Canadian Biotechnology Strategy
Overall Performance Report
1999-2002

Agriculture and Agri-Food Canada
Canadian Food Inspection Agency
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 -Policy Coordination
Canadian Biotechnology Advisory Committee

July, 2002

Executive Summary

The biotechnology industry is one of the world's fastest growing sectors, expanding four times faster than the G-7 average for all sectors. Advances in biotechnology that are taking place throughout the world are driving Canadian policies on biotechnology.

The government of Canada approved in June 1998 the Canadian Biotechnology Strategy for ensuring Canadians fully realize biotechnology's potential to improve Canadians' quality of life in terms of health, the environment, and social and economic development; and to position Canada as a responsible global leader in the development and application of biotechnology. It comprises seven ministers: Industry, Agriculture and Agri-Food, Health, Environment, Fisheries and Oceans, Natural Resources, and Foreign Affairs and International Trade.

In 1999, a total of $28.56 million earmarked in the fiscal framework for the fiscal years 1999-2002 was allocated among five CBS components: CBS Fund projects across federal departments, Canadian Biotechnology Secretariat (CBSec) / Policy Coordination, Canadian Biotechnology Advisory Committee (CBAC), the Corporate Communications Fund (CCF) and the Emerging Issues Fund (EIF).

Roughly two-thirds of the Fund was devoted to a range of CBS projects to assist federal departments and agencies in implementing the three CBS policy directions Stewardship, Benefits and Citizen Engagement, in collaboration with provincial governments, institutions, private sector and others.

The CBS Fund allocated 35% of funds towards science–based projects; 11% to communications on biotechnology issues; 9% on projects that developed regulatory frameworks and international standards for biotechnology; 5% to improve the Canadian biotechnology sector's access to international markets; 2% to improved capacity building; 4% to research and release statistics on the biotechnology industry in Canada. Less than 1% was allocated to develop federal policy research on privacy issues raised by the availability of genetic information and to coordinate and developed the accountability and evaluation framework for the CBS.

In addition, 32% was allocated to CBSec to support the activities of CBAC, the expert advisory panel, and for consultations with Canadians and CBSec – Policy Coordination to monitor and evaluate the CBS Fund, and provide support for the various interdepartmental CBS committees.

CCF allocated 2% to support the interdepartmental Communications Working Group, which provided communications advice and supported federal departments and agencies through regular public opinion research, bi-weekly media and stakeholder analysis, a CBS web-site, and coordination of communications activities across the government.

The federal Government supported other initiatives under CBS. It provided funding to Genome Canada to develop and implement a national strategy in genomics research for the benefit of Canadians; invested in the Canadian Regulatory System for Biotechnology (CRSB); created 9 networks of Centres of Excellence directly involved in biotechnology research; throughTechnology Partnerships Canada (TPC) invested strategically in research, development and innovation, in order to encourage private sector investment and promote economic growth; supported researchers in hospitals, universities and research centres across Canada though The Canadian Institutes of Health Research (CIHR); created The National Institutes for Nanotechnology to improve studies on cellular constituents such as genes, proteins and lipids, and presented a draft and bill of the Assisted Reproduction Technology Act.

Provincial governments in Canada have also increased their efforts in the biotechnology sector over the past three years, most notably in Ontario and Quebec. Provincial government focuses are in the economic development of the biotechnology industry, rather than regulation and citizen engagement.

Canadian Biotechnology Strategy Fund: Phase I

INTRODUCTION

In the spring of 1998, the federal government conducted a series of consultations on the renewal of the 1983 National Biotechnology Strategy. From this renewal process emerged the *Canadian Biotechnology Strategy* (CBS), approved by Cabinet in June 1998. Included in the CBS was a total of $28.56 million earmarked in the fiscal framework for the CBS Fund for the fiscal years 1999-2000 to 2001-2002, the establishment of a governance structure and the Canadian Biotechnology Advisory Committee.

The CBS Fund built upon the previous National Biotechnology Strategy by:

- Creating a policy framework (vision, guiding principles, goals, themes) that integrates social, ethical, health, economic, environmental and regulatory considerations;
- Establishing a balanced and broad-based advisory committee (CBAC);
- Addressing public information and participation;
- Providing the context for strengthening the business, regulatory and investment climate; and
- Improving government's ability to manage horizontal issues.

