Canadian Biotechnology Strategy Fund Financial Annual Report 2002-03

Agriculture and Agri-Food Canada Canadian Food Inspection Agency Department of Justice Environment Canada Foreign Affairs and International Trade Fisheries and Oceans Health Canada Industry Canada Statistics Canada Natural Resources Canada National Research Council

Canadian Biotechnology Secretariat Canadian Biotechnology Advisory Committee

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Canadian Biotechnology Secretariat

CBS Policy Framework for 2002-03

The renewal of funding for the Canadian Biotechnology Strategy (CBS) Fund was approved by Treasury Board Ministers in April 2002 at \$9.52 million per year from 2002-2003 to 2004-2005.

The CBS vision is to enhance the quality of life of Canadians in terms of health, safety, the environment, and socio-economic development by positioning Canada as a responsible world leader in biotechnology.

The CBS guiding principles: reflect Canadian values; engage Canadians in open dialogue; promote an innovative economy, sustainable development, competitiveness, public health and scientific excellence; and ensure responsible action and cooperation domestically and internationally.

The goals of the CBS reflect the need for Canadians to have access to, confidence in, and benefit from safe and effective biotechnology-based products and services. This is to be achieved largely through an effective scientific base and by maintaining excellence in Canada's regulatory system.

The CBS themes support the strategy's goals, and require partnerships with the provinces/territories, industry, academia, consumers, environmental groups and other interested parties. The ten themes are public confidence, communication and awareness, research and development, regulation to protect health and the environment, biotechnology for public health advantage, intellectual property, commercialization, international leadership, human resources, policy-relevant data collection, and sector strategies. Annex C details the working groups established to advance these areas, with associated resource allocations, and Annex D indicates allocations by theme.

In 1999, the Biotechnology Deputy Minister Coordinating Committee (BDMCC) established three strategic policy directions to guide horizontal biotechnology work of the CBS Fund:

- <u>Stewardship</u>: ensuring effective stewardship of biotechnology in the areas of health, safety, and the environment;
- <u>Benefits</u>: maximizing the many social, economic, and environmental benefits associated with biotechnology products and applications; and
- <u>*Citizen Engagement:*</u> engaging a wide spectrum of Canadians on biotechnology and its role in society.

The strategy provided a dual-track policy framework of ensuring effective stewardship of federal efforts on biotechnology while maximizing economic benefits for Canadians.

The Treasury Board Submission, approved in 2002, contains the objectives for the CBS pillars.

Strategic Objectives for Stewardship

The strategic objectives for the *Stewardship* policy direction for 2002-2003 are:

- To ensure that Canada's domestic policy and regulatory framework better anticipates and responds to priority biotechnology developments;
- To better influence international and regulatory frameworks including international methodologies, protocols and standards for monitoring and detecting biotechnology products and applications;
- To encourage other policy approaches and increase safe use of biotechnology;
- To ensure that Canada has the science base to support the regulatory process; and
- To ensure that Canada is prepared to address new public policy challenges related to genetic information and privacy.

The broad responsibility of Government creates public expectations for a wide stewardship role that protects the health and safety of Canadians. The Government of Canada has a direct role in the regulation of many biotechnology 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 ensure 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.

Strategic Objectives for Innovation (Benefits)

Strategic objectives for the *Innovation* policy direction are:

- To improve commercialization success;
- To maximize health and environmental benefits;

- To maximize the enabling effect of biotechnology; and
- To maximize biotechnology R&D investments.

For Canadians, the potential benefits of biotechnology are enormous with respect to quality of life. Biotechnology offers new therapeutics for treatment of diseases, new vaccines for prevention, new diagnostic tests, and new genetic testing for susceptibility to disease. It also 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 of lower costs and improved productivity.

Most industrialized countries are targeting biotechnology as one of the most important sources of jobs and economic growth in the 21st Century. The global market for biotechnology products is expanding at an unprecedented rate.

Strategic Objectives for Citizen Engagement

Strategic objectives for the *Citizen Engagement* policy direction are:

- To communicate with, respond to, and engage Canadians on emerging and existing issues;
- To improve transparency in decision-making in Canada; and
- To understand the strategic implications of major cultural shifts and value trends both in Canada and abroad.

