, U.S., biotechnology companies had raised \$22.1B from public and private financings, almost double the \$12B amount raised in 1999, and nearly triple the \$8.1B figure in 1998. In 1997 Canadian biotechnology sales accounted for close to five% of the global market and has since likely declined. The G-7 countries and some major developing countries have targeted biotechnology as vital for the 21<sup>st</sup> century and are pouring enormous resources into R&D and financing. In 1997, biotechnology revenues per capita were \$100.5 for the U.S., \$46.3 for Australia, \$36.6 for Canada, and \$30.8 for the E.U. biotech countries.

In 1997, Canada's biotechnology sector was second only to the U.S. in terms of R&D intensity, R&D per employee and the percentage of biotechnology employment in the labour force. The Canadian biotechnology industry has grown tremendously in recent years, and exports of Canadian biotechnology products almost doubled from 1993 to 1997.

#### **Canadian Industry and Challenges:**

Within Canada, most biotechnology companies show great promise and are maturing rapidly, but they have not yet reached the commercial product stage. In 1997 Canada's biotechnology industry ranked second in the world in terms of number of companies, has \$1.1 billion in revenues, \$400 million in exports with 11,500 good, knowledge-based jobs. Five companies each have at this time capital values of over \$1B where there was none five years ago. This current strength in biotechnology can be attributed to a number of Canadian strengths arising from strong leadership up to this point: government support for innovation that includes strong funding for research, favourable taxation policies; an excellent scientific research base and strategic partnerships; an internationally recognized regulatory system; and a first-rate business environment, stable investment climate and market access within North America.

In 1997 the first Statistics Canada survey of Canadian biotechnology companies indicated that three quarters were small or medium-sized businesses. The health and agri-food sectors represented 95% of Canadian biotechnology sales. Three quarters of the Canadian companies are in the health or agri-food sectors. Biotechnology R&D expenditures was \$600M and the health

sector accounted for 90% of that research. Biopharmaceuticals comprise only 5% of world prescription drug sales but they account for about 30% to 50% of all drugs in development.

Three important characteristics distinguish biotechnology from the information technology and most other knowledge-based industries: 1) a strong entrepreneurial SME segment exists but very few large Canadian firms exist to advance a project from proof-of-concept to production and distribution; 2) the strong public sector presence in terms of R&D funding and the regulatory frameworks; and 3) the product development cycle requires very long lead times (for example, up to \$500 million and 10 years to develop a bio-pharmaceuticals product).

The economic benefits for Canada become more significant if more product development can be retained within Canada. Sales of biopharmaceutical products or technologies at the earliest stage result in modest royalties from the partner (2 to 5 percent of sales worldwide). However, if sales occur after drugs are taken through Phase I clinical trials, companies receive on average 5% to 10% of world sales. If all three stages of clinical trials are completed and marketing approval granted, royalties on worldwide sales jump to about 25% and with manufacturing rights the company can increase its return to over 35%.

#### **Strategic Economic Direction:**

An overwhelming portion (87%) of biotechnology R&D in Canada is in the Health Sector. The biopharmaceutical segment promises major social and economic benefits. Already, its medicines, vaccines and other health-related devices and products have helped to reduce or eradicate many diseases and improve life expectancy. Biotechnology is one of the world's fastest growing sectors. World sales of biopharmaceuticals have grown more than seven-fold over the past decade and should exceed \$18B (U.S.) by 2003. Canadian firms have developed three of the 24 biopharmaceuticals approved for sale on the world market. A January 2000 survey by CIHR indicates that selected Canadian biopharmaceutical firms have more than 400 products in the pipeline. Biopharmaceuticals requires particular attention in the areas of regulations and access to capital at the early or R&D stage.

A thriving biotechnology industry in the future will be largely built on genomics research. Genomics and bioinformatics technologies and techniques are fundamentally changing the way that drugs are being discovered and developed. The acceleration of the selection process for best drug candidates and the reduction in the cost of pre-clinical and clinical studies could collectively save at least \$200M (U.S.) and two to three years per drug. Canada's recent \$160M investment in Genome Canada is based on anticipated economic benefits in the health-related area alone of \$1B in new investment in Canadian genomics companies, \$100-\$300M in new MNE investments into Canada, twenty new core companies; one to three international top tier successful biotechnology companies; 500 to 1,000 new jobs in the industry; and 2,000 new genomics-related jobs and product sales of \$500M.

#### **Public Confidence:**

Public support of biotechnology is strongest in the health and medical applications. This support for the benefits of biopharmaceuticals depends upon a strong regulator system to ensure that research into the safety of the application is comprehensive and publicly available. For health applications, the majority of Canadians are prepared to take some risk.

**Government Action:**

There is a need to build upon the work that is being done to strengthen the regulatory capacity. In that regard we must address issues related to the policy framework and business climate in order to realize the health benefits for Canadians.

There is a need to strengthen support for biotechnology within the marketplace, improve competitiveness in the sector, and address the human skills gap. Industry Canada has produced a strategic plan entitled, "Pathways to Growth: Opportunities in Biotechnology", that emphasizes the need to address key opportunities and challenges for biotechnology in: R&D, technology transfer and commercialization; financing and access to capital; skills development and human resources; regulation and intellectual property; and, foreign investment and trade. These challenges can be grouped under two key priorities that require immediate attention:

- **Public confidence.** Addressing citizens concerns with biotechnologies is critical for the future growth potential of the industry as well as the health, safety and privacy of Canadians.
- **Enhancing commercialization.** Canada needs to build on its strengths in R&D and clinical trials and improve its capacity for turning scientific breakthroughs into new commercial products by addressing such key factors as access to patient risk capital and ensuring an adequate supply highly skilled people.

**CRITICAL SECTOR PRIORITIES**

1. Incremental initiatives underway or planned to effectively manage challenges of modern biotechnology applications within core mandate (risks and benefits).

**COMPETITIVENESS:****Technology Foresight and Technology Transfer**

- Industry Canada (IC) is developing a technology roadmap for the biopharmaceutical sector.
- IC will expand its Biotechnology Gateway to create stronger links to the biotechnology activities of other federal departments and agencies.

**Early Stage Commercialization**

- IC has begun to work closely with other groups in Industry Canada on commercialization and technology transfer, such as Technology Partnerships Canada (TPC). IC will continue to facilitate networking fora to share best practices in the commercialization of bio-pharmaceutical discoveries.

**Financing and Capital Requirements**

- To improve the practices used to supply capital so that the biotechnology sector can achieve its full potential, IC will continue to support efforts to provide for the early stage biopharmaceutical development through activities that will create more incubator sites and an expansion of the Industrial Technology Advisors activities.
- IC will review its policies for later-stage product development, including TPC.
- IC has begun an in-depth analysis of the financing issues of biotechnology, including biopharmaceuticals. Alternative approaches will be developed to encourage venture capital investment in biotechnology. Proposals will also be developed on tax policies (eg. SR&ED tax).

**Trade and Investment**

- IC will continue to support the implementation of a branding Canada pilot program for biopharmaceuticals in Boston. The results of this pilot will guide future investment promotion activities.
- IC will build upon efforts to promote the biopharmaceutical sector, a Trade Team Canada priority sector, abroad in the priority export markets.

**Intellectual Property**

- IC will consider additional measures to improve the service delivery of Canada's Intellectual Property Office.

**2. Visionary initiatives leading into the next mandate which would signal, domestically and internationally, that Government consider biotechnology a strategic technology and is prepared to undertake substantive initiatives to position Canada as a responsible and responsive world leader.**

**MARKETPLACE:****Public Confidence**

- IC and Health Canada will take a pro-active role in the interdepartmental effort to develop federal policy on privacy, ownership and benefits of genetic data to sustain public support for biopharmaceuticals and to address the needs of research and development activities, and the commercialization of bioinformatics/genomics technologies.
- CIHR will emphasize the following pressing issues: a national policy on research involving human fetal and embryonic stem cells; the correct balance between privacy of health information, and access for research purposes; intellectual property (particularly related to patenting of "higher" life forms); Canada's research capacity to address social, legal, and ethical issues related to biotechnology research and its applications; the oversight of research involving human subjects, and their protection from research risk; and increasing Canada's human resource capacity for technology transfer activities.
- The work of Genome Canada and CBAC will complement this visionary work on the social and ethical issues that are key to realizing the health benefits.



**Intellectual Property**

- IC has begun to review whether Canada's intellectual property regime adequately supports biotechnology innovation and investment in Canada. The patenting of higher life forms is the most important outstanding issue.

**COMPETITIVENESS:****R&D**

- IC will seek support for a second round of financing for large-scale program funding through Genome Canada to sustain Canada's anticipated leadership role in genomics, the discipline that is the basis of the vast majority of new biotechnology products and services in health, agriculture, aquaculture, forestry, environment, and informatics and software.

**3. Horizontal Issues** Representing areas of common interest which the community should best approach collectively to ensure an integrated, horizontal approach, and a stronger voice for change.

**MARKETPLACE:****Public Confidence**

- Health Canada and other regulatory departments and agencies will invest in the long term needs of biotechnology regulation and will respond to the future recommendations of the Royal Society's expert panel and CBAC, in a transparent manner would be in the right directions. There will be inter-departmental cooperation to provide a leadership role for Canada in building international regulatory capacity. IC will work with Health Canada to help remove impediments within the regulatory regime to biopharmaceutical investments and commercialization in Canada.

**COMPETITIVENESS:****Technology Foresight and Technology Transfer**

- IC will work with NRC and other federal organizations to develop a strategic, world-class technology foresight program that will benefit the biopharmaceutical sector and other sectors within the biotechnology industry.
- CIHR will develop an informed capacity for early issue-identification and opportunity-identification in relation to biotechnology.

**Innovation Capacity**

- NSERC proposes to investment of \$15M annually in new funding to boost the innovation capacity of the biotechnology community.

**SKILLS DEVELOPMENT:**

- IC will support efforts to address the skills gap. This includes the work to expand programs by the HRDC (ie. The Biotechnology HR Council), development of business skills through the cluster effect of Genome Canada, expanded recruitment and retention of skilled employees for small start-up companies through NRC biotechnology incubator expansions, and the federal government's use of the recent \$90M to establish more specialized and technical resources for federal biotechnology regulation.
- IC will complete a feasibility study/proposal in Spring 2001 for a new skills development program targeted at science and engineering graduates that will then be put forward for consideration to HRDC.
- NSERC proposes to invest \$25M annually in new funding to double the number of postgraduate scholarships and postdoctoral fellowships in the life sciences.
- NSERC proposes to invigorate the research efforts of university researchers in cell biology, molecular genetics and plant biology with \$45M in new funding annually by providing world-class support to help train the next generation of skilled biotechnology workers and to generate the new discoveries crucial for the industry to grow.

## FISHERIES AND OCEANS (DFO) SECTOR STRATEGY SUMMARY

Biotechnology enhances DFOs ability to ensure conservation and a sustainable fishery based on scientific research. DFO researchers are currently funded by the CBS for projects that range from DNA identification tools which can define the genetics of stocks; to the development of genetically improved fish stocks for aquaculture and conservation; improved feeds, for better digestibility and lowered faecal output; to CEPA equivalent (Canadian Environmental Protection Act) regulations on transgenic aquatic organisms under the Fisheries Act.

### Immediate Priorities

#### Enhancement of Wild Fisheries

- Development of DNA technology to define the population structure of commercially important fish and shellfish; development of molecular markers for stock identification to assist DFO in its role of enforcement.

#### Conservation and Stewardship

- Application of DNA technologies to stock assessment to identify threatened fish stocks the purposes of conservation and stewardship; develop methods to prevent breeding of escaped farmed fish with wild fish; and methodology to alleviate habitat deterioration.

#### Aquaculture Support

- Identification and selection of appropriate species for aquaculture; genetic techniques in the production of diagnostics and vaccines to control disease; understanding of how a foreign gene in a transgenic fish behaves relative to the genetic background of the host species.

### Long-Term Initiatives - 2005 and Beyond:

#### Aquaculture

As present harvesting technology can cause strain on ocean fisheries, new directions in aquaculture include improved methods for effluent management; sterilisation technology; plant-based feeds; molecular genetic techniques for breeding programs of aquaculture species.

#### Bioremediation

DFO researchers are working in collaboration with other government agencies and industry on remediation of Canada's oceans and ports using micro-organisms for the clean up of oil spills and other contaminants. This is an area where DFO and Canada can take a leading role in the development of bioremediation technologies.

#### Bioprospecting

Bioprospecting for novel chemicals that can be extracted from marine animals and plants is growing in importance. DFO could work closely with industry (i.e. biopharmaceutical companies) by providing scientific advice, as well as developing regulations to protect biodiversity by preventing over-harvesting of rare marine animal and plant species.

## ENVIRONMENT SECTOR STRATEGY

*"The next century will be defined as the age of biotechnology...  
just as the past twenty years has been defined as the age of information technology"*  
The Wall Street Journal, November 17, 1999

### 1. Vision for Modern Biotechnology

The federal government's vision is to enhance the quality of life of Canadians in terms of health, safety, the environment and social and economic development by positioning Canada as a responsible world leader in modern biotechnology. For the environment sector, our vision is a Canada where people make responsible decisions about biotechnology from an environmental perspective. This vision will ensure that the environment is sustained for the benefit of present and future generations.

### 2. Context

With biotechnology, science has given us something fundamentally new - perhaps the most significant "new" thing since the Brundtland Commission introduced the concept of sustainable development in 1988. It has changed our conceptualization of food, medicine, and of life itself.

As such, biotechnology offers government, for the first time, the opportunity to manage a technology within a sustainable development context. However, advances in biotechnology are rapid and will challenge all governments, independently and collectively. Effective governance will depend on our ability to manage potential risks, anticipate future issues and position ourselves to respond to these as soon as possible. If we are successful in this and at communicating our actions, public confidence will be engendered and government will be able to turn its efforts both to creating a business climate that allows Canadian firms to successfully compete and to promoting social benefits of biotechnology.

### 3. Critical Sector Priorities

#### 3.1 Incremental Initiatives

##### 3.1.1 Stewardship

For the federal government, stewardship is more than simply ensuring a strong, scientifically sound regulatory system -- it means the management of natural resources in an environmentally beneficial way. This includes understanding the interaction of products of biotechnology and ecosystems and managing potential risks arising from this.

#### *Regulatory*

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Draft

November 20, 2000

In comparison to other nations, our regulatory system is generally seen as strong, and the public has consistently supported a strong regulatory system.

The accelerating volume of new products places significant demands on the regulatory system and on the government's ability to regulate biotechnology. For example, substantial new products are being developed in: applications of animal and fish biotechnology, including the production of organs for transplantation into humans, and disease resistant animals; the production of pharmaceuticals and new foods from plant species; drugs and medical devices; environment bio-remediation products; and forestry and aquaculture products. With the rapid advances in biotechnology, the time between laboratory experiments and the marketing of finished products is continuously shrinking from decades to just a matter of months. There is a major risk that our regulatory systems will not be well positioned or adaptive enough to allow for unexpected products and innovations, nor that they will be adequately resourced to allow for increased workloads.

Another potential resource challenge for the government stems from the listing of other acts and regulations under Schedules 2 and 4 of CEPA '99. If the other departments cannot meet the September 2001 deadline, Environment Canada will be responsible for conducting environment assessments for 'toxic' under CEPA until the other departments can do so legally.

To meet the current and potential challenges facing our regulatory system, we have identified the following regulatory priorities:

- Managing administrative issues concerning CEPA '99, including legal and policy criteria for cradle-to-grave assessment and listing of other Acts and Regulations in CEPA's schedules;
- Contingency resource planning for the regulatory system for new substances review and for expected increase in workloads for environmental assessment and for compliance and enforcement; and
- Assessing ability to respond to emergencies and releases from manufacturing facilities.

#### *Ecosystem Science*

To maintain, restore and enhance the ecological integrity and economic productivity of our natural capital, we need to understand ecosystems, how they are changing and why. In March 1999, Environment Canada held a biotechnology workshop which identified four priority areas where efforts should be focused:

- developing methods to enhance scientific understanding of gene transfer events under representative field conditions;
- identifying ecological pathways through which biotechnology products generate effects on ecosystems, wildlife and biodiversity;
- improving understanding of effects of biogenetic-based toxins and genetically altered plants on wildlife, biodiversity and ecosystem health; and

- understanding *in situ* impacts of bioengineered plants already in widespread use.

### 3.1.2 Benefits (Economic, Health and Social)

Biotechnology is transforming conventional production and manufacturing processes and contributing many environmental benefits such as the reduction or elimination of toxins, climate change mitigation and waste reduction. Bio-based products may improve the sustainability of natural resources, environmental quality and national security whilst competing economically. Canadian companies that use biotechnology have reported not only a reduction in environmental degradation but also lower costs and an increase in quality and/or productivity.

The trend line for growth in biotechnology-based technologies is exponential. However, the Canadian economy and its science-based institutions are not positioned strategically to engage in it. Canada is falling behind many other countries, such as the US and the EU, in its capacity for science, knowledge and stewardship as well as the exploration of potential environmentally friendly technologies. Preliminary results from a study benchmarking Canada against Western European countries, the United States and Japan place Canada second last in terms of federal funding per capita for environmental technologies. Industry Canada also reports that by 2010 the US plans to triple bio-energy and bio-product production from renewable resources and the EU plans to double its bio-energy production.

The most important factors in preventing the diffusion of biotechnology is the need for technical and scientific expertise both within and outside the firm, a lack of information about biotechnology and a lack of commercially viable applications. In order to both realize the above environmental and economic benefits and to overcome the barriers to diffusion, the federal government is pursuing a variety of initiatives.

- Fostering and promoting the development of applications of environmentally beneficial technologies, such as bioremediation, biocatalysis, abatement and use of renewable feedstocks, that contribute to sustainable development through federal initiatives, such as the Canada Foundation for Innovation, the Sustainable Development Technology Fund, the Panel on Energy Research and Development and the establishment of the Canadian Biodiversity Network
- Supporting a strong R&D and innovation climate with complementary commercial diffusion of results through programs such as genomics research (three-year \$55M for internal capacity, \$160M Genome Canada for external capacity and the establishment of a National Centre of Excellence on Genomics for Sustainable Development), Technology Partnerships Canada and IRAP.

- Developing economic and performance measurement tools, including benchmarking studies, to measure technologies for sustainable development.

### 3.1.3 Citizen Engagement

Polling data show that Canadians are very concerned about the long-term impacts of biotechnology on the environment (EnviroNics, December 1999; preliminary results from Earncliffe/Pollara, Fall 2000) yet they also believe environmental biotechnology applications can have societal benefits (Creative Research, 1999). More at the heart of biotechnology discussions is the matter of consumer confidence and comfort with the new biotechnology-based products. Research shows that, while some 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 and that burdens are equitably balanced with benefits. There is a need to ensure that Canadians and least developed countries are publicly engaged in discussions of the implications of any social and ethical issues concerning the development of policies and regulations for biotechnology products and processes.

We need to develop outreach activities and information products for engagement of industry, associations, investors, the public, NGOs and least developed countries to:

- Reassure society that we have a strong, up-to-date regulatory system, including continued effort to increase the level of transparency in the regulatory system.
- Demonstrate that the government is actively engaged to build the science capacity required to monitor the environmental effects of products of biotechnology.
- Inform Canadians that the federal government is committed to realizing the benefits of environmental applications of biotechnology while ensuring, first and foremost, environmental protection and the health and safety of Canadians.

### 3.2 Leadership Initiatives

#### *Stewardship*

**Signing and ratification of Biosafety Protocol MC:** The Conference of the Parties to the Convention on Biological Diversity adopted the Cartagena Protocol on Biosafety on January 29, 2000 which outlines international regulations to protect biological diversity from the potential risks posed by transborder movement of living modified organisms.

**Ecosystem Science MC to understand impacts of genetically modified organisms (GMOs):** We need to improve our understanding of ecological pathways by which ecosystems, wildlife and diversity are affected by products of biotechnology, including understanding impacts of gene transfer in the environment, and cumulative effects of multiple uses of biotechnology products. In addition, we need to increase our capacity

to monitor the effects of GMOs on our environment. This ecosystem science will also support regulatory decision-making and strengthen the sustainable development framework.

#### *Benefits*

**Biomass MC:** The potential environmental benefits include reductions in greenhouse gases that contribute to undesirable climate change and global warming and thereby support the Kyoto Protocol and reduction in toxic substances, which will also benefit human health. In addition, such investment can boost the development of products and processes that are renewable, more readily biodegradable, less polluting, can utilize organic materials currently considered as waste, can contribute to cleaner industrial products and processes, and result in improved product quality, productivity and costs. Economic advantages include: benefits to the agricultural and forestry sectors as well as to rural, remote and aboriginal communities; new export opportunities; the stabilization of energy prices through alternative sources; and enhanced energy security.

#### **4. Horizontal Issues**

Research, development and commercial application of biotechnologies, which have environmental, economic and societal benefits, requires strong interdisciplinary research and technology transfer capabilities. To compete effectively with well-funded research networks in the US and Europe, a major, on-going investment is required by the federal government.

The demand by industry, government and the research community for experts in biotechnology as well as for business managers, regulatory affairs, communications, marketing and other specialists who are biotechnology literate is very competitive and is accelerating. The result is a significant gap between the demand for such multidisciplinary experts and the corresponding supply. A couple possible strategies would be to develop mid-career mechanisms to facilitate skills upgrade and to develop effective multidisciplinary curricula in post secondary institutions.

Finally, almost all biotechnology issues have international and policy dimensions (trade, investment, regulation, IP, etc.), which are growing and becoming more complex and intertwined. It will be necessary to increase our capacity to gather and analyse intelligence and to utilize strategically our linkages with international fora to achieve specific policy objectives.



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- Application of DNA technologies to stock assessment to identify threatened fish stocks the purposes of conservation and stewardship; develop methods to prevent breeding of escaped farmed fish with wild fish; and methodology to alleviate habitat deterioration.

#### Aquaculture Support

- Identification and selection of appropriate species for aquaculture; genetic techniques in the production of diagnostics and vaccines to control disease; understanding of how a foreign gene in a transgenic fish behaves relative to the genetic background of the host species.

### Long-Term Initiatives - 2005 and Beyond:

- Aquaculture

As present harvesting technology can cause strain on ocean fisheries, new directions in aquaculture include improved methods for effluent management; sterilisation technology; plant-based feeds; molecular genetic techniques for breeding programs of aquaculture species.

- Bioremediation

DFO researchers are working in collaboration with other government agencies and industry on remediation of Canada's oceans and ports using micro-organisms for the clean up of oil spills and other contaminants. This is an area where DFO and Canada can take a leading role in the development of bioremediation technologies.

- Bioprospecting

Bioprospecting for novel chemicals that can be extracted from marine animals and plants is growing in importance. DFO could work closely with industry (i.e. biopharmaceutical companies) by providing scientific advice, as well as developing regulations to protect biodiversity by preventing over-harvesting of rare marine animal and plant species.

## **DEPARTMENT OF FISHERIES AND OCEANS (DFO) STRATEGY**

### **ACCOMPLISHMENTS SINCE AUGUST 1998**

The primary role of DFO is conservation-based management of the fisheries resources and the environment. However, there is also clearly the important secondary role of conducting scientific research that assists strong and responsible resource-based industries (wild harvests of fish and shellfish, and aquaculture). DFO is an active participant in the Canadian Biotechnology Strategy (CBS) program and five DFO researchers are currently funded by CBS for projects that range from broodstock development methodologies for aquaculture or conservation, to the development of transgenic salmon, to the writing of regulations.

Another interest of DFO is in the use of genetically modified fish as research models to understand the technology and their potential interaction in the environment. Regulations for aquatic biotechnology under the Fisheries Act that will be equivalent to the requirements of the current Environmental Protection Act in Canada are being written at DFO. To date, DFO has developed a draft policy on the use of genetically-modified aquatic organisms in response to industry initiatives that are planning to request permission to grow genetically modified salmon and trout in sea cages.

Biotechnology enhances departmental ability to ensure conservation and a sustainable fishery. DNA methods to identify superior broodstocks; improved feeds, that are better and more quickly digested, resulting in lowered faecal and nutrient output to the environment; genetic engineering of improved fish stocks. DNA identification tools can define the genetic and other limits of stocks, especially those that are mixed or which undertake migrations. Herring, lobster, haddock, Pacific rockfish and Pacific salmon are among the species for which DFO is developing stock discrimination techniques using DNA technology. As an example, DFO is also using DNA identification tools to differentiate between species of abalone so that those illegally harvested in B.C. may be identified from those harvested elsewhere in the world.

### **BROAD SECTOR TRENDS AND BIOTECHNOLOGY ACTION PLAN FOR 2000-2005**

Aquatic biotechnology efforts can be grouped into five main areas that are of importance globally, and also to Canada. These are:

1. enhancement of wild fish, shellfish and aquatic plant harvests;
2. conservation and stewardship;
3. aquaculture, including extension of aquaculture techniques to land-based practices.
4. bioremediation and environmental preservation;
5. bioprospecting;

Based on the current available information and feedback from DFO research scientists, the following is an action plan for the next five years:

## 1. Immediate Priorities

### A. Enhancement of Wild Fisheries

- Development of DNA technology to define the population structure of commercially important fish and shellfish and to identify the elements of biodiversity to be conserved. This information is key to understanding fishing impacts and recoveries, and will enable management of sustainable mixed-stock fisheries.
- Application of existing DNA technologies to stock assessment via genetic fingerprinting (e.g. microsatellite analyses and RDA) to identify threatened fish stocks early enough to prevent overfishing.
- Development molecular markers for forensic and stock identification of confiscated fish and shellfish to assist fishery workers in identification of illegally harvested products.

### B. Conservation and Stewardship

- Develop new criteria using cutting-edge genetic and molecular biology methods to identify threatened fish stocks early enough for conservation and stewardship.
- Continue development of methods to prevent breeding of escaped farmed fish (including transgenics) with wild fish and habitat deterioration.

### C. Aquaculture Support

- Selection of species for aquaculture, e.g. herbivores versus carnivores, to relieve pressure on oceans.
- Identification of genetic structures of potentially important aquaculture species to aid in the rapid selection of desired traits to improve the performance of farmed fish.
- Techniques for isolation of genes (DNA, RNA) and the use of genetic material in the production of recombinant proteins for drugs, vaccines, hormones etc. that could be used to enhance aquaculture, e.g. by preventing or controlling disease.
- Understanding how foreign genes in transgenic fish species behave against the different genetic backgrounds of the host species.

Marine aquaculture technologies can also be modified and extended to land-based aquaculture.

## 2. Identification and planning for new initiatives beyond 2005:

### • Aquaculture

Aquaculture is growing rapidly world-wide but most practices are based on very low technology, many of which can cause further strain upon ocean fisheries. Present practices require the capture of wild fish to feed the carnivorous farmed species, effluent and chemical residues may be harmful to sensitive marine or brackish habitats and wild fish are collected as broodstock for developing new aquaculture species. This area is one in which Canada can take a leading role in the application of biotechnology to develop sustainable aquacultural

practices.

New directions in aquaculture include:

1. Development of new methods for fish effluent management.
2. Developments of new methods for sterilisation of transgenic or otherwise genetically modified fish other than the current triploidy methods.
3. Development of plant-based feeds.
4. Developing molecular genetic techniques for breeding programs to improve performance of aquaculture species, especially new aquaculture candidates to reduce pressure on wild fish populations.

- Bioremediation

DFO researchers are working in collaboration with other government agencies and industry on remediation of Canada's oceans and ports. Microorganisms are being studied for their potential for cleaning up of oil spills and other contaminants. This is an area where DFO and Canada can take a leading role in development of bioremediation technologies.

- Bioprospecting

Bioprospecting for novel chemicals that can be extracted from marine animals and plants is an increasing important activity in many countries. DFO could work closely with industry (especially biopharmaceutical companies) to develop this potentially important sector by providing scientific advice as well as developing regulations to prevent over-harvesting of rare marine animals and plants that can lead to extinction but potentially destroy the ecosystem in which they exist.

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## Forest Sector Summary

### Vision

- ☐ To promote the sustainable development of Canada's forests and competitiveness of the Canadian forest sector for the well-being of present and future generations of Canadians by:
  - developing innovative strategies for intensive forestry on selected areas and producing value-added products,
  - addressing key environmental issues,through the environmentally responsible development and uptake of forest biotechnology.

### Role of biotechnology

- ☐ Biotechnology can contribute to:
  - a healthy and productive forest;
  - the management of waste utilization;
  - the development of more energy efficient, more environmentally friendly processes;
  - spin-off technologies and products applicable to the sectors of health and agriculture.
- ☐ The forest and building products industry is one of Canada's leading manufacturing sectors and a major economic force in all regions of the country.
- ☐ Canada is extremely well positioned to be a leader in forest biotechnology research and development.

### Policy Objectives

- ☐ Provide knowledge and technologies to contribute to enhanced tree productivity on selected lands.
- ☐ Provide knowledge and technologies to develop energy efficient, environmentally sound processes for the forest sector.
- ☐ Develop safe and effective deployment strategies for biotechnology-derived products.
- ☐ Foster the uptake of forest biotechnology, including spin-offs.

### Critical Sector Priorities: ongoing support will be sought

- ☐ **Genomics:** received support for 2000-2002, will still be a high priority area in the areas of molecular genetics, DNA markers, forest pathology, fungal genetics, cellular and molecular biology, plant tissue culture, host-pathogen interactions, immunology, molecular entomology, molecular virology, and protein biochemistry.
- ☐ **Regulatory research:** received support for 2000-2002, will still be a high priority area. Forest biotechnology research and environmental safety research will be conducted in support of the regulatory framework.
- ☐ **Public Awareness and Citizen Engagement in Risk Communication:** received support for 2000-2002, will be extremely important in the years to come. Public opinion research and focus group studies will be used to evaluate current public opinion on forest biotechnology issues. Information on forest biotechnology will be produced for the public, such as brochures, websites, posters and information sessions. Educational support for teachers, and learning tools will be developed.

### Critical Sector Priorities: additional support will be sought

- ☐ Long term monitoring of the environmental impact of the release of genetically modified organisms into forest ecosystems.
- ☐ Issues of biodiversity and identification and control of exotic pests.
- ☐ Strengthened support to forest products and pulp and paper biotechnology.
- ☐ Technology transfer, pilot projects and cooperatives to implement new forestry practices based on biotechnology.
- ☐ Issues of intellectual property and patenting of higher life forms.
- ☐ International forest biotechnology policy, business and partnership issues.
- ☐ Communication and dialogue activities aimed at the general public and the forest sector.

## Forest Sector Working Group Strategy

### Background

- *Biotechnology is an enabling tool for maintaining and enhancing the competitiveness of Canada's forest sector industries*
  - in 1998, an estimated 10 per cent of the core Canadian biotech companies provided products and services to the forest sector
  - about one third of these firms provide biotechnology products and services in forest regeneration and forest protection
  - the remainder provide biotechnology services to the P&P manufacturing firms in the area of bio-bleaching processes and waste management and mill effluent detoxification processes
- *Canada is a leader in forest biotechnology research and development*
  - the R&D effort in forest biotechnology is for the most part supported by the federal government in the areas of fundamental research, biosystematics, forest regeneration, forest protection and environmental risk assessment.
  - The Canadian Forest Service has built strong core expertise and facilities for biotechnology research, in which it invests approximately \$9.0 million annually.
  - Forintek and Paprican (Pulp and Paper Research Institute of Canada) are involved in biotechnology related to wood products and in pulp and paper processing, respectively.
  - Canadian Universities have several scientists involved in this area and funded through NSERC or provincial grants.
  - A number of private industries are also involved in forest biotechnology research, and small-sized companies are under development.
- *The Canadian forest and building products industry is one of Canada's leading manufacturing sectors and a major economic force in all regions of the country*
  - accounts for 11 percent of the manufacturing Gross Domestic Product (GDP)
  - provides jobs directly and indirectly to over a million Canadian workers
  - contributes \$31 billion to the country's trade balance
  - accounts for 20 per cent of the world trade of forest products
  - makes Canada the world's largest forest products exporter
- *Biotechnology can contribute to:*
  - a healthy and productive forest, essential for the forest, wood, and paper industry
  - the management of waste utilization and use of more energy efficient, cleaner and more environmentally friendly processes, also essential for maintaining the competitiveness of Canada's forest product industries
- *The Canadian Forest Service (CFS) has received funding under the renewed Canadian Biotechnology Strategy:*
  - this funding allows the CFS to considerably strengthen its activities in the areas of: forest biotechnology research and development; regulations governing products of forest biotechnology; commercialization and competitiveness of Canadian forest biotechnology products; international forest biotechnology issues; public awareness of Canadian forest biotechnology; stewardship issues that are related to forest biotechnology.

## Accomplishments since CBS announced August 1998:

### Stewardship:

#### *Regulations*

- NRCan officials participate in the OECD Working Group for the Harmonization of Regulations for Genetically Modified Organisms. Canada was a co-organizer of the OECD workshop on Environmental Impacts of Transgenic Trees held in Trondheim, Norway, Nov. 1999 and provided support for the Canadian Delegation's participation to the workshop
- NRCan participates in the interdepartmental working group to develop Canada's position with respect to the Biosafety Protocol. The Conference of the Parties to the Convention on Biological Diversity adopted the Cartagena Protocol on Biosafety on January 29, 2000 which outlines international regulations to protect biological diversity from the potential risks posed by transborder movement of living modified organisms.
- NRCan participates in the CBS Interdepartmental Working Group on Regulations related to the environmental release of genetically modified organisms
- NRCan contributes to the development of a sound regulatory system for genetically modified trees, under the authority of the *Seeds Act* administered by the Canadian Food Inspection Agency (CFIA), by: organizing federal/provincial meetings on the issue; coordinating the efforts of an expert advisory committee mandated to provide guidance to the CFIA; producing Biology Companion Documents to the CFIA regulatory guidelines for the species of poplar, white pine, white spruce and Sitka spruce.

#### *Environmental impact assessment research:*

- A protocol has been established for extracting and specifically detecting a unique transgenic tree marker gene in soil, and to determine the stability of genomic DNA contained in plant tissue in soil
- Competition and gene flow among co-infecting transgenic and wild type microorganisms has undergone preliminary examination. No gene transfer was initially detected between viruses; the possibility of DNA recombination between virus and cells is being investigated
- Laboratory and field studies have been conducted to evaluate the persistence of free DNA and bacterial transformation in forest litter and aquatic substrates
- Ecological risk assessment is underway to determine the potential for development of insect resistance to transgenic spruce containing the Bt toxin gene

#### *Intellectual property:*

- A report has been published on Intellectual Property / Freedom to Operate with respect to transgenic trees

**Public communication and education, outreach:***Publications*

Brochures, pamphlets and booklets were produced targeted both to the general public and informed stakeholders. These include brochures on genetically modified trees, genetically engineered baculoviruses, somatic embryogenesis, and environmental impact of GMOs. As well, posters and bookmarks were designed. In addition, the CFS Biotechnology Website has been redesigned to include more comprehensive biotechnology information. A NRCan departmental Biotechnology website has been developed.

*Presentations*

Presentations were made and information was distributed to teachers at the Key Foundation summer seminar series and to NRCan employees. A forest biotechnology booth was created and displayed at several events, such as the BioAtlantech, Ottawa Life Sciences Council and Canadian Institute of Forestry meetings.

*Teacher Support*

Support for the Key Foundation included both presentations on forest biotechnology to teachers, as well as formation of a steering committee to develop a teaching unit on forestry and forest biotechnology. In addition, French translation was provided for a forestry brochure produced in English by the Key Foundation. A slide presentation complete with speakers notes has been produced to be made available as a teaching tool.

*Public opinion*

The workshop entitled, "Forest Biotechnology and Public Opinion: Risk Issues Management and Public Dialogue", was conducted at the International Society for Plant Molecular Biology in Quebec City, June 2000. Three invited speakers addressed (i) major issues surrounding the potential environmental deployment of genetically modified trees, (ii) strategies for risk issue management emphasizing the need for public dialogue on forest biotechnology issues, and (iii) current Canadian public attitudes and opinions towards biotechnology applications in forestry.

Public discussions on forest biotechnology were organized. Four focus groups (two per city) were conducted in Toronto, Ontario and Prince George BC in March 2000; and four focus groups were conducted in June 2000 in Quebec City, Quebec and Halifax, Nova Scotia. The objectives of the research were to a) investigate issues associated with forest biotechnology in urban and rural areas, and b) to test communications messaging and materials on forestry biotechnology developed for broad public distribution.

**Benefits:***Genomics research*

- Several stress-inducible genes from poplar and spruce have been cloned, sequenced and analyzed



- The gene for a fungal protein associated with white pine blister rust infection has been isolated, cloned and sequenced
- A putative gene conferring cold tolerance has been isolated, cloned and sequenced from white spruce
- An improved strategy for mass propagation of recombinant virus in spruce budworm larvae has been initiated for pre-commercialization
- Antifeedant chemical compounds in red maple leaves which may be responsible for the resistance to feeding by forest tent caterpillar larvae have been identified and purified
- The juvenile hormone esterase gene of spruce budworm was cloned and sequenced
- Many genes and open reading frames of spruce budworm and its viruses have been identified and sequenced. The fusolin gene has been totally sequenced and the biochemical properties of the protein have been characterized. The homologue of the gene in baculoviruses has been identified, cloned and sequenced. Gene patenting is being investigated. The defensin gene has been identified, cloned and sequenced.
- Somatic embryogenesis has been developed for eastern white pine and jack pine using zygotic embryos. Somatic embryogenesis has been induced from needle explants isolated from developing buds of black and white spruce
- DNA has been extracted and amplified from a single leg of the exotic species of bark beetle
- DNA markers in coding genes of several forest pathogens has led to the development of user-friendly colorimetric diagnostic assays

## Opportunities

- Canada's forest products industry's future depends on practising responsible forest management principles for sustainable development to provide for both protection and efficient use of Canada's forests.
- Intensive forestry and zoning of forests for different level of management are receiving increased attention in Canada. The Canadian Council of Forest Ministers have recently agreed to the policy plan Forest 2020, an innovative Canada-wide approach to increase the conservation value of forests while ensuring the continued growth of the forest industry. Stakeholder consultations are currently underway for final approval of the plan. This plan provides an opportunity to attract investment into potential new forestry initiatives, such as high yield, fast growing plantations.
- Canada is a leader in forest biotechnology research and policy development. This could lead to a cautious uptake of biotechnology by forest managers, provided that Canada has the foresight to support this emerging field.

The commercial release of genetically engineered forest products in Canada is not expected for at least 5 to 10 years. This provides an opportunity to advance the environmental impact research that will be required to answer concerns regarding the environmental safety of these products.

## Challenges

Forest companies hesitate to commit to long term research, and innovation in Canada's managed forests is slow to occur. A major challenge to Canada relates to the willingness of governments to implement policies which would foster innovation and investment in the forest resource and forest products industries.

Global environmental issues, including global climate change, conservation of old-growth forests and their associated biodiversity, have led to the development of international conventions and trade issues that impact on the forest sector. Responsible environmental stewardship is becoming key to consumer acceptance of wood and wood products.

The complexity of the forest ecosystem is well recognized, and is not yet well understood. Scientific data on the characteristics, ecology and environmental impacts of transgenic trees needs to be strengthened. However, no risk assessment will ever conclude that there is "no" risk, as there will always be unknowns. The adequacy / appropriateness of the scientific methodology used by regulatory agencies must be ensured, as they may also impact on the labelling of forest products according to the Forest Certification Standards.

Potential restrictions in the use of basic enabling technologies result from issued patents. These already cover a broad spectrum of technologies and genes, and may influence research activities.

Several international activist groups have collectively launched a major international campaign against genetically engineered trees in 2000. Thousands of experimental trees have been destroyed in North America; of these, very few were actually genetically engineered. This is a concern also for conventional tree breeders who risk losing their research materials. Public awareness and education programs are thus strongly needed in this area.

Market access may become a critical issue if countries importing Canada's forest products decide to put in place moratoria on genetically modified trees, or trees that have been treated with genetically modified biopesticides.

Social and ethical frameworks are required for overall biotechnology activities in Canada. The question of patenting higher life forms is of primary concern, as it could provide protection for developers and encourage research investments from the private sector.

## Vision

- Maintain Canada's position among the world's leaders in the manufacture of forest products and maintain Canada's position as the world's largest exporter of forest products by:
    - developing innovative strategies for intensive forestry on selected areas and producing value-added products
    - addressing key environmental issues
- through the environmentally responsible development and uptake of forest biotechnology.