INTERDEPARTMENTAL COORDINATION

The federal internal governance structure for biotechnology comprises seven ministers whose portfolios most closely touch on biotechnology matters: Industry, Agriculture and Agri-Food, Health, Environment, Fisheries and Oceans, Natural Resources, and Foreign Affairs and International Trade.

The Biotechnology Ministerial Coordinating Committee (BMCC), chaired by the Minister of Industry, oversees the CBS and addresses issues that cut across the mandates of various federal departments and agencies.

The Biotechnology Deputy Minister Coordinating Committee (BDMCC), also chaired by Industry Canada, meets as required to provide strategic policy guidance and to establish the government's priorities with respect to biotechnology.

The Biotechnology Assistant Deputy Minister Coordinating Committee (BACC) is co-chaired by Industry Canada (permanent) and another department (currently Health) on a rotational basis. BACC has one representative from each of the seven key biotechnology departments, as well as one from NRC and one member representing the three granting

councils (Canadian Institutes of Health Research (CIHR), Social Sciences and Humanities Research Council of Canada (SSHRC) and Natural Sciences and Engineering Council of Canada (NSERC)), collectively referred to as "the Tri-Council".

The Biotechnology Director General Coordinating Committee (BDGCC) provides a forum for early discussion of policy options and issues of mutual concern to develop recommendations on these policy issues. It is chaired by the Executive Director of the Canadian Biotechnology Secretariat (CBSec) and meets as required to ensure interdepartmental coordination at the senior staff level.

CBS POLICY FRAMEWORK

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

The CBS guiding principles are to: 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 maintaining excellence in Canada's regulatory system.

The CBS themes were established to implement the strategy's goals in partnership with 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; technology commercialization; international issues; human resources; policy-relevant data collection; and sector strategies.

In 1999, the BDMCC established three strategic policy directions to be followed for roughly equal allocations of the CBS Fund:

Stewardship: ensuring effective stewardship of biotechnology in the areas of health, safety and the environment;

Benefits: maximizing the many social, economic and environmental benefits associated with biotechnology products and applications;

Citizen engagement: engaging a wide spectrum of Canadians on biotechnology and its role in society.

ALLOCATION OF CBS FUNDS

In 1999, a total of $28.56 million over three years was allocated among five CBS components.

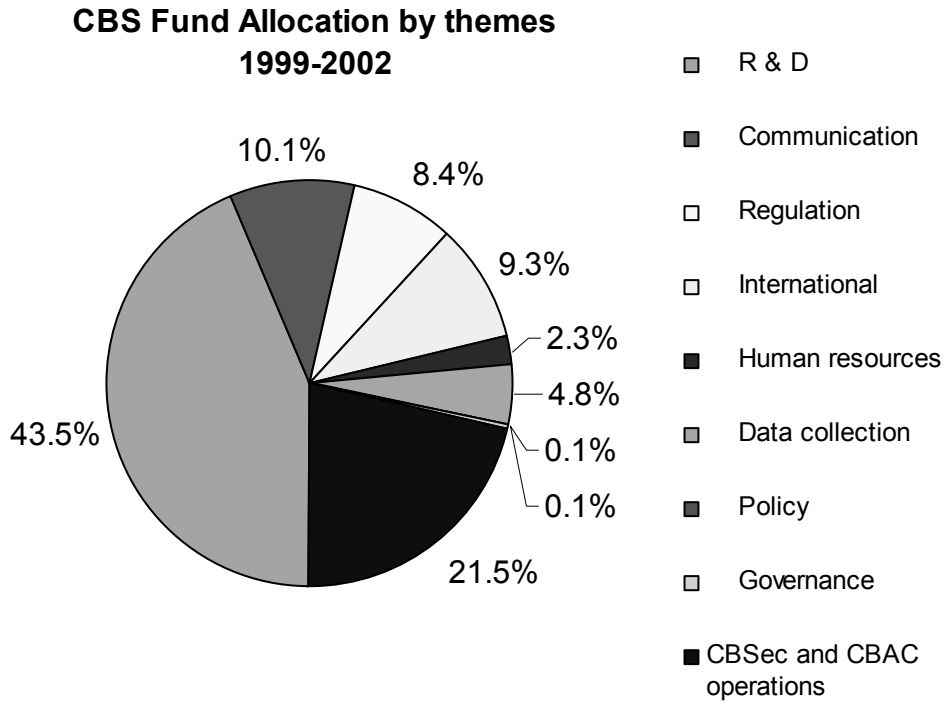
- Roughly two-thirds of this amount ($18.25 million) was devoted to a range of CBS projects to assist federal departments and agencies in implementing the three CBS policy directions, in collaboration with government and private sector partners (the "CBS Fund).