Horizontal Accountability System for CBS Financial Management and Reporting

The Results-based Management and Accountability Framework (RMAF) was developed to allow the Government of Canada to measure the success of its horizontal management of biotechnology. It supports evaluation of the objectives achieved and the overall effectiveness of the CBS.

The CBS community has put in place an important planning, monitoring, collecting, reporting, information and networking tool to support the accountability, performance measurement and reporting requirements described in the RMAF approved in January 2002

In 2002, the Canadian Biotechnology Secretariat (CBSec) with the support of the Reporting and Accountability Working Group finished the development of an upgraded version of an online Tracking System to allow federal government departments to easily report on the performance of the CBS.

The system provides easy access to an important planning, monitoring and information tool by tracking project progress and fund usage by outputs and activities, as well as, performance indicators related to outcomes and key results. The system ensures that results information is available for informed decision-making.

Project managers are required to provide detailed deliverables, as well as report on funds received and expended during the length of their projects. Then, the system estimates lapsing funds automatically. Project managers are able to ascertain their project allocations and expenses by outputs and activities, which are tracked by the system.

This system produces a range of reports to allow the policy coordinators, departmental leaders, and project managers to evaluate project progress and rapidly detect any delays or funding problems, thus allowing for reallocation of funds if necessary.

The tracking system acts as a networking and communication tool by providing access to current information on project description, contact names, and e-mail addresses.

This system is designed to collect information related to other biotechnology initiatives besides the CBS Fund, including data from federal and provincial governments, institutions, NGOs, the private sector and other international organizations. This section of the system is under development and will help to minimize over-lap of activities among these biotechnology players.

In the future, the system could support the financial reporting of other groups under the CBS that are presently reporting independently, such as the Canadian Regulatory System for Biotechnology (CRSB) and the Federal Genomics Research program. This will reduce the reporting burden for the federal government departments involved in the strategy.

The official launch of this system was set for December 2002, but due to the extension of the training sessions and feedback received from departments, it was formally launched in March 2003.

Allocation of CBS Funds for 2002-2003

Current biotechnology priorities have evolved since the CBS fund was initiated in 1999-2002. During the CBS Fund phase I from 1999-2002, priorities were largely focused on R&D. In 2002-03, priorities were oriented to policy development to reflect the dynamic pace of the biotechnology agenda in Canada, and the availability of new funding specifically designed to support biotechnology R&D.

The approved Treasury Board Submission for 2002-2005 provides flexibility for the allocation of the CBS funds after the approval of a work plan for each fiscal year.

The following projects were approved for 2002-2003.

Stewardship Projects

2002-01	The Development and Enactment, under the Fisheries Act, CEPA (1999)
	Equivalent Regulations for Products of Aquatic Biotechnology
2002-02	Biotechnology, Ethics and Public Confidence
2002-03	Use and Protection of Private Genetic Information in the Context of
	Work- part 1: Analytical Component
2002-04	Use and Protection of Private Genetic Information in the Context of
	Work-Part 2: Development of Policy Options
2002-05	Gene Bank Inventory within Health Canada
2002-06	Genetic Material Survey – Biotechnology Companies
2002-06	Gene Bank Inventory of Other Federal Department
2002-07	An Assessment of Genetic versus Health Information
2002-08	The Disincentives to Predictive Genetic Testing
2002-09	Assessment of Science Advancement Impacting Federal Management of
	Genetic Privacy and Information
2002-13	Overview and Analysis of Human Rights Law
2002-14	Overview and Analysis of Genetic Privacy Law
2002-15	Dedicated Poll on Genetic Information and Privacy
2002-16	Genetic Privacy and Information Working Group Secretariat
2002-17	Cartagena Protocol on Biosafety
2002-18	Addressing International Biotechnology Policy Challenges
2002-19	International Stewardship: Scoping and Delivering a Capacity Building
	Strategy in Developing Countries
2002-20	Mapping the Debate and Strengthening Regulatory / Policy Developments
	in Forest Biotechnology
2002-21	Completing the CGSB Voluntary Labelling Standard for Foods in order to
	Meet Consumer Information Needs in the Area of Food Biotechnology
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International Harmonization of Safety Criteria for Foods and Feeds and Environmental Assessment of Transgenic Plants
Towards Developing a National Science Policy to Strengthen Stewardship
of Human Health-related Biotechnologies Strategies for Long-Term Health and Environmental Effects - Plans and
Strategies
Long-Term Ecosystem Effects of GMO's (EEGMO) Program
Quantitative Measurement of GMOs-Phase I
Monitoring and Assessing Potential Gene Flow from GMO Canola to
Other Brassica Crops and Crucifer Weeds
Evaluating Movement of BT-Resistant Canola
Guidance Document for Ecological Effects of Microbial Products
Assessment of Transgenic Fish for Environmental Risk
Legal and Jurisprudence Analysis on Privacy and Discrimination.