## Policy Objectives

- Provide the knowledge base and technologies to contribute to enhanced tree productivity on selected lands
  - ☐ develop fundamental understanding of production and protection systems
  - ☐ develop technologies to produce genetically improved superior and fast growing trees
  - ☐ develop environmentally acceptable forest protection
- Develop safe and effective deployment strategies for biotechnology-derived products
  - ☐ develop scientific expertise and provide advice to ensure environmental safety
  - ☐ promote frameworks for science-based regulatory and intellectual property protection
  - ☐ promote public awareness as to the benefits and costs of biotechnology
- Foster the uptake of forest biotechnology
  - ☐ develop innovative client partnerships and technology transfer mechanisms
  - ☐ aggressively market spin-off technologies
  - ☐ advocate responsible use of biotechnology in forestry applications

## Action Plan With Priorities and Deliverables 2000-2005

- **Genomics:** received support for 2000-2002, will still be a high priority area until 2005 in the areas of molecular genetics, DNA markers, forest pathology, fungal genetics, cellular and molecular biology, plant tissue culture, host-pathogen interactions, immunology, molecular entomology, molecular virology, and protein biochemistry. This will involve partners in national research networks of the Canadian Forest Service, universities, provinces, the private sector, and other federal departments.
- **Environmental impact research for regulatory support:** received support for 2000-2002, will still be a high priority area until 2005. Forest biotechnology research and environmental safety research will be conducted in support of the regulatory framework.
- **Public Awareness and Citizen Engagement in Risk Communication:** received support for 2000-2002, will be extremely important in the years to com. Public opinion research and focus group studies will be used to evaluate current public opinion on forest biotechnology issues.

Information on forest biotechnology will be produced for the public, such as brochures, websites, posters and information sessions. Educational support for teachers, and learning tools will be developed.

**Priority areas that will require additional support in coming years:**

- **Long term monitoring of the environmental impact of the release of genetically modified organisms into forest ecosystems. This includes research toward a better understanding of current forest ecosystem processes.**
- **Issues of biodiversity and identification and control of exotic pests.**
- **Forest research in relation to climate change: genetics and breeding for adaptation (disease and drought tolerance); increased biomass production; bio-fuel conversion.**
- **Technology transfer, pilot projects and cooperatives to implement new forestry practices based on biotechnology.**
- **Technology forecast and competitive intelligence.**
- **Issues of intellectual property and patenting of higher life forms.**
- **International forest biotechnology policy, business and partnership issues.**
- **Communication and dialogue activities aimed not only at the general public, but also at the forest sector.**

## **Partners**

- **Federal Departments and agencies involved in the Canadian Biotechnology Strategy**
- **Research institutes, universities, National Centres of Excellence**
- **Provincial departments of Natural Resources and Forestry**
- **Industrial Associations & Individual Companies in the forest biotechnology sector and in the forest sector**
- **Non-Governmental Organizations such as BIOTECanada, the Key Foundation, and regional associations**

## **BIOTECHNOLOGY PRIORITIES HEALTH SECTOR STRATEGY**

### **VISION**

To be a world leader in the responsible development, regulation and use of biotechnology to achieve health benefits for Canadians

### **CONTEXT**

Biotechnology promises to deliver new ways of preventing and treating diseases and enhancing our health. Work on microbial genetics and related biotechnology is well developed. It has increased our capacity to identify agents of infectious disease, to detect these microorganisms, to study the relevant disease process and to develop and implement surveillance and disease control strategies. The first draft of the human genome has been published and scientists in universities and in the private sector are moving quickly to transfer this information into a wide range of applications. Scientists in Canada have become world leaders and major contributors to the study of genetic diseases, making major new advances in muscular dystrophy, diabetes and cystic fibrosis. Knowledge of the human genome will have implications related to the identification, surveillance and control of many chronic diseases, but also to such areas as susceptibilities to both chronic and infectious diseases, the utility of certain therapeutic strategies, and more. It will have a dramatic impact upon health systems, as medicine moves to a more personalized, proactive model, and genomic-based therapeutics, diagnostics, screening, and prevention tools become dominant.

Public opinion research has demonstrated that, for biotechnology, Canadians give top priority to realizing the potential health benefits. Further, Canadians rate health research as one of the most important investments overall for the federal government (National Angus Reid Poll, June 2000). They expect the Government of Canada to lead in this aspect but, perhaps more importantly, to stringently ensure the safety of the products and the technology, with particular focus on potential health and environmental implications. At present, Canadians seem cautiously accepting of the regulatory oversight of most products, but consumer confidence is a delicate poise.

Biotechnology in health also presents an important economic opportunity for Canada, as discoveries with health benefits are brought to markets. In 1997, Canada's biotechnology industry ranked second in the world in terms of number of companies, had \$1.1 billion in revenues, \$400 million in exports with 11,500 good knowledge-based jobs. The health and agri-food sectors represented 95% of Canadian biotechnology sales and 75% of companies, and 90% of the biotechnology R&D in Canada was in the health sector (Statistics Canada, Biotechnology Firm Survey, 1998). World sales of biopharmaceuticals have grown more than seven-fold over the past decade and should

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exceed \$18 billion (US) by 2003. Canadian firms have developed three of the 24 biopharmaceuticals approved for sale on the world market. A January 2000 survey by CIHR indicates that selected Canadian biopharmaceutical firms have more than 400 products in the pipeline.

Canada's strong positioning in this sector can be attributed to: government support for innovation that includes major funding for research; favourable taxation policies; an excellent scientific research base and strategic partnerships; an internationally recognized regulatory system; and a first-rate business environment; a stable investment climate, and market access within North America. Within Canada, most biotechnology companies show promise and are maturing rapidly, but have not yet reached the commercial product stage.

Many of the possibilities related to biotechnology challenge us as a society with their ethical, social and regulatory implications. An enhanced pace of discovery, an increasingly competitive global environment, and heightened public expectations for rapid and responsible translation of research findings have combined to challenge the ability of the research community and government to respond. In the next mandate, health gain and health stewardship through advancement in biotechnology are timely issues to champion.

## **PRIORITIES**

### **A strong stewardship role:**

The Government of Canada and, specifically, Health Canada has a direct stewardship role in the regulation of many products of biotechnology, including genetically-modified foods and new therapeutic products. The direct role of Health Canada and the broader responsibilities of the Government of Canada create public expectations of a wider stewardship role, addressing social, legal and ethical issues. The ethical issues range from intellectual property and the patenting of higher life forms, to genetic testing and research, to appropriate management of genetic information.

A leadership role in the regulatory system involves developing and maintaining a strong scientific base, including the expansion of the fundamental knowledge base, a clear, transparent regulatory or decision-making framework, citizen-engagement and appropriate social and ethical treatment. Government action at the international level is an important aspect, just as is action at the international level by other governments or non-governmental groups which can have a strong affect on the national situation.

### **Biotechnology for health advantage:**

The Government is committed to working with provincial and territorial counterparts and with stakeholders to ensure a modern health system that meets the needs of Canadians in

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the future. The biotechnology health sector (human genomics, molecular medicine, pharmaceuticals, nutrition) and other non-traditional areas such as natural health products are rapidly becoming important aspects of our modern health system.

In order to fully realize the potential health benefits of biotechnology, several issues need to be addressed. The climate in Canada needs to be supportive. Support for research, which underpins the discovery, regulation and innovation process, must be internationally competitive. Companies should find a climate to enter the Canadian regulatory system for product approval at the same time as they approach other jurisdictions. New products must be adopted by the health care system, and mechanisms to better link product approval with provincial formularies should be examined. Issues related to new products replacing existing products and potentially increased cost pressures need to be addressed.

Several important characteristics distinguish biotechnology from the information technology and most other knowledge-based industries in Canada: 1) a strong entrepreneurial small and medium-sized enterprise sector exists but very few large Canadian firms exist to advance a project from proof-of-concept to production and application; 2) the strong public sector presence in terms of R&D funding and the regulatory frameworks; and 3) the product development cycle requires very long lead times, for example, up to \$500 million and 10 years to develop a bio-pharmaceuticals product.

Moreover, genomics and bioinformatics are fundamentally changing the way that drugs are being discovered and developed. The acceleration of the selection process for best drug candidates and the reduction in the cost of pre-clinical and clinical studies could collectively save at least \$200M (U.S.) and two to three years per drug.

The Government of Canada must address issues related to the policy and regulatory framework and the business climate in order to realize the health benefits for Canadians. Key issues to be addressed include: R&D; financing and access to capital; skills development and human resources; regulation and intellectual property; technology transfer and commercialization; and, foreign investment and trade.

## INCREMENTAL INITIATIVES

**Investing in Knowledge Infrastructure:** Canada needs an appropriate human resource capacity - in the supporting scientific areas, in the regulatory areas and relating to the broader social, legal and ethical considerations.

Through CIHR, the Government of Canada will invest in leading-edge research across Canada in all aspects of biotechnology relating to health, including bio-medical research, clinical research and research respecting health systems, health services, the health of populations, and societal and cultural dimensions of health. Increased investment in

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research will: expand the platform of basic knowledge about how living organisms function; increase understanding of the current and future impact of biotechnology on health; support regulatory policy; contribute to ethical, social, and economic considerations; expand our research capacity (human resources); and, facilitate the translation of research results into improved health and more effective health care.

Canada needs to keep pace with international investment in competitive, peer-reviewed research, particularly as the industrialized world invests heavily in health research and development. At present, the average CIHR grant is only 1/3 the value of an average National Institutes of Health grant, 1/2 that of support in the U.K. To ensure that Canada is able to capture the tremendous opportunity in health research, significantly enhanced investment in health research through CIHR must continue into the next mandate.

There is a need to improve technology foresight; to develop an informed capacity for early issue-identification. CIHR, through the Scientific Directors of Institutes and with partners across the health community, including Health Canada, will be in a unique position to identify, capture and convey informed insight from the "front-lines" of research. Industry Canada is developing a technology roadmap for the biopharmaceutical sector.

Aspects of biotechnology challenge current legislative tools. Products may be specifically tailored to individuals and the traditional approach to drug product approval and license may not be feasible or desirable. In some instances, instead of reviewing a product, it may be critical to examine the validity of the information upon which a procedure, maybe a diagnostic test, is based.

Work on the Human Genome Project, and the generation of genetic information related to resistance or predisposition to disease that will ensue, indicates the need for appropriate social and ethical treatment. It has given rise to concerns as to whether or not appropriate safeguards are in place to ensure acceptable protection of the privacy of health information. There is a need to improve the oversight of research involving human subjects.

The biotechnology sector requires attention to financing and capital requirements. Efforts will continue to provide for the early stage biopharmaceutical development through activities that will create more incubator sites and expanded activities of Industrial Technology Advisors. Alternative approaches to financing will be developed to encourage venture capital investment in biotechnology. As well, proposals will be developed on tax policies.

**Investing in transparency:** Recent surveys show that Canadians are concerned about the unknowns associated with biotechnology products such as genetically-modified foods. However, public support of biotechnology is strongest in the health sector. Extensive collaborative efforts between Health Canada and other federal departments to provide

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pertinent information to the public and to other stakeholders on the regulatory process used to assess the safety of genetically-modified foods has alleviated some of the concerns. Continued effort to increase the level of transparency is essential to maintain public confidence in the regulatory system. Responding to the recommendations of the Royal Society's Expert Panel on Genetically-Modified Foods in a timely, transparent manner will be critical to maintaining confidence. Canada must continue to build on its ability to provide sound, unbiased information on the products of biotechnology that will be the basis of regulatory decision making and communication with the public.

**Investing in citizen engagement:** Citizen engagement is critical to maintaining consumer confidence in our regulatory system and in the products of biotechnology. The Government of Canada should continue to engage the public on different issues related to biotechnology, both directly and through the work of the Canadian Biotechnology Advisory Committee. In so doing, policies need to be developed on privacy, ownership and benefits of genetic data to sustain public support for biopharmaceuticals and the application of bioinformatics and genomics technologies.

**Science Capacity in Biotechnology:** Strength in science provides the basis for scientifically sound and appropriate regulations, policy and evaluation to ensure that products pose no unreasonable risk to Canadians. To demonstrate leadership, an increment in the science capacity is now both an opportunity and a strategic necessity.

Recombinant DNA technology has provided for the development of biotechnology-derived and engineered protein therapeutics and DNA vaccines. The growth continues unabated, reflected in the number and scope of products in the developmental pipeline. Superimposed on this, the explosion of knowledge related to genomics, proteomics, and functional genomics will add to a large increase in the number of product submissions, as well as increased use of these techniques to address such issues as disease surveillance.

Bioinformatics encompasses all computational storage and the generation and analysis of data relating to organisms, their genomes, derivative proteins, their biological regulations and interactions. Bioinformatics is key to generating data for all aspects of our science base and policy analysis, including generating and interpreting data from our surveillance activities. It will also become an important tool in determining potential long term effects of biotechnology products. Strengthening our surveillance capacity will in turn lead to an increased ability to identify environmental markers, susceptible populations, emerging pathogens and more.

Support for research, in government laboratories, extramural settings, and for large-scale program funding through Genome Canada will be critical to maintaining a leading role in biotechnology and genomics.

D R A F T October 31 2000 5

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## **Overview of Biotechnology Activities**

### **Department of Foreign Affairs and International Trade**

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#### **DFAIT Vision**

Within the broader life sciences and biotechnology agenda, the Department promotes Canadian views, policies and goals in bilateral and multilateral fora to position Canada as a responsible user and developer of life sciences and as a hospitable environment for research and investment. The Department applies its expertise in international relations to foster biotechnological capabilities committed to enhancing quality of life world-wide. By establishing sound policies and positions on biotech, Canada and the international community stand to profit from health, environmental and economic benefits.

#### **Context**

These activities on behalf of Canadian biotechnology are carried out within the specific mandate of the Department of Foreign Affairs and International Trade (DFAIT) which is: to negotiate trade and investment agreements and to resolve disputes on behalf of Canadian stakeholders; to work with representatives of other countries to develop international laws and regulations; to ensure that Canadian policies are consistent with our international obligations; to help Canadian businesses to promote and sell their goods and services in foreign markets; to encourage the flow of investment and new technology into Canada; to promote international human rights, peace and security through our relations with individual countries as well as through our membership in international organizations; to promote Canadian educational institutions abroad; to enhance Canadians' understanding of international trade and foreign policy issues through public information programs, media relations activities, consultations, the Internet Web site and other outreach activities.

#### **Activities**

The Department of Foreign Affairs and International Trade (DFAIT) conducts many diverse activities in biotechnology reflecting the role of the Department in representing Canadian views, goals and policies abroad. DFAIT's role is one of partnership and collaboration with other government departments and agencies that have the lead or shared responsibility in a particular area, such as: industry, science, technology, environment, health, security, agriculture and food and development.

There are several key areas of activity for DFAIT: market access issues which include the development of sound trade policy; trade and investment promotion efforts which are aimed at enhancing the position of Canadian companies abroad, attracting additional capital and technology, as well as promoting Canadian technology internationally, specifically in biotech where Canada is a leader; and foreign policy issues, which include human security, environmental challenges and international cooperation.

Through posts abroad and the International Trade Centres, DFAIT promotes the

international marketing of all evolving and enabling technologies such as biotechnology and its various applications. In order for the industry to mature, it requires international financing and partnering, information on markets and opportunities, forums to showcase its capabilities and expertise to promote the developments in the industry. Consequently, it is critical to have an effective strategy to promote the image of Canada in the minds of international investors.

DFAIT aims to increase the profile of Canadian companies by promoting them abroad and by providing international market research to help companies target their efforts, and to form strategic alliances internationally, between the private sector and research institutions. This can only be achieved when staff abroad are familiar with the issues associated with biotechnology - and through the CBS-funded Capacity Building in Biotechnology Courses, DFAIT is providing trade commissioners and business development officers with the knowledge of the science, regulatory issues and commercial process to be able to promote effectively Canadian capabilities and strengths.

DFAIT also provides market reports and analysis, which present a wide array of elements that characterize particular international markets including issues of intellectual property, public opinion, as well as research partnerships, technology transfer and sales and commercial development opportunities. These reports are available on the Department's info-export website.

DFAIT supports a network of Science and Technology counsellors at key Canadian Missions abroad, who serve as points-of-contact for S&T policy and market intelligence reporting, coordinating high level visits to foster biotechnology cooperation and for bilateral S&T agreements. Along with support from business development officers in Ottawa, this network focuses on the promotion and facilitation of R&D collaboration between Canadian and foreign technology companies and research organizations, including the biotechnology sector. In March 2000, a very successful Venture Financing and Technology Partnering Mission to Korea, Taiwan and Singapore resulted in several earnest follow up discussions and serious consideration for partnership work by several participants in Asia as well as in North America. Along with outreach activities, this network develops technology partnering profiles on Canadian biotechnology companies and research institutes such as those that participated at BIO 2000 held in Boston, last March. Future activities include a "Functional Foods" Mission to Korea and Japan for February 2001, a Biotech Venture Financing and Technology Partnering Mission to Europe (Switzerland, Germany, France, Sweden, and Italy) planned for February or March 2001, and a Venture Financing forum to be organized at BIO 2001 in San Diego in June 2001.

## **Multilateral Fora**

### **The World Trade Organization (WTO)**

The failed launch of a new WTO round last December, at the Ministerial Meeting in Seattle, led to the demise of the Canadian proposal for a WTO Working Party on Biotechnology. Since then, biotechnology discussions within the WTO have been confined to the Committee on Sanitary and Phytosanitary Measures (SPS Committee), the Committee on Technical Barriers to Trade (TBT Committee) and the Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS Council). Within the TBT and SPS Committees, the discussion has focussed on notifications that various WTO Members have made with respect to measures and technical regulations regarding

genetically modified organisms (GMOs) and whether these measures and technical regulations are consistent with the rights and obligations of the WTO Agreements. These discussions will continue until more consensus on the issue of GMOs emerges or until WTO jurisprudence emerges from possible trade disputes involving GMOs. The Canadian Food Inspection Agency (CFIA) leads on SPS issues with participation from DFAIT, HC and AAFC. The lead on TBT issues is within DFAIT with participation from IC, CFIA and others.

With respect to the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Canada is participating in the built-in review of Article 27.3(b) of the TRIPS Agreement. This provision allows WTO Members to exclude from patentability plants and animals other than micro-organisms (e.g., bacteria, yeast, algae, fungi, cell, etc.), provided that protection for new plant varieties is available (many Members, including Canada, have chosen to adopt the UPOV system for plant variety protection). It also permits WTO Members to exclude from patentability essentially biological processes for the production of plants and animals (e.g., cross-fertilization of plants) other than microbiological processes. The differences in the positions of developing country Members and the U.S., EU and Japan suggests that this article will likely be re-opened in a future WTO round.

### **World Intellectual Property Organization (WIPO)**

An Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore has been established by the World Intellectual Property Organization to examine, among other issues, how access to genetic material may be regulated as well as the criteria used in evaluating biotechnological inventions for patentability. Canada will be participating in this work. Although the issues are novel and very complex, developing countries will press for quick progress in the analysis phase and may even seek to enter negotiations within 3-5 years. Industry Canada is the lead on the intellectual property issues.

### **United Nations Fora**

#### Convention on Biological Diversity (CBD)

Environment Canada and DFAIT co-led the negotiations of the Cartagena Protocol on Biosafety (CPB) under the UN CBD. DFAIT remains active in the post-negotiation process, including consultations on signing, ratifying and implementing the CPB. DFAIT is likewise engaged in the parent body convention as it applies to biotechnology and genetic resources.

#### Food and Agriculture Organization (FAO)

Negotiations are ongoing to amend the International Undertaking on Plant Genetic Resources with a view to ensuring Canada's access to plant genetic resources that are the basis for food and agriculture in Canada as well as conserving the biodiversity necessary for world food security. Intellectual property rights issues arising from the benefit-sharing provisions of the proposed new Undertaking constitute a significant challenge for domestic commercial interests. These negotiations are scheduled to be completed by the end of the year. However, it will likely take another two full negotiation sessions to resolve all of the institutional and other issues remaining in the proposed

agreement before it can be put forward to FAO Council for approval. Agriculture and Agri-Food Canada leads the negotiations, with DFAIT providing advice on legal, policy and institutional aspects of the Undertaking in order to ensure that it is consistent with other international environmental and intellectual property rights instruments to which Canada is party.

#### Codex Alimentarius Commission

The work of the Codex Alimentarius and its subsidiary bodies is primarily aimed at elaborating standards for food safety. As such, the lead for Codex-associated work is within HC and CFIA. However, as the work of Codex takes on an increasingly trade-oriented dimension, DFAIT's profile within these files is likewise increasing. Biotechnology is discussed within several Codex Committees: General Principles, the Committee on Food Labelling, and the Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology. DFAIT's involvement is primarily from the trade policy point of view, looking to ensure that standards developed and adopted in Codex are consistent with our trade policy goals and our rights and obligations in treaties and agreements to which Canada is a party.

#### **Organization for Economic Cooperation and Development (OECD)**

The OECD has an extensive and long-standing program relating to biotechnology (e.g. clean industrial processes, safe drinking water, health, genetic testing etc.) as well as program related to food aspects of biotechnology. The Canadian mission to the OECD maintains Canada's day-to-day presence in OECD work including biotechnology. Many other Departments participate and lead delegations to particular work groups or meetings on biotechnology including IC, EC, HC, AAFC and DFO.

#### **Other Multilateral Fora**

##### Biological and Toxin Weapons Convention (BTWC)

The Biological and Toxin Weapons Convention (BTWC) entered into force in 1975 and has been ratified by 144 states. The Convention bans the development, production, acquisition, stockpiling and retention of microbial or other biological agents or toxins, in types and in quantities that have no justification for prophylactic, protective or other peaceful purposes. It also bans weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict. The actual use of biological weapons is prohibited by the 1925 Geneva Protocol.

Through DFAIT and DND, Canada is playing an active role in the ongoing negotiation of a verification protocol in the BTWC Ad Hoc Group (AHG) in Geneva. It is hoped that the Protocol will be concluded before the fifth quinquennial Review Conference of the BTWC in November 2001, as the negotiating mandate of the AHG expires at that time. The verification Protocol will have implications for industry in terms of transparency and compliance, and will govern such issues as the submission of mandatory declarations, and field/facility investigations.

G8

DFAIT has the lead coordination role on G8 issues. Over the past two summit cycles, G8 leaders have discussed the human genome and the food safety aspects and environmental impacts of biotechnology. The coordination process involves close consultation within the department - in the areas of intellectual property and human rights - as well as with other government departments including Industry Canada, Health Canada, AAFC, CFIA and Justice. G8 Sherpas and/or Foreign Affairs Sous-Sherpas will continue to address the human genome at G8 meetings and follow up on other biotechnology commitments from the Okinawa Communiqué.

### **Bilateral Fora**

In addition to the various multilateral contacts and areas of cooperation, Canada maintains bilateral contacts with many countries on biotechnology issues through its missions abroad. Posts act as the conduit of information and facilitate contact between the appropriate Canadian bodies and their foreign equivalents. These activities range from science and technology cooperation, to technology transfer facilitation, to trade promotion, to bilateral cooperation on technical issues, to registering our concerns regarding regulatory approaches and market access issues. DFAIT continues to monitor foreign regulatory systems in cooperation with Health Canada and CFIA closely, making representations where appropriate.

Together with other relevant departments, Canada has undertaken technical cooperation with several important partners such as the EU, Japan and the USA. This cooperation is strategic in that the intent is to encourage more openness and cooperation on issues related to biotechnology between the four parties (the Quad). Posts abroad serve as the primary point of contact for information on legislation and consumer actions which may have an effect on Canadian goods, including those derived through biotechnology.

(For more specific details on bilateral cooperation with select partners, see Annex I.)

## ANNEX I

### European Union

Over the past 4 years the Department has worked closely with the biotech industry to re-secure market access for GM canola exports to the EU which peaked at \$425 million in 1994. The PM has raised this issue at EU/Canada Summits and most recently with French President Chirac in June 2000. As well, DFAIT and 15 EU posts worked in tandem with Aventis in a March 1998 EU lobbying campaign which successfully won approval for an Aventis GM canola.

In November 1999, Canada hosted a successful dialogue in Ottawa of 12 EU and 10 Canadian biotech experts. The meeting established a sense of trust between the delegations and produced a joint EU/Canada report on molecular characterization which is an essential building block towards harmonization. At the Ministerial level, the EU and Canada have agreed to continue this dialogue so as to explore the development of a common approach to GMO approvals.

The Department is assessing how to promote biotech in the EU. For example, we are planning a visit of 10 Members of European Parliament (MEPs) to Canada in May-June 2001. Initial planning will have MEPs visit Saskatoon to see biotech in an agricultural context, as well as Montreal where they would see biotech in a medical context. The group would be led by Robert Sturdy, UK MEP who is the President of the EU Parliamentary Delegation for Relations with Canada. We understand that when the concept of this tour was first raised with Canadian industry in May 2000 that there had been considerable support and offers of funding.

### United States

In the US, Canada's goal is to position ourselves to maximize the benefits derived from investment, trade, technology exchanges and business partnerships with the United States in biotechnology and its related applications. Some of the supporting activities include:

1. Increase promotional efforts in the biotechnology sector;
2. Consult and collaborate with 14 U.S. based Canadian Trade Offices relative to maximizing opportunities for Canadian biotechnology industry;
3. Identify relevant Canadian/U.S. companies and organizations; clusters, centers of excellence, etc.; and
4. Obtain and analyze market information and intelligence in Canada and the U.S. with respect to the biotechnology industry.

### Japan

DFAIT seeks to establish contacts with Japanese counterparts and share views on the international rules in biotechnology products, including views on the relevance of biotechnology-related work underway in various international fora. For example, DFAIT coordinates Canadian comments on Japan's WTO notifications related to biotechnology as well as comments on the development of its policies on labelling for foods containing organisms derived from biotechnology. On the margins of the Tokyo Codex meetings in March 2000, the Canadian Embassy hosted a networking event with Japanese Ministry of Health and Welfare and Ministry of Agriculture Forestry and Fisheries officials



involved in biotechnology food regulations to initiate a dialogue between the DFAIT/Technical Barriers and Regulations Division and Health Canada officials with the main Japanese regulatory officials on areas for collaboration and information sharing.

DFAIT, in collaboration with Agriculture and Agri-Food Canada (AAFC), is involved in awareness raising and information dissemination about biotechnology products and services to its Japanese counterparts. Highlights of activities are listed below:

- ☐ GMO Study for Japan - Ontario Ministry of Agriculture Food and Rural Affairs in cooperation with the B.C. and Manitoba provincial governments and AAFC - to be completed November 2000
- ☐ Translation of "A Growing Appetite for Information" into Japanese - AAFC
- ☐ Canada/Japan Pre-Consultations and Consultations on GMO Canola
- ☐ Canada Japan Business Committee May 2000 meeting - Presentation by AAFC Policy Branch on GMOs
- ☐ GMO fact-finding missions to Canada

#### South Asia Region

In the South Asia region, consisting mainly of India, Pakistan, Bangladesh and Sri Lanka, biotechnology is not yet considered a priority sector. With growing economies, and a bright economic outlook in the region, companies in the region, and especially India, are starting to position themselves to establish partnerships, and collaborations, with foreign firms, including those in Canada. While this positioning may take a period of up to five years, we can look to India as being a regional leader in the biotechnology sector.

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## Mining Strategy for Biotechnology Summary

### Context

In the last round of projects funded by CBS, the mining sector did not obtain any funding since the work that MMSL performs does not involve any genomic related research. MMSL continues to be involved in biotechnology, now concentrated primarily in the mining sector in three areas: bioleaching, microbial ecology and effluent treatment. Work in these areas meet sector priorities of enhanced competitiveness and sustainable development. These are also likely areas of growth for biotechnology in the mining industry in the future.

The environmental consequences and liabilities traditionally associated with mining operations pose significant challenges, and technological solutions are needed to meet increasingly stringent environmental requirements across Canada. It has been generally agreed that biotechnology holds real potential as a means to better protect the environment from consequences and liabilities associated with mining operations. While there are few large scale commercial installations in Canada at present, there are a number of biotechnology based processes that are undergoing field demonstration trials. Some of the more promising are: inhibition of microbial activities that lead to the production of acid mine drainage, underground reactive barriers and an understanding of the microbial processes involved in arsenic cycling. In addition, there is increased interest in environmental applications, especially with regard to sulphide reducing bacteria and their application to the removal of metals from contaminated surface and ground waters.

Bioleaching has the potential in Canada to exploit low-grade, remote mineral reserves in an environmentally sensitive way. Some observers in the industry believe that increasing the kinetics and efficiency of microbially catalysed leaching processes under conditions specific to the climate in Canada, huge reserves of copper that up to now could not be economically processed using conventional technology can be brought into production to meet future copper demand. Even though much of the early work in this field in the 1970's and 1980's was initiated in Canada, the development and application of bioleaching technology is taking place in other countries. What is needed at this point is a determination of why biotechnology is not used more often in Canada when there are so many examples of commercially successful application in other countries.

Some of the projects underway at MMSL are in the areas of: bioleaching, redistribution of metals in sediments due to microbial activity, microbial ecology, effluent treatment and phytoremediation.

### Challenges

The challenges continue to be in reducing the perceived risk to the mining industry in applying biotechnology. Part of this is due to the lack of commercial applications in Canada and also with the lack of knowledge about biotechnology in general. MMSL is trying to alleviate these problems through: involving the mining industry where possible in its internal projects; examining the applicability of biotechnology to the Canadian context; and educating the industry through workshops and technical sessions at conferences.

In addition, operators in the mining sector do not tend to focus on research but, rather, prefer to purchase that which has been proven, often in other countries. Consequently, industrial funding for biotechnology development has been and will continue to be, limited to very specific industrial issues, where no proven, cost effective, alternative technologies exist. This makes it difficult to get funding from the mining industry at this early stage of technology development.

Funding from the Canadian Biotechnology Strategy would allow the work being performed at MMSL to be expanded internally as well as with other partners in the mining sector, universities and other

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government departments. This would likely increase the rate of acceptance of biotechnology as a viable option for environmental as well as for processing applications by the mining industry in Canada.

## Template for Working Group Action Plan Strategy

### Vision for modern biotechnology

As described in the Mining and Energy Sectors Final Report, biotechnology is expected to influence increasingly operations in the mining sectors with significant benefits anticipated in the areas of land site remediation, improved economics and reductions in environmental liabilities. The mining and metals sector contributes \$24.4 billion to the Canadian GDP and generates over 10% of Canada's merchandise trade surplus. It also accounts for nearly 55% of the volume of rail and port movements, employs almost 350,000 Canadians and sustains 150 communities across the country. Given these numbers even small improvements and innovations can generate significant value and affect a significant number of Canadians.

In the last round of projects funded by CBS, the mining sector did not obtain any funding since the work that MMSL performs does not involve any genomic related research. MMSL continues to be involved in biotechnology, now concentrated primarily in the mining sector in three areas: bioleaching, microbial ecology and effluent treatment. Work in these areas meet sector priorities of enhanced competitiveness and sustainable development.

### Context

MMSL still believes that there are opportunities in the area of biotechnology for the mining sector in the areas of bioleaching and environmental applications. Bioleaching has the potential in Canada to exploit low-grade, remote mineral reserves in an environmentally sensitive way. Some observers in the industry believe that increasing the kinetics and efficiency of microbially catalysed leaching processes under conditions specific to the climate in Canada, huge reserves of copper that up to now could not be economically processed using conventional technology can be brought into production to meet future copper demand. Even though much of the early work in this field in the 1970's and 1980's was initiated in Canada, the development and application of bioleaching technology is taking place in other countries. What is needed at this point is a determination of why biotechnology is not used more often in Canada when there are so many examples of commercially successful application in other countries. The first task will aim to answer this question by focusing in on examples of its use (both present and past) in Canada as well as in other countries. Once the barriers to its application in Canada have been identified then a focused R&D program can be developed in areas of identified in cooperation with industry as having the greatest potential for full scale application. This is the aim of the bioleaching project that is presently underway at MMSL.

The environmental consequences and liabilities traditionally associated with mining operations pose significant challenges, and technological solutions are needed to meet increasingly stringent environmental requirements across Canada. It has been generally agreed that biotechnology holds real potential as a means to better protect the environment from consequences and liabilities associated with mining operations. While there are few large scale commercial installations in Canada at present, there are a number of biotechnology based processes that are undergoing field demonstration trials. Some of the more promising are: inhibition of microbial activities that lead to the production of acid mine drainage, underground

reactive barriers and an understanding of the microbial processes involved in arsenic cycling. In addition, there is increased interest in environmental applications, especially with regard to sulphide reducing bacteria and their application to the removal of metals from contaminated surface and ground waters. These are the areas we feel will have significant opportunities in the future.

### **Critical sector priorities**

MMSL plans to continue its work in the areas of sustainable development and enhanced competitiveness. A brief description of some initiatives under way at MMSL with priorities and deliverables are provided below.

- **Bioleaching:** The objective of this project is to determine the applicability of microbially catalysed leaching of ores and mine waste to recover metal values under Canadian climatic conditions. Bioleaching is perceived as one of the mineral processing technologies that can transform the economics of low-grade or complex ores and can drive the commercialization of the vast reserves of low-grade base metal ores in the future. Researchers are near completion of the first phase of this project which is to provide the status of current bioleach techniques and to identify areas where MMSL can best focus its research efforts. This is a 32 month project with a budget of \$650K. This project aims to determine the applicability of bioleaching to ores and mine wastes in Canada; develop a protocol to assess the bioleachability of different ores and mine waste materials; and to demonstrate bioleaching at a mini pilot-scale. (December 2003)

- **Redistribution of Metals in Sediments Due to Microbial Activity:** This project is being performed in collaboration with the Geological Survey of Canada. One of the objectives is to identify the diagenetic processes that distribute or redistribute metals in lake sediments. Understanding the behaviour of metals in sediments may assist in distinguishing anthropogenic (human activity) versus natural origin of various metals. MMSL's contribution to this is in determining the role that microbes play in modifying redox reactions within the sediments. The budget for this 10 month project is \$50K. This research is one of the first comprehensive studies to integrate quantitative mineralogical, geochemical, microbial and numeric approaches into understanding the processes that are involved with the redistribution of metals in a freshwater system. The results in the final report are expected to have implications with respect to the source of metals in lake sediments. The final report is due April 2002.

- **Ammonia removal from Mine Effluents using a Rotating Biological Contactor:** This project aims to determine the applicability of a rotating biological contactor for the removal of ammonia from mining effluents. MMSL performed work in this area previously for the Ammonia Consortium. This is a 8 month project with a budget of \$60K. The final report due April 2001 will outline the technical feasibility of using the RBC for ammonia removal and will also present the economics of implementing it at a typical mine site. Preliminary results will be presented at a conference in January 2001.

- **Microbial Ecology:** MMSL is also involved in several projects that require expertise in the

area of microbial ecology. In these we determine the type and number of bacteria present at locations of contamination due to mining and other related industrial activities. Characterization of the microbial population associated with some remedial options, such as the buried reactive barrier technology will provide a more thorough understanding of these processes which are required for optimizing the performance of these technologies. Some of these projects are being performed in cooperation with the University of Waterloo. MMSL is involved in several on-going projects in this area.

- **Phytoremediation:** Two scientists were seconded to Cominco in Trail, British Columbia to provide advice and assistance in the area of anaerobic/wetland cells that were treating metal contaminated leachate. The work involved examining the mechanisms that are taking place within the reactor and assisted Cominco in optimizing the performance of the anaerobic cells. This served as a valuable learning experience and will allow us to determine if MMSL will develop expertise in phytoremediation. It is expected that by December 2001 a decision will be made whether MMSL will develop any expertise in this area.

- **Biotechnology in Mining Workshop at MetSoc 2001:** MMSL is coordinating a workshop and technical sessions at the Metallurgical Society (A Division within the Canadian Institute of Mining, Metallurgy and Petroleum) Meeting to be held in Toronto in August 2001. The overall theme of the conference is Productivity through Technological Innovation; one of the sub-themes is biotechnology and the metals sector. MMSL is actively involved in setting up the program for the workshop and will be presenting some material on its work in this area. The objective of this is to provide basic information on the applicability of biotechnology to the mining sector and to discuss current technologies that have been commercialized. This two day workshop will likely attract 50 people and will publish its workshop notes to be available to the mining industry. (August 2001)

#### Communications Plan

Communications will be made primarily through workshops, conference presentations and scientific journal publications. Regular updates are also planned on web pages dedicated to biotechnology at Natural Resources Canada.

#### Partners

Research and funding partnerships have been established with a number of agencies, in both academia and industry with activities being focused at NRCan. This is in keeping with the feedback received in the consultations which recognized the importance of the government taking a leadership role to focus the R&D efforts in this area. Academia's role would be to provide fundamental R&D, participate in the transfer of information and provide skilled personnel. Industry will provide key challenges and provide resources and a long term commitment to developing applications of biotechnology in the sector. Partners already involved are: The Geological Survey of Canada, Environment Canada, Department of Fisheries and Oceans, Waterloo University, Carleton University, Inco, Falconbridge, and Cominco.

#### Challenges

The challenges continue to be in reducing the perceived risk to the mining industry in applying biotechnology. Part of this is due to the lack of commercial applications in Canada and also with the lack of knowledge about biotechnology in general. MMSL is trying to alleviate these problems through: involving the mining industry where possible in its internal projects; examining the applicability of biotechnology to the Canadian context; and educating the industry through workshops and technical sessions at conferences.

In addition, operators in the mining sector do not tend to focus on research but, rather, prefer to purchase that which has been proven, often in other countries. Consequently, industrial funding for biotechnology development has been and will continue to be, limited to very specific industrial issues, where no proven, cost effective, alternative technologies exist. This makes it difficult to get funding from the mining industry at this early stage of technology development.

## **Positioning Canada as a Leader in the Bioeconomy Summary**

### **An Innovation Prescription for Canada's Biotech Firms**

#### ***The Impact of the Bioeconomy will be Dramatic***

- Ernst & Young *Biotechnology Industry Report, Millennium Edition* predicts that biotechnology will reshape virtually every other industry it intersects with. From agriculture to chemicals and manufacturing processes, from drug discovery to computer nanotechnology, biotechnology is creating platforms for new products and markets on many fronts. In particular, the convergence of Biotech with IT is revolutionising both fields and opening vast new markets.
- The new knowledge that comes from intensive R&D is considered the currency of the Bioeconomy. The Bioeconomy is the future of biotechnology.
- Whole new industries are being formed and traditional ones are restructuring to seize the coming opportunities. There is no doubt that biotechnology, when fully developed, will bring at least as many benefits and positive impacts to Canadian society as ICT does. It is the most promising area for Canada's progress in the KBE.

#### ***Other Countries are Moving Quickly and are now Ahead of Canada***

- Other countries are investing massively in biotech research in an effort to capture the potential of the Bioeconomy.
- These global investments are already negatively affecting our own Bioeconomy growth and there are signs that our industry will suffer badly without concerted effort.

#### ***The Canadian Biotech Firm – Gloomy Prospects***

- Recent studies show that the Canadian biotechnology industry has slipped from second position behind the United States in 1998, to fourth place today. Given the heavy investments by other countries, Canada's standing can only fall further.
- Our biotech industry is still young and vulnerable. There are troubling signs that despite some strong activity, this industry faces considerable pressure. There is an increase in our venture capital flowing to biotech companies outside of Canada along with trained scientists, managers and IP. Financing difficulties mean that our mostly smaller Canadian companies are forming alliances with



foreign firms to develop their products to the point where most new product development of Canadian biotechnology is done offshore.

- Our firms are also becoming prime targets for take-overs by larger heavily resourced firms because they are undervalued. Our IP is ending up in the hands of foreign companies at bargain-basement prices. Remaining firms are competing with aggressive new entities for venture capital and new infrastructure such as incubators, technology platforms, demonstration facilities, and technology transfer centres.

### ***Genomics – an Industry Opportunity only Partially Realised***

- Canada's under-investments in genomics infrastructure have already placed our firms at a competitive disadvantage with respect to the generation of intellectual property in this key domain for the next two decades. Without infrastructure there is little IP generated, without IP there is little comparative advantage for firms. Already, over 170,000 genes and gene fragments have been patented around the world. Canada does not yet have one major public genomics company.
- The Federal Government's recent investment in this field will ensure that Canada is not shut out of this area but we will never reap what we could have if our investment had been swifter and greater.