- The Canadian Biotechnology Advisory Committee (CBAC) received $6.5 million to support the activities of its expert advisory panel and for consultations with Canadians.

- The Canadian Biotechnology Secretariat (CBSec) received $2.5 million to monitor and evaluate the CBS Fund, and to provide support for the various interdepartmental CBS committees.

- A $650,000 Communications Fund was established to support the inter-departmental Communications Working Group which provides communications advice and support to federal departments and agencies.

- A $650,000 Emerging Issues Fund (EIF) was created to provide flexibility to BACC to quickly access funds for new or emerging priorities.



REVIEW OF CBS FUND

CBS Fund Projects

Selection process:

The CBS projects were selected by a peer review process, whereby the project proposals were distributed to participating government departments/agencies and rated on five selection criteria: significance; benefits from outcome; likelihood of success; incrementality; and collaboration. In addition, the projects were selected to give equal weighting to the three strategic policy directions: benefits; stewardship; and citizen engagement. Results were tabulated by a third party and the final suite of projects was selected by consensus.

The original peer review process selected 29 projects. One project was cancelled in the first year of the CBS (1999-00) and the funds were re-allocated by BACC to four additional projects. Thus, a total of 32 projects were supported by the CBS Fund during the reporting period.

Results:

The 32 CBS Fund projects were led by 11 federal departments and agencies, and involved significant collaboration with provincial governments, universities, hospitals, private companies, and international organizations. Leveraging of funds, through contributions from the various partners, effectively doubled the size of the CBS projects fund to total $38.26 million. Of equal importance, collaborative efforts on the CBS projects have resulted in the construction of valuable communication channels within the Canadian biotechnology community.

More than one-half of the funds for the CBS projects were allocated toward science-based projects, which were evenly distributed between the Stewardship and Benefits pillars. Stewardship projects used scientific research to establish health and environmental regulations for biotechnology products and applications. Benefits projects expanded Canada's research and development (R&D) base to support Canadian competitiveness in the biotechnology sector and related industries including agri-food, forestry, aquaculture and environmental technologies.

The majority of the scientific research focussed on the field of genomics. Canadian scientists have developed genomics-based diagnostic tools that will be used to screen biotechnology products for potential pathogens, detect genetically-modified organisms (GMOs) in forests and diagnose human, animal and plant pathogens using "DNA chips". Regulatory scientists have been able to increase their understanding of how GMOs may impact other elements of the environment including plants, insects, soil communities, forests and wild fish populations. In order to support continued Canadian innovation in genomics and related fields, the Canadian Bioinformatics Resource (CBR) was funded by

CBS. The CBR provides the computing infrastructure that will allow Canadian scientists to access important genomics databases and programs from around the world.

The CBS Fund also supported R&D projects that developed new technologies for Canadian industries. Bioremediation products were field tested to allow the clean up of contaminated waste sites using plants, trees and microorganisms. Natural chemical products in trees were identified with the goal of producing insecticides to protect forest resources from insect damage. Genetic databanks were developed to improve aquaculture breeding programs and to manage wild fish and lobster populations in Atlantic Canada.

In addition to R&D advancements, CBS projects aimed to benefit the Canadian biotechnology sector by improving its access to international markets, participating in international trade arenas related to biotechnology issues, and producing comprehensive databases of biotechnology activities and companies in Canada. An example of improving Canada's access to international markets is found in the Building Biotechnology Expertise project. Under this project, five week-long Capacity Building workshops were delivered in partnership with regional biotechnology industry associations. These workshops enabled and improved the ability of government officers, particularly those abroad, to identify market opportunities, gather technical market intelligence and better promote Canada's biotechnology industry. Each course covered the science, applications, component technologies and business elements necessary to understanding biotechnology and effectively promoted the commercial capabilities of the Canadian biotechnology companies internationally.