Innovation Projects

2002-31	Analysis of the Canadian Biotechnology Sector: Building the Knowledge
	Base
2002-32	Benchmarking and Best Practices of Regulatory Approval Systems
2002-33	The Assessment of Commercialization Needs of Biotechnology
2002-34	Building Biotechnology Expertise within the Trade Commissioner Service
2002 25	and Government
2002-35	Biotechnology Statistics Program
2002-36	Developing Highly Qualified Personnel in the Canadian Biotechnology
	Sector
2002-37	Phytoremediation and Other Technologies and Approaches
2002-38	Promoting the Benefits of Bioproducts and the Bioeconomy
2002-39/A	Improve Knowledge of Technology Trends- Post-Genomics and
	Proteomics Study
2002-39/B	Biopharmaceutical Industry Roadmap Component of the NRC's
	Biopharmaceutical Technology Roadmap and Forecasting Exercise
2002-39/C	Technology Foresight and Competitive Intelligence: a Pilot Project on
	Proteomics and the Health Sector
2002-40	Biopharmaceuticals Technology Roadmap (TRM)
2002-41	Strengthen R&D Infrastructure in Canada
	-

Citizen Engagement projects

2002-42	Enhancing Outreach and Consumer Understanding: Addressing New
	Environmental and Health Issues Associated with Products of
	Biotechnology
2002-43	Informing and Engaging Federal Decision Makers

2002-45	Biotechnology Regulatory Assistance Virtual Office (BRAVO) Enhancement/ Biotechnology Regulatory Pathway to Market
	Development (BioRPM)
2002-46	Biotechnology and the Consumer -Phase II Development & Citizen
	Engagement Strategy
2002-47	Public Environment, Media Analysis & Communications Support

Foundation Project

2002-48 CBS Results-based Management and Accountability Framework

Emerging Issues Fund Allocation (2002-2003)

The Emerging Issues Fund (EIF) was created to provide resources to CBS departments and agencies for new or emerging priorities. A total of \$270,000 was allocated to the EIF in this fiscal year for the following projects:

- 2002-49 International Policy Scan for Bio-based Economy
- 2002-50 Molecular Farming
- 2002-51 Trend Analysis Report on Biotechnology Patent Data
- 2002-54 Study of Current Levels of Understanding of Federal Decision Makers

\$68,000 was transferred from the EIF to the Canadian Biotechnology Advisory Committee (CBAC) to support the Acceptability Spectrum project (the development of a new tool to support dialogue on contentious issues) and \$50,000 to Industry Canada for an emerging priority on Bio Products.

Financial Performance 2002-2003

CBS Fund:

On April 25 2002, Treasury Board Ministers approved the CBS Fund Treasury Board Submission for 2002-2005. This submission allocated specific amounts by department for 2002-03, and a detailed workplan was presented for this fiscal year. Overall financial performance for 2002-03 is summarized in Annex A. As indicated in Annex B, a total of \$6 million was allocated among three strategic pillars: Stewardship (\$3.2 million), Innovation (\$1.6 million) and Citizen Engagement (\$1.0 million). In addition, \$3.52 was allocated to CBSec to support CBAC and secretariat operations, including RMAF reporting and the EIF.