### ***A Clear Role for the Federal Government***

- Governments around the world have recognised the unique role they play in developing the Bioeconomy. Only public investment can sustain the expensive R&D research programs – the core research platforms - that firms turn into marketable technologies. Only public investment can build the costly infrastructure – like pilot plants and test sites – that firms require commercializing products. Federal support can also sustain smaller firms through the years until traditional financing is possible and federal governments can create an environment that fosters innovation.
- Canada needs to coalesce around a deliberate strategy to build the Bioeconomy. Public opinion research has shown that Canadians are looking to the federal community to show this leadership.

### ***Our Vision is that Canadians will be among the first to Benefit from the Bioeconomy***

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The federal government must take decisive action on three fronts:

1. It must dramatically expand support for knowledge creation through research and development – including heavy investment in its own labs – in four areas:

New Industry Applications;  
Health & Wellness;  
Sustainable Environment; and  
Research in Support of the Regulatory System.

2. It must recognise regional strengths and support emerging technology clusters; and

3. It must ensure that its actions are effectively coupled to the innovation needs of Canadian firms.

- Along with this revamping of federal R&D there must be parallel efforts to sustain a supportive environment for our firms. These initiatives would include programs for stronger links among universities, industry and governments, better commercialisation of R&D results from public and academic labs; swifter regulatory review of biotech products and better access for firms to enabling infrastructure for biotechnology research.

### ***Canada will Reap a Triple Dividend***

- Canada has the opportunity to reap a triple dividend by becoming a lead player in the industrial development of the bioeconomy: sustainable economic development, enhanced health and social benefits, and exportable technologies and new, hybrid products.

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## Recommendations

### Governance

- Develop a governance structure to co-ordinate government R&D efforts to develop the bio-economy in Canada;
- Manage federal research and development efforts against four strategic applications areas: New Industry Applications, Health and Wellness, Sustainable Environment; and Research in Support of the Regulatory Regime;
- Study and alleviate systemic barriers to the participation of federal researchers within the Canadian innovation system.

### Research

- Dramatically increase federal funding of R&D in order to develop enabling platforms in: Bioinformatics; Distributed, grid-based information systems and databases; Functional genomics; Vectors for gene therapy; High throughput screening; Combinatorial chemistry; Proteomics; Structural genomics; Metabolic profiling; Systems biology; Nanotechnologies and microfluidics; Separation technologies; Pilot plants and demonstration facilities; and Other new and emerging technologies;
- Convert funding for the federal genomics capacity from limited term to ongoing A-base;
- Increase the investment in Genome Canada and in government laboratories carrying out genome related research;
- Establish systems biology institutes for agriculture, aquaculture, and the environment, to parallel investments in the Canadian Institutes for Health Research;
- Establish computational biology and nanotechnology institutes and research capacity;
- Rapidly expand the development of the Canadian Bioinformatics Network to cope with the anticipated massive increases in demand for data storage and processing capacity that will accompany the use of genomics technologies all across our economy;
- Continue to develop Canada's high speed communications networks through CANAIRIE to allow the emergence of a distributed yet integrated research

and bioinformatics capacity available within every hospital, university and research institute across Canada;

- Strengthen the linkages between the Genome Centres and the Canadian Light Source and support efforts to establish a Canadian Structural Genomics capability;
- Support research efforts to develop an environmental management methodology and framework against which the environmental impacts and long-term sustainability of new technologies may be assessed

### **Innovation Support**

- Make significantly increased investments in federal biotechnology R&D institutions located within strong regional centres in order to strengthen Canada's existing technology clusters in biotechnology and position them for further growth and the attraction of increased direct foreign investment;
- Establish a technology foresight capacity within government;
- Make large-scale pilot plants, separation facilities, and technology demonstration facilities accessible to Canadian companies;

### **Traceability of Standards**

- Establish science to develop standards for the bio-economy and to ensure the traceability of these standards to the national metrology institute and the MRA;

### **Human Resources**

- Expand human resource development for the biotechnology industries through the NSERC, SSHRC, and the CIHR;

### **Commercialisation**

- Strengthen the capacity of federal research institutions and universities to create value through technology transfer and the creation of new industrial enterprises by building upon the strengths of the IRAP and CTN networks;
- Establish specialised incubation facilities for biotechnology and genomics-based companies co-located or close to major centres of biotechnology R&D infrastructure across Canada; and

### **Management**

- Encourage the development of networks of experienced managers and executives to mentor newly emerging start-up companies in biotechnology

- Increase support to biotechnology companies through the IRAP and CTN networks
- Increase the supply of personnel trained in technology management

**Finance**

- Study the funding needs and opportunities of emerging companies in this sector and support the development of new support instruments including venture capital and co-development opportunities.
- Review existing instruments (IRAP, TPC, SDTF, AAFC MIP, TEAM, CCAF) and consider how these may be adjusted to support the needs of developing firms

## **Positioning Canada as a Leader in the Bioeconomy Strategy**

### **Summary**

The most promising area for Canada's further progress in the knowledge-based economy lies with the bioeconomy. The bioeconomy is characterised by rapid change and convergence of previously distinct industries and technologies. This convergence is driven by a transformation in the underlying science of biology into a field that is now characterised by vast quantities of precise information.

To stay competitive in this era of information biology, businesses have to learn how to manage and profit from the new knowledge; Government will play a key role. Canada is strong in two key drivers of this new era – biotechnology and information technologies. This provides a tremendous opportunity for the nation. However, in order to benefit, Canada will need to refocus its programs and resources to take account of the underlying convergence and transformation.

The federal government's posture must shift from the defensive to an active promotion of benefits. Federal regulators must become engaged in this shift if they are to keep up with the aggressive pace of development of the technology and if Canadians are to benefit.

The federal government must dramatically elevate the importance it attaches to the benefits that this area can deliver. The opportunities are as great as those provided by information and communications technologies. The federal government must take decisive action on three fronts:

- It must dramatically expand support for knowledge creation through research and development;
- It must recognise regional strengths and support emerging technology clusters; and
- It must ensure that its actions are effectively coupled to the innovation needs of Canadian industry.

Canada will need to act quickly because already there are clear indications that other nations are ahead of us in terms of new technology development and investments. In addition, there are signs that Canadian firms are significantly disadvantaged with respect to their competitors around the world.

The strategy will emphasise four interrelated and strategic applications and research areas:

- New Industry Applications;
- Health & Wellness;
- Sustainable Environment; and
- Research in Support of the Regulatory System.

## The Vision for the Bioeconomy in Canada

The science of biology is undergoing a dramatic and fundamental shift to a discipline characterised by vast quantities of information. Progress in biology has as much to do with information and communications technologies as it does with genes. This shift is producing enormous opportunities for benefits to society and the economy. Indeed, the development of the bioeconomy will be the grand challenge for Canada over the next two decades. It will provide Canadians with sustainable economic development; enhanced social and health benefits; and exportable technologies and products.

*Our vision is that Canadians will be amongst the first to benefit from the development of a sustainable bioeconomy.*

These developments are dependent upon advances in knowledge derived from traditional biology, genetics and metabolic engineering, and by the wave of developments in the modern information-based biology disciplines of molecular biology, genomics, proteomics, bioinformatics and biotechnology.

The same basic science and research has opened up unprecedented opportunities for advances in human health and wellness through improved pharmaceuticals, nutraceuticals, vaccines, functional foods and diagnostics. It also offers new opportunities in sustainable economic development and industrial processes all across the Canadian economy.

The emergence of the bioeconomy is inevitable. It is driven by major global economic trends including rapidly increasing global populations, increased purchasing power, an extreme shortage of arable land world-wide, and the need to take action to minimise global environmental impacts. These will result in an inevitable growth in demand for food, pharmaceuticals, and industrial products combined with an ever more urgent need to meet these demands within a sustainable economic development framework.

Vital national interests affecting every Canadian are involved and Canadians expect government researchers to remain actively engaged and to play a central role in these developments.

Canada has the opportunity to reap a triple dividend by becoming a lead player in the industrial development of the bioeconomy: sustainable economic development; enhanced health and social benefits; and exportable technologies and products. In order to succeed we must aggressively expand our knowledge base and we must sustain the development of Canadian industrial innovation capacity.



## The Bioeconomy

The explosion of discoveries in the biological sciences over the last decade have laid the foundation for widespread application of new knowledge and associated biotechnologies to new and emerging, as well as traditional, industries. Collectively, these developments are being referred to as the bioeconomy.

There is no doubt that the impact of biotechnology will be extensive. According to the Ernst & Young *Biotechnology Industry Report, Millennium Edition* biotechnology is positioned to reshape virtually every other industry it intersects with, as it is to redefine our lives. From agriculture to chemicals and manufacturing processes, from drug discovery to computer nanotechnology, biotechnology is creating platforms for new products and markets on many fronts.

However, the bioeconomy is not just about biotechnology, it is about a new way to integrate knowledge and conduct business. Bill Gates points out that the twenty-first century will also be about velocity: the speed of business and the speed of change. To stay up with and anticipate change, governments and businesses need radically better information flow. The successful companies of the next decade will be the ones that use digital tools to reinvent the way they work.

As convergence continues, the boundaries between the biotechnology industry and an array of disparate market sectors are blurring, leading to a large number of new, hybrid products.

For example, convergence of biotechnology is taking place with the chemicals industry. Industrial manufacturing processes have traditionally relied upon high temperature, high-energy noxious chemicals that produced hazardous wastes and excess phosphorus. Enzymatic reactions, however, can safely serve the same role; that is, to bring together reactants to promote the stability of the intermediate state of a reaction. The biocatalytic approach can be transferred from living systems to a variety of manufacturing processes. Enzymes such as lipases, proteases, cellulases, and amylases can be substituted for both noxious and high-temperature chemicals. This approach can be applied to a wide range of manufacturing areas, including the processing of grain, and the production of detergents, starches and textiles.

Around the globe, industry is shifting from chemistry-based solutions to biology-based solutions in response to the demand for environmentally sustainable industrial, agricultural, aquacultural, and silvaculture technologies. The shift concerns both the protection of the environment and the preservation of non-renewable resources. Biology-based solutions respond to the need for higher productivity with lower environmental impacts and lower chemical inputs to

production processes. There is clear evidence of these trends in the vast restructuring of the global chemical industry that has occurred over the past ten years. Most of the major players have divested their commodity chemical production businesses and most have aggressively sought out intellectual property positions in the bioeconomy through acquisitions of small biotechnology companies and through mergers. Others have responded by creating subsidiaries focussed upon opportunities in the bioeconomy.

A further example of convergence can be found in the emergence of genomics and proteomics, technologies that are predicted to revitalise a sagging pharmaceutical industry. Despite their huge investments the rate at which new drugs reach the market has decreased markedly over the past 15 years. On average, a typical top-tier pharmaceutical company now brings an innovative drug to market only once every 27 months. To achieve a healthy 10 per cent annual growth in sales revenues, however, the figure must exceed one new drug every six months. Genomics promises to give rise to an entirely new class of medicines that could rescue the pharmaceutical industry.

These new medicines will use human genes, proteins and antibodies to regenerate tissues that have been damaged by age, disease, or trauma.

Biotechnology has also expanded the diversification of agriculture by breaking down the barriers between sciences and bringing together scientists from fields that have traditionally not co-operated. Advances in molecular genetics and transformation technology have opened the door to a new industry, Molecular Farming. This emerging industry is providing economical and reliable platforms for the production of vaccines, therapeutic proteins, industrial enzymes and a host of other innovative and beneficial products. The use of plants, animals, insects and cell cultures as bioreactors for the commercial-scale production of recombinant proteins and peptides is one of the fastest-growing applications of biotechnology. Research and commercialisation activities are expanding rapidly. The potential for the development of high quality, cost effective health care products alone is substantial. Molecular farming technologies are fostering a revolutionary marriage of agriculture and health care. Molecular farming offers farmers the potential for development of new crops and new uses for crops. Through the diversification of agriculture, Molecular Farming could enhance the viability of rural communities.

Biotechnologies are also being applied in the areas of prevention and pollution control and the development of green technologies. Major areas of activity are bioremediation, monitoring tools, environmental chemistry, biopesticides, environmental ecotoxicology, and biosensors and industrial effluent treatment.

*The new knowledge derived from intensive research and development is the currency of the bioeconomy.*

Canada has an opportunity to be a clear leader in this explosion of new knowledge, ideas and benefits from biotechnology R&D. This will only occur if the nation takes deliberate steps to transform ideas into action, potential into reality, and discoveries into solutions.

*To capitalise on the opportunity, Canada needs to identify a clear strategy for the bioeconomy.*

This document presents a vision, centred on research and development and innovation, designed to ensure that Canada remains competitive and that all Canadians have the opportunity to benefit from the myriad of new products and services predicted to emerge from the new bioeconomy.

## World Trends

Canada is not alone in seeing the tremendous potential of the new bioeconomy. Other jurisdictions around the world have taken deliberate steps to attract bioscience researchers and investment and this is already having a negative impact on the growth of our own bioeconomy.

**Table I: Comparative Statistics for the Biotechnology Industry**

Factor	Canada	U.S.	Europe
Population / Million	30	270	727
Product Sales / \$M	\$979	\$18,460	N/A
Revenue / \$M	1,141	24,708	4,251
R&D Expenses / \$M	403	12,780	2,980
R&D Intensity	35%	52%	70%
Number of Companies	320	1,274	1,351
Average Revenue / \$M	5.1	19.4	4.1
Average R&D / \$M	1.8	10.0	2.9
Total Employees	11,000	140,000	53,500

As of August 2000, U.S., biotechnology companies had raised \$22.1B from public and private financing, almost double the \$12B amount raised in 1999, and nearly triple the \$8.1B figure in 1998.

By comparison, Canadian companies raised \$1.5 billion in the first six months of 2000. Recent studies published in 2000 (Ernst & Young, Burrill & Co.) indicate that the Canadian biotechnology industry in terms of size, investments and growth, has slipped from a second position behind the United States in 1998, to fourth place. This is certainly cause for concern. Canadians will not secure the benefits of the bioeconomy without a strong Canadian industry.

Other developed nations are gearing up in order that they might capture economic and social benefits within their borders. The USA is still the most important player with 1274 companies, employing 153,000, with sales of \$19B. However, Europe is rapidly closing the gap with 1351 companies, employing 53,500, with sales of \$5B. France and Germany have taken significant steps to establish leadership positions in biotechnology. Germany, for example, has grown its biotechnology sector substantially during the past five years. An estimated 400 start-up companies have emerged in this period. Over the past 15 years the number of scientists involved in biopharmaceutical research in France has grown by 50 per cent. The French government is committing US\$380 million over the next five years to support biotechnology companies and also offers investment tax incentives amounting to 25 per cent of R&D spending.

**Table II: Market Capitalisation of US Biotechnology Companies, November 2000**

<b>Technology Companies</b>					
Broad Enabling Technology: Market Leadership		Enabling Technology: Niche Player		Enabling Technology: Not Market Leader	
Millenium	\$13B	Maxgen	\$1.6B	Geron	\$0.6B
HGS	\$9B	Talarik	\$1.5B	Genaissance	\$0.45B
Abgenix	\$6.5B	Exelixis	\$1.5B	Dendreon	\$0.50B
Affymetrix	\$2.7B	Caliper	\$1.2B	Variagenetics	\$0.50B
		Orchid	\$1.2B		
		Sangamo	\$0.85B		
<b>Drug Discovery Companies</b>					
On Market with Sales		Phase III or NDA: Large Market		Phase III Niche Market	
IDEC	\$8B	Enzon		Isis	\$0.45B
Gilead	\$5B		\$2.6B	Coulter	\$0.50B
COR	\$3.4B	Praecis	\$1.8B	Vical	\$0.50B
		Tanox	\$1.4B	Intrabiotics	\$0.50B
		Avigen	\$0.7B	Antigenetics	\$0.35B

Canada must act now to ensure that it is not overwhelmed by the growing dominance of the US and European initiatives. We are in a period of rapid change and industry faces many challenges to stay competitive. In addition to genomics, proteomics, bioinformatics and high throughput drug screening, nanotechnology will be the next field to have a dramatic impact on scientific progress. Munster, Germany has been designated the site of the first European Centre for Nanotechnology. It will be opened in 2002 with an initial investment of DM14.5 million (approximately C\$20 million). In January 2000, the United States President Bill Clinton announced a US\$247 million nanotechnology initiative.

The speed with which genomics information is being commercialised is an excellent indicator of how the new bioeconomy is being developed and how countries can gain a competitive advantage. Genome sciences are transforming every aspect of the industry. In fact, genomics can be thought of as an industry sector to itself characterised by upwards of 100 companies, located principally in the US and Europe, that have emerged almost overnight. As of December 31, 1999, the combined market capitalisation of the top 20 genomics companies totalled over US \$26 billion.

However, as yet, Canada has no public genomics company.

## **The Biotechnology Industry in Canada**

Over the past fifteen years Canadian industry has developed an excellent foundation upon which to build a viable bioeconomy in Canada. In 1983, the federal government launched the Canadian Biotechnology Strategy recognising the potential that this new technology offered and aiming at building a biotechnology industry in Canada. The strategy provided significant public R&D, massive new infrastructure and co-ordination of biotechnology activities across government.

In the comparatively short period since the Strategy was initiated, Canadian biotechnology firms have brought products to market that will directly benefit Canadians. These products include:

- Drugs that treat AIDS;
- Treatments for age-related macular degeneration,
- Vaccines against meningitis and other childhood diseases;
- Improved varieties of Canola and winter wheat;
- Vaccines to protect fish health for aquaculture; and
- Engineered enzymes that replace chlorine in pulp bleaching and lower the environmental impacts of paper mills.

The strategy is well recognised as a success story of federal foresight and

action. Concerted R&D efforts across a number of jurisdictions, changes in the federal intellectual property regime, supportive actions within provincial formularies, and the emergence of a Canadian venture capital sector combined to create a biotechnology sector in Canada that is the envy of many nations around the world.

Today Canada has over 300 biotechnology firms that employ over 11,000 people with sales of well over \$1B.

In recent months, there has been a flurry of activity in the public markets as at least ten Canadian companies are preparing to file, or have already filed, Initial Public Offerings. In 2000, there have been three successful biotechnology IPOs: Arius Research Inc., of Toronto, Neurochem Inc. of Montreal, and Chromos Molecular Systems of Vancouver. Currently there are 70 publicly held Canadian biotechnology companies.

However, in Canada, our under-investments in genomics infrastructure have placed our firms at a competitive disadvantage with respect to the generation of intellectual property in this key domain for the next two decades. Without infrastructure there is little IP generated, without IP there is little comparative advantage for firms. Already, over 170,000 genes and gene fragments have been patented around the world. Canada does not yet have one major public genomics company. The only player of any note is MDS Proteomics, which is currently private, with a capitalisation of approximately \$600 million.

Other countries have already surpassed our nation's investment in biotechnology to the point where our biotechnology industry is under serious threat. There is an increase in venture capital flowing to biotech companies outside of Canada along with trained scientists, managers and IP. Financing difficulties mean that our mostly smaller Canadian companies are forming alliances with foreign firms to develop their products to the point where most new product development of Canadian biotechnology is done offshore. Our firms are also becoming prime targets for take-overs by larger heavily resourced firms because they are undervalued. We will lose our IP at bargain-basement prices while competing with aggressive new entities for venture capital and new infrastructure such as incubators, technology platforms, demonstration facilities, and technology transfer centres.

#### **Table III: The Biotechnology Industry in Canada**

**STRENGTHS**

- Presence of a small number of world-class pharmaceutical companies who are committed to investing 11% of sales in R&D activity in Canada
- Canada's history as successful pioneers in the agrifood sector
- Supportive venture capital community
- Strong higher education and research centres
- Ability to generate a pipeline of talented people
- Record of successful research capabilities and findings in medicine and related fields
- The cost of conducting research in Canada is considerably cheaper than in many competing countries, including U.S. and Western Europe

**WEAKNESSES**

- A large number of companies are in their early stages, where the survival risk is still high
- Decision-making for large Pharmaceutical companies operating in Canada is usually made at head-offices outside Canada. This slows down our ability to conclude more alliances
- Canada's industrial infrastructure and our existing cost structure does not play towards our ability to retain manufacturing activities
- Canada cannot rely on the demands originating from its local market alone
- Limited number of specialised venture capitalists with the expertise and network to support the growth of biotech companies
- Access to public financing markets is cyclical and unreliable
- With early rounds of financing being very small, senior management spends a disproportionate amount of time raising money rather than managing their business
- Almost all of our biotech companies are insufficiently capitalised to carry out the full development of novel drugs and must rely heavily on alliances from a very early developmental stage
- Regulations with regard to approval of new drugs in Canada tend to be slower than other jurisdictions – significant progress is being made in the US by the FDA to speed their process, to gain a competitive advantage
- Agbiotech companies suffer from low product margins, which makes capturing returns on long term product development more difficult
- The low product margins, and overall lower returns make it difficult to attract venture capital investment for agbiotech focused SME start-ups
- Consolidation in the agriculture industry, in the absence of strong SME formation, is causing more concern with respect to industry concentration and with it reduced competition, reduced industrial presence in Canada, and reduced private expenditures on R&D

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## **Developing the Bioeconomy in Canada**

There is no doubt that biotechnology, when fully developed, will bring at least as many benefits and positive impacts to Canadian society as ICT does. However, there is a reasonable doubt that these benefits would be capitalised and realised in Canada without sustained federal government investment for research and development and the innovation infrastructure supporting Canada's firms.

Governments must invest in this field as opposed to relying on industry investment because of the disproportionate level of capital infrastructure required, the length of time it takes for research products to make it to market, and the precompetitive nature of much of the basic research that industry requires.

## **Organising Principles and Governance**

As Canada acts to boost its research and development investments across all of these domains it must also ensure that its efforts are well co-ordinated and mutually supportive. This will require the development of new partnerships across federal departments and agencies, between industry and academia. It will also require that barriers to collaboration between these various sectors be torn down.



Currently, there are systemic barriers to the participation of Canadian government researchers in the national research agenda. These cause inefficiencies in the national and regional systems of innovation that support Canadian industry.

A new governance structure must be developed to co-ordinate R&D efforts across the various organisational structures so that the technology platforms for the bioeconomy may be developed most efficiently. This will require extensive consultation and co-operation between all parties and overall facilitation and co-ordination at the federal level.

### **Innovation Systems Support: Research and Development**

Research and development is central to all aspects of the development of this sector of the economy. The underlying science is undergoing tremendous shifts and there is a rapid expansion of knowledge. As indicated earlier, there is now a convergence of disciplines and formerly distinct industries which needs to be encouraged and supported if we are to take full advantage of the rapid expansion in this field.

To maximise the benefits derived from hitherto separate technology areas, we propose that R&D be enhanced under four interrelated and strategic applications areas that will support our industry and sustain our efforts towards leadership in this emerging bioeconomy:

- New Industry Applications,
- Health and Wellness,
- Sustainable Environment; and
- Research in Support of the Regulatory Regime.

Each area would have a series of supporting R&D efforts and would be anchored by application of strategic enabling technologies including:

- Bioinformatics
- Distributed, grid-based information systems and databases
- Functional genomics,
- Vectors for gene therapy
- High throughput screening
- Combinatorial chemistry
- Proteomics
- Structural genomics
- Metabolic profiling
- Systems biology
- Nanotechnologies and microfluidics
- Separation technologies
- Pilot plants and demonstration facilities; and

- Other new and emerging technologies.

It is essential that the federal government increase its investment in Genome Canada and in government laboratories carrying out genome related research. Funding for these initiatives must be extended and expanded.

Bioinformatics will continue to be a crucial enabling technology. There will be an essential requirement to rapidly expand the development of the Canadian Bioinformatics Network to cope with the anticipated massive increases in demand for data storage and processing capacity that will accompany the use of genomics technologies all across our economy. It will also be necessary to continue to develop Canada's high speed communications networks through CANAIRIE to allow the emergence of a distributed yet integrated research and bioinformatics capacity available within every hospital, university and research institute across Canada.

### **Innovation Systems Support: The Regulatory Regime**

Around the world, it is recognised that the quality of the regulatory regime has a profound influence upon the rate and effectiveness of innovation within a jurisdiction. Certainly, companies wish to be assured that the regulatory regime is efficient and that it fully protects the interests of consumers. In this regard, both the regulator and the regulated share a common interest. In addition, and principally because of the high costs of drug development and the limited window of time for patent protection, companies require a speedy processing of applications. In the USA, regulators have responded with increased efficiency and FDA approvals in the first six months of 2000 represented 75 percent of approvals granted during each of the two previous years and included a robust list of biotechnology products. Indeed, the mean time for FDA approval has fallen consistently over the past five years, from 30 to 10 months. Canadian companies need to be assured that the regulatory regime will be as efficient in this country as it will be in other jurisdictions.

The issues facing regulators in Canada continue to develop in scale and in complexity and regulators must keep up as the field develops. The field is exploding. For these reasons, it is essential that regulators remain coupled to the benefits agenda. Only by being up to speed on the science through a close involvement in research can regulators maintain the edge that will allow them to make informed and efficient decisions. In the same fashion, the benefits agenda will develop most effectively if its proponents are informed about the government's position on emerging public policy issues that may be addressed through regulation.

It remains to be seen whether the Canadian public will accept this proposed close coupling between regulators and the benefits agenda as in the public interest and it will be essential to address the question of the perception of

conflict-of-interest that such a positioning would inevitably raise.

### **Innovation Systems Support: Technology Clusters**

As a result of decisive federal government actions in the past, Canada has had remarkable success in developing regional technology clusters in the bioeconomy. Strong federal research institutions, effectively coupled to local universities and a growing cluster of local firms, catalysed the emergence of strong regional systems of innovation that provided the knowledge, people, capital and infrastructure for the efficient development of the bioeconomy in specialised locations across Canada. For example, NRC's Biotechnology Research Institute in Montreal has been very influential in helping to build the cluster of biotechnology companies focussed on human health in that region. The Plant Biotechnology Institute has worked with Agriculture and AgriFood Canada, local firms and universities to build Saskatoon into a centre for agricultural innovation. These locations have proven themselves better able to create, retain and grow new companies. They have also shown themselves to be able to attract direct foreign investment. This investment has further increased the attractiveness of these regions. However, recent federal investments have lacked the focus of the past. Moreover, they have not been directed towards these key federal government laboratories. Consequently, it has been reported that the biotechnology-related technology clusters may lose their momentum and growth and that industrial investment may slow or move offshore.

This should be contrasted with Canada's undoubted success in developing an indigenous ICT industry. Patient investments in federal research institutions like DND, CRC, and NRC contributed to Ottawa's success as a high technology cluster capable of attracting in companies and capital from outside our borders.

The presence in Ottawa of homegrown firms like Nortel Networks, JDS Uniphase, Newbridge, Mitel, Cognos, Jetform and Corel has encouraged direct foreign investment from around the world. In 2000 alone, Ottawa has seen significant investments from the USA (CISCO Systems), Finland (Nokia), France (Alcatel), and the UK (Marconi). In addition, foreign venture capital is beginning to flow to Ottawa to support the start-up and growth of local photonics companies. In August 2000, an Ottawa start-up company, Trillium Photonics, was created with \$10M from the Palo Alto venture capital Company, Mohr Davidow Ventures. Mohr Davidow has also announced that it has a US\$150M fund available to support start-up companies in the Ottawa region. Other sources of venture funding are derived from those experienced, Ottawa-based, technology managers who have withdrawn significant accumulations of capital from previous start-ups and who are comfortable investing in and guiding the development of new start-up enterprises.

The economic dynamic in Ottawa is the dynamic of a self-sustaining technology

cluster that has reached the critical mass for lift-off. This does not yet exist in any of Canada's biotechnology clusters. They are far from lift-off. The pace of development of biotechnology is an order of magnitude slower than that in ICT and the industry is young. This is the reason that governments must sustain their investments over longer periods of time.

### **Innovation Systems Support: Financing**

The Pathways to Growth document warns of a five-fold increase in the amount of capital needed over the next decade for our smaller biotech firms. This need is particularly urgent for proof of concept, early stage ventures, and in second and third round financing and in regions where VC is hard to come by (as in the Atlantic). Most Canadian VCs have shorter investment times than their US counterparts. The latter investors usually commit themselves for five to ten years until companies go public. Canadian VCs also commit on average less than comparable US firms. A united federal community needs to work together to use the same proactive techniques the ICT industry relied on to support early-stage firms to realise their promise and attract investment, to showcase these firms to financiers, and to provide links with financing programs that really work for smaller firms.

### **Innovation Systems Support: Incubation and Commercialisation Programs across Canada**

The special needs of our nascent biotechnology firms, that start out from universities or government and face many years of struggle before they can even begin to attract financing, has to be recognised. These firms have said that they require incubator facilities that link them into established powerhouse research organisations that have the scientists, facilities and resources to turn to. They also need business and management acumen and ongoing mentoring.

There is a need to ensure that all major communities across Canada have these facilities that spin-off and starts-ups can turn to. These incubator sites would be linked to larger research centres and offer the range of research, business and management services required.

The capacity of federal research institutions and universities to create value through technology transfer and the creation of new industrial enterprises must be strengthened by building upon the strengths of the IRAP and CTN networks.

### **Innovation Systems Support: NCEs**

The special needs of NCEs must also be considered. Some of these are related to health and biotechnology and form essential elements in the innovation system. Investment has to continue. As well, the special needs of commercializing IP flowing from NCEs must be accounted for in the Incubation

and Commercialization Programs noted above.

### **Innovation Systems Support: Technology Forecasting and Competitive Intelligence**

Strong technology foresight and competitive intelligence capacities should be established in Canada; there is a need to mount a world-class program that would build on established federal strength in biotechnology. A team of researchers, engineers, librarians and business experts would provide the core for a comprehensive initiative. The program would target technology foresight and competitive intelligence in biotechnology for government, universities and firms that would in turn identify key areas for future investment and growth.

### **Innovation Systems Support: Human Resources**

Industry is facing a shortage for specialists in management, scale-up and production as well as science in newly created fields such as bioinformatics. There is a need to increase the number of highly trained personnel through NSERC, SSHRC and CIHR.

### **Innovation Systems Support: Public Awareness and Education**

Public awareness and education relevant to acceptance of working and living in the bioeconomy era is a critical area that was not effectively dealt with during the implementation of the first wave of agricultural biotechnologies (late 1990's). It will be essential to fully involve the Humanities and Social Science Departments of Canadian Universities through the establishment of funded, multidisciplinary programs dealing with awareness and societal impacts, etc.

### **Strategic Applications and Research Area: New Industry Applications**

Industrial application efforts would centre on new products, new bioprocessing techniques, superior industrial processes, and increasing the value of by-products.

Research in this area would include:

#### ***Novel industrial products/processing systems***

A wide range of environmentally friendly, bio-based processes and products will play a major role within the bioeconomy. These include: novel/stable enzymes to be used in industrial processes; biodegradable plastics and other bio-polymers produced through genetically engineered crops and microbes; novel vegetable oils for industrial applications; novel bio-chemicals; and industrial starches produced from genetically modified plants for use in manufacturing processes and new products such as carbonless paper.

**Aquaculture**

Canada will lead the world in the focused application of all aspects of genome research to problems dealing with marine issues - aquaculture, fish disease, production enhancement (transgenic or enhanced traditional breeding), stock characterisation, fish nutrition, etc.

Global aquaculture production is proceeding at an increasing rate. Wild fish catch has peaked and in many areas of the world, and for many species, it is declining. Thus the increasing appetite for a healthier protein source in seafood is driving the increasing demand for cultured foods from the sea. Aquaculture products will also include biomaterials and health products.

Fish farms can pollute the environment. Technology and know-how is needed so farms can be located anywhere on land, where better control can be achieved of water quality, pathogen entry, escape of farmed fish to the environment, therapeutic output, pathogen escape from the farm, and siltation and other solids output.

**Agriforestry and Novel Forest Products**

The cultivation of rapidly growing woody species will offer new attractive economic opportunities for millions of hectares considered to be either marginal or unsuitable for traditional crops. Additionally, the genetic engineering of trees for superior/novel products can be expected to become a reality. Canada possesses more than 40% of the world's northern forests and should therefore be in a position to be the world leader in bio-based forestry technologies.

**Biofuels**

The application of advanced biological knowledge and technologies will make it economically feasible to produce biofuels from plant biomass (including woody species). Research approaches will include modification of plant-based substrates as well as development of improved enzyme systems and novel microbial/fungal hydrolytic systems.

The achievement of this goal will require sustained R&D commitments from appropriate federal and university laboratories. The biofuels program would complement other major national energy programs.

**Strategic Applications and Research Area: Health and Wellness**

With the ageing of North American population, there will be a shift towards different types of illnesses and the development of new therapies and therapeutics. There are also increased pressures to reduce health costs, and pharmaceutical firms are turning their attention more towards preventive medicines and diagnostics. The emerging fields of nutraceuticals and functional foods will continue to grow rapidly.

Advanced research in vaccine development, genomics-based drug discovery, and novel delivery systems will be key areas of activity in the next few decades.

The application of molecular farming technologies to produce valuable health care products (antibiotics, therapeutic proteins, enzymes) from genetically engineered plants, microbes, fungi, and animals will require continued research support to ensure viability for this new industry. The traditional interface between medical (nutritional/therapeutic) and agricultural production systems will be completely seamless in a fully functioning bioeconomy.

Technologies and research in this platform would include:

#### ***Comparative Genomics***

To study the changes in gene expression associated with diseased states (e.g. neurogenomics, cancer genomics) or with states of infection (pathogenomics). These studies would provide the technological infrastructure for the development of preventative strategies and better, more tailor-made therapeutics and improved vaccines.

#### ***Computer Modelling of Biological Systems***

A convergence of computer science and life science will be very important for various applications. One of these is the so-called "cybercell", i.e. computer models of living cells that could be manipulated to mimic the changes leading to diseased states. Such models could be used to test various interventions to prevent disease or to reverse damage. Computer models and computational approaches could also be used to design better vaccines, i.e. to find the antigen fragment that would elicit the strongest immune response.

#### ***Gene Therapy***

To develop a host of viral and non-viral vectors for gene therapy: adenovirus, retrovirus, adeno-associated virus, and non-viral vectors such as polymers and lipids. Centres to develop and supply these vectors already exist in the US (NIH) and France (Genethon, French government). A centre is crucial for providing high quality material, expertise and trained personnel for gene therapy in hospitals and research centres in Canada. Most of this material now originates from the US at very high cost.

#### ***Medical Devices***

Early medical diagnosis plays a critical role in the costs of the health care system and the state of the Canadian economy. The earlier a disease is diagnosed, the earlier it is treated and the better is the prognosis for the patient. Patients return to work earlier, work more productively, and contribute normally to the Canadian economy. The early treatment is done at a minimum cost to the health care system. Thus, both health care costs and the economy benefit from

a country's capability for early and accurate diagnosis of human disease.

Sophisticated medical instruments make many of the early diagnoses. Canada imports more than 90% of these instruments. These include CAT scanners, MRI scanners, ultrasound instruments, and X-ray machines. This occurs despite a good array of talent in the fundamentals of these areas in universities and institutes. Canada has no industrial leader in this field.

### **Strategic Applications and Research Area: Sustainable Environment**

The application of biosciences to environmental issues and challenges offers an important long-term approach to enhancing the quality of the environment. New enterprises based on the application of environmental technologies will emerge and thus environmental type industries could also be listed as examples of new bio-industries. However, substantial public R&D activity will be required, as much of the activity in this area will also be for "public good".

The needs and environmental challenges to be addressed by the environmental industry are mainly in the following areas:

- Pollution control and prevention (water, groundwater, air, soils)
- Environmental management and risks analysis
- Industrial sustainable development
- Climate change (greenhouse gases)

Key activities will include:

#### ***Developing an environmental management methodology***

It is important to develop a sound environmental management framework with which to assess environmental impacts and progress towards the objectives of sustainable economic development. This is a new and integrated discipline that takes a systems approach to the problem and measures the inputs, impacts and outcomes of technologies over their complete lifecycles. Without such a disciplined approach it is extremely difficult to assess the benefits of new technologies. Such an approach is essential if technology development and policy-making decisions are to be taken with a sound foundation.

#### ***Programs to stabilise/reduce greenhouse gas emissions***

A number of organisations have developed long-term R&D blueprints to address the climate change issue. The bioeconomy strategy should involve co-ordination of components of these blueprints. It is particularly important to ensure that these efforts are developed within a consistent and sound environmental management assessment approach in which a systems approach is taken to assess the integrated environmental impact and progress towards overall sustainability.



***Phyto/Bioremediation***

Genetic modification and/or plant microbial management approaches should be increasingly employed to reduce both inorganic and organic environmental contaminants. NRC along with Environment Canada, the University of Saskatchewan and the University of Guelph already have initiated some work in this area, however, a comprehensive long-term, strongly supported program needs to be established. Remediation technologies will offer opportunities for the establishment of a range of SMEs.

***Adapting plants and animals to tolerate enhanced environmental stress***

Genetic modification of crops and livestock would be required to adapt production systems to those environmental stresses associated with climate change. Even without anticipated changes associated with climate change, Canada's geographic position dictates that much of its areas are affected by environmental stress (cold, drought, salinity). Genes discovered through genomic approaches should be employed to develop productive strains with enhanced stress tolerance.

***Reduction/elimination of biohazards in Canadian water***

Application of biotechnologies in terms of advanced/efficient biodiagnostics and soil microbial and plant-based strategies should play a major role in complementary physical/chemical approaches to the effective stewardship of Canada's fresh water supplies. Animal vaccines to eliminate pathogens at source are also urgently required.

**Strategic Applications and Research Area: Research in Support of the Regulatory Regime*****Traceability of Standards***

Without an internationally accepted standards regime, trade in bioproducts will be restricted.

In this regard, it is important to note that member states of the European Union are beginning to require that all trade agreements ensure traceability of standards to the Metre Convention through the Mutual Recognition Agreement signed by 47 signatory nations. In practice this means that national standards must be traceable to the national metrology institute. Furthermore it means that national metrology institutes around the world must develop mutual recognition arrangements adequate to support international trade in bioproducts.

In Canada's case the statutory responsibility for metrology rests with the National Research Council and its Institute for National Measurement Standards. As yet the INMS has little capacity to support this requirement. In fact no Canadian standard in this area has the required traceability.

Consequently Canadian products may be exposed to non-tariff barriers.

The Advisory Committee on Science and Technology recently published the BEST report on the role of federal science and technology. This report recognises standards as a distinct area of government interest and a proper area for it's in house laboratory research.

The need to develop standards for bioproducts and genetically modified organisms that are traceable to MRA is an area that demands urgent federal actions.

## Conclusion

The transformations underway in biology, in particular its convergence with information and communications technology, will dramatically affect the lives of all Canadians and they will radically reshape our economy. For Canadians to benefit, the federal government must respond and actively pursue a benefits agenda based upon a strong research and development infrastructure that is closely coupled to the needs of Canadian firms. Unless this is done, Canadians will be bystanders as others develop the most important sector of the knowledge-based economy in the twenty-first century. Without strong Canadian firms the economic and social benefits encompassed by this opportunity will not be returned to Canadians.

The implications for the research enterprise are dramatic and they require a large-scale national response. The federal government must set out a bold national vision and strategy to ensure that Canadians can participate in the bioeconomy and to support our biotechnology firms. The strategy will require concerted action at all levels of government but with leadership vesting with the federal community. It will require a dramatic increase in the levels of investment in R&D and a significant re-investment in federal R&D initiatives around the theme of sustainable development of biotechnologies. The goal is to develop a suite of technology platforms that will support the bioeconomy in Canada.

Along with this revamping of federal R&D there must be parallel efforts to sustain a supportive environment for our firms. These initiatives would include programs for stronger links among universities, industry and governments, better commercialisation of R&D results from public and academic labs, and better access for firms to enabling infrastructure for biotechnology research.

Federal investments should be carefully targeted to support development of technology clusters in regions across Canada that have the potential to create, grow and retain new companies and thereby become strong attractors of incoming direct foreign investment.

## Recommendations

### Governance

- Develop a governance structure to co-ordinate government R&D efforts to develop the bio-economy in Canada;
- Manage federal research and development efforts against four strategic applications areas: New Industry Applications, Health and Wellness, Sustainable Environment; and Research in Support of the Regulatory Regime;
- Study and alleviate systemic barriers to the participation of federal researchers within the Canadian innovation system.