Canadian stewardship was enhanced by projects that developed regulatory frameworks and international standards for biotechnology products such as GM crops, trees and animals. Important legal and ethical issues were also examined, including those related to genetic information and privacy. In efforts to improve stewardship internationally, DFAIT, in partnership with HC and CFIA, undertook a project called Capacity Building in Developing Countries. The project has promoted internationally recognized regulatory and safety assessment approaches critical to maintaining a safe food supply as well as information/knowledge transfer. As well as providing an opportunity to further Canada's international stewardship role, the project promoted sound regulatory approaches in line with the safety standards of key multilateral fora such as CODEX, which in turn, contribute to our efforts to maintain market access for Canadian biotechnology products.

Canadian Biotechnology Advisory Committee (CBAC)

The 21-member Canadian Biotechnology Advisory Committee (CBAC) was established by Ministers to provide them with independent, expert advice on ethical, social, economic, scientific, regulatory, environmental and health aspects of biotechnology.

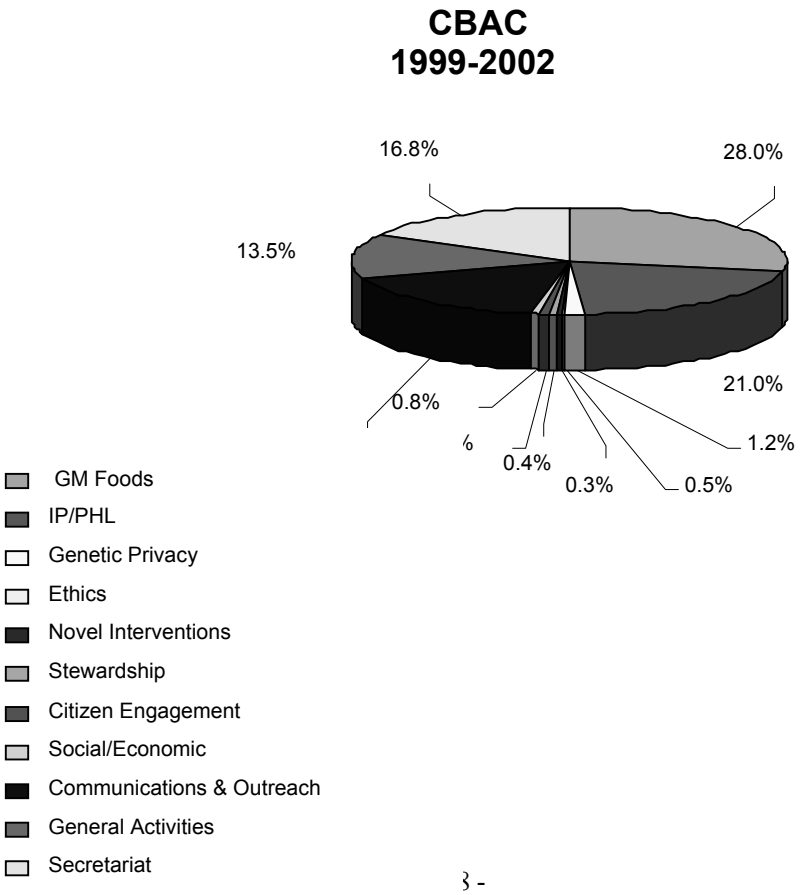
There are two categories of CBAC activities: general activities and special projects. General activities are those of a broad, ongoing nature such as monitoring biotechnology developments, facilitating public awareness of biotechnology, maintaining a forum for citizen engagement and participating in a variety of outreach activities. Special projects

involve the in-depth study of and public consultation on specific subjects as a basis for providing advice to government. Each special project is directed by a project steering committee made up of CBAC members.