The remainder of this section drills down on financial results under each of the major program areas.

a. Stewardship:

Of the \$3.32 million allocated to Stewardship from the CBS Fund, \$3.25 million was expended to ensure Canada's domestic policy and regulatory framework, to better influence international and regulatory frameworks, to encourage other policy approaches and increase safe use of biotechnology, to build the Canadian science base to support the regulatory process, and to address new public policy challenges related to genetic information and privacy.

Details of the CBS Fund expenditures under <u>Stewardship</u> follow:

- \$1.26 million for policy-related projects to address ethics and public confidence, use and protection of private genetic information, legal overview and analysis related to genetic information, privacy law and human rights law, long-term effects of Genetically Modified Organisms (GMO's), safety criteria for foods and feeds, and to strengthen stewardship of human health-related biotechnologies;
- \$895,000 for stewardship R&D in different sectors, such as health, environment, agriculture, fisheries and industry;
- \$395,000 to support international stewardship work on a capacity-building strategy in developing countries and the Cartagena protocol;
- \$360,000 for data collection, which is important to advance analysis and understanding of the biotechnology stewardship issues and trends; and
- \$340,000 to support regulations for developments related to the Fisheries Act, forestry, voluntary labelling, and molecular farming.

b. Innovation:

Innovation is an important element of the CBS. While the CBS fund allocated a total of \$1.6 million to the Innovation pillar, \$1.7 million was expended (as indicated in Annex B), including EIF allocations, to pursue its main objectives as follows: to improve commercialization success, maximize health and environmental benefits, maximize the enabling effect of biotechnology; and maximize biotechnology R&D investments.

CBS Fund expenditures under Innovation are summarized as follows:

- \$618,000 was invested in R&D to understand factors influencing commercialization, phytoremediation, technology trends post-genomics and proteomics, the biopharmaceutical industry and technology roadmap, and to strengthen the R&D infrastructure in Canada;
- \$549,900 was invested in policy work related to regulatory approval systems, biotechnology expertise, bioproducts, the bio-based economy, privacy and discrimination, and knowledge management;
- \$435,000 was expended to continue four surveys developed by Statistics Canada under the Biotechnology Statistics Program (Federal S&T Expenditures in Biotechnology, Biotechnology Industrial R&D, Biotechnology Use and Development Survey, and International Comparisons) to support the CBS community. Other specific surveys have been conducted in various departments to develop baseline data for analysis of the Canadian biotechnology sector, proteomics, and biotechnology patents in Canada and abroad; and
- \$100,000 was expended to assess the biotechnology human resources requirements and needs in Canada.

c. Citizen Engagement

Understanding Canadians' perspectives on applications of biotechnology is a key feature of the CBS Fund. While \$1 million was allocated for this initiative, a total of \$1.03 million was expended (as indicated in Annex B) on the following objectives¹: to enhance outreach and consumer understanding of regulatory information; to inform regulatory policy developments by engaging Canadians and opinion leaders or decision makers; to improve the understanding of governance in biotechnology; to enhance the "Bravo" web-

¹ The \$31,080 discrepancy is attributed to the rollover funds from the previous year in the amount of \$11,080 and the emerging issue funds allocated to the project titled "Knowledge Management for Federal Decision Makers" in the amount of \$20,000.

site, which provides information on technology applications such as xenotransplantation, stem cell research, gene therapy, transgenic animals and nanotechnology; to conduct ongoing media and stakeholder analysis and public opinion research; to develop and support the communications web-site; and to study the current levels of understanding of federal decision-makers.

d. Foundation:

A total of \$250,000 was spent on *Foundation* work.

\$187,000 was expended to improve the CBS governance structures through the implementation of the RMAF, including the upgrade of the CBS Tracking System, departmental reporting support, the CBS Formative Evaluation, and the development of the first CBS Public Report. The CBS Tracking System was redesigned at a cost of \$55,060 to support the RMAF requirements approved in January 2002. \$102,000 was expended in 10 federal government departments to complete data collection in the CBS Tracking system by the summer of 2002. All departments finished their data collection before March 2002. The CBS community has expended \$29,880 to assemble the first CBS public report from 1998-2003 that is available on the Bioportal website². In addition, \$50,000 was expended for one staff resource assigned to manage, support and report on the CBS Tracking system.