### Research

- Dramatically increase federal funding of R&D in order to develop enabling platforms in: Bioinformatics; Distributed, grid-based information systems and databases; Functional genomics; Vectors for gene therapy; High throughput screening; Combinatorial chemistry; Proteomics; Structural genomics; Metabolic profiling; Systems biology; Nanotechnologies and microfluidics; Separation technologies; Pilot plants and demonstration facilities; and Other new and emerging technologies;
- Convert funding for the federal genomics capacity from limited term to ongoing A-base;
- Increase the investment in Genome Canada and in government laboratories carrying out genome related research;
- Establish systems biology institutes for agriculture, aquaculture, and the environment, to parallel investments in the Canadian Institutes for Health Research;
- Establish computational biology and nanotechnology institutes and research capacity;
- Rapidly expand the development of the Canadian Bioinformatics Network to cope with the anticipated massive increases in demand for data storage and processing capacity that will accompany the use of genomics technologies all across our economy;
- Continue to develop Canada's high speed communications networks through CANAIRIE to allow the emergence of a distributed yet integrated research

and bioinformatics capacity available within every hospital, university and research institute across Canada;

- Strengthen the linkages between the Genome Centres and the Canadian Light Source and support efforts to establish a Canadian Structural Genomics capability;
- Support research efforts to develop an environmental management methodology and framework against which the environmental impacts and long-term sustainability of new technologies may be assessed

### **Innovation Support**

- Make significantly increased investments in federal biotechnology R&D institutions located within strong regional centres in order to strengthen Canada's existing technology clusters in biotechnology and position them for further growth and the attraction of increased direct foreign investment;
- Establish a technology foresight capacity within government;
- Make large-scale pilot plants, separation facilities, and technology demonstration facilities accessible to Canadian companies;

### **Traceability of Standards**

- Establish science to develop standards for the bio-economy and to ensure the traceability of these standards to the national metrology institute and the MRA;

### **Human Resources**

- Expand human resource development for the biotechnology industries through the NSERC, SSHRC, and the CIHR;

### **Commercialisation**

- Strengthen the capacity of federal research institutions and universities to create value through technology transfer and the creation of new industrial enterprises by building upon the strengths of the IRAP and CTN networks;
- Establish specialised incubation facilities for biotechnology and genomics-based companies co-located or close to major centres of biotechnology R&D infrastructure across Canada; and

### **Management**

- Encourage the development of networks of experienced managers and executives to mentor newly emerging start-up companies in biotechnology

- Increase support to biotechnology companies through the IRAP and CTN networks
- Increase the supply of personnel trained in technology management

### **Finance**

- Study the funding needs and opportunities of emerging companies in this sector and support the development of new support instruments including venture capital and co-development opportunities.
- Review existing instruments (IRAP, TPC, SDTF, AAFC MIP, TEAM, CCAF) and consider how these may be adjusted to support the needs of developing firms



## Biotechnology for the 21<sup>st</sup> Century Strategy

NSERC is a leading funder of biotechnology research and development in Canada and is well positioned to strategically invest new resources in critical areas that will assist the Canadian biotechnology industry to grow and prosper. Biotechnology is about people: their ideas, their scientific discoveries, and their drive to commercial success. All of these concepts are what NSERC strives to achieve through our investments in **people, discovery and innovation.**

NSERC funds biotechnology research through many of our discipline based Grant Selection Committees (e.g. Cell Biology, Molecular and Developmental Genetics, Plant Biology), a Strategic Projects area devoted to biotechnology, and many university-industry collaborations through our Research Partnerships programs. Recent conservative estimates place NSERC's biotechnology funding at roughly **\$37 million per year**. This funding helps to support hundreds of university researchers, postgraduate students and postdoctoral fellows to conduct research at the leading edge of biotechnology. Included in NSERC's most recent budget plan "Fuelling Innovation: Implementing NSERC's Strategic Plan For the Period 2001-2005" was a goal to use new funding to more than double the biotechnology capacity of Canadian universities. The plan for biotechnology is highlighted below under the theme areas of **people, discovery and innovation.**

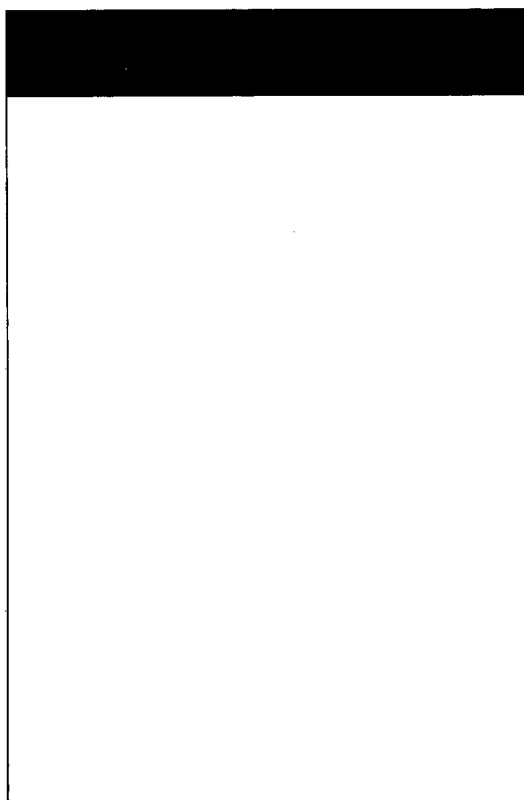
### People

Canada needs highly qualified people who have the knowledge and skills to work at the leading edge in solving problems, producing innovations, and adding value in all areas. Canada's success in the new economy is increasingly dependent on its human capital. In our knowledge-based economy, productivity gains are a function of the development of human capital, which in turn is the engine for technological advance. Moreover, many Canadian biotechnology companies report that they cannot find the highly skilled individuals always needed. The Canadian Biotechnology Human Resource Board has found that there will be a growing demand for more people and new skills across the Canadian biotechnology industry. Already a significant employer of highly educated and skilled workers - scientific and technical jobs in biotech firms are filled largely by people with post-graduate degrees, NSERC's primary focus of student support. The biotechnology industry can be expected to create nearly 300 to 500 new jobs annually in scientific research and technical and support in the short-term, with much larger growth rates anticipated as the industry matures.

Through NSERC's scholarships and fellowships programs the next generation of biotechnology researchers and skilled personnel will be developed. To meet the growing

demand for these individuals NSERC proposes to double the number of postgraduate scholarships and postdoctoral fellowships in the life sciences. **NSERC is prepared to invest \$25 million per year of new funding to develop the personnel required by Canadian industry.** Four to five hundred additional individuals with master's and doctorate degrees in the core science disciplines demanded by biotechnology industry would enter the workforce annually. These additional highly trained people would ensure the growth, and wealth-generating capacity of Canadian biotechnology industries continues to expand.

### Discovery



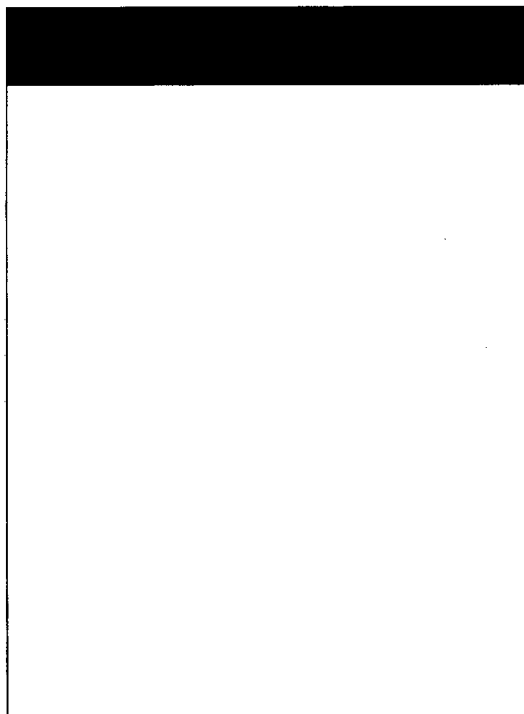
Canadian university researchers are known

for their excellence and productivity. They conduct basic research at the leading edge (see side bar) in all areas of biotechnology, and their research often creates opportunities for important Canadian advances and innovations. These scientific and pre-commercial opportunities have the potential to produce significant advances in biotechnology research or to lead to new goods or services in the market. However, due to inflationary pressures of conducting research that often involves new methods which are intrinsically more

expensive, today's researchers often lack the proper resources to conduct world-class research. Yesterday's biologist may have had to pay for field trips and storage cabinets for his samples. Today, that same biologist needs DNA analytical equipment. A growing number of university faculty in the life sciences will also be retiring soon and replaced by much younger and more research-intensive professors.

NSERC intends to invigorate the research efforts of university researchers in cell biology, molecular genetics and plant biology by providing them with the world-class support that they need to help train the next generation of skilled biotechnology workers and to generate the new discoveries crucial for the industry to grow. **Forty-five million dollars per year will be required to undertake this objective.**

### Innovation



It has been well documented that

universities play a strategic role in strengthening Canada's innovative capacity and productivity performance. Universities train highly qualified people who create and build knowledge-based firms. Universities are a major source of ideas for new products and processes that add value in the global market. Tremendous opportunities exist to exploit the discoveries of Canada's leading research universities. NSERC has had a great deal of



success in the creation of biotechnology spin-off firms (see side bar) and new products and processes based upon university research.

In addition, NSERC will continue to develop the linkages between industry and university research laboratories that create wealth for the country. The demand for such programs is in excess of our ability to respond. New NSERC funds will effectively lever new contributions from industrial and other partners. We will create opportunities for a strong university research community to assist in the development of an innovative private sector.

**An investment of \$15 million per year in new funds will be required to boost the innovation capacity of the biotechnology community funded by NSERC.**

### **Summary**

NSERC is poised to make the critical investments in biotechnology training and research this country desperately requires. To truly develop a vibrant and growing biotechnology sector in Canada will require some up-front investment in the knowledge infrastructure based in Canada's universities. For a relatively small sum of \$85 million per year, the development of the skilled workers that the Canadian biotechnology industry needs and the additional benefits realized from the new discoveries and innovation flowing from university-based biotechnology research will be assured.

October 17, 2000

1 1

## Mining Strategy for Biotechnology Summary

### Context

In the last round of projects funded by CBS, the mining sector did not obtain any funding since the work that MMSL performs does not involve any genomic related research. MMSL continues to be involved in biotechnology, now concentrated primarily in the mining sector in three areas: bioleaching, microbial ecology and effluent treatment. Work in these areas meet sector priorities of enhanced competitiveness and sustainable development. These are also likely areas of growth for biotechnology in the mining industry in the future.

The environmental consequences and liabilities traditionally associated with mining operations pose significant challenges, and technological solutions are needed to meet increasingly stringent environmental requirements across Canada. It has been generally agreed that biotechnology holds real potential as a means to better protect the environment from consequences and liabilities associated with mining operations. While there are few large scale commercial installations in Canada at present, there are a number of biotechnology based processes that are undergoing field demonstration trials. Some of the more promising are: inhibition of microbial activities that lead to the production of acid mine drainage, underground reactive barriers and an understanding of the microbial processes involved in arsenic cycling. In addition, there is increased interest in environmental applications, especially with regard to sulphide reducing bacteria and their application to the removal of metals from contaminated surface and ground waters.

Bioleaching has the potential in Canada to exploit low-grade, remote mineral reserves in an environmentally sensitive way. Some observers in the industry believe that increasing the kinetics and efficiency of microbially catalysed leaching processes under conditions specific to the climate in Canada, huge reserves of copper that up to now could not be economically processed using conventional technology can be brought into production to meet future copper demand. Even though much of the early work in this field in the 1970's and 1980's was initiated in Canada, the development and application of bioleaching technology is taking place in other countries. What is needed at this point is a determination of why biotechnology is not used more often in Canada when there are so many examples of commercially successful application in other countries.

Some of the projects underway at MMSL are in the areas of: bioleaching, redistribution of metals in sediments due to microbial activity, microbial ecology, effluent treatment and phytoremediation.

### Challenges

The challenges continue to be in reducing the perceived risk to the mining industry in applying biotechnology. Part of this is due to the lack of commercial applications in Canada and also with the lack of knowledge about biotechnology in general. MMSL is trying to alleviate these problems through: involving the mining industry where possible in its internal projects; examining the applicability of biotechnology to the Canadian context; and educating the industry through workshops and technical sessions at conferences.

In addition, operators in the mining sector do not tend to focus on research but, rather, prefer to purchase that which has been proven, often in other countries. Consequently, industrial funding for biotechnology development has been and will continue to be, limited to very specific industrial issues, where no proven, cost effective, alternative technologies exist. This makes it difficult to get funding from the mining industry at this early stage of technology development.

Funding from the Canadian Biotechnology Strategy would allow the work being performed at MMSL to be expanded internally as well as with other partners in the mining sector, universities and other

2 2

government departments. This would likely increase the rate of acceptance of biotechnology as a viable option for environmental as well as for processing applications by the mining industry in Canada.

**From:** Jackie Holden  
**To:** David Swol; John Prentice; Tom Richardson  
**Date:** Fri, Nov 24, 2000 4:08 PM  
**Subject:** Report on Nov. 23 Biotech ADMs meeting

Hi everyone,

The following is a short summary of yesterday's Biotechnology ADM Co-ordinating Committee. Information was provided by Kimberly Empey of the Canadian Biotechnology Secretariat, as Jan was unable to attend the meeting.

The meeting was attended by Andre Gravel and Bart Bilmer of CFIA, Diane Gorman of Health Canada, Yvan Hardy of NRCan, John Davis of DFO, John Giroux (?) of DFAIT, Peter Hackett of NRC, Barry Stemshorn of Environment Canada and a number of observers.

The lead item on the agenda was a presentation on public opinion research regarding biotech by Elly Alboim of the Earncliffe group. No hard copies have been distributed yet (they're holding off on circulating this until after the election), but we should receive it next week.

Based on Earncliffe's research, Alboim said that government needs to put a leadership agenda in place on biotech, and noted that the status quo wasn't good enough. The survey confirmed that Canadians are not opposed to biotech products, as long as they see them as being of personal or environmental benefit. It also confirmed that Canadians think there are some lines we shouldn't cross (e.g. cloning humans).

The second agenda item was an update on the Deputies Exercise - Diane Gorman of Health Canada provided a debrief of the November 22 meeting between our DM, Peter Harder, Marie Fortier of HC, and Ian Green. Diane noted that Deputies want to move from a business as usual approach to developing a leadership agenda. There was a view that all DMs haven't involved their policy shops sufficiently and that there isn't yet a consensus around town on what such an agenda would look like.

Diane stated that Industry Canada's long deck which was being prepared for the Nov. 29 CCDM meeting (now postponed) will be put on the shelf for the moment. She noted that Peter Harder would instead be taking the lead in pulling together a policy "think piece" (format yet to be determined) and that our department, Health Canada, CBS and others would help feed into this. Next meeting of DMs is expected to be called for mid-December.

Regarding the development of common transition material, a 3-page draft overview note on life sciences and biotech for the next mandate has been drafted - Roy Atkinson of the CBS is looking for comments by Nov. 27. Sector strategies were also circulated to ADM Committee members on Nov. 21. A revised version of these documents, including sector strategy summaries, will be sent out to Committee members on Nov. 28.

A sub-committee (consisting of Environment Canada, Health Canada and CFIA) will be developing a piece on science and regulation - no info. on timeline.

An R&D piece was presented by Peter Hackett of the NRC - he plans to talk about this with ADMs within the next couple of weeks.

Please call me if you have any questions regarding these notes.

Thanks,  
Jackie Holden  
759-7221

**CC:** Jan Dyer

## Ideas for Regu.

- biotech: life sciences regulation.
- investing in long term research
- strengthening of existing reg system.
- ~~understanding~~ understanding of the science.
- there are lines we won't cross.
- not blocking innovative agenda
- there are lines we won't cross.
- i.d. benefits forces a change in opinion
- int'l agreement is imp.
- no pushing of info, but ability to pull
- want experts to make decisions
- ethics are a personal decision

BACC notes

Nov. 23, 2004

D. Gormon  
new DEATT → John

Nitch Davies

Yvonne Hardy

E.L.

B. Stawski

P. Hackett

A. Green

J. Davis

1. Earncliffe

- 2 surveys - CBS, Reg & Science  
1500 1200

- still doing focus groups → after election  
- much less political reliability than  
MIR's / etc think!!

- Awareness

growing steadily (>59%)  
> 50% (>75% of info seekers)

- no movement in interest, knowledge, engagement  
i.e. casual observers

→ benign interest: neutral to positive

- > 50% have talked about it

< 10% v. familiar

< 20% negative → ~~concern~~

10% strong: - favour

51

21

8. strong -ve

→ has to be > 20%

for damage to govt / comp

- less certain about health, env, food.

- not concerned re: the future

- words are up:

62  
100  
33  
16  
↓  
+ve

"technology" casts a fire

- bio tech → no sign we react

- GM drives us up → hazardous, emergency

sounds intrusive / inappropriate

- decision - making on a case by case basis  
- marginal

- medical → health → env. → agri & food  
intrusiveness, Xing boundaries, pl. / an / health

- on focus grps → food & health

- ultimately, it is the purpose that is imp.  
describing the ~~the~~ method → we.

↓  
personal benefits - health

cosmetic applications : animal goes into plants - low  
to make food look better

- assessment of govt is weakening

- not an enforced comment

- govt shld have a larger role, regulating reasonable,  
balancing the various interests

E A F P

Sep 2006 1 13 43 27

Feb 2007 46 29

priorities → health & env. → long term health & env  
→ ec. priorities → ethical use

- comparison of perceived priorities & govt's performance → where the govt's priorities are the inverse.



- overall govt positioning
- req. for balanced positioning that shows the govt understands it is managing the <sup>current</sup> p/b questions
- testing the <sup>current</sup> key messages yielded strong supports
- central CBS pillars (stewardship, benefits, cit. engagement) still v. salient & appropriate.
- agree somewhat agree
- 41 - 47 - 7 - 3

- govt can play dual roles
- greater emphasis on reg, res, sci
- feel balance is too much on finance.
- govt shld work with others

- shld govt ↑ reg?

54 - 35

Accept Accept

- long term risks - central driver of uncertainty
- until you know → stop
- if show benefits, they back away

- need strong

- required acceptance of some risk.

46

8 - 36 - 7 - 7

→ Can't stop, rage

- proceed, despite some risk

- encourage level + unknown risk (worded same ways)  
22-50-65-90

- can separate risks & benefits  
- sed govt

Emphasis	safety	cc	both
(today)	15	22	46
(in future)	27	10	60

↓ implies no resistance to both

promote & regulate  
both - 72  
impossible - 23

- uncertainty about reg system  
- but <sup>there is</sup> underlying confidence  
- uncertainty

- indiv. govt depts inspire confidence vs govt as a whole

- 8 9 5 2  
1-11-38-26 (16% DV)

- products should meet higher standards  
- confidence in products (< 20% not)

→ CFIA - VC C. Scientist not  
15 56 22 6

→ passed laws (e.g.) → the message.

→ tell what is involved → more conf.

→ food

VC C SC Not  
29 52 14 5

- good science is the arbiter of public approval  
- wait govt to be decision-maker.

Best avail.  
Science  
in the  
arbiter non  
Feb

SA A D SD  
29 - 52 - 14 - 7  
10 - 55 - 26 - 7

- scientists are highly credible (esp. non-industry funded univ. sciences)  
- govt shld inform people about brotch & let people decide

66-286

- GM foods
- not fundamentally risky or unsafe
- food on groc store is safe, has been tested

↓  
but vulnerable:

Food

- growing personal discomfort
- food safety system is sound
- benefits arguments force a Δ in opinion
- ~~eg~~ - pesticide argument

have you eaten 35% (Feb: 30, 0.99: 25)  
discomfort about buying → weight

foreign bans of gm foods

OK if safe? yes: 56 no: 38.

- want int'l agreements

- strength is #5 → BS Protocol: 35-46  
- don't want other foreign products into other countries

- patenting - <sup>more</sup> HGP seem as +ve.
  - more benefits than risks
  - d.n. like patenting → "i" drives up prices & restricts access (not moral) objection

- genetic privacy
  - govt should ensure privacy
  - <sup>reject</sup> insurance companies asking
  - d.n. want employers to have right to ask
  - more altruistic uses acceptable, eg pop health studies

### - communications

- the msgs are stronger than the NGO
  - health care messages
  - ec. food, reg msgs are weaker

- want to pull the info, not having info pushed at them

### - public inv.

- want experts to make decisions
- d.n. want ethical → a personal decision

~~Other~~

### Other conclusions

- v-consistent answers

- no engagement, support

// benign,  
stable

- Solve what we can turn the corner

? take the offence on the benefits  
side

- if there's a will to give it pride of  
place, it can be done  
re: innovate agenda.

↓  
focus: health / <sup>medical</sup> ~~care~~ benef. <sup>vs</sup>  
↳ incl. health industry

- to date we've been defensive

- people won't cheer, but won't be  
large opposition.

- will still require strong goal keeping

- need a persuasive edge

- understand, in vesting in things we won't cross  
eg. human cloning

- vulnerable on the science side

- AG → using and date is confidence?

→ EA: need to show our value added

regulators have more credibility

RA → use of term "life sciences" → no assoc. with

biotechnology

EA: biotech = science, labs, test tubes

no benefit from  
of word technology

MD → jobs<sup>skills</sup> for kid

EA: people see as 4re

if kids learn, will get a good job.

⊗ survey will be sent around next week

(Back to Agenda)

2. Minutes from Conf. call

- HC - re: Tech foresight.

3. DM Dinner Meeting

- small grp of DMs to meet

- P. Harder, PCO, DD, SW

- met yesterday → vision for brotch

- want to take a <sup>strong</sup> leadership role, but  
want to get it right

- not going to CCDM in next short while

- P.H., DD, SW bringing together 3 short pieces  
→ DMs have not see EA's  
presentation

∴ do affect sector strategies,  
as a note



→ but DECK will be

∴ no more work on → PA will  
take  
com

→ lead min, governance structures, etc.

∴ no DM mtg next week - will be at P Harder

### 3. Horizontal Piece

- K. Dodds wrote to - no more Deft
- ⊗ - RA work to DM's Dinner
- the piece

→ initial concept

each sector piece dev  
use to create hori

- NRC - integrate sector <sup>RE</sup>
- they are not repre  
sector pieces

- URC - fracture sector 5

- DG - useful to brief min.

- horiz. reg. piece needed. right balance?
- useful for making horiz. piece

B. Stashko - discussed at DMS challenge  
talking about

- DMS - how regs are impacting on innovation  
agenda - doing a review

D. Gorman - mutual recognition agreement - 42 states have signed

- 5 SET strategies

- gov't has paid more att'n to external vs. internal

RA

- long term risks
- system has to work

→ Harden, Water, Dodge  
→ 3 p. overall + 1 pager on each coord. sector  
- set things by DM advice before going to CCEU

↓  
last week of Nov

→ Mynak in Kyoto  
→ no other DMS contribute to?

- Week 1 - ideas
- 2 - put together
- 3 - present



### 3. Horizontal Piece

- K. Dodds wrote the 3 pager - with DG, Office
- ⊗ - RA will take comments
- the piece that goes forward

- useful concept

- each sector piece developed and  
use to create horizontal piece.

- NRC - integrate sector <sup>R&D</sup> pieces into their docs?
- they are not represented into the other  
sector pieces

- VRCA - fracture sector strategies

- DG - useful to brief min.

- horiz. reg. piece needed. right to know?
- useful for making horiz. piece.

B. Stashko / discussed at DMS challenge team  
talking about

- DMS - how regs are impacting on innovation

D. Germ / agenda - doing a review.  
mutual recognition agreement - 42 sectors have signed!  
need for merging? they are going to COM.

- 5 SET strategies

- gov't has paid more att'n to external vs. internal

RA

- long term risks
- system has to work

PCO

need to create interest, excitement

Long. application to regions of CAV

NRE

- paper ~~focused~~ strategy focused on regions / clusters vs. <sup>uniform</sup> ~~speedy~~
- Mtl., Sask

DG <sup>me</sup> Summary

- almost DM vision

- heron piece is worthwhile

- reform DMS

- send comments

- no further on sector pieces

- R&D → Peter Hackett

- Regulation & Stewardship

→

BS

Stewardship

D Gorman

need ideas

→ not blocking innovation

→ need further meeting / strategy ~~meeting~~

B. Stangor

Reg →

alternatives to reg =

- other approaches?

- fear of compromising <sup>innovator</sup> agenda

→ in some cases, reg are the foundation of <sup>competitive</sup> ~~success~~ <sup>edge</sup>

→ need to focus on certain areas

→ present an attractive reg. regime vs. other countries

also, agreement in Preliminary Principle ✓  
- a paper was agreed to.

→ Mtg on Stewardship / Reg<sup>n</sup> (Pillar) - AG, BS, DG

Ⓢ new E&I report

**From:** <Atkinson.Roy@ic.gc.ca>  
**To:** NCR4.OTTFPI6(bbilmer),AGCAN.INTERNET("judith.young@nrc.ca","wwright.tom@ic.gc.ca","Wright.Tom@ic.gc.ca","Cynthia.Wright@ec.gc.ca",...  
**Date:** Mon, Nov 20, 2000 1:08 PM  
**Subject:** NRC's contribution on R&D and Innovation

Attached are two papers from NRC on R&D and innovation. The Bio.summ... document is a 5 page summary.

?? blank pages  
→ need 2<sup>nd</sup> paper

Judith Young has asked us to pass them along to you ASAP, but advises that there will be a covering memo that will follow shortly.

-----Original Message-----

**From:** Hackett, Peter A. (VP-Res) [mailto:Peter.Hackett@nrc.ca]  
**Sent:** Monday, November 20, 2000 1:02 PM  
**To:** Atkinson, Roy: CBSec  
**Cc:** Miville, Linda: CBSec  
**Subject:** FW: Revised version / from Judith Young

Mr. Atkinson,

Dr. Hackett requested I forward these two documents for your information and for distribution to other government departments.

<<Bio3.doc>> <<Bio.summary.fin.doc>>

> If you have additional questions please contact me.  
>

Louise Lajeunesse  
A/Head Office Support Unit, RPSO-VPO  
Room 1015, Sussex  
Tel: (613) 993-9244  
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**CC:** AGCAN.INTERNET("Louden.David@ic.gc.ca")

## **Positioning Canada as a Leader in the Bioeconomy**

### **An Innovation Prescription for Canada's Biotech Firms**

#### ***The Impact of the Bioeconomy will be Dramatic***

- Ernst & Young *Biotechnology Industry Report, Millennium Edition* predicts that biotechnology will reshape virtually every other industry it intersects with. From agriculture to chemicals and manufacturing processes, from drug discovery to computer nanotechnology, biotechnology is creating platforms for new products and markets on many fronts. In particular, the convergence of Biotech with IT is revolutionising both fields and opening vast new markets.
- The new knowledge that comes from intensive R&D is considered the currency of the Bioeconomy. The Bioeconomy is the future of biotechnology.
- Whole new industries are being formed and traditional ones are restructuring to seize the coming opportunities. There is no doubt that biotechnology, when fully developed, will bring at least as many benefits and positive impacts to Canadian society as ICT does. It is the most promising area for Canada's progress in the KBE.

#### ***Other Countries are Moving Quickly and are now Ahead of Canada***

- Other countries are investing massively in biotech research in an effort to capture the potential of the Bioeconomy.
- These global investments are already negatively affecting our own Bioeconomy growth and there are signs that our industry will suffer badly without concerted effort.

#### ***The Canadian Biotech Firm – Gloomy Prospects***

- Recent studies show that the Canadian biotechnology industry has slipped from second position behind the United States in 1998, to fourth place today. Given the heavy investments by other countries, Canada's standing can only fall further.
- Our biotech industry is still young and vulnerable. There are troubling signs that despite some strong activity, this industry faces considerable pressure. There is an increase in our venture capital flowing to biotech companies outside of Canada along with trained scientists, managers and IP. Financing difficulties mean that our mostly smaller Canadian companies are forming alliances with

foreign firms to develop their products to the point where most new product development of Canadian biotechnology is done offshore.

- Our firms are also becoming prime targets for take-overs by larger heavily resourced firms because they are undervalued. Our IP is ending up in the hands of foreign companies at bargain-basement prices. Remaining firms are competing with aggressive new entities for venture capital and new infrastructure such as incubators, technology platforms, demonstration facilities, and technology transfer centres.

### ***Genomics – an Industry Opportunity only Partially Realised***

- Canada's under-investments in genomics infrastructure have already placed our firms at a competitive disadvantage with respect to the generation of intellectual property in this key domain for the next two decades. Without infrastructure there is little IP generated, without IP there is little comparative advantage for firms. Already, over 170,000 genes and gene fragments have been patented around the world. Canada does not yet have one major public genomics company.
- The Federal Government's recent investment in this field will ensure that Canada is not shut out of this area but we will never reap what we could have if our investment had been swifter and greater.

### ***A Clear Role for the Federal Government***

- Governments around the world have recognised the unique role they play in developing the Bioeconomy. Only public investment can sustain the expensive R&D research programs – the core research platforms - that firms turn into marketable technologies. Only public investment can build the costly infrastructure – like pilot plants and test sites – that firms require commercializing products. Federal support can also sustain smaller firms through the years until traditional financing is possible and federal governments can create an environment that fosters innovation.
- Canada needs to coalesce around a deliberate strategy to build the Bioeconomy. Public opinion research has shown that Canadians are looking to the federal community to show this leadership.

### ***Our Vision is that Canadians will be among the first to Benefit from the Bioeconomy***

-

The federal government must take decisive action on three fronts:

1. It must dramatically expand support for knowledge creation through research and development – including heavy investment in its own labs – in four areas:

New Industry Applications;  
Health & Wellness;  
Sustainable Environment; and  
Research in Support of the Regulatory System.

2. It must recognise regional strengths and support emerging technology clusters; and

3. It must ensure that its actions are effectively coupled to the innovation needs of Canadian firms.

- Along with this revamping of federal R&D there must be parallel efforts to sustain a supportive environment for our firms. These initiatives would include programs for stronger links among universities, industry and governments, better commercialisation of R&D results from public and academic labs; swifter regulatory review of biotech products and better access for firms to enabling infrastructure for biotechnology research.

### ***Canada will Reap a Triple Dividend***

- Canada has the opportunity to reap a triple dividend by becoming a lead player in the industrial development of the bioeconomy: sustainable economic development, enhanced health and social benefits, and exportable technologies and new, hybrid products.

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## Recommendations

### Governance

- Develop a governance structure to co-ordinate government R&D efforts to develop the bio-economy in Canada;
- Manage federal research and development efforts against four strategic applications areas: New Industry Applications, Health and Wellness, Sustainable Environment; and Research in Support of the Regulatory Regime;
- Study and alleviate systemic barriers to the participation of federal researchers within the Canadian innovation system.

### Research

- Dramatically increase federal funding of R&D in order to develop enabling platforms in: Bioinformatics; Distributed, grid-based information systems and databases; Functional genomics; Vectors for gene therapy; High throughput screening; Combinatorial chemistry; Proteomics; Structural genomics; Metabolic profiling; Systems biology; Nanotechnologies and microfluidics; Separation technologies; Pilot plants and demonstration facilities; and Other new and emerging technologies;
- Convert funding for the federal genomics capacity from limited term to ongoing A-base;
- Increase the investment in Genome Canada and in government laboratories carrying out genome related research;
- Establish systems biology institutes for agriculture, aquaculture, and the environment, to parallel investments in the Canadian Institutes for Health Research;
- Establish computational biology and nanotechnology institutes and research capacity;
- Rapidly expand the development of the Canadian Bioinformatics Network to cope with the anticipated massive increases in demand for data storage and processing capacity that will accompany the use of genomics technologies all across our economy;
- Continue to develop Canada's high speed communications networks through CANAIRIE to allow the emergence of a distributed yet integrated research



and bioinformatics capacity available within every hospital, university and research institute across Canada;

- Strengthen the linkages between the Genome Centres and the Canadian Light Source and support efforts to establish a Canadian Structural Genomics capability;
- Support research efforts to develop an environmental management methodology and framework against which the environmental impacts and long-term sustainability of new technologies may be assessed

### **Innovation Support**

- Make significantly increased investments in federal biotechnology R&D institutions located within strong regional centres in order to strengthen Canada's existing technology clusters in biotechnology and position them for further growth and the attraction of increased direct foreign investment;
- Establish a technology foresight capacity within government;
- Make large-scale pilot plants, separation facilities, and technology demonstration facilities accessible to Canadian companies;

### **Traceability of Standards**

- Establish science to develop standards for the bio-economy and to ensure the traceability of these standards to the national metrology institute and the MRA;

### **Human Resources**

- Expand human resource development for the biotechnology industries through the NSERC, SSHRC, and the CIHR;

### **Commercialisation**

- Strengthen the capacity of federal research institutions and universities to create value through technology transfer and the creation of new industrial enterprises by building upon the strengths of the IRAP and CTN networks;
- Establish specialised incubation facilities for biotechnology and genomics-based companies co-located or close to major centres of biotechnology R&D infrastructure across Canada; and

### **Management**

- Encourage the development of networks of experienced managers and executives to mentor newly emerging start-up companies in biotechnology

- Increase support to biotechnology companies through the IRAP and CTN networks
- Increase the supply of personnel trained in technology management

### **Finance**

- Study the funding needs and opportunities of emerging companies in this sector and support the development of new support instruments including venture capital and co-development opportunities.
- Review existing instruments (IRAP, TPC, SDTF, AAFC MIP, TEAM, CCAF) and consider how these may be adjusted to support the needs of developing firms

## Positioning Canada as a Leader in the Bioeconomy

### Summary

The most promising area for Canada's further progress in the knowledge-based economy lies with the bioeconomy. The bioeconomy is characterised by rapid change and convergence of previously distinct industries and technologies. This convergence is driven by a transformation in the underlying science of biology into a field that is now characterised by vast quantities of precise information.

To stay competitive in this era of information biology, businesses have to learn how to manage and profit from the new knowledge; Government will play a key role. Canada is strong in two key drivers of this new era – biotechnology and information technologies. This provides a tremendous opportunity for the nation. However, in order to benefit, Canada will need to refocus its programs and resources to take account of the underlying convergence and transformation.

The federal government's posture must shift from the defensive to an active promotion of benefits. Federal regulators must become engaged in this shift if they are to keep up with the aggressive pace of development of the technology and if Canadians are to benefit.

The federal government must dramatically elevate the importance it attaches to the benefits that this area can deliver. The opportunities are as great as those provided by information and communications technologies. The federal government must take decisive action on three fronts:

- It must dramatically expand support for knowledge creation through research and development;
- It must recognise regional strengths and support emerging technology clusters; and
- It must ensure that its actions are effectively coupled to the innovation needs of Canadian industry.

Canada will need to act quickly because already there are clear indications that other nations are ahead of us in terms of new technology development and investments. In addition, there are signs that Canadian firms are significantly disadvantaged with respect to their competitors around the world.

The strategy will emphasise four interrelated and strategic applications and research areas:

- New Industry Applications;
- Health & Wellness;
- Sustainable Environment; and
- Research in Support of the Regulatory System.

## The Vision for the Bioeconomy in Canada

The science of biology is undergoing a dramatic and fundamental shift to a discipline characterised by vast quantities of information. Progress in biology has as much to do with information and communications technologies as it does with genes. This shift is producing enormous opportunities for benefits to society and the economy. Indeed, the development of the bioeconomy will be the grand challenge for Canada over the next two decades. It will provide Canadians with sustainable economic development; enhanced social and health benefits; and exportable technologies and products.

*Our vision is that Canadians will be amongst the first to benefit from the development of a sustainable bioeconomy.*

These developments are dependent upon advances in knowledge derived from traditional biology, genetics and metabolic engineering, and by the wave of developments in the modern information-based biology disciplines of molecular biology, genomics, proteomics, bioinformatics and biotechnology.

The same basic science and research has opened up unprecedented opportunities for advances in human health and wellness through improved pharmaceuticals, nutraceuticals, vaccines, functional foods and diagnostics. It also offers new opportunities in sustainable economic development and industrial processes all across the Canadian economy.

The emergence of the bioeconomy is inevitable. It is driven by major global economic trends including rapidly increasing global populations, increased purchasing power, an extreme shortage of arable land world-wide, and the need to take action to minimise global environmental impacts. These will result in an inevitable growth in demand for food, pharmaceuticals, and industrial products combined with an ever more urgent need to meet these demands within a sustainable economic development framework.

Vital national interests affecting every Canadian are involved and Canadians expect government researchers to remain actively engaged and to play a central role in these developments.

Canada has the opportunity to reap a triple dividend by becoming a lead player in the industrial development of the bioeconomy: sustainable economic development; enhanced health and social benefits; and exportable technologies and products. In order to succeed we must aggressively expand our knowledge base and we must sustain the development of Canadian industrial innovation capacity.

## The Bioeconomy

The explosion of discoveries in the biological sciences over the last decade have laid the foundation for widespread application of new knowledge and associated biotechnologies to new and emerging, as well as traditional, industries. Collectively, these developments are being referred to as the bioeconomy.

There is no doubt that the impact of biotechnology will be extensive. According to the Ernst & Young *Biotechnology Industry Report, Millennium Edition* biotechnology is positioned to reshape virtually every other industry it intersects with, as it is to redefine our lives. From agriculture to chemicals and manufacturing processes, from drug discovery to computer nanotechnology, biotechnology is creating platforms for new products and markets on many fronts.

However, the bioeconomy is not just about biotechnology, it is about a new way to integrate knowledge and conduct business. Bill Gates points out that the twenty-first century will also be about velocity: the speed of business and the speed of change. To stay up with and anticipate change, governments and businesses need radically better information flow. The successful companies of the next decade will be the ones that use digital tools to reinvent the way they work.

As convergence continues, the boundaries between the biotechnology industry and an array of disparate market sectors are blurring, leading to a large number of new, hybrid products.

For example, convergence of biotechnology is taking place with the chemicals industry. Industrial manufacturing processes have traditionally relied upon high temperature, high-energy noxious chemicals that produced hazardous wastes and excess phosphorus. Enzymatic reactions, however, can safely serve the same role; that is, to bring together reactants to promote the stability of the intermediate state of a reaction. The biocatalytic approach can be transferred from living systems to a variety of manufacturing processes. Enzymes such as lipases, proteases, cellulases, and amylases can be substituted for both noxious and high-temperature chemicals. This approach can be applied to a wide range of manufacturing areas, including the processing of grain, and the production of detergents, starches and textiles.

Around the globe, industry is shifting from chemistry-based solutions to biology-based solutions in response to the demand for environmentally sustainable industrial, agricultural, aquacultural, and silvaculture technologies. The shift concerns both the protection of the environment and the preservation of non-renewable resources. Biology-based solutions respond to the need for higher productivity with lower environmental impacts and lower chemical inputs to

production processes. There is clear evidence of these trends in the vast restructuring of the global chemical industry that has occurred over the past ten years. Most of the major players have divested their commodity chemical production businesses and most have aggressively sought out intellectual property positions in the bioeconomy through acquisitions of small biotechnology companies and through mergers. Others have responded by creating subsidiaries focussed upon opportunities in the bioeconomy.

A further example of convergence can be found in the emergence of genomics and proteomics, technologies that are predicted to revitalise a sagging pharmaceutical industry. Despite their huge investments the rate at which new drugs reach the market has decreased markedly over the past 15 years. On average, a typical top-tier pharmaceutical company now brings an innovative drug to market only once every 27 months. To achieve a healthy 10 per cent annual growth in sales revenues, however, the figure must exceed one new drug every six months. Genomics promises to give rise to an entirely new class of medicines that could rescue the pharmaceutical industry.

These new medicines will use human genes, proteins and antibodies to regenerate tissues that have been damaged by age, disease, or trauma.

Biotechnology has also expanded the diversification of agriculture by breaking down the barriers between sciences and bringing together scientists from fields that have traditionally not co-operated. Advances in molecular genetics and transformation technology have opened the door to a new industry, Molecular Farming. This emerging industry is providing economical and reliable platforms for the production of vaccines, therapeutic proteins, industrial enzymes and a host of other innovative and beneficial products. The use of plants, animals, insects and cell cultures as bioreactors for the commercial-scale production of recombinant proteins and peptides is one of the fastest-growing applications of biotechnology. Research and commercialisation activities are expanding rapidly. The potential for the development of high quality, cost effective health care products alone is substantial. Molecular farming technologies are fostering a revolutionary marriage of agriculture and health care. Molecular farming offers farmers the potential for development of new crops and new uses for crops. Through the diversification of agriculture, Molecular Farming could enhance the viability of rural communities.