In February 2000, CBAC identified five special projects that it should focus on over the following years: 1) regulation of genetically modified food; 2) protection and exploitation of biotechnological intellectual property and the patenting of higher life forms; 3) incorporating social and ethical considerations into biotechnology; 4) and the use of novel genetically based interventions; 5) genetic information and privacy. A total of $4,183,470 was spent on CBAC activities from 1999-2002. The allocation of these funds is indicated in the chart below.

CBAC began its work by focussing on the first two projects described above. More than 45 expert reports, research studies and think pieces have been produced. In addition, CBAC has undertaken comprehensive public and stakeholder consultations with members of industry, non-governmental organizations, academia and interested Canadians. CBAC has also conducted individual stakeholder hearings, multi-stakeholder workshops, electronic fora and other forms of web-based consultations in order to seek the views of Canadians. Interim reports on CBAC's first two projects were released in 2001; final reports are expected in early summer 2002.

CBAC web site address is: http://cbac-cccb.ca



Canadian Biotechnology Secretariat (CBSec)

CBSec has provided support to the biotechnology ministerial committees (BACC, BDGCC, BDMCC, BMCC) to coordinate, monitor and evaluate the CBS Fund. To facilitate this process, CBSec has implemented an on-line tracking system to effectively monitor and evaluate each of the 32 CBS projects.

CBSec directed the creation of the CBS Results-Based Management and Accountability Framework (RMAF). The framework was developed by the CBS Accountability Working Group, which is composed of policy and evaluation personnel from the seven signatory ministers, as well as representatives from the CFIA, NRC and the Results Measurement and Accountability group of the Treasury Board Secretariat (TBS). The objective of the framework was to allow the Government of Canada to measure the success of its horizontal management of the biotechnology file via the CBS. In doing so, the framework described performance measurement and reporting requirements for federal departments and agencies participating in CBS. The RMAF was approved in January 2002.

Communications Strategy

The Communications WG has served as a focal point for the CBS community by coordinating government messages and communications on biotechnology issues. The Working Group's achievements include the facilitation of five "waves" of public opinion research which have provided the CBS community with valuable data concerning the Canadian public's views on a wide range of biotechnology issues. The Working Group has also coordinated an analysis of biotechnology media coverage during 2000-01and 2001-02 and it has updated the CBS website.

Canadian Biotechnology Strategy Fund
Canadian Biotechnology Secretariat
FINANCIAL OVERVIEW - ACTUALS
1999-2002

	CBS FUND ACTUALS					
PROJECTS	**1999-00 (Actual)**	**2000-01 (Actual)**	**2001-02 (Actual)**	**Total CBS Fund**	**Partners Contributions**	**Total Project**
CBS FUND PROJECTS						
R & D	$3,454.85	$3,244.34	$3,130.96	$9,830.15	$9,988.50	$19,818.65
Communication	$1,151.65	$1,024.25	$952.20	$3,128.10	$1,475.20	$4,603.30
Regulation	$876.42	$787.50	$848.10	$2,512.02	$1,310.00	$3,822.02
International	$384.38	$479.58	$427.04	$1,291.00	$2,942.00	$4,233.00
Human resources	$158.00	$225.90	$233.10	$617.00	$408.00	$1,025.00
Data collection	$399.00	$332.10	$339.30	$1,070.40	$1,099.50	$2,169.90
Policy	$0.00	$45.27	$4.73	$50.00	$0.00	$50.00
Governance	$0.00	$33.81	$0.00	$33.81	$0.00	$33.81
Sub-Total Projects	**$6,424.30**	**$6,172.75**	**$5,935.43**	**$18,532.48**	**$17,223.20**	**$35,755.68**
POLICY DIRECTION						
CBAC (*) O&M	$698.94	$2,023.64	$1,460.90	$4,183.47	$0.00	$4,183.47
Policy and Coordination (*) O&M	$968.08	$591.86	$226.38	$1,786.32	$0.00	$1,786.32
CBAC & CBSec salaries (*)	$522.60	$736.61	$924.38	$2,183.59	$0.00	$2,183.59
EBP and Accomodation (*)	$281.06	$268.12	$305.67	$854.84	$0.00	$854.84
CCF	$0.00	$312.06	$328.86	$640.92	$0.00	$640.92
EIF (*)	$0.00	$73.13	$23.70	$96.83	$0.00	$96.83
BACC Reallocation	$0.00	$0.00	$33.53	$33.53	$0.00	$33.53
Sub-Total Policy Direction	**$2,470.67**	**$4,005.42**	**$3,303.42**	**$9,779.51**	**$0.00**	**$9,779.51**
TOTAL	**$8,894.97**	**$10,178.17**	**$9,238.85**	**$28,311.99**	**$17,223.20**	**$45,535.19**