e. The Canadian Biotechnology Advisory Committee (CBAC)

CBAC expended a total of \$1.13 million to monitor and report developments in biotechnology, to provide advice to Ministers on emerging issues that require the Government's attention, and to support communication and outreach activities to stimulate debate and dialogue among Canadians. CBAC's communication efforts during 2002-03 were directed towards two major goals:

- Publishing and promoting two final reports, *Patenting of Higher Life Forms* and *improving the Regulation of Genetically Modified Foods*, which were the culmination of more than two years of work on special projects dating from the inception of CBAC;
- Increasing CBAC's visibility and ability to engage Canadians through a major redesign of the CBAC website and awareness materials (brochures, bookmarks, etc), as well as the development of an exhibit program.

All of CBAC's research, consultation papers, reports and communication materials are available on the CBAC web site at <u>www.cbac-cccb.ca</u>

² http://www.biostrategy.gc.ca/english/view.asp?x=540

During 2002-03, CBAC provided the following major outputs:

Consultations:

- 1. Long Term Monitoring of Health Effects Related to Genetically Modified Foods in Canada Post Market Surveillance and the Role of Labelling
- 2. Exploratory Committee Examines an 'Acceptability Spectrum' for GM Foods
- 3. Examination of Biotechnology and Health Innovation

Project Reports:

- 1. <u>The CBAC Annual Report</u> from January 2002 to December 2002
- 2. Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada
- 3. Patenting of Higher Life Forms and Related Issues
- 4. Patenting of Higher Life Forms and Related Issues: Summary of Comments, Responses to CBAC Interim Report

CBS Fund Partner Contributions 2002-03

CBS funded projects received total partner contributions of \$2.1 million as follows:

- Federal departments and agencies operating budgets \$1.57 million
- Private sector \$293,000
- Other institutions \$269,000

Looking Forward

The 2003-04 workplan for the Canadian Biotechnology Strategy (CBS) is focused on undertaking strategic, horizontal work required to develop a coherent biotechnology agenda that captures the benefits of biotechnology while managing the associated risks.

The three pillars of the CBS –Innovation, Stewardship, and Citizen Engagement– provide the framework to address two new strategic priorities approved by the Biotechnology Deputy Ministers Coordinating Committee in December 2002. These priorities are *biotechnology in health innovation*, and *building the bio-based economy*.

This work plan will address gaps in our current knowledge base and will provide the analysis required for decision-making on new strategies that will have an impact on growth and development of biotechnology in Canada. As a whole, the workplan ranges from specific data-generating projects to framework development and analysis of policy options that inform new strategies. Integral to the package is horizontal work that capitalizes on synergies and builds on work already underway.

Conclusion

During 2002-03, the CBS Fund was invested under three pillars (Stewardship, Innovation and Citizen Engagement) in 53 biotechnology projects spread across ten federal government departments (AAFC, DFAIT, DFO, EC, HC, HRDC, IC, DOJ, NRCan, VAC), two agencies (StatsCan, CFIA), and one council (NRC). A fourth pillar, Foundation, was included for the first time in order to enhance the government's ability to inform biotechnology decision-making. This fiscal year, the CBS Fund has been more oriented to policy development activities in emerging areas in biotechnology.

Important work has been performed related to ethics and public confidence, genetic information and privacy, long-term effects of Genetically Modified Organism (GMOs), regulatory approval systems, bio-based economy, privacy and discrimination, and knowledge management.

CBAC continues to provide advice to Ministers on emerging issues that require the Government's attention, and to support communication and outreach activities to stimulate debate and dialogue among Canadians. This fiscal year, two major reports have been finalized "Patenting of Higher Life Forms" released in June 2002 and "Improving the Regulation of Genetically Modified Foods followed in August 2002.

The CBS community is actively building a strong accountability framework to allow the Government of Canada to measure success. The CBS Fund RMAF and an upgraded tracking system are in place to support the community towards achieving this goal.

To continue contributing to the CBS vision, the 2003-04 workplan for the CBS is focused on undertaking strategic, horizontal work required to develop a coherent biotechnology agenda that captures the benefits of biotechnology while managing the associated risks.