Biotechnologies are also being applied in the areas of prevention and pollution control and the development of green technologies. Major areas of activity are bioremediation, monitoring tools, environmental chemistry, biopesticides, environmental ecotoxicology, and biosensors and industrial effluent treatment.

*The new knowledge derived from intensive research and development is the currency of the bioeconomy.*

Canada has an opportunity to be a clear leader in this explosion of new knowledge, ideas and benefits from biotechnology R&D. This will only occur if the nation takes deliberate steps to transform ideas into action, potential into reality, and discoveries into solutions.

*To capitalise on the opportunity, Canada needs to identify a clear strategy for the bioeconomy.*

This document presents a vision, centred on research and development and innovation, designed to ensure that Canada remains competitive and that all Canadians have the opportunity to benefit from the myriad of new products and services predicted to emerge from the new bioeconomy.

## World Trends

Canada is not alone in seeing the tremendous potential of the new bioeconomy. Other jurisdictions around the world have taken deliberate steps to attract bioscience researchers and investment and this is already having a negative impact on the growth of our own bioeconomy.

**Table I: Comparative Statistics for the Biotechnology Industry**

Factor	Canada	U.S.	Europe
Population / Million	30	270	727
Product Sales / \$M	\$979	\$18,460	N/A
Revenue / \$M	1,141	24,708	4,251
R&D Expenses / \$M	403	12,780	2,980
R&D Intensity	35%	52%	70%
Number of Companies	320	1,274	1,351
Average Revenue / \$M	5.1	19.4	4.1
Average R&D / \$M	1.8	10.0	2.9
Total Employees	11,000	140,000	53,500

As of August 2000, U.S., biotechnology companies had raised \$22.1B from public and private financing, almost double the \$12B amount raised in 1999, and nearly triple the \$8.1B figure in 1998.

By comparison, Canadian companies raised \$1.5 billion in the first six months of 2000. Recent studies published in 2000 (Ernst & Young, Burrill & Co.) indicate that the Canadian biotechnology industry in terms of size, investments and growth, has slipped from a second position behind the United States in 1998, to fourth place. This is certainly cause for concern. Canadians will not secure the benefits of the bioeconomy without a strong Canadian industry.

Other developed nations are gearing up in order that they might capture economic and social benefits within their borders. The USA is still the most important player with 1274 companies, employing 153,000, with sales of \$19B. However, Europe is rapidly closing the gap with 1351 companies, employing 53,500, with sales of \$5B. France and Germany have taken significant steps to establish leadership positions in biotechnology. Germany, for example, has grown its biotechnology sector substantially during the past five years. An estimated 400 start-up companies have emerged in this period. Over the past 15 years the number of scientists involved in biopharmaceutical research in France has grown by 50 per cent. The French government is committing US\$380 million over the next five years to support biotechnology companies and also offers investment tax incentives amounting to 25 per cent of R&D spending.

**Table II: Market Capitalisation of US Biotechnology Companies, November 2000**

<b>Technology Companies</b>					
Broad Enabling Technology: Market Leadership		Enabling Technology: Niche Player		Enabling Technology: Not Market Leader	
Millenium	\$13B	Maxgen	\$1.6B	Geron	\$0.6B
HGS	\$9B	Talarik	\$1.5B	Genaissance	\$0.45B
Abgenix	\$6.5B	Exelixis	\$1.5B	Dendreon	\$0.50B
Affymetrix	\$2.7B	Caliper	\$1.2B	Variagenetics	\$0.50B
		Orchid	\$1.2B		
		Sangamo	\$0.85B		
<b>Drug Discovery Companies</b>					
On Market with Sales		Phase III or NDA: Large Market		Phase III Niche Market	
IDEC	\$8B	Enzon		Isis	\$0.45B
Gilead	\$5B		\$2.6B	Coulter	\$0.50B
COR	\$3.4B	Praecis	\$1.8B	Vical	\$0.50B
		Tanox	\$1.4B	Intrabiotics	\$0.50B
		Avigen	\$0.7B	Antigenetics	\$0.35B



Canada must act now to ensure that it is not overwhelmed by the growing dominance of the US and European initiatives. We are in a period of rapid change and industry faces many challenges to stay competitive. In addition to genomics, proteomics, bioinformatics and high throughput drug screening, nanotechnology will be the next field to have a dramatic impact on scientific progress. Munster, Germany has been designated the site of the first European Centre for Nanotechnology. It will be opened in 2002 with an initial investment of DM14.5 million (approximately C\$20 million). In January 2000, the United States President Bill Clinton announced a US\$247 million nanotechnology initiative.

The speed with which genomics information is being commercialised is an excellent indicator of how the new bioeconomy is being developed and how countries can gain a competitive advantage. Genome sciences are transforming every aspect of the industry. In fact, genomics can be thought of as an industry sector to itself characterised by upwards of 100 companies, located principally in the US and Europe, that have emerged almost overnight. As of December 31, 1999, the combined market capitalisation of the top 20 genomics companies totalled over US \$26 billion.

However, as yet, Canada has no public genomics company.

## **The Biotechnology Industry in Canada**

Over the past fifteen years Canadian industry has developed an excellent foundation upon which to build a viable bioeconomy in Canada. In 1983, the federal government launched the Canadian Biotechnology Strategy recognising the potential that this new technology offered and aiming at building a biotechnology industry in Canada. The strategy provided significant public R&D, massive new infrastructure and co-ordination of biotechnology activities across government.

In the comparatively short period since the Strategy was initiated, Canadian biotechnology firms have brought products to market that will directly benefit Canadians. These products include:

- Drugs that treat AIDS;
- Treatments for age-related macular degeneration,
- Vaccines against meningitis and other childhood diseases;
- Improved varieties of Canola and winter wheat;
- Vaccines to protect fish health for aquaculture; and
- Engineered enzymes that replace chlorine in pulp bleaching and lower the environmental impacts of paper mills.

The strategy is well recognised as a success story of federal foresight and

action. Concerted R&D efforts across a number of jurisdictions, changes in the federal intellectual property regime, supportive actions within provincial formularies, and the emergence of a Canadian venture capital sector combined to create a biotechnology sector in Canada that is the envy of many nations around the world.

Today Canada has over 300 biotechnology firms that employ over 11,000 people with sales of well over \$1B.

In recent months, there has been a flurry of activity in the public markets as at least ten Canadian companies are preparing to file, or have already filed, Initial Public Offerings. In 2000, there have been three successful biotechnology IPOs: Arius Research Inc., of Toronto, Neurochem Inc. of Montreal, and Chromos Molecular Systems of Vancouver. Currently there are 70 publicly held Canadian biotechnology companies.

However, in Canada, our under-investments in genomics infrastructure have placed our firms at a competitive disadvantage with respect to the generation of intellectual property in this key domain for the next two decades. Without infrastructure there is little IP generated, without IP there is little comparative advantage for firms. Already, over 170,000 genes and gene fragments have been patented around the world. Canada does not yet have one major public genomics company. The only player of any note is MDS Proteomics, which is currently private, with a capitalisation of approximately \$600 million.

Other countries have already surpassed our nation's investment in biotechnology to the point where our biotechnology industry is under serious threat. There is an increase in venture capital flowing to biotech companies outside of Canada along with trained scientists, managers and IP. Financing difficulties mean that our mostly smaller Canadian companies are forming alliances with foreign firms to develop their products to the point where most new product development of Canadian biotechnology is done offshore. Our firms are also becoming prime targets for take-overs by larger heavily resourced firms because they are undervalued. We will lose our IP at bargain-basement prices while competing with aggressive new entities for venture capital and new infrastructure such as incubators, technology platforms, demonstration facilities, and technology transfer centres.

#### **Table III: The Biotechnology Industry in Canada**

**STRENGTHS**

- Presence of a small number of world-class pharmaceutical companies who are committed to investing 11% of sales in R&D activity in Canada
- Canada's history as successful pioneers in the agrifood sector
- Supportive venture capital community
- Strong higher education and research centres
- Ability to generate a pipeline of talented people
- Record of successful research capabilities and findings in medicine and related fields
- The cost of conducting research in Canada is considerably cheaper than in many competing countries, including U.S. and Western Europe

**WEAKNESSES**

- A large number of companies are in their early stages, where the survival risk is still high
- Decision-making for large Pharmaceutical companies operating in Canada is usually made at head-offices outside Canada. This slows down our ability to conclude more alliances
- Canada's industrial infrastructure and our existing cost structure does not play towards our ability to retain manufacturing activities
- Canada cannot rely on the demands originating from its local market alone
- Limited number of specialised venture capitalists with the expertise and network to support the growth of biotech companies
- Access to public financing markets is cyclical and unreliable
- With early rounds of financing being very small, senior management spends a disproportionate amount of time raising money rather than managing their business
- Almost all of our biotech companies are insufficiently capitalised to carry out the full development of novel drugs and must rely heavily on alliances from a very early developmental stage
- Regulations with regard to approval of new drugs in Canada tend to be slower than other jurisdictions – significant progress is being made in the US by the FDA to speed their process, to gain a competitive advantage
- Agbiotech companies suffer from low product margins, which makes capturing returns on long term product development more difficult
- The low product margins, and overall lower returns make it difficult to attract venture capital investment for agbiotech focused SME start-ups
- Consolidation in the agriculture industry, in the absence of strong SME formation, is causing more concern with respect to industry concentration and with it reduced competition, reduced industrial presence in Canada, and reduced private expenditures on R&D

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## **Developing the Bioeconomy in Canada**

There is no doubt that biotechnology, when fully developed, will bring at least as many benefits and positive impacts to Canadian society as ICT does. However, there is a reasonable doubt that these benefits would be capitalised and realised in Canada without sustained federal government investment for research and development and the innovation infrastructure supporting Canada's firms.

Governments must invest in this field as opposed to relying on industry investment because of the disproportionate level of capital infrastructure required, the length of time it takes for research products to make it to market, and the precompetitive nature of much of the basic research that industry requires.

## **Organising Principles and Governance**

As Canada acts to boost its research and development investments across all of these domains it must also ensure that its efforts are well co-ordinated and mutually supportive. This will require the development of new partnerships across federal departments and agencies, between industry and academia. It will also require that barriers to collaboration between these various sectors be torn down.

Currently, there are systemic barriers to the participation of Canadian government researchers in the national research agenda. These cause inefficiencies in the national and regional systems of innovation that support Canadian industry.

A new governance structure must be developed to co-ordinate R&D efforts across the various organisational structures so that the technology platforms for the bioeconomy may be developed most efficiently. This will require extensive consultation and co-operation between all parties and overall facilitation and co-ordination at the federal level.

### **Innovation Systems Support: Research and Development**

Research and development is central to all aspects of the development of this sector of the economy. The underlying science is undergoing tremendous shifts and there is a rapid expansion of knowledge. As indicated earlier, there is now a convergence of disciplines and formerly distinct industries which needs to be encouraged and supported if we are to take full advantage of the rapid expansion in this field.

To maximise the benefits derived from hitherto separate technology areas, we propose that R&D be enhanced under four interrelated and strategic applications areas that will support our industry and sustain our efforts towards leadership in this emerging bioeconomy:

- New Industry Applications,
- Health and Wellness,
- Sustainable Environment; and
- Research in Support of the Regulatory Regime.

Each area would have a series of supporting R&D efforts and would be anchored by application of strategic enabling technologies including:

- Bioinformatics
- Distributed, grid-based information systems and databases
- Functional genomics,
- Vectors for gene therapy
- High throughput screening
- Combinatorial chemistry
- Proteomics
- Structural genomics
- Metabolic profiling
- Systems biology
- Nanotechnologies and microfluidics
- Separation technologies
- Pilot plants and demonstration facilities; and

- Other new and emerging technologies.

It is essential that the federal government increase its investment in Genome Canada and in government laboratories carrying out genome related research. Funding for these initiatives must be extended and expanded.

Bioinformatics will continue to be a crucial enabling technology. There will be an essential requirement to rapidly expand the development of the Canadian Bioinformatics Network to cope with the anticipated massive increases in demand for data storage and processing capacity that will accompany the use of genomics technologies all across our economy. It will also be necessary to continue to develop Canada's high speed communications networks through CANAIRIE to allow the emergence of a distributed yet integrated research and bioinformatics capacity available within every hospital, university and research institute across Canada.

### **Innovation Systems Support: The Regulatory Regime**

Around the world, it is recognised that the quality of the regulatory regime has a profound influence upon the rate and effectiveness of innovation within a jurisdiction. Certainly, companies wish to be assured that the regulatory regime is efficient and that it fully protects the interests of consumers. In this regard, both the regulator and the regulated share a common interest. In addition, and principally because of the high costs of drug development and the limited window of time for patent protection, companies require a speedy processing of applications. In the USA, regulators have responded with increased efficiency and FDA approvals in the first six months of 2000 represented 75 percent of approvals granted during each of the two previous years and included a robust list of biotechnology products. Indeed, the mean time for FDA approval has fallen consistently over the past five years, from 30 to 10 months. Canadian companies need to be assured that the regulatory regime will be as efficient in this country as it will be in other jurisdictions.

The issues facing regulators in Canada continue to develop in scale and in complexity and regulators must keep up as the field develops. The field is exploding. For these reasons, it is essential that regulators remain coupled to the benefits agenda. Only by being up to speed on the science through a close involvement in research can regulators maintain the edge that will allow them to make informed and efficient decisions. In the same fashion, the benefits agenda will develop most effectively if its proponents are informed about the government's position on emerging public policy issues that may be addressed through regulation.

It remains to be seen whether the Canadian public will accept this proposed close coupling between regulators and the benefits agenda as in the public interest and it will be essential to address the question of the perception of

conflict-of-interest that such a positioning would inevitably raise.

### **Innovation Systems Support: Technology Clusters**

As a result of decisive federal government actions in the past, Canada has had remarkable success in developing regional technology clusters in the bioeconomy. Strong federal research institutions, effectively coupled to local universities and a growing cluster of local firms, catalysed the emergence of strong regional systems of innovation that provided the knowledge, people, capital and infrastructure for the efficient development of the bioeconomy in specialised locations across Canada. For example, NRC's Biotechnology Research Institute in Montreal has been very influential in helping to build the cluster of biotechnology companies focussed on human health in that region. The Plant Biotechnology Institute has worked with Agriculture and AgriFood Canada, local firms and universities to build Saskatoon into a centre for agricultural innovation. These locations have proven themselves better able to create, retain and grow new companies. They have also shown themselves to be able to attract direct foreign investment. This investment has further increased the attractiveness of these regions. However, recent federal investments have lacked the focus of the past. Moreover, they have not been directed towards these key federal government laboratories. Consequently, it has been reported that the biotechnology-related technology clusters may lose their momentum and growth and that industrial investment may slow or move offshore.

This should be contrasted with Canada's undoubted success in developing an indigenous ICT industry. Patient investments in federal research institutions like DND, CRC, and NRC contributed to Ottawa's success as a high technology cluster capable of attracting in companies and capital from outside our borders.

The presence in Ottawa of homegrown firms like Nortel Networks, JDS Uniphase, Newbridge, Mitel, Cognos, Jetform and Corel has encouraged direct foreign investment from around the world. In 2000 alone, Ottawa has seen significant investments from the USA (CISCO Systems), Finland (Nokia), France (Alcatel), and the UK (Marconi). In addition, foreign venture capital is beginning to flow to Ottawa to support the start-up and growth of local photonics companies. In August 2000, an Ottawa start-up company, Trillium Photonics, was created with \$10M from the Palo Alto venture capital Company, Mohr Davidow Ventures. Mohr Davidow has also announced that it has a US\$150M fund available to support start-up companies in the Ottawa region. Other sources of venture funding are derived from those experienced, Ottawa-based, technology managers who have withdrawn significant accumulations of capital from previous start-ups and who are comfortable investing in and guiding the development of new start-up enterprises.

The economic dynamic in Ottawa is the dynamic of a self-sustaining technology

cluster that has reached the critical mass for lift-off. This does not yet exist in any of Canada's biotechnology clusters. They are far from lift-off. The pace of development of biotechnology is an order of magnitude slower than that in ICT and the industry is young. This is the reason that governments must sustain their investments over longer periods of time.

### **Innovation Systems Support: Financing**

The Pathways to Growth document warns of a five-fold increase in the amount of capital needed over the next decade for our smaller biotech firms. This need is particularly urgent for proof of concept, early stage ventures, and in second and third round financing and in regions where VC is hard to come by (as in the Atlantic). Most Canadian VCs have shorter investment times than their US counterparts. The latter investors usually commit themselves for five to ten years until companies go public. Canadians VCs also commit on average less than comparable US firms. A united federal community needs to work together to use the same proactive techniques the ICT industry relied on to support early-stage firms to realise their promise and attract investment, to showcase these firms to financiers, and to provide links with financing programs that really work for smaller firms.

### **Innovation Systems Support: Incubation and Commercialisation Programs across Canada**

The special needs of our nascent biotechnology firms, that start out from universities\_or\_government and face many years of struggle before they can even begin to attract financing, has to be recognised. These firms have said that they require incubator facilities that link them into established powerhouse research organisations that have the scientists, facilities and resources to turn to. They also need business and management acumen and ongoing mentoring.

There is a need to ensure that all major communities across Canada have these facilities that spin-off and starts-ups can turn to. These incubator sites would be linked to larger research centres and offer the range of research, business and management services required.

The capacity of federal research institutions and universities to create value through technology transfer and the creation of new industrial enterprises must be strengthened by building upon the strengths of the IRAP and CTN networks.

### **Innovation Systems Support: NCEs**

The special needs of NCEs must also be considered. Some of these are related to health and biotechnology and form essential elements in the innovation system. Investment has to continue. As well, the special needs of commercializing IP flowing from NCEs must be accounted for in the Incubation



and Commercialization Programs noted above.

### **Innovation Systems Support: Technology Forecasting and Competitive Intelligence**

Strong technology foresight and competitive intelligence capacities should be established in Canada; there is a need to mount a world-class program that would build on established federal strength in biotechnology. A team of researchers, engineers, librarians and business experts would provide the core for a comprehensive initiative. The program would target technology foresight and competitive intelligence in biotechnology for government, universities and firms that would in turn identify key areas for future investment and growth.

### **Innovation Systems Support: Human Resources**

Industry is facing a shortage for specialists in management, scale-up and production as well as science in newly created fields such as bioinformatics. There is a need to increase the number of highly trained personnel through NSERC, SSHRC and CIHR.

### **Innovation Systems Support: Public Awareness and Education**

Public awareness and education relevant to acceptance of working and living in the bioeconomy era is a critical area that was not effectively dealt with during the implementation of the first wave of agricultural biotechnologies (late 1990's). It will be essential to fully involve the Humanities and Social Science Departments of Canadian Universities through the establishment of funded, multidisciplinary programs dealing with awareness and societal impacts, etc.

### **Strategic Applications and Research Area: New Industry Applications**

Industrial application efforts would centre on new products, new bioprocessing techniques, superior industrial processes, and increasing the value of by-products.

Research in this area would include:

#### ***Novel industrial products/processing systems***

A wide range of environmentally friendly, bio-based processes and products will play a major role within the bioeconomy. These include: novel/stable enzymes to be used in industrial processes; biodegradable plastics and other bio-polymers produced through genetically engineered crops and microbes; novel vegetable oils for industrial applications; novel bio-chemicals; and industrial starches produced from genetically modified plants for use in manufacturing processes and new products such as carbonless paper.

### ***Aquaculture***

Canada will lead the world in the focused application of all aspects of genome research to problems dealing with marine issues - aquaculture, fish disease, production enhancement (transgenic or enhanced traditional breeding), stock characterisation, fish nutrition, etc.

Global aquaculture production is proceeding at an increasing rate. Wild fish catch has peaked and in many areas of the world, and for many species, it is declining. Thus the increasing appetite for a healthier protein source in seafood is driving the increasing demand for cultured foods from the sea. Aquaculture products will also include biomaterials and health products.

Fish farms can pollute the environment. Technology and know-how is needed so farms can be located anywhere on land, where better control can be achieved of water quality, pathogen entry, escape of farmed fish to the environment, therapeutic output, pathogen escape from the farm, and siltation and other solids output.

### ***Agriforestry and Novel Forest Products***

The cultivation of rapidly growing woody species will offer new attractive economic opportunities for millions of hectares considered to be either marginal or unsuitable for traditional crops. Additionally, the genetic engineering of trees for superior/novel products can be expected to become a reality. Canada possesses more than 40% of the world's northern forests and should therefore be in a position to be the world leader in bio-based forestry technologies.

### ***Biofuels***

The application of advanced biological knowledge and technologies will make it economically feasible to product biofuels from plant biomass (including woody species). Research approaches will include modification of plant-based substrates as well as development of improved enzyme systems and novel microbial/fungal hydrolytic systems.

The achievement of this goal will require sustained R&D commitments from appropriate federal and university laboratories. The biofuels program would complement other major national energy programs.

### **Strategic Applications and Research Area: Health and Wellness**

With the ageing of North American population, there will be a shift towards different types of illnesses and the development of new therapies and therapeutics. There are also increased pressures to reduce health costs, and pharmaceutical firms are turning their attention more towards preventive medicines and diagnostics. The emerging fields of nutraceuticals and functional foods will continue to grow rapidly.

Advanced research in vaccine development, genomics-based drug discovery, and novel delivery systems will be key areas of activity in the next few decades.

The application of molecular farming technologies to produce valuable health care products (antibiotics, therapeutic proteins, enzymes) from genetically engineered plants, microbes, fungi, and animals will require continued research support to ensure viability for this new industry. The traditional interface between medical (nutritional/therapeutic) and agricultural production systems will be completely seamless in a fully functioning bioeconomy.

Technologies and research in this platform would include:

#### ***Comparative Genomics***

To study the changes in gene expression associated with diseased states (e.g. neurogenomics, cancer genomics) or with states of infection (pathogenomics). These studies would provide the technological infrastructure for the development of preventative strategies and better, more tailor-made therapeutics and improved vaccines.

#### ***Computer Modelling of Biological Systems***

A convergence of computer science and life science will be very important for various applications. One of these is the so-called "cybercell", i.e. computer models of living cells that could be manipulated to mimic the changes leading to diseased states. Such models could be used to test various interventions to prevent disease or to reverse damage. Computer models and computational approaches could also be used to design better vaccines, i.e. to find the antigen fragment that would elicit the strongest immune response.

#### ***Gene Therapy***

To develop a host of viral and non-viral vectors for gene therapy: adenovirus, retrovirus, adeno-associated virus, and non-viral vectors such as polymers and lipids. Centres to develop and supply these vectors already exist in the US (NIH) and France (Genethon, French government). A centre is crucial for providing high quality material, expertise and trained personnel for gene therapy in hospitals and research centres in Canada. Most of this material now originates from the US at very high cost.

#### ***Medical Devices***

Early medical diagnosis plays a critical role in the costs of the health care system and the state of the Canadian economy. The earlier a disease is diagnosed, the earlier it is treated and the better is the prognosis for the patient. Patients return to work earlier, work more productively, and contribute normally to the Canadian economy. The early treatment is done at a minimum cost to the health care system. Thus, both health care costs and the economy benefit from

a country's capability for early and accurate diagnosis of human disease.

Sophisticated medical instruments make many of the early diagnoses. Canada imports more than 90% of these instruments. These include CAT scanners, MRI scanners, ultrasound instruments, and X-ray machines. This occurs despite a good array of talent in the fundamentals of these areas in universities and institutes. Canada has no industrial leader in this field.

### **Strategic Applications and Research Area: Sustainable Environment**

The application of biosciences to environmental issues and challenges offers an important long-term approach to enhancing the quality of the environment. New enterprises based on the application of environmental technologies will emerge and thus environmental type industries could also be listed as examples of new bio-industries. However, substantial public R&D activity will be required, as much of the activity in this area will also be for "public good".

The needs and environmental challenges to be addressed by the environmental industry are mainly in the following areas:

- Pollution control and prevention (water, groundwater, air, soils)
- Environmental management and risks analysis
- Industrial sustainable development
- Climate change (greenhouse gases)

Key activities will include:

#### ***Developing an environmental management methodology***

It is important to develop a sound environmental management framework with which to assess environmental impacts and progress towards the objectives of sustainable economic development. This is a new and integrated discipline that takes a systems approach to the problem and measures the inputs, impacts and outcomes of technologies over their complete lifecycles. Without such a disciplined approach it is extremely difficult to assess the benefits of new technologies. Such an approach is essential if technology development and policy-making decisions are to be taken with a sound foundation.

#### ***Programs to stabilise/reduce greenhouse gas emissions***

A number of organisations have developed long-term R&D blueprints to address the climate change issue. The bioeconomy strategy should involve co-ordination of components of these blueprints. It is particularly important to ensure that these efforts are developed within a consistent and sound environmental management assessment approach in which a systems approach is taken to assess the integrated environmental impact and progress towards overall sustainability.

***Phyto/Bioremediation***

Genetic modification and/or plant microbial management approaches should be increasingly employed to reduce both inorganic and organic environmental contaminants. NRC along with Environment Canada, the University of Saskatchewan and the University of Guelph already have initiated some work in this area, however, a comprehensive long-term, strongly supported program needs to be established. Remediation technologies will offer opportunities for the establishment of a range of SMEs.

***Adapting plants and animals to tolerate enhanced environmental stress***

Genetic modification of crops and livestock would be required to adapt production systems to those environmental stresses associated with climate change. Even without anticipated changes associated with climate change, Canada's geographic position dictates that much of its areas are affected by environmental stress (cold, drought, salinity). Genes discovered through genomic approaches should be employed to develop productive strains with enhanced stress tolerance.

***Reduction/elimination of biohazards in Canadian water***

Application of biotechnologies in terms of advanced/efficient biondiagnostics and soil microbial and plant-based strategies should play a major role in complementary physical/chemical approaches to the effective stewardship of Canada's fresh water supplies. Animal vaccines to eliminate pathogens at source are also urgently required.

**Strategic Applications and Research Area: Research in Support of the Regulatory Regime*****Traceability of Standards***

Without an internationally accepted standards regime, trade in bioproducts will be restricted.

In this regard, it is important to note that member states of the European Union are beginning to require that all trade agreements ensure traceability of standards to the Metre Convention through the Mutual Recognition Agreement signed by 47 signatory nations. In practice this means that national standards must be traceable to the national metrology institute. Furthermore it means that national metrology institutes around the world must develop mutual recognition arrangements adequate to support international trade in bioproducts.

In Canada's case the statutory responsibility for metrology rests with the National Research Council and its Institute for National Measurement Standards. As yet the INMS has little capacity to support this requirement. In fact no Canadian standard in this area has the required traceability.

Consequently Canadian products may be exposed to non-tariff barriers.

The Advisory Committee on Science and Technology recently published the BEST report on the role of federal science and technology. This report recognises standards as a distinct area of government interest and a proper area for it's in house laboratory research.

The need to develop standards for bioproducts and genetically modified organisms that are traceable to MRA is an area that demands urgent federal actions.

## Conclusion

The transformations underway in biology, in particular its convergence with information and communications technology, will dramatically affect the lives of all Canadians and they will radically reshape our economy. For Canadians to benefit, the federal government must respond and actively pursue a benefits agenda based upon a strong research and development infrastructure that is closely coupled to the needs of Canadian firms. Unless this is done, Canadians will be bystanders as others develop the most important sector of the knowledge-based economy in the twenty-first century. Without strong Canadian firms the economic and social benefits encompassed by this opportunity will not be returned to Canadians.

The implications for the research enterprise are dramatic and they require a large-scale national response. The federal government must set out a bold national vision and strategy to ensure that Canadians can participate in the bioeconomy and to support our biotechnology firms. The strategy will require concerted action at all levels of government but with leadership vesting with the federal community. It will require a dramatic increase in the levels of investment in R&D and a significant re-investment in federal R&D initiatives around the theme of sustainable development of biotechnologies. The goal is to develop a suite of technology platforms that will support the bioeconomy in Canada.

Along with this revamping of federal R&D there must be parallel efforts to sustain a supportive environment for our firms. These initiatives would include programs for stronger links among universities, industry and governments, better commercialisation of R&D results from public and academic labs, and better access for firms to enabling infrastructure for biotechnology research.

Federal investments should be carefully targeted to support development of technology clusters in regions across Canada that have the potential to create, grow and retain new companies and thereby become strong attractors of incoming direct foreign investment.

## Recommendations

### Governance

- Develop a governance structure to co-ordinate government R&D efforts to develop the bio-economy in Canada;
- Manage federal research and development efforts against four strategic applications areas: New Industry Applications, Health and Wellness, Sustainable Environment; and Research in Support of the Regulatory Regime;
- Study and alleviate systemic barriers to the participation of federal researchers within the Canadian innovation system.

### Research

- Dramatically increase federal funding of R&D in order to develop enabling platforms in: Bioinformatics; Distributed, grid-based information systems and databases; Functional genomics; Vectors for gene therapy; High throughput screening; Combinatorial chemistry; Proteomics; Structural genomics; Metabolic profiling; Systems biology; Nanotechnologies and microfluidics; Separation technologies; Pilot plants and demonstration facilities; and Other new and emerging technologies;
- Convert funding for the federal genomics capacity from limited term to ongoing A-base;
- Increase the investment in Genome Canada and in government laboratories carrying out genome related research;
- Establish systems biology institutes for agriculture, aquaculture, and the environment, to parallel investments in the Canadian Institutes for Health Research;
- Establish computational biology and nanotechnology institutes and research capacity;
- Rapidly expand the development of the Canadian Bioinformatics Network to cope with the anticipated massive increases in demand for data storage and processing capacity that will accompany the use of genomics technologies all across our economy;
- Continue to develop Canada's high speed communications networks through CANAIRIE to allow the emergence of a distributed yet integrated research

and bioinformatics capacity available within every hospital, university and research institute across Canada;

- Strengthen the linkages between the Genome Centres and the Canadian Light Source and support efforts to establish a Canadian Structural Genomics capability;
- Support research efforts to develop an environmental management methodology and framework against which the environmental impacts and long-term sustainability of new technologies may be assessed

### **Innovation Support**

- Make significantly increased investments in federal biotechnology R&D institutions located within strong regional centres in order to strengthen Canada's existing technology clusters in biotechnology and position them for further growth and the attraction of increased direct foreign investment;
- Establish a technology foresight capacity within government;
- Make large-scale pilot plants, separation facilities, and technology demonstration facilities accessible to Canadian companies;

### **Traceability of Standards**

- Establish science to develop standards for the bio-economy and to ensure the traceability of these standards to the national metrology institute and the MRA;

### **Human Resources**

- Expand human resource development for the biotechnology industries through the NSERC, SSHRC, and the CIHR;

### **Commercialisation**

- Strengthen the capacity of federal research institutions and universities to create value through technology transfer and the creation of new industrial enterprises by building upon the strengths of the IRAP and CTN networks;
- Establish specialised incubation facilities for biotechnology and genomics-based companies co-located or close to major centres of biotechnology R&D infrastructure across Canada; and

### **Management**

- Encourage the development of networks of experienced managers and executives to mentor newly emerging start-up companies in biotechnology



- Increase support to biotechnology companies through the IRAP and CTN networks
- Increase the supply of personnel trained in technology management

### **Finance**

- Study the funding needs and opportunities of emerging companies in this sector and support the development of new support instruments including venture capital and co-development opportunities.
- Review existing instruments (IRAP, TPC, SDTF, AAFC MIP, TEAM, CCAF) and consider how these may be adjusted to support the needs of developing firms

**From:** Deacon, Stella: CBSec  
**To:** NCR4.OTTFP12 (AGRAVEL, afraser, JHOLLEBONE), NCR4.OTTF...  
**Date:** Thu, Oct 5, 2000 12:26 pm  
**Subject:** Notice for Biotechnology ADM Coordinating Committee on October 11, 2000, 2:00-4:00

Direction from Biotechnology Deputies on October 3

Deputies at their meeting on October 3 positively viewed the approach proposed by BACC to, in broad terms, evolve the federal biotechnology agenda from one of sound management to one of visionary leadership. In order to do this, Deputies have asked BACC to further refine sector strategies for biotechnology for the Deputies meeting on October 24th. To prepare, a BACC meeting has been scheduled on October 11, 235 Queen Street, 2-4 p.m., in 7-East Lobby boardroom, (proposed agenda attached).

Deputies further agreed that sector strategies be expanded to highlight recommendations for the government to expand the policy agenda in accordance with: incremental initiatives underway or planned (e.g. biosafety funding, GM food regulation); substantial visionary initiatives where Canada could truly take a leadership position (e.g. large scale biomass conversion); and horizontal initiatives (e.g. science and R&D) that cut across sectors (see template below).

Deputies further agreed that whatever the choices on transition timing, a federal biotechnology vision and integrated plan were still needed that were grounded on these strategies, as well as the management plan and governance structure to support them. They are looking to BACC for an expanded vision and direction.

#### Development of Sector Strategies

The new tack calls for the development of robust sector strategies that identify the role of modern biotechnology and the challenges and opportunities it presents to the sector for future development.

In addition, and as importantly, sector champions are to identify horizontal components of their sector strategies that could impact on other sectors and which would benefit from a system-wide horizontal approach.

For the BACC meeting of October 11 we are proposing that concise 2-4 page plans be prepared and presented by the sector champions or their representatives which highlight the major priorities into the next mandate and differentiate them by "management" (incremental, core functions) and "leadership" (new) initiatives. Given the agenda, no more than 5 minutes please.

A proposed template is attached for the sector strategies. Those who have already submitted material, please don't despair, revise. Sector champions or their representatives are to present their material at BACC, on October 11, understanding that it is preliminary.

Proposed Sector / Horizontal Champions (subject to final discussion at BACC):

Agriculture - Yaprak Baltacioglu → *has she contacted AG or had info prepared?*  
Health - Diane Gorman  
Environment - Robert Slater  
Forestry - Yvan Hardy  
Mining - Yvan Hardy  
? [ Bio-Products and Bio-Energy - Yvan Hardy and Yaprak Baltacioglu  
Fisheries - John Davis  
? [ Biotechnology - John Banigan

Please note that Peter Hackett of the NRC has advised that he will lead, through the R&D working group, a system-wide review of future science needs in order to build the bio-economy in Canada.

#### Management Structure and "Pillar" Champions

At the BACC retreat of September 22, three interim "pillar" champions were assigned: Diane Gorman for Stewardship; John Banigan for Benefits; and Robert Slater for Citizen Engagement. Time will be set aside for brief reports if available, on the status of the working groups under the pillars in order to further advance renewal of the CBS management framework. Attached is the current proposal for restructuring to support CBS implementation which had been previously distributed, with a proposed Working Group Structure by Pillar.

#### Critical Path

A proposed critical path is attached for discussion at BACC on October 11.

#### CBS Fund

This item was postponed from the BACC Retreat due to time constraints. Decisions will be sought in two areas: agreement on the 1999-00 Report; and strategic directions for allocating CBS 2000-01 lapsing funds. Please include the published report and memorandum previously distributed at the October 22 retreat in your briefing material.

Please note that a revised vision deck will be developed for the meeting. It will be distributed in advance if at all possible, or tabled at the meeting. We will also advise you if we are successful in finding a larger meeting room. 7-East Lobby Boardroom holds 14 around the table and about 10 observers.

Thank you  
Stella  
946-8928

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Attachment **MANAGEME.WPD** : Management Plan.wpd  
Attachment **TEMPLATE.WPD** : template sector plan.wpd  
Attachment **AGENDAOC.WPD** : agenda October 2000.wpd  
Attachment **CRITICA2.DOC** : critical path for distribution.doc

**CC:** NCR4.OTTFPI2 (MMEUNIER) , NCR4.OTTFPI6 (NNISHIKAWA) , OT...

## BACC Meeting of September 22, 2000

### Agenda Item 5 - The Management Structure for Delivering on the Government's Integrated Plan for Biotechnology

#### Attachments

1. Alternate Working Group Structure that would align with the three CBS policy pillars and priorities to deliver the CBS integrated plan into the next mandate.
2. Proposed Terms of Reference for the coordinating committee at the ministerial, deputy and ADM levels (BMCC, BDMCC and BACC) drawn largely from the original Memorandum to Cabinet (MC) seeking approval of the renewed Canadian Biotechnology Strategy (new proposals shown in red.)
3. Letter signed by the Prime Minister establishing the Biotechnology Ministerial Coordinating Committee.

#### For Consideration:

- The coordination machinery at the DM and ADM levels was established through the MC whereas the, Biotechnology Ministerial Coordinating Committee was established subsequently by the Prime Minister.

Is this appropriate for the CBS?

- **What working group structure is needed to deliver on the CBS integrated plan?**

While the current working group structure has worked effectively to achieve the early priorities of the CBS, and with Jim Mitchell's investigation of the roles and responsibility of the CBSec, it is timely to revisit it now. The question is what is the optimal structure for delivering on the government's *integrated* plan, and for communicating strategically the government's strategic message of *good governance* related to integrating in a balanced manner stewardship, benefits and citizen engagement agendas.

Members to re-examine the working group sub-structure that supports the coordinating committees with a view to making changes where appropriate.

Should the working groups be aligned by objective (stewardship, benefits, citizen engagement) rather than by function (e.g. R&D, regulation, intellectual property).

- **How do we make the new management structure work effectively?**

The core issue has to do with creating a vision that will attract the commitment of DMs, ADMs and their staff, and clarify accountabilities. Members to re-examine the terms of reference of the CBS coordinating committees with a view to clarifying the mandates, responsibilities and their personal commitment. For consideration:

- ADMs champions to oversee delivery of each of the three key CBS pillars (consistent with Jim Mitchell report of June 30, 2000).
- All federal initiatives of the CBS partners, with a significant biotech component, and which might impact on the delivery and/or perception of delivery, of the government's integrated biotech plan, come before BACC for review in term of consistency and balance of the overall government plan for biotechnology.

Canadian Biotechnology Secretariat  
21 September 2000

Attachment 1

**CBS ADM Champions and WG Chairs, 2000-2001**

Three Pillars: Stewardship, Benefits, Citizen Engagement

<b>CBS Theme</b>	<b>Working Groups/ Committees</b>	<b>WG Chair</b>
<b>I. Stewardship: Options for ADM Champion(s) - HC, EC, CFIA, DFO</b>		
<b>Enhancing the Regulatory System<sup>1</sup></b>	<b>Regulations</b>	<b>Health TBD Bart Bilmer Vic Shantora</b>
<b>Addressing Social and Ethical Issues</b>	<b>Ethics and Public Confidence</b>	<b>Tim Flaherty</b>
	<b>Genetic Privacy</b>	<b>Roy Atkinson</b>
<b>Science for Stewardship</b>	<b>Eco-System Science (likely to come under auspices of "5NR")</b>	<b>EC - TBD</b>
	<b>GM Food (Royal Society)</b>	<b>HC - TBD</b>
<b>Issues Management (new issues added as required)</b>	<b>GM Foods (science, labelling, regulation)</b>	<b>HC - TBD</b>

<sup>1</sup>Includes international initiatives such as CODEX, OECD, G-8 and Biosafety Protocol

**II. Benefits: Options for ADM Champion(s) - IC, AAFC, DFAIT, EC, HC, NRCan, NRC, Tri-Council, DFO**

<b>Supporting Health and Environmental Benefits</b>	<b>Health Benefits</b>	<b>HC - TBD IC - Emmy Verdun</b>
	<b>Environmental Benefits</b>	<b>Ed Norrena Tom Wright</b>
<b>Economic Growth</b>	<b>Economic Growth</b>	<b>Emmy Verdun</b>
	<b>Intellectual Property</b>	<b>Susan Bincoletto Bill Boddis</b>
	<b>International Trade</b>	<b>Claudio Valle</b>
	<b>Sector Strategies:</b> • <b>Agriculture / Agri-Food</b> • <b>Forestry/ Bio-fuels/Bio-mass</b> • <b>Fisheries / Aquaculture</b> • <b>Health / Bio-pharmaceutical</b> • <b>Environmental Solutions</b>	<b>Departments</b>
<b>Science for Benefits</b>	<b>R&amp;D</b>	<b>Judith Young Kelly Van Koughnet Ken Sato</b>
<b>Policy-Relevant Data Collection and Analysis</b>	<b>Data and Statistics</b>	<b>Fred Gault</b>

**III. Citizen Engagement: Options for ADM Champions - CBSec, IC, BACC Stewardship Co-Chair, EC *not* others!**

<b>Citizen Engagement</b>	<b>Corporate Communications</b>	<b>Stella Deacon / David Loudon</b>
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#### ***IV. CBS Operational Committees***

<b><i>CBS Fund</i></b>	<b><i>Interdepartmental Coordinating Committee</i></b>	<b><i>Norma Burlington</i></b>
<b><i>CBS Audit and Evaluation</i></b>	<b><i>Audit and Evaluation</i></b>	<b><i>Kimberly Empey</i></b>

S:\CBST\AMENU\Phase-4\BCC\BACC\Management Structure\Management Plan

Attachment 2

## **Terms of Reference<sup>2</sup>**

### **BIOTECHNOLOGY MINISTERIAL COORDINATING COMMITTEE (BMCC)**

#### **Mandate**

The BMCC is an executive coordinating body in which Ministers, collectively and individually can turn for discussion or advice on cross-cutting issues. The committee as a group, or individual Ministers, may refer issues to the external Canadian Biotechnology Advisory Committee (CBAC) for examination. In addition it provides broad guidance and receives advice from the coordinating bodies at the deputy and assistant deputy minister levels which are responsible for implementing the Canadian Biotechnology Strategy.