Results-based Management and Accountability Framework

An inter-departmental working group has developed a Results-based Management and Accountability Framework (RMAF) that describes the accountability and performance measurement and reporting requirements for those federal government departments and agencies participating in the CBS, and is intended to provide guidance for the eventual evaluation of the objectives achieved and overall effectiveness of the Strategy.

The RMAF outlines the outputs as well as the intermediate and long-term results to be pursued in each of the three pillars (benefits, stewardship and citizen engagement), and in leadership and management. These include *Indicators of Accountability* that are assigned to the CBS structures and to the CBS partners where there is a direct accountability relationship to the CBS. As well, in areas where there is a limited direct accountability relationship between the CBS structures and the outputs and outcomes of the CBS partners. *Indicators of Progress* are assigned to CBS partners to measure progress of the

federal government towards the key results. In this way the RMAF is able to tackle the horizontal nature of the CBS.

In addition, a reporting strategy will systematically report on CBS performance and ensure that reporting commitments are established is in draft form. Included in the draft strategy is a proposal that all CBS partners and CBSec (for the CBS structures) report against the agreed performance indicators, by CBS pillars, on an annual basis. As well, a survey of CBS partners will be undertaken every two years on the efficacy of the CBS.

The creation of this RMAF responds to the Treasury Board Secretariat requirement to create a Results-Based Management and Accountability Framework prior to any funding submission for a renewed CBS and comments found in the *Report of the Commissioner of the Environment and Sustainable Development – 2000* to improve CBS reporting.

Reporting and Monitoring System

The Canadian Biotechnology Strategy (CBS) has instigated a detailed reporting and monitoring system for the CBS Fund projects. This online tracking system provides easy access to an important monitoring and information tool. Firstly, the system acts as a detailed monitoring tool by tracking project progress and fund usage. Project leaders are required to provide a detailed timeline of their project complete with the dates they expect to reach important project milestones. Leaders must indicate when they reach each milestone as well as provide explanation for any delays. As well, each project must report on funds received and used during the length of their projects. This information allows the CBS to evaluate project progress and rapidly detect any delays or funding problems allowing for reallocation of funds if necessary. Secondly, the tracking system acts as a networking and communication tool by providing access to current information on project descriptions, contact names and progress.

Financial Executive Summary

The following section provides a financial overview of the CBS Fund during the course of three fiscal years from April 1999 to March 2002 also referred as phase I.

The CBS Fund allocated $28.56 and it was spent a total of $28.3M. The difference is the lapsed funds from 2001-02, which are going to be rolled-over in 2002-03. A total of $18.5M was allocated to the CBS projects across the seven federal departments involved and $9.8M to Policy direction (CBAC, CBSec, EIF and CCF).

The CBS Fund projects have been categorized by themes and subsequently by project as follows: R&D, Communication, Regulation, International, Human Resources, Data Collection, Policy and Governance.

During phase I of the Fund it was allocated $9.8M to R&D, $3.1M to Communication, $2.5M to Regulation, $1.3M to International, $617K to Human Resources, $1M to Data Collection, $50K to Policy, $33.81K to Governance and $9.8M to Policy.

Other A base contributions to CBS projects were received from other partners including federal and provincial governments, private sector, institutions and others. These contributions totaled $17M.

Lead departments contributed $7M, other federal government departments excluding lead departments for each project $4.8M, provincial governments contributed (31% higher that the total committed) $152.2K, private sector $3.6M, Institutions $885K and others $730K.

Seven projects shared CBS funds across different federal government departments.

CBAC spent $4.2M among different activities on GM Foods, IP/Patenting of Higher Life Forms (PHL), Genetic Privacy, Ethics, Novel Interventions, Stewardship, Citizen Engagement, Social/Economic, Communications and Outreach, and general activities. Policy Coordination spent $1.8M.