Annex A

CBS Fund Financial Overview 2002-2003

Department		CBS Funds (000)					
(Operating and Capital	Allocation	EIF	Carry			Evnenditures	Unovnondod
funds and related- EBP	(All pillars)	Expenditures	forward	Transfer	Sub-total	Expenditures All pillars	funds
and Accommodation)	(/ p	Experiance	All pillars			, in pinare	Tunido
AAFC	\$200				\$200	\$200	\$0
CBSec *	\$900	\$35	\$11		\$946		\$14
CFIA	\$450				\$450		\$0
DFAIT	\$450				\$450	•	\$74
DFO	\$205				\$205	\$205	\$0
EC	\$735				\$735	\$735	\$0
HC	\$650				\$650	\$650	\$0
HRDC	\$75				\$75	\$63	\$12
IC	\$850	\$40			\$890	\$873	\$16
DOJ	\$380				\$380	\$380	\$0
NRC	\$630				\$630	\$630	\$0
NRCan	\$290				\$290	\$290	\$0
StatsCan	\$300				\$300		\$0
VAC	\$85				\$85	\$85	\$0
Sub-Total	\$6,200	\$75	\$11		\$6,286	\$6,169	\$116
CBAC Operations	\$1,133		\$203		\$1,336	\$1,128	\$208
Sub-Total	\$1,133		\$203		\$1,336	\$1,128	\$208
CBSec (O&M)	\$615		\$203		\$535		\$ 200 \$152
	\$015		ψU		ψ000	ψ002	ψ152
Sub-Total	\$615		\$5		\$535	\$382	\$152
CBSec (salaries)	\$979		\$0	\$130	\$1,109		\$2
EBP	\$196		\$0	\$26	\$222		\$0
Accommodation	\$127		\$0	\$0	\$127		\$0
Sub-Total			\$0.00	\$156	\$1,458		\$2
Emerging Issues Fund	\$270		\$10	-\$158	\$122	\$35	\$87
Transfer to fund high							
priority proposals 2002-							
03 (details on proposals are included under							
each respective pillar)							
and CBAC to fund \$68							
to the acceptability							
spectrum.							
Sub-Total			\$10	-\$158	\$122		\$87
TOTAL (O&M and		\$75	\$229	-\$88	\$9,737	\$9,171	\$565
salaries)							

salaries) * This includes project 2002-48 (RMAF implementation) only O&M expenses, salary expenses are included in CBSec's salaries.

CBS Allocation by pillar (\$000)						
Pillar	Allocation	Percentage of total	Expenditures	Percentage of total		
Stewardship	\$3.320.0	55%	\$3.249.1	53%		
Innovation	\$1,680.0	28%	\$1,703.4	28%		
Citizen Engagement	\$1,000.0	17%	\$1,030.4	16%		
Foundation			\$186.8	3%		
Total	\$6,000.0	100%	\$6,169.7	100%		

Annex B: CBS Fund 2002-2003 Allocation and expenditure by Pillar

Annex C

Working Group	\$000	Percentage of total	
Analysis	\$648.5	11%	
Ethics	\$175.0	3%	
Health and Ecosystem Science	\$1,185	19%	
Regulatory	\$615.0	10%	
Biosafety	\$295.0	5%	
International	\$501.3	9%	
Bioproducts	\$225.0	4%	
Communications and Outreach	\$1,030.0	17%	
Genetic Information & Privacy	\$927.8	15%	
Reporting and Accountability	\$187.0	3%	
S&T	\$380.0	6%	
Total	\$6,169.7	100%	

CBS Fund 2002-2003 Overview by Working Group

Annex D

CBS Fund 2002-2003 Overview by Theme

CBS allocation by Theme				
Theme	Expenditures (\$000)	Percentage of total		
Communication	\$1,030.4	17%		
Data collection	\$795.0	13%		
Governance	\$186.9	3%		
Human Resources	\$100.0	1%		
International	\$395.0	6%		
Policy	\$1,809.0	29%		
Regulation	\$340.0	6%		
Research and Development	\$1,513.4	25%		
Total	\$6,169.7	100%		