#### **Composition**

Coordinator: Minister of Industry

Members: Ministers from the Departments of Industry, Agriculture and Agri-Food, Health, Environment, Fisheries and Oceans, Natural Resources and International Trade.

#### **Modus Operandi**

The chair / coordinator will call and coordinate meetings on behalf of his colleagues. Meetings will be called as required typically annually in the fall as preparation for the budget cycle.

Ministers may also deal with issues off-line as, for example, when needed to approve joint documents such as Memoranda to Cabinet, Treasury Board Submissions, Communications with CBAC, and other forms of joint correspondence).

The Canadian Biotechnology Secretariat to provide support in the form of document preparation meeting logistics, and minute preparation.

#### **Accountability**

Ministers may bring forth progress reports or proposals to the Cabinet Committees on Economic or Social Union, or other cabinet committees, on behalf of BMCC as required.

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<sup>2</sup>Drawn largely from the Memorandum to Cabinet on the renewal of the Canadian Biotechnology Strategy. Substantive new proposals for consideration are shown in red.

## **Terms of Reference**

### **BIOTECHNOLOGY DEPUTY MINISTER COORDINATING COMMITTEE (BDMCC)**

#### **Mandate**

Provide strategic policy guidance and advice both to the Biotechnology ADM Coordinating Committee and the Biotechnology Ministerial Coordinating Committee.

Approves the CBS priorities and integrated work plan.

Monitors implementation of the CBS work plan.

#### **Composition**

Chair: Deputy Minister of Industry

Members:

Deputy Ministers from the Departments of Agriculture and Agri-Food, Health, Environment, Fisheries and Oceans, Natural Resources, and International Trade, plus the chair.

The president of the National Research Council.

The president-representative on behalf of the Tri-Council: Canadian Institutes of Health, the Natural Sciences and Engineering Research Council and the Social Sciences and Humanities Research Council

BACC Co-chairs to serve as *ex officio* members

#### **Modus Operandi**

The chair will call and coordinate meetings on behalf of his colleagues.

Meetings will be called as required but no fewer than twice annually, and always prior to a Biotechnology Ministerial Coordinating Committee meeting.

Deputy Ministers may also deal with issues off-line as, for example, when needed to approve joint documents such as Memoranda to Cabinet, Treasury Board Submissions, Communications with CBAC, and other forms of joint correspondence.

The Canadian Biotechnology Secretariat to provide support in document preparation, meeting logistics, and minute preparation.

#### **Accountability**

The BDMCC is accountable to the Biotechnology Ministerial Coordinating Committee.

CFIA  
lets  
off  
not

## **Terms of Reference**

### **BIOTECHNOLOGY ASSISTANT DEPUTY MINISTER COORDINATING COMMITTEE (BACC)**

#### **Mandate**

BACC to operate as the hands-on Management Board for implementing the Canadian Biotechnology Strategy (CBS). It would:

- advise BDMCC on strategic priorities and issues related to the CBS and its implementation;
- set operational priorities and provide overall management coordination for the development and implementation of the CBS and related initiatives;
- strike standing and temporary working groups as required, and commits ADM Champions, Chairs and members from among departmental officials, and the CBS secretariat.
- prior to Cabinet consideration, review major biotech related initiatives arising within the federal government to ensure consistency with the Canadian Biotechnology Strategy and the balance within and among the three policy pillars and priorities of the CBS integrated plan.
- monitor progress on the implementation of the integrated CBS work plan and make such adjustments as are required;
- commit departmental resources to achieve the agreed work plan;
- provide direction to the Canadian Biotechnology Secretariat and related departmental activities;
- recommend priorities and approve projects for funding from the CBS Fund; and
- propose meetings of the Biotechnology DM Coordinating Committee.

## Composition

### Co-Chairs:

CFIA to  
co-chair

Assistant Deputy Minister of Industry and a co-chair from one of the CBS departments whose mandate falls predominantly on the stewardship<sup>3</sup> side of the Canadian Biotechnology Strategy agenda, i.e., Departments of Health, Environment, and Agriculture and Agri-Food/CFIA, DFO.

The co-chair on the stewardship side would be rotational on a two year basis.

### Members:

Assistant deputy ministers from the Departments, Agriculture and Agri-Food, Health, Environment, Fisheries and Oceans, Natural Resources and International Trade, plus the permanent co-chair.

CFIA  
left off  
list.

The Vice-President of Research of the National Research Council.

A vice-president representative on behalf of the Tri-Council: Canadian Institutes of Health, the Natural Sciences and Engineering Research Council and the Social Sciences and Humanities Research Council.

Ad Hoc or time limited membership may be used to include ADMs from other departments or agencies that have CBS related responsibilities for issues that are under active review by CBAC (e.g., Justice, HRDC, TBS, Finance for Genetic Privacy issues)

## Modus Operandi

Meetings will be at the call of the co-chairs approximately every 4-6 weeks.

Rotational co-chair to serve for two year term.

ADM members or representatives who can speak to the issues to attend; observers only by invitation.

The Canadian Biotechnology Secretariat to provide support in document preparation, meeting logistics, and minute preparation.

## Accountability

BACC reports to the Biotechnology DM Coordinating Committee through its co-chairs who will will serve as *ex officio* members.

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<sup>3</sup>Stewardship refers to the mandate for protecting human and animal health as well as the environment, and to reflecting Canadian values.

## **Template for Sector Strategy for Biotechnology**

(As agreed at Meeting of Biotechnology Deputy Minister Coordinating Committee, October 3)

### **Vision for Modern Biotechnology**

- Role of Biotechnology
- Policy Objectives
- Goals

### **Context**

- Key Science Trends
- Competing Initiatives of Other Countries
- Public Opinion in Canada

### **Critical Sector Priorities (Ministers Need to Know About)**

1. Incremental initiatives underway or planned to effectively manage challenges of modern biotechnology applications within core mandate (risks and benefits), including funding and timing.

#### **Examples:**

- new human reproductive technologies;
  - funding for eco-system science;
  - ratification of Biosafety Protocol;
  - measures to strengthen regulatory system
  - management of GM food issues
2. visionary initiatives leading into the next mandate which would signal, domestically and internationally, that Government consider biotechnology a strategic technology and is prepared to undertake substantive initiatives to position Canada as a responsible and responsive world leader. Please include timing and funding.
- large scale biomass infrastructure plan

### **3. Horizontal Issues**

- Representing areas of common interest which the community should best approach collectively to ensure an integrated, horizontal approach, and a stronger voice for change.

#### **Examples:**

- Science
- Commercialization
- others

# Biotechnology ADM Coordinating Committee

WEDNESDAY, OCTOBER 11, 2000

Location TBD - 235 Queen Street

2:00 - 4:00 p.m.

## AGENDA

1. **Opening** *John Banigan*
  - ▶ Approval of Agenda
2. **Direction from BDMCC October 3<sup>rd</sup>**
  - ▶ The Path Forward to Develop Vision and Integrated Federal Plan on Biotechnology
3. **Development of Sector / Horizontal Strategies** *Champions*
  - ▶ Preliminary Presentation by Champions
4. **Management Structure to Support Implementation of New Vision**
  - ▶ Stewardship *Diane Gorman*
  - ▶ Benefits *John Banigan*
  - ▶ Citizen Engagement *Robert Slater*
5. **Critical Path**
6. **Preparation for Ministerial Meeting November 9**
  - ▶ Vision Deck
  - ▶ Review Ministers meeting agenda
7. **CBS Fund** *Norma Burlington*
  - ▶ Strategic Approach For Allocating Emerging Issues Fund
8. **Closing & Next Steps**

**Issue:** Critical Path for the Creation of an Integrated Federal Biotechnology Vision & Plan

**Objective:** To create a renewed and expanded biotechnology vision for the next mandate that will: implement substantive and integrated transition briefings of Ministers and map a process to make this vision happen.

Timing	Event	Vision Development
October	BACC Oct 11 BDMCC Oct 24	<ul style="list-style-type: none"> <li>- Identify leads and develop Sector Strategies &amp; strategic approach for select horizontal issues</li> <li>- Finalize vision deck which integrates sector &amp; horizontal initiatives from strategies to be rolled up under three pillars approach</li> <li>- Consider / affirm management structure to support new vision</li> </ul>
November December	BMCC Nov 9 BACC Mtg TBD  22	<ul style="list-style-type: none"> <li>- Present latest POR, renewed biotech vision &amp; plan, and CBAC update to Ministers</li> <li>- BACC meeting to review approach and approve a path forward to give direction to community on realizing renewed vision and plan</li> <li>- mobilize intramural community to engage / expand / finalize sector strategies (sector leads to coordinate community meetings) and horizontal strategies (horizontal champions to coordinate intramural community)</li> <li>- Input to Budget process as appropriate ??</li> </ul>
January / February 2001	BACC Meeting  Budget Announcement	<ul style="list-style-type: none"> <li>- Approve and implement integrated plan and recommendations on management and governance structure to deliver vision</li> <li>- Possible CCEU Information item on biotechnology (TBC)</li> </ul>
Spring 2001	Election?	-Initiate planning process for new policy cycle (SFT & Budget 2002)
Summer 2001	Government Returns Departmental briefings	- Sector & Horizontal leads to continue development of MCs that implement first phase of vision
Fall 2001		Bring MCs to Cabinet
February 2002	Budget Announcement	Biotech items funded

MC ??  
↓  
2002 only?



Prepared for BACC October 11, 2000

CBS

**From:** Nora Nishikawa  
**To:** GW1.X400."C=CA;A=govmt.canada;P=gc+ic;G=Stella;S=D...  
**Date:** Thu, Sep 28, 2000 6:49 pm  
**Subject:** URGENT - Material For Biotech Deputies -Reply

Stella,

Sorry, but we were unable to access the deck until late today. Further to the attachments, as per the BACC discussions, the separation of the business plan from the vision deck looks good.

We would make a small suggestion that the vision deck may need a bit more refinement to more clearly highlight key messages which are still a bit "buried" in some of the slide text. For example, the background is broad over the first 2 slides before you get to the slide outlining what has been done under CBS and that this approach worked. In particular on slide 6, the strong regulatory oversight should be linked to the strong desire expressed to see more long term research to support the system done.

The deck is near to what we believe was envisioned by BACC as taking the Ministers through the four stages of 1) this is what we have accomplished to date and it worked to meet immediate needs; 2) we are hearing through public opinion more about what public expects; 3) we can link these public expectations and questions to what we have to address as potential issues and gaps; 4) here is our proposed strategic direction as to how these new frontiers need to be addressed.

Look forward to seeing the final version to go to DMs.

Nora

>>> Deacon, Stella: CBSSec 09/28 9:48 am >>>

To Biotechnology ADM Coordinating Committee Members:

Please find attached an advance draft copy of documentation for the upcoming meeting of Biotechnology DMs on October 3rd.

- 1) A draft agenda (which included the agenda for the DMs meeting of October 24)
- 2) A draft "Vision" deck for discussion entitled "The Path Forward on the Biotechnology Strategy" -- New document as per BACC decision
- 3) A draft management deck for background entitled "Canadian Biotechnology Strategy: Developing a Business Plan for the Next Mandate" (background only)

Mr. Peter Harder, has been away so today at 3 p.m. will be our first opportunity to brief him in person on the meeting and to review material. We learned of the meeting yesterday. Therefore, could you please have a look in particular at the 13-page vision deck that is attached and let us know your views. A final package from Harder to his DM colleagues will be sent after he has had a chance to approve the material.

Further to your recommendation at the BACC meeting on September 22, discussion

at the first DM meeting on October 3 will centre upon the vision and forward agenda only; discussion at the second meeting on October 24 will broaden to include a presentation on the full POR results of our two surveys, the package of material going forward to Ministers, and the management plan and structure to deliver results on the renewed vision.

If you have any comments on the vision deck please direct them to me as Roy is attending a full meeting of CBAC for most of the day.

Thank you

Stella  
946-8928

Stella  
946-8928

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Attachment **AGENDAB0.WPD** : Agenda BDMCC Oct 3 2000 final.wpd  
Attachment **BIOTECHB.PPT** : Biotech Bus Plan.ppt  
Attachment **VISIONDE.PPT** : Vision Deck with Graphics.ppt

CC: OTTFPI2.JHOLLEBONE, bbilmer, OTTAWAEM2.Policy.Hews...

Meeting with D. Gorman

Oct 10,  
2000

CBS WG on Regs

- 1986 -
- Fed Framework →
- S/C on Env. Response
- CBS → MC
- TBS
- Petition
- Accountability
- CBAC.

Ongoing

- comment on regs
- intl events - OECD
- forum for issues

Future

- management of \$90M - accountability
- exchange of info
- BS Protocol impact → <sup>reg</sup> capacity bug
- RSC / CBAC Reports
- Parl. Reports → labelling?
- \$100K, \$400K → studies → reg "competitiveness" : benchmarking survey

other joint initiatives

- CERA Δs

- intl science

- resource person!

Mtg with D. Gorman.

→ Oct 24th - DM

→ 3 → risk; sector; gov structure.

- the public consults
- dedicate.

## Needs

- resources

- secretariat

- ID the chunks - how will the chunks be dealt with

↓  
HR → strategy! on staff! → train!  
→ data base!  
other...

comm

growth of products

BE - long term ecosystem research  
- share the work!

#0-SM

- ADM - Reg inspection.

- put forward a program

integrity

→ attracting people to

univ.

- only HC

- SET - Graduate app. strategy

- consumer - pa

- VS - to do a 1 p. summary

**From:** Atkinson, Roy: CBSec  
**To:** NCR4.OTTFPI2 (AGRAVEL, afraser, JHOLLEBONE), NCR4.OTTF...  
**Date:** Fri, Sep 29, 2000 1:28 pm  
**Subject:** Material for Meeting of Biotechnology Deputy Minister  
Coordinating Committee

*But, is someone going to this meeting?*

Please find attached a final copy of documentation for the upcoming meeting of Biotechnology DMs on October 3rd. The two attached decks have had some minor revisions based on comments received yesterday. Attachments include:

- 1) A draft agenda (which included the agenda for the DMs meeting of October 24)
- 2) A draft "Vision" deck for discussion entitled "The Path Forward on the Biotechnology Strategy"
- 3) A draft management deck for background entitled "Canadian Biotechnology Strategy: Developing a Business Plan for the Next Mandate" (background only)

Thank you,

Roy

*No. 4.*

*Please follow up with Andros. This deck is a bit better than Thursdays - the key messages are there, but not highlighted as suggested or in the order suggested.*  
*pt*

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Attachment **AGENDAB0.WPD** : Agenda BDMCC Oct 3 2000 final.wpd  
Attachment **VISIOND0.PPT** : Vision Deck with Graphics final.ppt  
Attachment **ANXABIO0.PPT** : Anx A Biotech Bus Plan 03.ppt

**CC:** NCR4.OTTFPI6 (NNISHIKAWA), OTTAWAEM2.POLICY (labellm, ...

## **Biotechnology Deputy Minister Coordinating Committee**

**235 Queen Street, 11<sup>th</sup> Floor  
Executive Boardroom**

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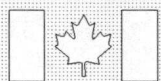
### **October 3, 2000 4:00 p.m. to 5:00 p.m.**

- |             |  |                            |
|-------------|--|----------------------------|
| 4:00 - 4:05 | 1. <b>Opening Remarks</b>  | <i>Peter Harder, Chair</i> |
| 4:05 - 4:50 | 2. <b>The Canadian Biotechnology Strategy:<br/>Looking Ahead to the Next Mandate<br/>"Vision" Deck : "The Path Forward<br/>on the Canadian Biotechnology Strategy"</b> | <i>John Banigan</i>        |
| 4:55 - 5:00 | 3. <b>Next Steps</b><br>BDMCC October 24, 2000   | <i>All</i>                 |

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### **October 24, 2000 9:00 a.m. to 11:00 a.m.**

- |               |   |  |
|---------------|---|--|
| 9:00 - 9:05   | 1. <b>Opening Remarks</b>   | <i>Peter Harder, Chair</i>                                   |
| 9:05 - 9:30   | 2. <b>Update on Public Opinion Research</b>   | <i>Elly Alboim</i><br>Earncliffe Research<br>& Communication |
| 9:30 - 10:30  | 3. <b>Ministerial Presentation<br/>&amp; Briefing Package</b>   | <i>John Banigan</i>  |
| 10:30 - 10:50 | 4. <b>Management Plan for CBS</b><br>Draft Terms of Reference for Three Coordinating<br>Committees (Minister, DM and ADM) | <i>Diane Gorman</i>  |
| 10:50 - 11:00 | 5. <b>Next Steps</b><br>BMCC November 9, 2000   | <i>All</i>   |



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# *The Path Forward on the Canadian Biotechnology Strategy*

A Deck for the Biotechnology Ministerial  
Coordinating Committee (BMCC)

Draft for Discussion by BDMCC

October 3, 2000

Canada



## *Global Acceleration of R&D*

- ◆ Biotechnology research and development (R&D) expanding exponentially around the world (\$20B in 1995 to \$50B in 2005)
- ◆ Canada: Genome Canada, Canadian Institutes of Health Research, Canadian Foundation for Innovation, etc
- ◆ Human Genome sequenced, global race for applications
- ◆ U.S. government last year largest peace time increase in R&D budget - Bush and Gore both promise to double health R&D spending
- ◆ In 1998, Canada spent \$2.5/capita vs \$7 in Japan, \$9 in France, \$14 in UK and \$15 in U.S.



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## *Economic Growth*

- ◆ Canadian biotechnology industry generated \$1.1B in revenue compared to \$6.2B for EU, and \$25.7B for U.S.
- ◆ Canada rated 2<sup>nd</sup> (282) in companies in 1997 next to U.S. (1,283)
- ◆ UK expected to overtake Canada in number of firms
- ◆ Canadian companies spent \$585M on R&D compared to \$760M for UK and \$13.3B for U.S.
- ◆ Need to strengthen biotech capacity to retain international position



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# *Supportive Public Environment*

- ◆ Public confidence
  - ◆ Non-Government Organizations genetically modified food (GM Food) campaign did not capture public attention
- ◆ Public remains cautiously optimistic
  - ◆ Significant majority (61%) positive to biotechnology with entrenched negative minority (9%)
- ◆ Government has “yellow light” to proceed
  - ◆ Expects Government to be vigilant regulator
  - ◆ Supports seeking benefits while managing risks (87%)
  - ◆ Health, environment and economic benefits are top priorities



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# *Successful Management of Canadian Biotechnology Strategy*

- ◆ **Balanced Approach**
  - ◆ Regulatory enhancement
  - ◆ Genomics R&D funding
  - ◆ Response to Auditor General's petition
  - ◆ Canadian Biotechnology Advisory Committee (CBAC)  
Creation
- ◆ **Pro-active Low Profile GM Food Management**
- ◆ **Clearer separation of Government's promotion and regulatory functions**



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## *Time to Shift Gears ...*

- ◆ We are doing more but still falling behind
- ◆ Canadian position is eroding vis-à-vis other countries
- ◆ Public expects and will reward :
  - ◆ Strong regulatory oversight
  - ◆ Capturing of health, environment & economic benefits
  - ◆ Action to address critical social & ethical issues
- ◆ Issues are accelerating - visible pro-active leadership needed
- ◆ Time to shift gears and ramp up



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# *Vision and Leadership: Goals for the Mandate*

- ◆ Ramp up pro-active federal leadership to:
  - ◆ Build recognition for Canada as responsible world leader
  - ◆ Situate as smartest in developing/applying biotechnology
  - ◆ Support Finance Minister seeking improvement in Canada's R&D investment to gross domestic product from 15<sup>th</sup> in Organization for Economic Co-operation and Development to 5<sup>th</sup>
    - ◆ Biotechnology must keep pace and establish measurable goals
  - ◆ Ensure second to none in stewardship
    - ◆ World class science-based, standards, and regulatory regime
  - ◆ Provide timely management of critical social and ethical issues



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## *Next Six Months*

- ◆ Manage GM Food Issue
  - ◆ Royal Society, Labelling - Canadian General Standards Board (CGSB), CBAC
- ◆ Ensure Budget 2001 Delivers Biotechnology:
  - ◆ Eco-system Science investment
  - ◆ Biosafety Protocol investment
  - ◆ GM Food measures to address anticipated recommendations from Royal Society
  - ◆ Biotechnology prominent in other budget items
    - ◆ e.g., R&D investment, commercialization, venture capital, seeding of biotechnology clusters, human resources
- ◆ Publish Integrated Management Plan for Canadian Biotechnology Strategy (CBS)



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# *Delivering the Integrated Management Plan*

## ◆ Under Three Pillars:

- 1) Programs to Capture Benefits
- 2) Visible Leadership for Stewardship
- 3) Enhanced Information, Education and Citizen Engagement



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## *Capturing the Benefits*

- ◆ Focus on health, environment and economic
- ◆ Increase R&D funds
- ◆ Accelerate commercialization
  - ◆ technology transfer, increase risk investment capital, supply of highly qualified staff and training
- ◆ Nurture vibrant biotechnology clusters
- ◆ Promote international market access
- ◆ Develop and implement sector strategies



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# Stewardship

- ◆ Invest in R&D to underpin regulatory system
  - ◆ science on long term health & environment risks
- ◆ Address regulation science for future GM Foods
- ◆ Lead development of international science-based standards
  - ◆ Biosafety, food safety, World Trade Organizations
- ◆ Lead capacity building for developing countries
- ◆ Timely management of social issues
  - ◆ e.g., human cloning, fetal stem cell research, germ line therapy, genetic privacy, patenting of higher life forms



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# *Citizen Engagement*

- ◆ Implement CBS communications plan
- ◆ Provide clear accessible information to public
- ◆ Explore with Provinces educational opportunities
- ◆ Provide opportunities for citizens to engage in debates on key public issues



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## *What's next ...*

- ◆ Building on demonstrated foresight and successful approach to issue:
  - ◆ Manage short term (6 months) agenda
  - ◆ In new mandate - shift gears to accelerate visible, proactive federal leadership to implement CBS
  - ◆ Build on existing horizontal coordination structure put in place by Cabinet and Prime Minister



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# Canadian Biotechnology Strategy: Developing a Business Plan for the Next Mandate

October 2000

Draft 3 00.09.28

Canadian Biotechnology Secretariat

1

000193

# Planning the Biotechnology Strategy

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- ❑ The Canadian Biotechnology Strategy (CBS) provides the means to coordinate efforts of partner departments and agencies, to strengthen the three CBS pillars (Stewardship, Benefits, Engagement),
- ❑ Biotechnology-related initiatives take the form of:
  - ▶ CBS-coordinated horizontal initiatives
  - ▶ Relevant non-CBS horizontal initiatives
    - e.g., Biodiversity Convention (Biosafety Protocol), WTO, Climate Change
  - ▶ Department/agency initiatives
- ❑ The success of the CBS is measured by two mission-critical deliverables:
  - ▶ Public confidence in the regulatory system and in the means to address social and ethical issues
  - ▶ Benefits for Canadians in the areas of health, environment and the economy

# Maintaining Public Confidence

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- ❑ The Government's impact on public confidence will primarily be determined by:
  - ▶ Credibility of the regulatory system for protecting human health and the environment
  - ▶ Adequacy of support to the science underpinning of the regulatory system
    - Particularly with respect to long-term health and environmental issues
  - ▶ Commitment to addressing key social and ethical issues
    - Notably: cloning of human beings, stem cell research on human fetal tissue, genetic privacy, germ line therapy
  - ▶ Effectiveness of the effort to address GM food issues
  - ▶ Extent and quality of publicly-shared information on biotechnology issues
  - ▶ Quality of public dialogue on value-based, safety and environmental issues

# Delivering Benefits for Canadians

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- The effectiveness of the Government's efforts to support the generation and capturing of benefits will primarily be determined by:
  - ▶ Adequacy of R&D funding to support the science base
    - Human health
    - Environment
    - Agriculture
    - Natural resources
  - ▶ Policies and initiatives to stimulate commercialization and application
    - Technology transfer from labs to industry
    - Increased foreign and domestic investment capital
    - Growth of vibrant biotechnology clusters
  - ▶ Effective sector strategies for commercialization
  - ▶ Adequate supplies of highly qualified human resources
  - ▶ Success in promoting international market access for Canadian products



# CBS Business Planning for the Next Mandate

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- ☐ Achieving these critical deliverables requires an Integrated Business Plan
- ☐ The plan outlined in following pages identifies initiatives under way and planned, indicating areas for potential new investment
  - ▶ Short term (now to mid-mandate)
  - ▶ Medium term (second half of mandate)
- ☐ CBS partners are undertaking and developing initiatives in five key areas:
  - ▶ Enhancing the Regulatory System (Stewardship Pillar)
  - ▶ Addressing Social and Ethical Issues (Stewardship Pillar)
  - ▶ Supporting Health and Environmental Benefits (Benefits Pillar)
  - ▶ Fostering Economic Growth (Benefits Pillar)
  - ▶ Informing, Educating and Engaging Canadians (Engagement Pillar)
- ☐ Support for the science base plays a key role in all these areas

# 1. Enhancing the Regulatory System *Stewardship*

Objective: minimize risks to Canadians while positioning Canada internationally as a responsible leader in biotech regulation

□ Initiatives: First half of mandate and on-going

- ▶ Apply Budget 2000 Resources to enhance regulatory system (under way)
- ▶ Biosafety Protocol: Consult and ratify (DFAIT, EC)
- ▶ Canadian Environmental Protection Act: “Scheduling” of legislation (EC)
- ▶ Biodiversity Convention: Negotiation on access to genetic resources (EC)
- ▶ Granting Councils: Seek additional funding for biotech-related science (IC)
  - social and ethical issues (SSHRC)
  - basic science support (NSERC)
- ▶ Legislation and regulations: Develop or revise
  - Health Protection Act, CFIA legislation, aquatic biotech regulations, New Human Reproductive Technologies Bill
- ▶ GM Food: Respond to recommendations (HC, AAFC, CFIA, EC, DFAIT)
  - Royal Society Expert panel on Future of Food Biotechnology (possible Budget implications)
  - CBAC Consultation on GM Food Regulation
  - House of Commons Standing Committee on AAF Report on Labelling
- ▶ Strengthening Ecosystem Science: Seek funding in Budget 2001 (EC and others)

Continued...

## *Stewardship*

# 1. Enhancing the Regulatory System (cont.)

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### ☐ Initiatives: First half of mandate and on-going (continued)

- ▶ Scientific foresight capacity (CBS R&D Working Group)
  - Needs assessment and design (2001); Seek funding (2002)
- ▶ Policy Review for regulation of “Second Generation” products
  - Nutraceuticals, functional foods, molecular “pharming”, bio-mass (HC, CFIA, EC)
- ▶ Participation and leadership in international fora (DFAIT lead) → *HC, CFIA*
  - Develop principles for food safety assessments, labelling (CODEX, OECD, G-8)

### ☐ Initiatives: Second half of mandate

- ▶ Biosafety Protocol: funding to implement (DFAIT, EC)
- ▶ Policy review of novel therapeutic genetic interventions
  - Gene therapy, tissue engineering (HC, CIHR, IC)
- ▶ Proposal for regulation of “Second Generation” products
  - Nutraceuticals, functional foods, molecular “pharming”, bio-mass (HC, CFIA, EC)

## 2. Addressing Social and Ethical Issues

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Objective: Involve both experts and public in advising government on social and ethical implications of biotechnology

□ Initiatives: First half of mandate and on-going

- ▶ New Human Reproductive Technologies, stem cell applications: Legislation (HC)
- ▶ Financing of human stem cell research: policy and guidelines (CIHR)
- ▶ Genetic Privacy (research, insurance, employment, medical, health issues): Scope issues and options
  - Comprehensive review of privacy legislation (Justice)
  - Policy research, possible consultations (CBAC)
  - CBS Genetic Privacy Working Group (CBSec coordinating)
- ▶ Late-Onset Genetic Diseases: Expert Working Group (HC)
- ▶ Xenotransplantation: public consultations on social and ethical issues (HC)
- ▶ Policy research on reconciling non-science (value-based) issues with science-based regulatory system (CBAC, HC, EC)

□ Initiatives: Second half of mandate

- ▶ Ethics Framework: Develop and consult (CBAC)
- ▶ Genetic Privacy: Policy recommendations (responsible departments/agencies)

## *Benefits*

# 3. Health and Environmental Benefits

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Objective: Support development, application and commercialization of health and environmental benefits of biotech

### *Health Benefits*

- ❑ Initiatives: First half of mandate and on-going
  - ▶ Implementing CIHR (HC)
  - ▶ Public Health Advantage: Research and application of biotechnology to diagnosis, surveillance, prevention, treatment (HC, CIHR, Genome Canada)
  - ▶ Late-Onset Genetic Diseases: Policy Analysis (HC)
  - ▶ Technology Foresight for Health Applications and Costs (HC)
- ❑ Initiatives: Second half of mandate
  - ▶ Health R&D and Application: Refinancing CIHR (HC) and Genome Canada (IC)
  - ▶ Policy & Guidelines on potential/cost of novel biotech applications (HC)
  - ▶ Late-Onset Genetic Diseases: Implement Policy (HC)

Continued...

## *Benefits*

### 3. Health and Environmental Benefits (cont.)

---

#### *Environmental Benefits*

- Initiatives: First half of mandate and on-going
  - ▶ Environment Solutions Strategy for technology development, application and commercialization (EC, IC)
  - ▶ Environmental remediation of federal sites (EC)

## 4. Supporting Economic Growth

---

Objective: Support commercialization by developing a business climate in which the biotech industry can create benefits and by promoting international market access

### *Commercialization*

- ❑ Initiatives: First half of mandate and on-going
  - ▶ Economic Growth Strategy (IC)
    - Enhance early stage commercialization
    - Review capital requirements for the industry
    - Partner on Technology Foresight
    - Facilitate skills development
    - Foreign investment
    - Tax measures
    - Alternatives to encourage venture capital investment in biotech
  - ▶ Intellectual Property: Revise Patent Act (IC)
    - Patenting higher life forms
    - Patenting genetic material
  - ▶ Sector Strategies (AAFC, HC, EC, Forestry, Aquaculture)

Continued...

## 4. Supporting Economic Growth (cont.)

---

### *International Trade*

#### □ Initiatives: First half of mandate and on-going

- ▶ Investment Promotion: “Branding Canada” strategy (IC, DFAIT)
- ▶ WTO and other multilateral and bilateral fora (DFAIT and others)
  - Prepare for next round of trade negotiations
  - Multilateral activities (OECD, G8, etc.): Develop position on human, animal or environmental health and safety in relation to biotechnology
  - Codex Alimentarius Commission: develop Canadian position on labelling of GM Foods
  - Monitor and respond to bilateral trade regulations



## 5. Informing, Educating and Engaging

---

Objective: Ensure public access to balanced information and opportunities to participate in discussion of biotechnology issues of significance to Canadians

□ Initiatives: First half of mandate and on-going

- ▶ CBS Communications Strategy: Implement (CBSec)
  - redesigned CBS Web site and content
  - Public Report on Progress and Future Directions
- ▶ Departmental communications initiatives supporting CBS: Develop and implement under CBS umbrella (all partners)
- ▶ Biotechnology Gateway Site about to be launched (IC)
- ▶ Support to third party stakeholders communicating on biotech (e.g. Food Biotechnology Communications Network)
- ▶ New initiatives to educate public on biotech: Scope potential for federal-provincial cooperation (CBSec)
- ▶ CBAC “National Conversation” on major cross-cutting initiatives engaging Canadians: Support (CBSec)

# Conclusion

---

- ☐ The partners in the Canadian Biotechnology Strategy are continuing to develop the Integrated Business Plan and its component initiatives
- ☐ Many items represent the application of resources committed by the Government during the past two years, including:
  - ▶ Strengthening the regulatory system
  - ▶ Increasing support for intramural research
  - ▶ Funding CIHR and Genome Canada
- ☐ Some planned items will involve substantial new investments
  - ▶ Proposals for funding will be developed and put forward as appropriate
  - ▶ The CBS Integrated Business Plan will provide the overall context in which the Government can view such proposals

**From:** Bart Bilmer <bbilmer@cyberus.ca>  
**To:** NCR4.OTTFPI6(bbilmer)  
**Date:** Sat, Sep 23, 2000 1:51 pm  
**Subject:** [Fwd: Comments on DECK]

**From:** <Deacon.Stella@ic.gc.ca>  
**To:** AGCAN.INTERNET("bbilmer@cyberus.ca")  
**Date:** Mon, Sep 18, 2000 8:42 am  
**Subject:** RE: Comments on DECK

thanks Bart

-----Original Message-----

From: Bart Bilmer [mailto:bbilmer@cyberus.ca]  
Sent: September 17, 2000 10:42 PM  
To: Deacon, Stella: CBSec  
Cc: Atkinson, Roy: CBSec; jhollebone@em.agr.ca  
Subject: Comments on DECK

Hello Stella,

As requested, a few comments that I hope will be helpful in developing the next draft of the BMCC DECK. Again, I congratulate you all for pulling together a cohesive, coherent DECK on the widest of possible topics! It is not easy ...

I hope the following comments will be useful to you.

Bart

Slide 2: A further purpose may be to identify key priorities for funding in Budget 2001.

Slide 4: Under Stewardship, 2nd bullet, we may wish to identify the response to the petition by the Sierra Club as an achievement (note that the Royal Society & CBAC have not yet completed their reviews and consultations; voluntary labelling standard is still under development). May wish to identify the establishment of these processes as the achievements.

Under Engagement, could identify the management of a number of public issues by Departments / Agencies as achievements.

May wish to consider consolidating slides 4 and 5.

Slide 5: Under stewardship, 2nd bullet: Add HC.

Slide 6: Need to identify that we will want to give special priority or attention to one or two key issues.

Slides 8 to 17. Suggest identifying the pillars related to each of these slides, as per slide 7. After going by a few slides, it is easy to forget which activity is linked with which pillar.

Slide 8. May wish to indicate that we will have to respond to the Standing Committee Report on Labelling.

Under bullet 6, it is not expected that the CFIA's newest act (which

will not be called the CFIA Act) will be introduced in this mandate (and btw, it will not give authority for mandatory labelling).

Reworked bullet 8, as requested: (Currently the emphasis on precautionary principle in the DECK is greater than it merits, considering other ongoing international initiatives in which the PP is only one sub-component)  
Participating and leading in international fora, e.g. Codex, OECD / G-8  
- Development of international principles for food safety assessments, labelling and the precautionary principle

Slide 10: Suggested rewording: "Objective: Strengthen basic and applied R&D capacity to support the regulatory system and to protect health and the environment"

Bullet 2, 1st sub-bullet: should probably be moved to slide 9.

Slide 11. Has IC's ethics web site come on line? Do you wish to include it here?

Slides 12 & 13. You may wish to consider consolidating these 2, as there are 4 bullets under the "Benefits Pillar"--probably one too many.

Slides 14 & 15. May wish to consolidate into 1 slide.

Slide 16. May wish to be clearer on what "biotech benefits" mean, e.g. the development of new products of benefit to these sectors, e.g. new variety of wheat, new tools to monitor fish populations, etc. that will result in economic gains for Canada

Slide 17. One bullet under the "Engagement" pillar, makes this pillar seem rather weak. May wish to consider expanding on what is there, e.g. add "Supporting communications work of stakeholders," etc. You may wish to consider putting the "Engagement" pillar first, as it may be more top of mind for Ministers.

Slide 20: Again, may want to narrow to key, essential priorities for funding, e.g. in next 1-2 years, and 3-5 years. An examples may be: addressing marketplace and social policy issues to ensure benefits of biotechnology are realized, i.e. removing marketplace barriers.

BACE

Sept. 22, 2000

RA

G. Miller

C. H. R.

- AM - Oct. 5<sup>th</sup>, 24<sup>th</sup>
- MR - Nov.

Valler

S. B.

rev. S

Slater -

th ? - A. A. E.

Gorman

Adams (Hackett)

Alboin

BAEC

- new IC DM
- interested in biotech.
- transition is a focus
- need to focus on key provided by CBAC
- part of higher life.
- due to recent court decisions, growing
- CBAC accelerate its IP work.

## 2. DM / Min Agenda

- too ambitious
- DM - Oct 3
- Oct. 29

## 3. Update on POR

- 1<sup>st</sup> - last Oct ; 2<sup>nd</sup> ; Feb 2000

3<sup>rd</sup> - 2 surveys - tracking + regulat.

+ focus grps

- 750 interviews completed on each.

- no funds & in engagement

- "resigned" optimism + underlay of concern

BACE

Sept. 22, 2000

RA

G. Miller

C. H. R.

V. L. R.

A. R. S. B.

J. D. S.

J. S. L. R.

Judith ? - A. R. S.

D. G. R.

G. Adams (H. R. S.)

E. Alboin.

- DM - Oct. 5<sup>th</sup>, 24<sup>th</sup>.

- MR - Nov.

- new IC DM

- interested in biotech.

- transition is a focus

- need to focus on key opportunities  
provided by CBAC, RSC

- part of higher life forms

- due to recent court decisions, should

CBAC accelerate its IP work.

2. DM / Min Agenda

- too ambitious

- DM - Oct 3

- Oct. 29

3. Update on POR

- 1<sup>st</sup> - last Oct ; 2<sup>nd</sup> ; Feb 2000

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+ focus grps

- 750 interviews completed on each.

- no funds in engagement

- "resigned" optimism + underlay of concern

- strong endorsement of managing risk  
+ ~~fast~~ moving towards benefits
- conveying upon govt a special response
  - want govt to manage risks
  - concern re: env. implications !!
  - ~~moving up in concern~~
  - food & ag. less a concern
- awareness levels growing :  $> 1/2$  have seen (750%)
- interest is lower : (12 + 44 vs 15 + 49 % Feb)
- true to - biotech. - increased vulnerability (15%)
- using "g.m."  $\rightarrow$  drives up ve! (vs "biotech")  
(JBar - in focus groups  $\rightarrow$  use "life sciences")
- health  $\rightarrow$  benefits  $\approx$  "declining"
- support  $\rightarrow$  10 (strong) / 51 (support) / 9 (don't support)
- assessment of govt performance weak
- health - top priority
  - $\uparrow$  uncertainty
- priorities
  - env. protection - 3
  - long term health res - 2
  - enforcement



gov't role

- shld gov't encourage devel.

12 + 55 (increasing!)

- understand many risks + ~~not~~ obtaining benefit

38 + 49

- approve & regulate functions in gov't.

71% say you can if done properly

- reg.

- lack of awareness → affects confidence

- 12% excellent or good

- favourable to other nations

- 73 not confident

30% familiar 23% somewhat not - 40%  
34% - not at all

- ~~comparison~~ confidence

- food 14 + 46 + 27 + 12

- env 10 + 46 + ? + 12

most bottled products to meet higher stds - 62%

- of best evidence 17 56 15 8 Sept  
says safe 10 55 28 7 - Jan  
if OK

- 60% say experts shld make decisions

~~within 3~~

- 47% okay with unknown risks

product on shelves, safe.

S 35 + 39

F 27 + 44

N 18 + 51

must have been tested

42 + 33

comfort

~ 50%

buy

28 + 29 + 31 + 27 → reject.

↓  
not to  
know  
more!

safe to eat gm food

15 + 48 + 16 + 14

↓  
disagree → strongly

don't think  
gov't taking seriously

37 + 39

Can something

28 + 55

↓ use of pesticides in farming, I'd buy  
34 + 38 + 14 + 7

Comments

- positives trump the negatives
- simplified expl. of reg process are understood.
- want to get into when necessary or be given
- 66

34  
?

sent

26

made avail.

67

- labelling - info is too fragmentary

Overall

- moral dilemma, outweighed by benefits
- need to take science more seriously
- want to believe in gov't management, but it is fragile → we have to do a good job on safety

- McCain's did not impact as much as he thought!

→ can't take the technology

re-safety  
even Walker  
is seen as a  
local system  
1000215

→ the strategic message!

- strategic vision is needed
- don't bury science
- keep 3 pillars

Vision

- YB - what do we tell Minis → need to ID our aim
- build from where we are now!
  - what are we doing and not doing to get there

- B. Slater - CDNs want to adapt to it & profit from the benefits  
need stem & reg. system. ec, health.
- need analogues!! e.g. a science package
  - there is a big bio-fuels package going forward
  - message → projects → business plan.

- D. Groulx - long term research → investment in → but this won't be criticized
- dangerous to come out on one side!
  - CDNs have not seen leadership from govt of Canada
  - need more here!
  - not sure we need the business plan now
  - do we need several steps? → first

- Gabrielle → benefits should be stressed more public goal.
- in vision & outlay of strategy
  - show risks are being managed

CHP → need to stress "responsible leadership"

J. Baig - need to have something to inspire our leaders  
- benefits - science - resp. leadership  
are good  
- if #1 → needs to be affordable; answerable  
→ can't compete in some areas.

J. → CAN not devel BT in a resp. manner  
protecting the env. utilizing a reg. approach  
based on sound science.

H. Wang → leaders in helping countries develop  
their reg. system - strategy  
→ a leader in biotech regulation!

?? → smartest user & developer of biotechnology

RA → need to have benefits from & centre  
(cos. standardship)

D. Gorman → new info old. gave Min's more comfort  
→ CDNs not better

⊗ ✓ can say: you were right → now can  
be more aggressive

AGI → reg. system → needed to achieve benefits!  
- not an end in itself  
- once answer reg. questions!  
- public confidence is imp. on this!!  
→ Krebs → ministry reports to Parliament - not 4000217  
we need to maintain trust!

EC → contest - clear  
- red back 3

- smart message rather sense → need a slogan -  
- need to explain -  
- not 5 pages  
- if you did this project,  
... (you would achieve this)

Break

RA's document "Looking ahead to the next  
Mandate"

JBan → need to ID projects +  
identify with projects +

↓  
eg training scientists from 20 countries  
→ under the ES Protocol!

EC → it's worth the risk! ~~training into~~  
- need a flagship project to illustrate  
our work!

H. Wey → many of issues are management-focused,  
not ones of leadership  
not to know we are  
dealing with!

- D-Gorman
  - need to advance the MRC's
  - we are leading on some of these,  
eg. GM food → meeting with US etc.  
and leading well.
  - public is looking for leadership!
  - d.n. need to come to ministers with fears  
re GM foods → but with research  
on long term effects.
- Ya Baltac
  - need to showcase reg. system → long term etc.
  - ⊗ - capturing the benefits means selling  
to markets → need segregation  
eg. supply chain needs to be  
ready.  
- need further investment.



- not just <sup>under</sup> market access - theme
- need to tell a story with this as  
a theme!

André,

What Laprak is saying is important  
as it has implications for the

AG - 2 parts:

- reassurance that management of issues is going well
- moving away from a reactive mode to establish that we are leaders (2 or 3 items to illustrate)

example  
↓  
J-Brige = generic privacy (policy & logs)

DFO →

- good science
- social
- g.m. food
- more info!

} details in Annex



~~Project~~  
Policy issues around regulatory system  
as IDA by Iaprote

EE

The Document - need to get the executed

- FOR

- correct BT context (dimensions)

- describe management system

- tell people about it

- address shortcomings

- ID long term - vulnerability

- ID issues which will arise ? should be addressed in next update.

- Projects

- science recruitment

- genetic privacy

H. Wang

- are we good managers  
or leaders?

EE

- need leaders - not just good managers.

D-Goma

- risky to ID projects  
- ID projects better

- project - govt-wide management

- build in a provision to come back with more details!

TB - here's what we've done to be good managers

- to be leaders → here's what we need to do!

---  
- in broad areas!

D Goema

TB → what Namark will be saying?

1 - this is what you did if it worked

2 - management ~~relationships~~

3 [here is what the public thinks?  
- info on markets / trends  
- now + position re taking leadership role]

4 - here are potential issues / gaps  
we have to address them!

↓  
strategic direction!

leadership

benefit of <sup>renting</sup> ~~post~~ <sup>idea</sup> on management.

→ see <sup>wording</sup> ~~wording~~ on leadership

- significant



structure for leadership

## Next steps

→ <sup>mtg</sup> Friday → to DMs

→ BAC - by Wed. <sup>(Sept 28)</sup> → comments by Thurs!

→ to 3 co-chairs: Tues!

~~to DMs~~

- meet betw. 2 DMs mtgs? ~~etc~~

- will check after 1st

DM mtg?

(possibly Fri Oct 6<sup>th</sup>)

→ to CECU <sup>or full Cabinet!</sup> if mins say so!

SUSSEX CIRCLE  
LE CERCLE SUSSEX

Nigel K. Chippindale  
Principal

*See over*  
~~SECRET~~

50 O'Connor Street, Suite 1424, Ottawa, Ontario K1P 6L2  
Tel.: (613) 567-3200 Fax: (613) 567-4627 E-mail: [sussex@sus000224](mailto:sussex@sus000224)  
Internet: [www.sussexcircle.com](http://www.sussexcircle.com)

nchippin@netcom.ca

mtg with RA, AG

Aug 3rd  
2000

- nomination for Bob Slater
- ecosystem science.

RA looking @ items  
vis-à-vis budget &  
timing for next  
mandate.

- GM food & env. impact
- public environment improving
- Greenpeace

- env. is the vulnerability
- long term impacts.

} ecosystem science  
approach to env. review  
↳ post-market / pre-market  
do our own tests  
& monitoring

- impact on organic farming through out crossing
- how to maintain "pure" organic

↓  
CFIA has  
authority to  
do.

- trade impacts
- how will CAN deal  
export.

CBS -  
BAEC -  
DECK

will seek it!

Vision: ~~for 2000~~  
new me

- emphasize env. benefit
- PET - less GM

de use

- mand labelling
- Parli S/C
- CBAC

new file

- RSC? → CFIA has \$ ready to address needs!
- if there is mand labelling, people will feel  
better.

↓  
go to  
budget  
for more  
\$

- fr. of choice.

- how do we enforce. → resources + science question.

mtg with RA, AG

Aug 3rd  
2000

- nomination for Bob Slater

- ecosystem science.

RA looking @ items

vis-à-vis budget

timing for next

mandate.

- GM food & env. impact

- public environment improving

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- env. is the vulnerability

- long term impacts.

} ecosystem science  
approach to env. never  
↳ post-market / pre-market  
do our own tests  
& monitoring

- impact on organic farming through out crossing

- how to maintain "pure" organic

↓  
CFIA has  
authority to  
do.

- trade impacts

- how will CAN deal with  
export.

↓  
we will deal with it!

- emphasize env. benefits

- PEI - less GMD → ↑ disease, pesticide use

- mand labelling

- Parl. S/C

- CBAC

- RSC? → CFIA has \$ ready to address needs!

- if there is mand labelling, people will feel  
better.

- fr. of choice.

↓

- how do we enforce. → resources + science quest.

↓  
go to  
budget  
for moneys

- GM animals → for food

eg. GM fish

eg. pigs

John Phillips

→ approval in US

→ DFO

→ US, Chile → reports

+ identification

+ aquaculture & env.

- new leg? → for GM animals? could include  
→ new part of mandate

- conflict of interest

eg. IC → good for economy & safe, too

maybe they  
shouldn't say!

- restoring public confidence

= promoter separate from regulator

- how credible will RSC report & CBAC be?

- RA shld move out of IC.

→ to EC.

- education

- input into curriculum, eg. univ. → next generation of scientists

- general public info

- HR for ourselves

- broader science office



## - ethical debate

- human genome ! who owns it. & where does debate take place.
- xenotransplantation.

- patents. - threshold for patenting is too low.

- agriculture → issues.



patenting seeds, animals etc

- China - MOU → trade, info  
→ mutual recogn. of decisions.

⊗ → CHN's reg regime.

## - bio-terrorism

- security threats to crops, animals

## - BS Protocol

- CFIA's replacement.

10:30 - 11:30

- CBS meeting  
- AG  
- CHN →  
Sept. 22<sup>nd</sup>

**From:** Denise Major  
**To:** OTTFPI6.bbilmer  
**Date:** Mon, Jul 31, 2000 10:37 am  
**Subject:** BACC/CBSec Bilateral Meetings -Forwarded -Forwarded

Bart,

Could you please provide comments on the attached for Dr. Gravel.

Thanks

Denise

**CC:** OTTFPI6.lapointemc

→ simpler the better  
→ meet ahead of time

Meeting with Andre

- short, medium & long term  
priorities - corp. work progr.

- Ray  
- Aggr.

management plan of  
how govt should approach  
Protocol  
achieve

- balance: benefits, shareholding, rights

citizen eng / comm. / education  
- emerging issues → market access

- CBS funding optimization.  
↓  
2001-2002. for strategic impact.

- integrated comm plan  
- incl. corp / dept comm plans

**From:** <Atkinson.Roy@ic.gc.ca>  
**To:** NCR4.OTTPI2(agravel),AGCAN.INTERNET("nchippin@net...  
**Date:** Thu, Jul 27, 2000 4:13 pm  
**Subject:** BACC/CBSec Bilateral Meetings

When: August 3, 2000 10:30 AM-11:30 AM (GMT-05:00) Eastern Time (US & Canada) .

Where: 59 CAMELOT DR, Nepean - Ask for Dr. Gravel at the reception.

\*~\*~\*~\*~\*~\*~\*~\*~\*

( Roy Atkinson (ED for CBSec)  
( Nigel Chippindale(Consultant)  
( Dr André Gravel (EV-P)

CANADIAN FOOD INSPECTION AGENCY (CFIA)  
Office of the President

59 CAMELOT DR  
NEPEAN, ONTARIO  
Canada  
K1A 0Y9

Telephone (613) 225-2342 (4191)  
Fax (613) 228-6608

-----  
In Preparation for Bilateral on Developing CBS Strategy Documents  
I have asked for a meeting to get your advice on the themes and issues that should be reflected in our development of the Canadian Biotechnology Strategy (CBS) for the next mandate. In this regard, the Secretariat is proposing to "act as the pen" for the development of two main items:  
C An integrated policy plan covering priorities for the next five years, for consideration by Biotechnology Ministers at a planned November meeting

C A public document explaining what has been accomplished thus far by the CBS and what is to be the approach for the next five years  
I am therefore seeking your assistance and that of any of your staff whom you would like to involve. The attached material includes a suggested agenda for our meeting, while Attachment 1 explains the approach more fully. Nigel Chippindale of Sussex Circle is working with me on this task.

In the main part of the meeting, we will be seeking your views on both the key issues and themes that will drive the biotechnology agenda in the next few years and the approaches that the government should take to addressing them. In other words, what should be the main thrusts of the CBS over the next mandate? We will take your input and that of other biotechnology ADMs and develop by the end of August a first draft paper for your comments. The aim is to prepare a deck for review by BACC in September and by DMs in October.

I would also like to solicit the assistance of your people in providing input for the paper we will need to develop. Attachment 3 presents a first

rough cut at the outline of such a paper. At this point, we are looking for contact names.

I will further be asking that your people provide material for the Calendar of Biotechnology Events that we have been asked to produce. We will also be seeking input with respect to CBAC research and outreach projects. We look forward to seeing you at the meeting.

Alain-Claude Arcand  
Executive Assitant  
Canadian Biotechnology Secretariat  
613-946-9208

For

Roy Atkinson  
Executive Director  
Canadian Biotechnology Secretariat  
613-946-8926

<<Agenda.wpd>> <<ATT-1A-schedule of Fall meetings1.wpd>> <<ATT-1-Proposal  
for developing plan.wpd>> <<ATT-2-Interview templtate.wpd>>  
<<ATT-3A-Templates for sectors and WG plan.wpd>> <<ATT-3-Index for  
intergrated plan.wpd>> <<ATT-4-Working groups and champions.wpd>>

## **AGENDA FOR BACC / CBSEC BILATERAL MEETINGS**

1. Proposal for Developing Integrated CBS Policy and Communications Plan (/Attachment 1) 5 minutes
2. Departmental Priorities for the Next Mandate (Attachment 2) 40 minutes
3. Departmental Requirements for: 5 minutes

Material for Deck on Integrated Plan for BMCC

Material for Public Document on Integrated Plan for CBS Publication and CBS Web site (Attachment 3 and 3A)

Specifically need:

- leader to develop policy input for BMCC deck, and to complete departmental sector plan for biotechnology (EX-level)
- leader to develop issues papers (10 themes and hot topics)

4. CBS Management Structure and Organisation (Attachment 4) 5 minutes
5. CBS and CBAC Information Requests 5 minutes

Attachment 1A

**FALL MEETINGS - PROPOSED SCHEDULE**

Committee	Date	Time	Venue
BDGCC	September 14, 2000	12:00 - 4:00 p.m.	810G - CD Howe
BACC Retreat	September 22, 2000	Whole day (-:00 a.m. - 5:00 p.m.)	Sheraton Penthouse (TBC)
BDMCC	October 3, 2000	4:00 - 5:00 p.m.	Executive Complex, 11 <sup>th</sup> . Floor - CD Howe (east tower)
BDMCC	October 24, 2000	9:00 - 11:00 a.m.	Executive Complex, 11 <sup>th</sup> . Floor - CD Howe (east tower)
BMCC **	November 2, 2000	8:30 a.m. - 10:00 a.m.	TBD

→ may change  
→ André in chair

\*\* Meeting date to be moved (November 16 ?)

## Attachment 1

### PROPOSAL DEVELOPING THE CBS INTEGRATED POLICY AND COMMUNICATIONS PLAN

There is a requirement for **two outputs**:

1. An integrated policy plan for DM and Ministerial consideration at their October and November meetings that would address substantively the stewardship, benefits and citizen engagement / communications agendas and the management plan for achieving the plan over the next five years.

The core of this would be the identification of the next set of CBS critical community and departmental deliverables - after Genome Canada, strengthening the regulatory system, and the creation of CBAC. In essence this is the next phase for consideration and approval of DMs and Ministers.

2. A public document that would explain what has been achieved in the first two years of CBS implementation, and layout the government's integrated management plan for managing the risks, achieving the benefits, as well as informing and engaging the public.

This document should also satisfy the CBS community's public commitment, as stated in the original CBS strategy and the response to the report of the Commissioner of Sustainable Development, for a public accounting of progress and a future vision based on the 10 priority themes identified through the extensive public consultations involving in the order of 5000 people.

#### An 8-Step Process Is Proposed:

1. Bilateral meetings between BACC members and CBSEC regarding departmental priorities and community priorities, challenges and opportunities (Attachment 1). Synthesize views on strategic priorities as part of integrated plan for Ministers and to guide public document.
2. Agree to Framework for Public Document (Attachment 2), and responsible manager / WG chairs to provide input in accordance with templates (Attachement 3).
3. CBSec obtains inputs from ADMs (1 above) and managers (2 above) and develops first draft of Ministerial deck and public document.
4. Meeting of WG Chairs on September 14 to refine first drafts of 3 above.
5. Draft 2 of deck and public document goes to BACC on 22 September.
6. CBSec to integrate corporate / departmental communications plans embedded in sector and issue plans into Integrated Communications Plan for Biotech.

7. Then a process of revisions as necessary following BDMCC meetings (October 3 and 24) leading to BMCC meeting tentatively scheduled for November 9 or 16.

C:\WINDOWS\TEMP\Proposal for Developing Plan.wpd



Attachment 2

## **Template for Meetings with BACC and ADM Invitees**

### **Environmental Scan For Next Five Years (Domestic and International)**

- Key opportunities
- Critical challenges/threats

### **Vision for the Next Mandate**

### **Desired Outcomes / Objectives For the Next Mandate (Top 3 to Focus Effort)**

- Benefits agenda
- Stewardship agenda
- Communications/education agenda

### **How to Achieve Desired Outcomes**

- Critical Enablers / Disablers to achieve each desired outcome/objective
- Policy or program directions for "early in the mandate" and "later in mandate" for each desired outcome/objective
- policy, research, consultations, negotiations

### **Management Plan to Achieve Desired Outcomes**

- Departmental and / or CBS management plan to achieve desired outcomes
- Note / discuss implications and options for CBS working group structures:

C:\WINDOWS\TEMP\Interview template.wpd

Attachment 3A

Template for Working Group Action Plans (Section C - Ten Themes) and Issues Management  
(Section E)

**Name of Working Group**

Accomplishments since CBS announced August 1998

Background

Opportunities

Challenges

Action Plan With Priorities and Deliverables 2000-2005

Communication Plan (information, education, outreach)<sup>1</sup>

Partners

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Template for Sector Policy and Communications Plans (Section D)

**Name of Sector**

Background

Vision

Policy Objectives

Action Plan With Priorities and Deliverables 2000-2005

Communications Plan

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<sup>1</sup>Communications plans should include target audiences, key messages, products and services, and an electronic strategy that will dovetail effectively with corporate activity.

## Partners

Attachment 3

**Canadian Biotechnology Strategy**  
**An Integrated Biotechnology Plan for a Better Tomorrow (Public Report)**

A. Minister's Opening Remarks

Working Together To Reap the Benefits and Manage the Risks  
Biotechnology is a Priority of Government  
(vision, policy objectives government roles, good governance)  
Federal Partners

**CBSec**

B. The Canadian Biotechnology Strategy

The Policy Framework  
Working Together - Stronger Horizontal Management  
The Canadian Biotechnology Advisory Committee  
Priorities for Action

**CBSec**

C. Priorities for Action

*The First Two Years*

Establishment of CBAC

Membership  
Work Plan  
Dialogue With Canadians

Early Priorities

Research and Development for the 21<sup>st</sup> Century - Genomics Federal Labs and  
Genome Canada  
Strengthening the Federal Regulatory System for Health and Safety  
Genetically modified food [Royal Society, CGSB, G-8, CBAC]  
Biosafety Protocol

**CBSec**

*What's Ahead*

Environmental scan of the big opportunities and challenges for biotechnology over next  
five years

(A framework wherein the 10 theme framework serves as the means address the

opportunities and challenges and move Canada towards fulfilling the three policy objectives related to benefits for Canadians, stewardship and citizen engagement. There should be something said on each of the ten themes to close the covenant with Canadians [and the AG!]. There will more substantive content for some areas than for others but that can be finessed. The ten themes are: Communications, R&D, Regulations, Promoting Biotech for Public Health & Safety, Modernizing IP Laws, Commercialization, Technology Transfer, International Issues (see section (F) below), Human Resources, Data and Statistics, Sector Strategies (see Sections (D) below).

**WG Chairs to submit reports; CBSec to develop introduction that would segue from 10 themes (means to an end) to 3 policy directions (desired outcomes) - template attached.**

D. A Sector Perspective On Outcomes, Objectives and Policy Directions

Health (HC, CIHR, IC)

- **vision** for the future: opportunities and challenges
- **policy action plan** that addresses stewardship and benefits in a integrated manner
- **communication action plan**, education, engagement

Environment (EC, IC)

- **vision** for the future: opportunities and challenges
- **policy action plan** that addresses stewardship and benefits in a integrated manner
- **communication action plan**, education, engagement

Agriculture and Agrifood (AAFC) *→ CFIA*

- **vision** for the future: opportunities and challenges
- **policy action plan** that addresses stewardship and benefits in a integrated manner
- **communication action plan**, education, engagement

Forestry (NRCan, IC)

- **vision** for the future: opportunities and challenges
- **policy action plan** that addresses stewardship and benefits in a integrated manner
- **communication action plan**, education, engagement

Aquaculture (DFO, EC)

- **vision** for the future: opportunities and challenges
- **policy action plan** that addresses stewardship and benefits in a integrated manner
- **communication action plan**, education, engagement

**ADMs to engage policy and communications expertise to articulate the public presentation of forward looking plans for their departments.**

E. An Issues Perspective Over the Next Five Years

Genetically Modified Food  
Genetic Privacy (related to R&D, health care, insurance and employment)  
Access to genetic resources  
Others...

**ADMs / CBSec to identify leads to deliver synopses agreed to.**

F. An International Perspective (Canada as a Responsible World Leader)

Environment

- Convention on Biodiversity
- Biosafety Protocol Ratification and Implementation, Precautionary Principle, etc.
- Access to Genetic Resources
- Capacity Building in LDCs
- other???

Environment and DFAIT to Lead

Sharing Benefits with Less Developed Countries

- Capacity Building and technology transfer
- R&D for LDC needs

**Environment and CIDA to Lead**

Genetically Modified Food

- Codex
- OECD Sub-Committee
- Harmonization of Regulations

~~APEC~~ **Health to Lead**

↳ CFI

Trade and Investment

- World Trade Organization
- Organization for Economic Development
- World Health Organization
- G-8 Nations
- WIPO and negotiations on IP

**DFAIT to Lead**

G. Closing Remarks

(Benefits and challenges to ensure Canada can be a responsible world leader for realizing benefits and maximizing the risks. Reference ensuring ongoing dialogue with provinces and interested Canadians through both departmental and CBS Secretariat mandates)

**CBSEC**

H. To Contact Us

# **CBS ADM Champions and WG Chairs, 2000-2001** Attachment 4

<b>CBS THEME</b>	<b>Working Group</b>	<b>ADM Champion</b>	<b>WG Chair</b>
<b>Public Confidence and Awareness</b>	Ethics	R. Atkinson (CBSec)	Tim Flaherty
	Communications	R. Atkinson (CBSec)	Stella Deacon
<b>R&amp;D (Includes Foresight, Technology Transfer)</b>	R&D (technology foresight and technology transfer)	P. Hackett (NRC) K. Mosher (MRC)	Judith Young / Kelly Van Koughnet
	Eco-System Science	K. Brown	Ken Sato
<b>Regulation to Protect Health and the Environment</b>	Regulations	Diane Gorman (HC) A. Gravel (CFIA) Barry Stemshorn (EC)	Health? Mark LeMay Bart Bilmer Vic Shantora
<b>Public Health Advantage</b>	Public Health Advantage	D. Gorman (HC)	Joel Weiner
<b>Intellectual Property (Patent Act)</b>	Intellectual Property	A. Sulzenko (IC)	Susan Bincoletto Bill Boddie
<b>Technology Commercialization</b>	High Growth Opportunities WG* (Business finance, venture capital, etc.)	J. Banigan (IC)	Christine Nymark
	High Growth Opportunities WG* Cluster Development (strong links to R&D, FDI, business finance)	" "	" "
<b>Human Resources</b>	High Growth Opportunities WG*	" "	" "
<b>International Issues</b>	Stewardship & LDC Capacity Building (Biosafety Protocol)**	Barry Stemshorn (EC)	Cynthia Wright
	Market Access	J. Fried (DFAIT)	André Dulude
	High Growth Opportunities WG* (Trade Promotion)	J. Banigan (IC) TBD (DFAIT)	Christine Nymark TBD (DFAIT)
	High Growth Opportunities WG* (Foreign Direct Investment)	J. Banigan (IC)	Christine Nymark
<b>Policy-relevant Data Collection and Analysis</b>	Data and Statistics	J. Banigan (IC)	Fred Gault

<b>Sector Strategies</b>	Agriculture and Agri-Food	J. Moses (AAFC)	Richard Tudor-Price
	Fisheries/Aquaculture	J. Davis (DFO)	Iola Price
	Environmental Solutions	Barry Stemshorn (EC) J. Banigan (IC)	Ed Norrena Lucien Bradet
	Forestry	Y. Hardy (NRCan) J. Banigan (IC)	Gordon Miller
	Health / Bio-pharmaceuticals	J. Banigan (IC)	Christine Nymark
<b>GM Foods</b>	Issues Management	D. Gorman (HC)	Health ?
<b>Federal Government Capacity Building</b>	Federal Capacity Building (Temporarily on hold)	R. Slater (EC)	TBD
<b>CBS Fund</b>	Interdepartmental Coordinating Committee	R. Atkinson (CBSec)	Norma Burlington

\*High Growth Opportunities (HGO) comprises: (Business finance, venture capital; Cluster Development; Human Resources; Trade Promotion; Foreign Direct Investment Promotion; Tech Transfer)

\*\*Stewardship & LDC Capacity Building (Biosafety Protocol) includes: Sustainable Development Indicators (OECD); R&D; Access to Genetic Resources.

S:\CBST\AMENU\Phase 4\BCCB\BACC\BACC Bilaterals Aug 2000\Working Groups and Champions.wpd

#### Two Options for Restructuring CBS Working Groups

1. Currently CBS makes use of horizontal working groups / committees [e.g regulation, R&D, Intellectual Property, ethics, communications, data and statistics] which focus on separate policy instruments, sector working groups, and special issues working groups [e.g. GM food, Genetic Privacy]. At the last BDGCC WGs related to commercialisation [technology transfer, HR, investment promotion, business finance] were collapsed into a single working group. In addition, Environment Canada identified ecosystem science as a special issue and a separate Working Group was struck. The others remain intact including the concept of sector WGs lead by the responsible departments.

One option is to maintain the current horizontal and sector WGs and replace DG committee with one of WG Chairs as management tier below ADMs. The WGs they would be tasked with developing policy research and policy / program proposals

2. The WGs could be restructured into 3 CBS WGs that address the three strategic objectives approved by BMCC [Benefits, Stewardship and Citizen Engagement] each led by ADM champion. The three working groups would be responsible for developing integrated policy and communications plans for achieving benefits, stewardship and citizen engagement.

In addition it is likely that issue-specific (e.g., genetic privacy, GM food) and topics without a natural "home" (e.g. ethics, corporate communication) would likely continue to be necessary. Departments would strike internal WGs / interdepartmental committees for issues that support their mandates (e.g., international trade, communications, data and statistics).



-1-

#### Minutes

BACC Meeting of JUNE 30, 2000 (ADMs only)  
Executive Complex, 235 Queen Street  
(See Annex A for list of participants)

#### **Item 1 - Genome Canada**

Brian Morrissey and Christine Nymark joined the BACC meeting for this item. They, along with Peter Hackett, lead the discussion on the role of government laboratories in Genome Canada.

#### **Decision:**

The CBS R&D Working Group will examine the Genome Canada agreement to develop a common understanding among government officials on the role of government laboratories in relation to Genome Canada, including what is or is not permissible under the agreement. This will help to ensure government labs working with future genome centers have the same information. Christine Nymark will provide input to the working group as requested.

#### **Item 2 - Petition to the Office of the Commissioner of Sustainable Development**

There was a discussion of progress to date in developing the response to the petitioners.

#### **Decisions:**

- . Bart Bilmer to prepare a progress report for BACC including the content of the response [highlighting challenging areas, signing strategy, schedule, etc..]
- . A telephone conference call to be held in early August for BACC members to discuss the proposed response and the mechanism for securing signatures of Ministers.

#### **Item 3 - Jim Mitchell Presentation on CBSec / CBAC, and BACC Operations.**

Jim Mitchell left after his presentation and BACC discussed the issues raised.

#### **Decisions:**

#### **BACC / CBSec**

In order to clarify CBAC's role as an independent arm's-length advisory body, and its accountability and reporting structures, it was agreed that:

-2-

• The CBSec budget be partitioned 75%/25% to provide CBAC  
with an annual budget of \$2,250,000

•

-3-

BACC support the development and signature of a Memorandum of Understanding between CBAC, the chair of the BDMCC and the CBSEC that clarifies the roles of CBAC, the CBSEC support to it, as well as the means for process departmental support for CBAC's work plan.

· A decision regarding the roles and resources of the CBSEC to support policy coordination and "corporate" operations be deferred until BACC has had the opportunity to give further thought to its role and deliverables.

### **BACC Operations**

There was wide-ranging discussion about the operations of BACC and its committees, the essence being:

- a desire among BACC members to find ways and means to simplify the operational requirements for planning, developing, implementing and monitoring the horizontal agenda;
- a recognition of the need for BACC's, BDMCC's and BMCC's plans and operations to be more strategic and able to embrace in an integrated and comprehensive manner the priorities issues and action plan in longer-term [5 years], the medium-term [2 to 5 years] and the shorter-term [1 to 24 months];
- the need for BACC members [separately and jointly] to have a more coherent and well informed vision of biotechnology's opportunities and challenges and the linkages among them [little time is spent on these types of issues by BACC members];
- Government / departmental plans and operations need to provide a balanced integrated agenda for benefits, stewardship and communications;
- a recognition that DMs and Ministers are expecting BACC to provide them with a well-formed coherent "corporate" work program for their review in October and November respectively;
- as part of the longer-term view, the plans and operations need to address both federal and national capacity [e.g. intelligence gathering, policy development, information sessions for Parliamentarians and other key groups];
- an effective effort will likely require more time and personal effort by BACC members;
- an effective government-wide program will in many cases require BACC members to engage their colleague ADMs in their departments, as well as their DMs and perhaps their Ministers;
- with an election coming, Ministers will want BACC to have in place a plan and rapid-response capacity to address

-4-

- emerging issues;
- the allocation process for the CBS Fund, while improved over past years, needs to be reconsidered for the next round in order to optimize its strategic impact. This will require greater top-down strategic leadership in lieu of a reliance on bottom-up processes.

**Decisions:**

Harvey Wong and Roy Atkinson to examine alternate business methods for BACC and its activities.

BACC to revisit the issues of organization and business methods for developing, implementing and monitoring the government-wide transition agenda.

*Canadian Biotechnology Secretariat  
July 6, 2000*

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ANNEX A

BACC - June 30, 2000 meeting

Participants:

Dr. Robert Slater	EC
Ms. Judith Moses	AC
Ms. Diane Gorman	HC
Mr. John Banigan	IS
Ms. Karen Mosher	CIHR
Dr. Peter Hackett	NRC
Mr. Harvey Wong	PCO
Dr. Yvan Hardy	NRCan
Dr. André Gravel	CFIA

Presenters

Ms. Christine Nymark	IS (LSB)	1 <sup>st</sup> . Item only - G.C.
Mr. Brian Morrissey		1 <sup>st</sup> . Item only - G.C.
Mr. Jim Mitchell	Consultant CBAC	3 <sup>rd</sup> . Item - CBSec /

Regrets

Mr. Jonathan Fried	DFAIT
Dr. John Davis	F&O



## Washington File

14 March 2000

### **Text: White House Press Release on Human Genome Project**

(Clinton and Blair say research should benefit health) (1470)

President Bill Clinton and British Prime Minister Tony Blair applauded  
international scientists working on the Human Genome Project (HGP) and  
their willingness to share their findings for the benefit of human  
health.

Speaking at a White House ceremony, the two leaders also emphasized  
that the legal protection of intellectual property is an important  
incentive for other scientists to use this data as the basis for  
further biomedical discoveries.

The Human Genome Project is an effort to map and identify the estimated 100,000 genes shaping the characteristics that make up a human being. The project is expected to "revolutionize the practice of medicine," according to the White House statement, and will lead to important new discoveries in detecting, preventing and curing diseases.

The Clinton administration is supporting the project with the pursuit of additional funding in the upcoming budget year. That action follows an eight-year pattern of funding increases for the HGP, which the White House statement describes as "the world's largest centrally coordinated biology research project ever undertaken."

Following is the text of the White House statement:

(begin text)

THE WHITE HOUSE

Office of the Press Secretary

March 14, 2000

THE HUMAN GENOME PROJECT: BENEFITING ALL HUMANITY

March 14, 2000

"Later this year, researchers will complete the first draft of the entire human genome, the very blueprint of life. It is important for all our fellow Americans to recognize that federal tax dollars have funded much of this research, and that this and other wise investments in science are leading to a revolution in our ability to detect, treat, and prevent disease."

President Clinton

January 27, 2000, "State of the Union"

At today's Medals of Science and Technology awards ceremony, the President will announce that he and Prime Minister Tony Blair have agreed on a statement of principle to ensure that discoveries from the human genome are used to advance human health. Their joint statement, to be issued in the U.S. and U.K. today, applauds researchers who have made their human genome sequence data freely available to the global scientific community and calls upon others to follow their lead. The statement also acknowledges the importance of intellectual property protection as an incentive for the development of important, new gene-based health care products.

#### ACCESS TO FUNDAMENTAL INFORMATION ABOUT THE HUMAN GENOME WILL IMPROVE HEALTH

The United States and the United Kingdom are the leading partners in the Human Genome Project -- the international effort to map and sequence the 3 billion 'letters' and to locate and identify the roughly 100,000 genes that make up the human genetic code.

This project will revolutionize the practice of medicine, providing the means to custom tailor treatments to the needs of each patient, and to prolong healthy life by predicting and preventing diseases.

Unencumbered access to the raw human sequence data will promote its use by scientists all over the world in their efforts to understand human biology and disease at the level of individual genes.

The single most important development in human biology in the short term will be the completion of the sequencing of the human genome. Government-funded research activities have made important contributions to this result. The private sector has also made significant advances in recent years.

The single biggest challenge to humankind will be to take this vast storehouse of information and rapidly develop new products to diagnose and treat human diseases. That process will require continued support for government research. It will also require a suitable environment for the private sector to develop new products, including appropriate

intellectual property protection.

The president's budget calls for a \$1-billion increase for biomedical research at the National Institutes of Health (NIH), to nearly \$18.8 billion. These funds will support merit-based, peer-reviewed research, largely conducted by individual investigators.

Biomedical research continues to pave the way toward better diagnostics, treatments, and cures. Recent breakthroughs have led to techniques that hold promise for treating Parkinson's disease, diabetes, heart disease, and many other debilitating disorders. As new health risks arise, prevention of disease also requires increased attention.

With the increase requested for FY 2001, NIH plans to focus on the following four themes: exploiting the power of genomics, reinvigorating clinical research, harnessing the expertise of allied scientific and engineering disciplines that contribute to biomedical research, and reducing disparities in health.

The increase will support research in areas such as diabetes, brain disorders, cancer, genetic medicine, disease prevention strategies, and development of an AIDS vaccine.

#### R&D BUDGET -- A BOLD COURSE OF STRATEGIC GROWTH AND PROSPERITY THROUGH DISCOVERY

The President and the Vice President remain unwavering in their support for science and technology as crucial investments in our future. These investments enable our nation to compete aggressively in the global marketplace, protect our environment and manage our natural resources in a sustainable manner, safeguard our national security from emerging threats, and spur the technological innovation that has contributed so much to our economic prosperity and quality of life.

The FY 2001 budget for R&D continues the important R&D trends established by the President and Vice President:

This is the eighth consecutive year that the President and Vice President have proposed increased investments in civilian research and development. Civilian R&D is up 43% since they have taken office.

It boosts funding for basic research by 7% -- a \$1.3 billion increase. Funding for basic research is up 52% since 1993.

R&D support to Universities increases 8% -- a \$1.3 billion increase. R&D support to Universities is up 53% since 1993.

Perhaps most important, this budget presents a balanced R&D portfolio, which recognizes the interdependence among the scientific disciplines. Gains in one field are often dependent on advances in others.

HUMAN GENOME PROJECT FACT SHEET



March 14, 2000

**Benefiting All Humanity.** The Human Genome Project (HGP), an international effort formally begun in October 1990, was planned to last 15 years, but rapid technological advances have accelerated the expected completion date by at least two years. The project's are to discover all of the approximate 100,000 human genes (the human genome) and make them accessible for further biological study and to determine the complete sequence of the 3 billion DNA subunits (bases). As part of the HGP, parallel studies are being carried out on selected model organisms such as the bacterium *E. coli* to help develop the technology and interpret human gene function. The HGP is also the first large scientific undertaking to address the ethical, legal, and social issues that may arise from such a project. The National Institutes of Health's National Human Genome Research Institute (NHGRI) and the Department of Energy's Human Genome Program together make up the U.S. Human Genome Project, the world's largest centrally coordinated biology research project ever undertaken. The U.K.'s Wellcome Trust, a private philanthropy, also contributes to the global initiative and supports one of the five principal large-scale human genome sequencing centers.

**Longer Lives and Better Health.** The project will reap enormous benefits for humankind, some that we can anticipate and others that will surprise us. Biologists and researchers will have access to detailed DNA information that is key to understanding the structure, organization, and function of DNA in chromosomes. Genome maps of other organisms will provide the basis for comparative studies that are often critical to understanding more complex biological systems. Information generated and technologies developed will revolutionize future biological explorations. Technology and resources generated by the Human Genome Project and other genomics research are already having a major impact on research across the life sciences. For example, the HGP has produced detailed maps that can be used to help pinpoint genes associated with particular diseases, leading to better treatment and prevention methods. A prime example is that families at risk of hereditary colon cancer can now be screened and lessen their chances of dying from this illness with surveillance and dietary measures. The potential for commercial development of genomics research also presents U.S. industry with a wealth of opportunities, and sales of DNA-based products and technologies in the biotechnology industry are projected to exceed \$45 billion by 2009.

**Strong Administration Support for Human Genome Research.** During the past eight years, President Clinton and Vice President Gore have increased the funding for this ambitious project by 165%, providing over \$2.6 billion in federal funds to the HGP.

Clinton/Gore Administration U.S. Human Genome Project Funding History  
(dollars in millions)

Year	NIH	DOE	Total
1993	\$106.1	\$63.0	\$169.1
1994	127.0	63.3	190.3

1995	153.8	68.7	222.5
1996	169.3	73.9	243.2
1997	188.9	77.9	266.8
1998	218.3	85.5	303.8
1999	283.6	89.8	373.4
2000	335.9	88.9	424.8
2001 Request	357.7	90.3	448.0
Total			\$2,641.9

(end text)

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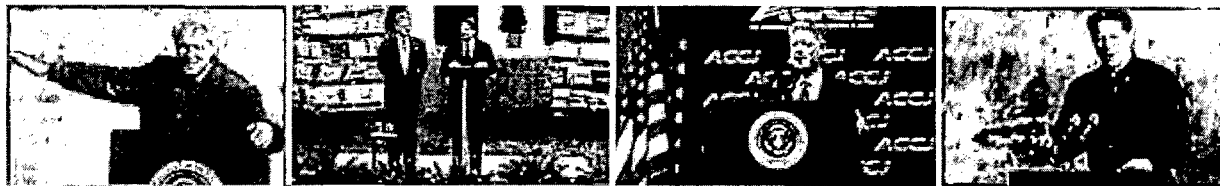
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THE WHITE HOUSE

## President Clinton Announces The Completion Of The First Survey Of The Entire Human Genome

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June 26, 2000

#### PRESIDENT CLINTON ANNOUNCES THE COMPLETION OF THE FIRST

#### SURVEY OF THE ENTIRE HUMAN GENOME

Hails Public and Private Efforts Leading to This Historic Achievement  
June 26, 2000

#### Remarks on the Completion of the First Survey of the Entire Human Genome Project (Text and Audio).

Today, at a historic White House event with British Prime Minister Tony Blair, President Clinton announced that the international Human Genome Project and Celera Genomics Corporation have both completed an initial sequencing of the human genome -- the genetic blueprint for human beings. He congratulated the scientists working in both the public and private sectors on this landmark achievement, which promises to lead to a new era of molecular medicine, an era that will bring new ways to prevent, diagnose, treat and cure disease. The President pledged to continue and accelerate the United States' commitment to helping translate this blueprint into novel healthcare strategies and therapies. He will underscore that this genetic information must never be used to stigmatize or discriminate against any individual or group. Our scientific advances must always incorporate our most cherished values, and the privacy of this new information must be protected.

#### DECODING THE HUMAN GENOME WILL LEAD TO NEW WAYS TO PREVENT, DIAGNOSE, TREAT, AND CURE DISEASE.

Alterations in our genes are responsible for an estimated 5000 clearly hereditary diseases, such as Huntington's disease, cystic fibrosis, and sickle cell anemia, and influence the development of thousands of other

diseases. Before the advent of the Human Genome Project, a joint project of HHS, DOE, and international partners in the United Kingdom, France, Germany, Japan, China, connecting a gene with a disease was a slow, arduous, painstaking, and frequently imprecise process. Today, genes are discovered and described within days. For example, in 1989, scientists found the gene for cystic fibrosis after a 9-year search; eight years later, largely because of the coordinated efforts of the Human Genome Project, a gene for Parkinson's disease was mapped in only 9 days. Now, scientists will be able to use the working draft of the human genome to:

- Alert patients that they are at risk for certain diseases. Once scientists discover which DNA sequence changes in a gene can cause disease, healthy people can be tested to see whether they risk developing conditions such as diabetes or prostate cancer later in life. In many cases, this advance warning can be a cue to start a vigilant screening program, to take preventive medicines, or to make diet or lifestyle changes that may prevent the disease.
- Reliably predict the course of disease. Diagnosing ailments more precisely will lead to more reliable predictions about the course of a disease. For example, a genetic fingerprint will allow doctors treating prostate cancer to predict how aggressive a tumor will be. New genetic information will help patients and doctors weigh the risks and benefits of different treatments.
- Precisely diagnose disease and ensure the most effective treatment is used. Genetic analysis allows us to classify diseases, such as colon cancer and skin cancer, into more defined categories. These improved classifications will eventually allow scientists to tailor drugs for patients whose individual response can be predicted by genetic fingerprinting. For example, cancer patients facing chemotherapy could receive a genetic fingerprint of their tumor that would predict which chemotherapy choices are most likely to be effective, leading to fewer side effects from the treatment and improved prognoses.
- Developing new treatments at the molecular level. Drug design guided by an understanding of how genes work and knowledge of exactly what happens at the molecular level to cause disease, will lead to more effective therapies. In many cases, rather than trying to replace a gene, it may be more effective and simpler to replace a defective gene's protein product. Alternatively, it may be possible to administer a small molecule that would interact with the protein to change its behavior. This is the strategy behind a drug in development for chronic myelogenous leukemia, which targets the genetic flaw causing the disease. It attaches to the abnormal protein caused by the genetic flaw and blocks its activity. In preliminary tests, blood counts returned to normal in all patients treated with the drug.

TODAY'S ANNOUNCEMENT REPRESENTS THE STARTING POINT FOR A NEW ERA OF GENETIC MEDICINE. The sequence represents only the first step in the full decoding of the genome, because most of the individual genes and their specific functions must still be deciphered and understood. This research has begun, and already, tens of thousands of genes have been identified, including some related to deafness, kidney disease, breast cancer, hereditary skeletal disorders, hemorrhagic stroke and diabetes, thus advancing the work of researchers worldwide at a rate that would have been impossible without these data. The Human Genome Project, which completed its version of the working draft two years ahead of schedule and under budget, will continue its longstanding practice of making all of its sequencing data available to public and privately funded researchers worldwide at no cost. Celera Genomics, which makes its sequencing data available by subscription, will also make its version of the consensus human genome sequence available to non-subscribers upon publication.

PRESIDENT CLINTON PLEDGES STRONG SUPPORT FOR GENETIC RESEARCH BY BOTH THE PUBLIC AND PRIVATE SECTORS. President Clinton reiterated the commitment of the United States to robust Federal support for basic scientific research facilitating medical application of the science. President Clinton also stated his support for a strong structure to review the medical, ethical and other issues presented by the expected new power of genetic medicine, building on the multi-million dollar investment the Human Genome Project already makes in research on the social, ethical and legal implications of this work. He recognized that research and development by biotechnology companies will be key to the translation of human genome sequence data into useful, new healthcare products and pledged to strengthen a business environment that will spur research and development in this vital sector. The President also reaffirmed his support for patenting genetic discoveries that have substantial and credible uses. By protecting and rewarding investment in research, consistent with current law, this policy of intellectual property protection will promote rapid conversion of basic knowledge into useful applications, while at the same time allowing a maximum free flow of basic scientific information.

TODAY'S ANNOUNCEMENT BUILDS ON THE CLINTON-GORE ADMINISTRATION'S STRONG COMMITMENT TO PROTECTING PRIVATE GENETIC INFORMATION. Since 1997, the President and Vice President have called for legislation that will guarantee that Americans who are self-employed or otherwise buy health insurance themselves will not lose or be denied that health insurance because of their genetic makeup. Last winter, President Clinton signed an executive order that prohibits every civilian Federal Department and agency from using genetic information in any hiring or promotion action. This historic action prevented critical information from genetic tests used to help predict, prevent, and treat diseases, from being used against Federal employees. In addition, President Clinton has endorsed the Genetic Nondiscrimination in Health Insurance and Employment Act of 1999,

introduced by Senator Daschle and Congresswoman Slaughter, that will extend these employment protections to the private sector and finish the job of helping to extend protections to individuals purchasing health insurance, begun with the Health Insurance Portability and Accountability Act.

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# **Science Advice for Government Effectiveness (SAGE)**

**A Report of the  
Council of Science and Technology Advisors**

**May 5, 1999**

# Science Advice for Government Effectiveness<sup>1</sup>

## *Background*

The Council of Science and Technology Advisors (CSTA) was established to provide the Cabinet Committee on Economic Union (CCEU) with external expert advice on internal federal government science and technology issues that require strategic attention. Recent government decisions in the areas of natural resources management (e.g., fish stocks) and public health and safety (e.g., the blood supply) have contributed to public concern regarding the ability of government to effectively address science-based issues. The CCEU recognizes the importance of these concerns and has asked the CSTA, as one of its initial tasks, to develop a set of principles and guidelines for the effective use of science advice in making policy and regulatory decisions. It is hoped that more effective use of science advice will reduce science-related crises of public confidence. In addition, science advice will play an important role in positioning the Canadian government to take advantage of the opportunities presented by advances in science and technology (e.g., the information highway). Capitalizing on these opportunities contributes to innovation, economic growth, public health and safety, and environmental protection.

Canada is not alone. Other countries are grappling with similar challenges and opportunities and are engaging in similar efforts to improve their science advisory processes. The adoption of Canadian science advice principles and guidelines will not only improve the government's ability to deal with science-based issues domestically, but will also ensure that Canada is well-positioned to lead any effort to develop international standards for science advice.

This report provides guidance on how to ensure that government decisions are informed by sound science advice. The report presents a set of six key science advice principles which can improve science-based decision making, and a series of concrete guidelines to facilitate the adoption of the principles espoused. Finally, the report presents options for how the government could implement the principles and guidelines, ensure their adherence by individual departments, and monitor their effectiveness.

In this report "science" is defined broadly to include the natural, health, and social sciences, mathematics, engineering, and technology. "Science advice" is defined as value-added guidance deriving from scientific theories, data, findings, and conclusions provided to inform policy and regulatory decision making.

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<sup>1</sup> This work draws heavily from the work of Sir Robert May (UK), David Beckler (US), Willie Smith (NZ) and others.



While the individual principles and guidelines espoused are consistent with many of the current practices in Canada and elsewhere, a clearly defined set of government-wide principles and guidelines for science advice is new to the Canadian federal government. Of the countries studied, only the UK has established formal government-wide science advice principles and guidelines. These were implemented within the last two years; too recently to provide a thorough evaluation of their effectiveness at this time.

## ***Context***

The emergence of the knowledge-based society has underscored the importance of sound science advice as a key input to policy formulation both nationally and internationally. The pervasiveness of science and technology is such that they now impact most core government functions. The issues facing governments are increasingly complex and require decisions that have profound impacts on societies and economies. Many of these decisions involve risk assessments that arouse public concerns about their health, safety and long term well-being; others attempt to capitalize on the opportunities afforded by advancements in science and technology.

As we enter the 21st century, government decision making is also taking place in a highly dynamic environment. Government decisions taken in a federal context may involve federal-provincial considerations. Policies and decisions often need to take into account the diverse physical and social considerations that exist in Canada. In addition, there are increasing concerns regarding the accountability and liability of scientists and decision makers. Fuelled by increased access to information, there is heightened public interest in science-based issues and greater emphasis on active public involvement in decision making. At the same time, there is greater public scepticism of science, government, industry, and the interactions among them. Greater science literacy and better communication of scientific uncertainty will increase the public's understanding of the capabilities and limitations of science.

This report addresses science advice. Clearly, decision making in government must consider a wide range of inputs and consult, as appropriate, advisors competent in other aspects of public policy (e.g., economics, public administration, social science, international affairs, etc.). Decision makers must exercise their legitimate role to weigh these multiple inputs and make choices. Science advice has an important role to play by contributing to government decisions which serve Canada's strategic interests and concerns in areas such as public health and safety, environmental protection, resource exploitation, wealth creation, innovation, and national security.

## ***Desirable Outcomes***

The Federal Government requires an effective science advisory process that leads to better government decisions, minimizes crises and unnecessary controversies, and capitalizes on opportunities. An effective advisory process brings sound science and the best science advice to bear on policy issues and ensures that:

- ◆ Ministers are confident that a rigorous and objective assessment of all available information was made in providing the advice;
- ◆ the public and parliamentarians are confident that government is using science in the best interests of Canadians, and that science advice provided to decision makers is credible; and,
- ◆ Canada has an enhanced ability to influence international solutions to global problems.

## ***Principles and Guidelines***

The science advice principles and guidelines that follow reflect the evolving context for government decision making. Their adoption will lead to the desirable outcomes identified above. When implemented these guidelines should remain largely consistent across government departments with only a small number of exceptions. Departments should justify any changes needed to tailor them to individual departmental situations.

### **I. Early Identification**

Decision makers need to be convinced of the importance of seeking science advice and recognize when science advice is needed. Departments need to anticipate, as early as possible, those issues (representing both challenges and opportunities) for which science advice will be required. A broad base of advice can lead to improvements in the timeliness of issue identification. Interdisciplinary, interdepartmental, and international cooperation should be in place to identify, frame, and address 'horizontal' issues.

#### ***Guidelines***

- ◆ Decision makers need to cast a wide net (consulting internal, external<sup>2</sup>, and international sources) to assist in the identification of issues requiring science advice.
- ◆ Decision makers need to communicate to scientists those policy areas requiring advice, and government scientists need to be able to recognize the connections between their research and potential policy issues.

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<sup>2</sup> External sources include, for example, other government departments, provincial governments, academe, industry, professional societies, and other interested parties.

- ◆ Departments need a sufficient and adaptable internal capacity to identify science issues and to assess, translate and communicate science for policy.
- ◆ Departments need to support and encourage their science and policy staffs to establish linkages with each other and with external and international sources.
- ◆ Departments need to maximize the use of expertise across government departments to identify and address 'horizontal' issues.

## **II. Inclusiveness**

Advice should be drawn from a variety of scientific sources and from experts in many disciplines in order to capture the full diversity of scientific schools of thought and opinion. Inclusiveness enhances the debate and draws in scientific findings which may not otherwise be considered; sound science thrives on the competition of ideas facilitated by the open publication of data and analyses. The market for science advice is global and the growing body of science knowledge available internationally must be brought to bear on policy issues. Inclusiveness aids in achieving sound science advice by reducing the impact of conflicts of interest or biases that exist among advisors.

### *Guidelines*

- ◆ Science input and advice needs to be sought from a wide range of sources; due weight needs to be given to the 'traditional knowledge' of local peoples; decision makers need to balance the multiple viewpoints received.
- ◆ While advice from external and international sources needs to be sought regularly, it is especially important to seek such advice in the following situations. Government also needs to consider engaging external, independent agencies to create advisory panels or to solicit advice in these circumstances:
  - the problem raises scientific questions that exceed the expertise of the in-house staff;
  - the issue is 'horizontal' or cuts across lines of jurisdiction within or among departments;
  - there is significant scientific uncertainty;
  - there is a range of scientific opinion; or,
  - there are potentially significant implications for sensitive areas of public policy and where independent scientific analyses can strengthen public confidence.
- ◆ Decision makers need to be open to both solicited and unsolicited advice from external sources.

### III. Sound Science and Science Advice

The public expects government to employ measures to ensure the quality, integrity, and objectivity of the science and the science advice it utilizes, and to ensure that science advice is considered seriously in decision making. Due diligence procedures for assuring quality and reliability, including scientific peer review, need to be built into the science advisory process. Where information is proprietary, external peer review needs to proceed with appropriate measures to maintain confidentiality. Science advisors need to contribute sound scientific information, unfiltered by other policy considerations. In developing policy, departments need to involve advisors in assessing the implications of various policy options.

#### *Guidelines*

- ◆ All advisory processes, including those involving traditional knowledge, need to be subject to due diligence. This should include rigorous internal and external review and assessment of all input, analyses, findings, and recommendations of advisors. The fact that information is proprietary should not preclude external review, although confidentiality of such information should be appropriately maintained.
- ◆ Science advice needs to be supported by research and policy analysis:
  - Decision makers need to ensure there are sufficient resources for supporting policy research and analysis to underpin the science advisory process.
  - Scientists need to have the flexibility to explore the range of conclusions and interpretations that the scientific findings might suggest.
  - A strong coupling needs to exist between the science advisors and the departmental policy and analytical support mechanisms.
  - Science advisors need to assist decision makers and science managers set research priorities and design an R&D base that will support future science-based decision making.
- ◆ Selection of advisors needs to:
  - be matched to the nature of the issue and the breadth of judgement required;
  - be balanced to reflect the diversity of opinions and to counter potential biases;
  - include at least some experts from other, not necessarily scientific, disciplines; and,
  - be regularly rotated, with replacements chosen to preserve balance of representation.
- ◆ Advice providers need to:
  - adhere to professional practice and conflict of interest guidelines;
  - clearly distinguish scientific fact and judgement from their personal views in formulating their advice; and
  - recognize the limits of science advice and the existence of other considerations in decision making.

◆ Departments need to:

- ensure in-house expertise to assess and communicate science (whether generated internally or externally) to decision makers;
- promote professional practices for those involved in the conduct, management and use of science<sup>3</sup>;
- provide and enforce conflict of interest guidelines. Considerations include:
  - advisors need to be required to declare any conflicts of interest prior to serving in an advisory capacity and to update such declarations throughout their term of service;
  - while the responsibility for documenting and avoiding conflicts of interest should be placed on the advisor, decision makers need to have the ultimate responsibility for protecting against actual or perceived conflicts of interests.
- clearly document the science advice received and report back to the advice providers how decisions are made.

◆ Decision makers need to:

- take care to separate scientific fact and judgement from personal views and judgements in formulating the questions to be addressed;
- be conscious of possible biases in the advice providers and be alert to indications of bias in the advice received; and
- involve science advisors in policy formulation, to help maintain the integrity of the advice throughout the decision making process.

#### **IV. Uncertainty and Risk**

Science in public policy always contains some uncertainty and often a high degree of uncertainty which must be assessed, communicated, and managed. As such, it is important to consider adopting a risk management approach. In addition to hazards, uncertainty may include potential benefits or opportunities which should not be ignored. The goal of risk management is scientifically sound, cost-effective, integrated actions that reduce risks while taking into account social, cultural, ethical, political, and legal considerations.

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<sup>3</sup> The report of the Best Practices Initiative, a joint effort led by Health Canada and the four natural resources related departments (NRCan, EC, AAFC, and DFO) on behalf of the ADMs Ad Hoc Committee on Science in Government, provides useful guidance in this regard. It presents a set of fundamental values, traits of key stakeholders, and best practices to ensure that federal government science is conducted credibly, managed effectively, and used wisely. Best practices are identified in the areas of organizational environment, accountability, science in decision making, review processes, and communications.

### *Guidelines*

- ◆ Departments require a clearly defined set of risk management guidelines, including how and when the precautionary principle<sup>4</sup> should be applied, in order to maintain confidence that a consistent and effective approach is being used across government.
- ◆ Science advisors need to ensure that scientific uncertainty is weighted fairly, is explicitly and fully identified in scientific results, and is communicated directly in plain language to decision makers; decision makers need to ensure that scientific uncertainty is given appropriate weight in policy decisions.
- ◆ Science advisors and decision makers need to communicate to the public and stakeholders the degree and nature of scientific uncertainty and the risk management approach utilized in reaching decisions.

## **V. Openness**

Democratic governments are expected to employ decision making processes that are transparent and open to stakeholders. Openness implies a clear articulation of how decisions are reached, policies are presented in open fora, and the public has access to the findings and advice of scientists as early as possible. It is essential that the public be aware of what the responsibility of government is in relation to the use of science. In addition, decision makers need to treat the science advisory function as an integral part of the management process. Effective relationships between decision makers and science advisors benefit from an understanding of their differing perspectives and approaches. Policy makers and advice providers need to communicate to ensure that policy makers are convinced the science advice is current and sound. In turn, advice providers need to be confident that their advice is considered seriously in decision making. Finally, there needs to be consultation with stakeholder groups and public discourse to ensure that public values are considered in formulating policy. Early and ongoing consultation both within government and with the public can mitigate greater negative debate and controversy when policies are announced.

### *Guidelines*

- ◆ Decision makers need to provide early warning of significant policy and regulatory initiatives to key interest groups, other governments or international organizations, as appropriate.
- ◆ Departments need to allow scientists freedom to pursue a broad base of inquiry and undertake widespread and thoughtful discussions. Departments need to make every effort to support and encourage scientists to publish their research findings and conclusions in external peer-reviewed publications. However, inevitably, circumstances will arise where the findings and conclusions will conflict with existing government

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<sup>4</sup> The 'precautionary principle' dictates that action to reduce risk should not await scientific certainty.

policies. In these cases, departments need to review both the policies and all of the relevant scientific findings and advice in order to determine how to proceed.

- ◆ Departments need to publish and disseminate widely all scientific evidence and analysis (other than proprietary information) underlying policy decisions, and show how the science was taken into account in policy formulation.
- ◆ Decision makers need to explain how the advice they received was used and why the ultimate decision was made.
- ◆ Departments need to consider using public meetings to present policy; scientists need to have a leading role in explaining their advice and policy officials need to describe how the advice was secured and how the policies have been framed in light of the advice.
- ◆ The level of expected risk and controversy and the need for timely decisions should guide the nature and extent of consultation undertaken, with higher levels of risk and controversy demanding a greater degree of public consultation. Decision makers need to balance the need for timeliness in reaching decisions with the need for effective consultation.

## VI. Review

The principle of review includes two elements: 1) subsequent review of science-based decisions to determine whether recent advances in knowledge impact the science and science advice used to inform the decision, and 2) evaluation of the decision making process. Appropriate accountability mechanisms need to be in place to ensure that these principles and guidelines for sound science advice are followed.

### *Guidelines*

- ◆ Departments need to institutionalize a follow-up process that includes, once decisions have been made, the provision of written responses to the findings and recommendations that emerged during the advisory process.
- ◆ Policy decisions need to be reviewed subsequently to determine whether recent advances in knowledge impact the science and science advice used to inform the decision. The period for review will depend on the state of the science (e.g., the level of uncertainty, rate of change in the scientific knowledge) and a maximum period before review should be identified at the time the decision is taken (e.g., establish a "best before" date).
- ◆ When asked to review past decisions, advisors should have access to all relevant information including previous analyses and official responses.
- ◆ Departments should capture best practices that emerge from the advisory process and feed these into their guidelines for use of science advice in the future.

## ***Implementation***

Implementing the principles and guidelines will help build public confidence in government decision making. Adherence to the principles and guidelines will also lead to better understanding of the contribution of science to departmental and government-wide missions and mandates.<sup>5</sup> A strategy for implementing the science advice principles and guidelines must include three elements: 1) promoting their adoption, 2) ensuring their adherence by individual departments and across government, and 3) monitoring their effectiveness. The following options are provided for consideration as part of an implementation strategy.

### **Promoting the Adoption of Science Advice Principles and Guidelines**

- ◆ Identify the people who can assist departments adopt the principles and guidelines.
- ◆ Provide professional development/training to government decision makers and scientists to improve science communication and the use of science advice in policy making.
- ◆ Make all government departments, not just the science-based departments and agencies (SBDAs), aware of the principles and guidelines and encourage their use when dealing with science laden issues.
- ◆ Communicate the existence of the principles and guidelines to stakeholders and the public, and publicise cases that illustrate best practice in the use of science advice.
- ◆ Consider creating a Parliamentary Committee tasked with the examination of science and technology issues. One of its functions could be oversight of the use of science advice in government decision making.

### **Ensuring Adherence and Accountability**

- ◆ Provide a template or simple checklist to assist decision makers ensure they have adhered to the principles and guidelines.
- ◆ Require annexes to Cabinet documents and legislation that demonstrate adherence to the principles and guidelines and recommend science review procedures.

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<sup>5</sup> CSTA recognizes that implementing these principles and guidelines will make demands on the government's science-based departments. The government's capacity to undertake science required to inform decision making will be examined as part of CSTA's broader examination of the roles of the federal government as a performer of S&T and its capacity to deliver on those roles.



- ◆ Designate a “departmental champion” within each science-based department (perhaps the Science ADM) responsible for:
  - Guiding the implementation of the science advice principles and guidelines and ensuring the department’s adherence;
  - Preparing an annual report of the department’s measures which demonstrate adherence to the principles and guidelines; and
  - Sharing best practices with their counterparts in other SBDAs.
- ◆ Departments establish, through their Deputy Ministers, a mechanism to ensure that science advice is received and acted upon in a timely fashion in reaching government decisions.
- ◆ Identify a government-wide coordination and accountability mechanism (possibilities include the Committee of Senior Officials (COSO) S&T Committee, the Ethics Counsellor, etc.) responsible for:
  - “Championing” the principles and guidelines government-wide;
  - Ensuring the application of the principles and guidelines to ‘horizontal’ issues;
  - Receiving the departmental annual reports and preparing a government-wide annual report on science advice (perhaps included as an annex to the Annual S&T Report);

### **Monitoring Effectiveness**

- ◆ Assess the application of the principles and guidelines through:
  - Audit mechanisms;
  - Reports to a designated “oversight function” such as a parliamentary committee (e.g., the proposed new Science and Technology Committee or the Natural Resources and Government Operations Committee) or the Auditor General;
- ◆ Measure the success of the government science advice principles and guidelines through review by an external advisory body (such as departmental science advisory committees and CSTA).

### **Conclusion**

The principles and guidelines contained in this report address how science advice should be sought and applied, but CSTA recognizes that the government must establish policies and make decisions when certainty does not exist and, at times, under extreme time constraints. The principles and guidelines espoused should not inhibit action, but rather guide action.

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## HEALTH PROTECTION IN THE NEW

### "FOOD SAFETY AND INSPECTION BILL"

April 22, 1999

The legislative consolidation of eight Acts dealing with food, including the food provisions of the *Food and Drugs Act*, and agricultural inputs will provide for a uniform and consistent approach to safety and quality standards and related requirements; provide for a more consistent approach in areas such as licensing, imports, offences and penalties; ensure continuing food safety and protection of consumers and facilitate intergovernmental cooperation and coordination. This legislative initiative, while not a radical departure from the past, is comprehensive and significant. With all the food provisions moved to the "Canada Food Safety and Inspection Bill", the *Food and Drugs Act* will now be known as the *Health Products Safety Act*.

The Canada Food Safety and Inspection Bill reaffirms the Minister of Health's responsibilities for establishing policies and standards respecting any matter that may affect the safety and nutritional quality of food. This Bill maintains the current federal system of "checks and balances" established by the government in creating the Canadian Food Inspection Agency (CFIA). The CFIA is responsible for enforcement of all provisions with respect to food and the Minister of Health retains the authority to set safety and nutritional standards and policies and assess the effectiveness of the Agency's activities related to food safety.

In the 1999 budget, the Government has recognized the importance of a safe, nutritious food supply to the health of Canadians. Among the health protection and promotion initiatives announced, the Government is investing \$65 million over the next three years to enhance its food safety programs in Health Canada and to develop new food safety and nutrition policies.

### The New Food Safety and Inspection Bill

The provisions related to food safety and nutrition in the *Food and Drugs Act* have been carried forward and new provisions have been designed to improve Health Canada's ability to carry out its mandate. The legislation makes more explicit the responsibility of the Minister of Health for any matter that may affect the safety and nutritional quality of food. There is a new provision giving the Minister of Health the authority to make an emergency food standard under specific circumstances. Furthermore, this new legislation allows for the development of health and safety standards that are suitable for regulating new technology. There is also a new provision prohibiting tampering, threats of tampering or causing the public to believe food has been tampered with.

The proposed Act, *Canada Food Safety and Inspection Act*, includes the following provisions:

### Section 3

This section establishes that the purpose of the Act is to contribute to food safety and to regulate food, agricultural or aquatic commodities and agricultural inputs.

### Section 5

This section defines the Minister of Health's responsibility for policies and standards relating to any matter that may affect the safety or nutritional quality of food. Most policies and standards set by Health Canada address the food itself e.g. maximum residue limits for an agricultural chemical in a vegetable. However, this provision makes it explicit that the Minister of Health's authority is not limited to the final food product itself, but can extend to any matter which may affect the safety of foods such as the preparation and production of food for sale.

### Section 15

The prohibition against the **sale** of unsafe food is brought forward from the *Food and Drugs Act*. It was revised to make it more explicit that the prohibition addresses conditions associated with the safety of the food supply. The revision includes a modification to former sub-section 4(b) (unfit for human consumption) which now reads "injurious to health". Former sub-section 4(c) (consists in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance) is now covered under section 24.

### Section 16

This provision prohibits the manufacturing of a food for sale under conditions that may render the food injurious to health. It is also brought forward from the *Food and Drugs Act*, with the difference that the meaning of "unsanitary conditions" has been clarified to cover not only the physical conditions under which a food is manufactured but also include a reference to manufacturing requirements e.g. processing equipment to prevent the production of unsafe food. With the increasing sophistication and automation of food processing in the manufacturing of food, it is important to use adequate processing equipment and controls in order to produce safe food.

Provisions 15 and 16 make it clear that we are concerned with both the process and the product .

### Section 31

There is a new provision providing the Minister of Health with the authority to make an emergency food standard which would have legal effect immediately from the time it is made. This authority would only be exercised under special circumstances i.e when the Minister of Health believes that a food poses a serious danger to public health and safety, the regulations are inadequate to protect the public, and immediate action is required to protect the public. This authority is subject to close review by the Governor in Council. It complements the CFIA recall power found in the *CFIA Act* which is a tool to enforce existing regulations or standards. An example of a situation that would trigger the use of an emergency food standard is the domoic acid incident that occurred in 1987. Several people became severely ill and some died in an outbreak of food poisoning which was linked to consumption of mussels. The mussels were contaminated with domoic acid, a chemical which was unknown at the time. In such a

situation, a standard could be quickly developed under this authority which would prohibit the sale of potentially implicated mussels.

Other aspects in developing this new Bill were the consolidation of similar provisions to provide for uniform and consistent compliance and enforcement activities across all commodities. It is with this thinking in mind that general prohibitions were developed which address both safety and trade and commerce matters. The former section 5 of the Food and Drugs Act is consolidated in Section 19 which is aimed at prohibiting the labeling, packaging, sale etc., of a food in a way that is false, misleading or deceptive or that is likely to create an erroneous impression.

The new Bill does not include section 3 of the *Food and Drugs Act* which prohibits the advertising of food as a treatment, preventive or cure for diseases. Section 3 concerns products sold as therapeutic products as opposed to food in the traditional sense. This prohibition will remain unchanged in the *Health Products Safety Act* and will be addressed as part of the broader review of the health protection legislation undertaken by Health Canada.

The definitions from the eight Acts being modernized were consolidated and revised to provide for uniformity. Both Health Canada and the Canadian Food Inspection Agency have identified that issues which may impact on other commodities covered by the *Health Products Safety Act*, most specifically the definition of food versus drug, will be addressed as part of the broader review on health protection legislation currently being undertaken by Health Canada.

The Act provides for the Governor in Council to make regulations for carrying out the purpose of this Act and to identify a regulation as being necessary to protect health.

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## HPB Transition Legislative Renewal

# THE CANADA FOOD SAFETY AND INSPECTION BILL AND HEALTH PROTECTION LEGISLATIVE RENEWAL

April 1999

## Legislative Review by Canadian Food Inspection Agency

Following the creation on April 1, 1997 of the Canadian Food Inspection Agency (CFIA), a review was launched of eight pieces of legislation which the CFIA administered and/or enforced. Five of these statutes related directly to food and food products. Of these, the *Food and Drugs Act* had primacy for health and safety. This Act was a shared responsibility, with Health Canada establishing health and safety standards for food and the CFIA enforcing them. Accordingly, Health Canada was involved in the Task Force on Legislation which the CFIA established in June 1997.

Health Canada and the CFIA determined that potential changes in the *Food and Drugs Act* which affected commodities other than food would be dealt with under Health Canada's broader review, as described below.

In November 1997, the CFIA released a consultation document: *Legislative Renewal - Exploring Options for Legislative Change*. With the participation of Health Canada, the CFIA then conducted consultations from November 1997 to March 1998 involving provincial, industry and consumer stakeholders. With strong support indicated for the consolidation and modernization of food legislation, the CFIA, in cooperation with Health Canada, issued *A Plan for Legislative Renewal: Summary Report* in October 1998. This report indicated that a project team of CFIA and Health Canada officials would be established to create a single food Bill and develop a regulatory plan. Both the 1997 and 1998 documents also noted that issues related to non-food areas of the *Food and Drugs Act* would be considered under Health Canada's review of all health protection legislation.

## Health Canada's Review of Health Protection Legislation

In early 1998, Health Canada embarked on a legislative renewal exercise to update and integrate existing health protection legislation into a coherent and flexible system to better meet current and future challenges. Federal health protection legislation consists of those Acts which enable government to take action to address risks to health before they lead to injury or disease. Four statutes were identified as being most in need of modernization: the *Food and Drugs Act* (1953), the *Hazardous Products Act* (1969), the *Radiation Emitting Devices Act* (1970) and the *Quarantine Act* (1970).

In the spring of 1998, Health Canada issued its own consultation document concerning the renewal of health protection legislation: *Shared Responsibilities/Shared Vision*. This discussion paper noted that a review of all CFIA legislation was underway to consolidate and modernize the various Acts dealing with food and that Health Canada

and CFIA officials were working in cooperation to ensure coordination of the two reviews. The paper was distributed to over 4,000

individuals and organizations with an interest in health protection and was posted on Health Canada's website. A free phone line and an e-mail address provided interested parties with the opportunity to provide feedback. Two-day workshops involving 600 participants followed in six cities across Canada in September and October 1998. Some members of the Minister of Health's Science Advisory Board also attended and contributed to these sessions. A document entitled *National Consultations Summary Report - Renewal of the Federal Health Protection Legislation*, is now available. To provide further opportunities for public participation, Health Canada also funded the Consumers' Association of Canada to conduct focus groups in five additional cities.

In the 1999 budget, the Government has recognized the importance of a safe, nutritious food supply to the health of Canadians. Among the health protection and promotion initiatives announced, the Government is investing \$65 million over the next three years to enhance its food safety programs in Health Canada and to develop new food safety and nutrition policies.

### Next Steps

Health Canada plans to release a proposal later this year for a renewed health protection legislative framework. A second round of consultations will follow and it is hoped that a Health Protection Act can be drafted for tabling in the year 2000.

Officials of Health Canada will also be working closely with the CFIA and consulting with stakeholders on a review of the food-related regulations associated with the former *Food and Drugs Act* to allow for effective implementation of the Canada Food Safety and Inspection Act.

Additional information on the review of the health protection legislation and HPB Transition is available at

<http://www.hc-sc.gc.ca/hpb/transition/index.html>.

### CANADA FOOD SAFETY AND INSPECTION BILL INTRODUCED IN HOUSE OF COMMONS.

### HEALTH PROTECTION IN THE NEW "FOOD SAFETY AND INSPECTION BILL".

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TRANSITION

# *National Consultations Summary Report*

RENEWAL  
OF THE  
FEDERAL HEALTH  
PROTECTION  
LEGISLATION

Canada

## 12. FOOD

### Food Standards

To guide its decisions concerning the quality and safety of food, Health Canada should adopt the Codex Alimentarius Commission's<sup>2</sup> Statement of Principles. The Codex Statement of Principles specifies how science is to be used by decision makers concerned with food safety and the extent to which decision makers should take other factors into account.<sup>3</sup>

Health Canada should also consider adding a section to the new legislation that would establish the Codex as the "default" reference for decision makers concerned with food safety. In other words, the standards, guidelines and recommendations of the Codex would automatically apply in the absence of relevant Canadian statutes or regulations.

As well, Health Canada should establish advisory groups to set standards and regulations regarding the enrichment of food and food products.

Finally, the Department should develop standards against which claims about the nutritional benefits of food could be measured.

### Labelling of Food

Food labelling and the health benefits attributed to food are important to Canadians, said participants in the consultations. Health Canada should take active measures to inform Canadians about food safety and nutrition. One way to do this would be to establish a clearing house that would provide health professionals and the general public with reliable, scientific information about nutritional and health claims, as well as adverse effects, such as allergic reactions.

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<sup>2</sup> An intergovernmental organization to which more than 150 countries are members, the Commission's mandate is the protection of consumer health and the promotion of fair trade practices regarding food.

<sup>3</sup> The Codex Statement of Principles reads as follows:

1. The food standards, guidelines and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of the food supply.

2. When elaborating and deciding upon food standards, Codex Alimentarius will have regard, where appropriate, for other legitimate factors relevant to the health protection of consumers, and for the promotion of fair practices in food trade. In this regard, it is noted that food labeling plays an important role in furthering both these objectives. When the situation arises that members of Codex agree on the necessary level of protection of public health but hold differing views about other considerations, members may abstain from acceptance of the relevant standard without necessarily preventing the decision by Codex.



Labels attached to food products are an important source of consumer information. However, labels alone can't do the job. Health Canada should use other tools to help educate Canadians about food and nutrition.

Consumers' right to know what is in the food they eat is more important than industry's need to keep secret "proprietary" information. Food processors should be required by law to list all the ingredients of their products, including nutrition enhancers (added vitamins and minerals) and other additives (preservatives, colouring, etc.). Labels should list ingredients by name rather than by using vague terms such as "artificial flavours" and "spices." Food labels should spell out the food's nutritional value and indicate whether it contains any genetically altered substances or has been subject to any special treatments (such as irradiation) during preparation. Food processors should also be required to provide, on request, information about how their products are produced, processed, stored and distributed.

*Putting too much information on food labels could overwhelm and desensitize consumers, to the point where they might ignore important notices.*

## **Health Claims for Food**

Opposing views were expressed regarding health claims on food and food products.

*Health claims for food and food products should not be permitted. But claims regarding the function of food—for example, the claim that a certain food can decrease cholesterol absorption—could be allowed.*

*Health claims for food should be permitted, provided they are based on scientific evidence. The supporting evidence should be evaluated by an independent panel.*

*Health claims for food should be permitted, provided they are backed by scientific evidence. The type, quantity and scientific rigour of the supporting evidence should be proportional to the degree of risk associated with the health claim. This arrangement, though desirable, might cause problems due to the difficulty of deciding what evidence was sufficient and appropriate in each case.*

## **Food Handling**

The federal health protection legislation should include standards of practice and hygiene for anyone engaged in food processing and preparation. Owners of restaurants and other food outlets should be required to provide employees with the facilities they need to meet the standards.

New Reproductive & Genetic Technologies - June '96

## EXECUTIVE SUMMARY

New reproductive and genetic technologies (NRGTs) include interventions which attempt to overcome infertility or manipulate the conventional conception process to produce a pregnancy and enable the identification of fetal genetic anomalies and fetal sex. The power of NRGTs to create life outside the womb has the potential to reshape society and redefine the lives of future generations.

The development and application of NRGTs in Canada has raised many profound social, ethical, legal and health issues. While some NRGTs can enhance health and well-being, others threaten human dignity and treat women, children and the reproductive process as commodities. Opinion is divided on many of these issues, and consensus has not yet fully emerged on their appropriate place in Canadian society. However, Canadians have made it clear that they are looking to the federal government to manage these technologies in a way that protects those most affected and reflects our collective values.

### ***Management of New Reproductive and Genetic Technologies***

The Government of Canada's strategy to bring about a comprehensive management regime for NRGTs has two components:

- outright prohibition of unacceptable technologies through legislation
- development of a legislated regulatory regime to manage acceptable technologies.

The need to consult with provincial/territorial governments and other stakeholders to reach a broad consensus has required a phased implementation process.

The first phase of this comprehensive management regime was the voluntary interim moratorium, announced by the Government of Canada in July 1995, on nine problematic new reproductive and genetic technologies. This was followed with the establishment of the Advisory Committee on the Interim Moratorium on NRGTs in January 1996. The moratorium was expedient pending legislation on prohibitions, but it has not been

completely effective. There have been reports of non-compliance by some individual practitioners and fertility centres. To prohibit these undesirable practices and others not included in the moratorium, the government is responding through legislative action to make these practices illegal.

The introduction of prohibitions legislation constitutes the second phase of the government's comprehensive management regime. The major purpose of this document is to put forward, for public comment, a description of the third phase — a legislated regulatory regime for NRGs. Non-legislative elements, such as a Framework for Sexual and Reproductive Health, are also being developed.

### ***Legislative Framework***

The legislative framework described in this document is based on several guiding ethical principles: the need to balance individual and collective interests; protection of the vulnerable; the appropriate use of medical treatment; and accountability. The final legislative package on NRGs will deal with the collection, processing, distribution and use of human reproductive and genetic materials and fetal tissue in the provision of medical procedures and the conduct of medical research.

The legislation is intended to:

- protect the health and safety of Canadians,
- ensure the appropriate treatment of human reproductive materials,
- protect the dignity and security of all persons, especially women and children.

### ***Elements of Legislation***

Canadians told the Royal Commission on New Reproductive Technologies that certain practices were unacceptable and violate the principles of respect for human life and dignity. The following prohibitions reflect Canadians' views and are derived from the interim moratorium:

- a) sex selection for non-medical purposes;
- b) buying and selling of eggs, sperm and embryos, including their exchange for goods, services or other benefits, but excluding the recovery of expenses incurred in the collection, storage and distribution of eggs, sperm and embryos for persons other than a donor. (This prohibition will come into force over a period of time to ease the transition from the current commercial system to an altruistic system.);
- c) germ-line genetic alteration;
- d) ectogenesis (maintaining an embryo in an artificial womb);
- ~~e) cloning of human embryos;~~
- f) creation of animal-human hybrids;
- g) retrieval of sperm or eggs from cadavers or fetuses for fertilization and implantation, or research involving the maturation of sperm or eggs outside the human body;
- h) commercial preconception or "surrogacy" arrangements. (This prohibition has been modified from the moratorium definition.)

#### ***Prohibitions Not Contained in the Moratorium***

Five additional practices are included in the legislation which were not part of the interim moratorium. These practices were added as they are inconsistent with the principles of human dignity and respect and the non-commercialization of reproduction. They are:

- a) transfer of embryos between human and other species;
- b) use of human sperm, eggs or embryos for assisted human reproduction procedures or for medical research without the informed consent of the donor(s);
- c) ~~research~~ on human embryos later than 14 days after conception;
- d) ~~creation~~ of embryos for research purposes only;
- e) offer to provide or offer to pay for prohibited services.

The government's intention is now to move forward with the third and most complex phase of its comprehensive NRGT management regime — the development of the regulatory component. This component would be introduced in a second bill to Parliament which would amend the

using stem  
cells



prohibitions legislation introduced in June 1996 when it becomes law. Canada would then have a single piece of legislation that contains both prohibitions and regulatory controls.

The main component of this management regime could be the establishment of a regulatory structure, possibly in the form of an agency, separate from Health Canada, which would report to the Minister of Health. Major functions would be to develop standards for the use of reproductive materials in medical research and practice, to issue licences to permit such activities, and to inspect to ensure compliance with these standards.

### ***Non-Legislative Components***

The management of NRGs must be viewed within the broader context of sexual and reproductive health in general. Within that larger context, a Framework for Sexual and Reproductive Health is being developed by Health Canada with input from the provinces and territories and non-governmental organizations. The prevention of infertility is one of the areas addressed within the overall context of sexual and reproductive health.

The government is examining the implications of a more open system of information sharing in egg, sperm and embryo donation that would protect the vulnerable and recognize, as a priority, the well-being of children. To expand upon the legislative provisions, the government will also work with provinces and territories, non-governmental organizations and the public to examine the place and future direction of prenatal diagnosis and genetics in Canadian society.

### ***Next Steps***

The federal government will initiate further consultations with provinces and territories, and with stakeholders, on a proposed regulatory structure and non-legislative components of the management regime. Public comment on this document is now being sought.