Health Canada Santé Canada

Horizontal Evaluation of the Genomics Research and Development Initiative

Final Report

Approved by

Departmental Executive Committee -
Finance, Evaluation and Accountability (DEC-FEA)
Health Canada

December 20, 2007

Canada

TABLE OF CONTENTS

Horizontal Evaluation of the Genomics Research and Development Initiative
(Final Report – 1 December 2006)
Management Action Plan

Recommendation	Management Action Plan	Forecast Completion	Action By
1. Federal support for the Genomic R&D Initiative as a separate initiative of the Canadian Biotechnology Strategy should continue. 2. Support for capacity building should continue as there is an ongoing and ever evolving need for building and maintaining capacity in genomics R&D. The Interdepartmental Working Group should develop a strategy which identifies the mechanisms needed to ensure that new capacity will continue to be supported and that the existing capacity is maintained.	Agreed. Steps will be taken to renew the Genomics R&D Initiative into a fourth phase based on continued capacity building. The Initiative will continue to be integrated into the larger government-wide S&T Strategy. A justification (i.e. business case) for continuation of the Initiative will be developed. A submission to the Treasury Board for funding renewal of the Genomics R&D Initiative will also be developed. NRC as Chair of the Working Group will take the lead on developing the submission with input from all participating departments.	May 2007 September 2007	Genomics R&D Working Group[1] Genomics R&D Working Group
3. The Interdepartmental Genomics R&D ADM Coordinating Committee should explore specific ways in which interdepartmental projects could be encouraged to address government-wide genomics R&D priorities. This could include a pool of money set aside for interdepartmental projects as well as other options. This Committee should also precisely articulate these priorities and revisit them as needs evolve.	Agreed. Approaches that encourage interdepartmental projects will continue to be supported by the Genomics R&D ADM Coordinating Committee. Criteria will be established by participating departments as part of project evaluations in the next phase (Phase 4) to include an element that addresses interdepartmental collaboration based on government-wide priorities. Mechanisms to support this approach will be considered as part of the business case development.	May 2007	Genomics R&D ADM Coordinating Committee with support from the Working Group
4. The Interdepartmental Genomics R&D ADM Coordinating Committee should also work with Treasury Board to investigate opportunities for federal scientists to participate more significantly in Genome Canada projects.	Agreed. The limitations imposed on federal labs that limit participation in Genome Canada projects has been identified as a severe impediment by participating departments. This issue has also been identified by the S&T Integration Board. Efforts will continue to seek solutions with the Treasury Board and a sub-committee of the Working Group will be struck to investigate options. One consideration would be to extend the definition of eligibility to match that used by the Tri-council agencies; another would be to expand the definition of matching funds to include intramural funds like the Genomics R&D Initiative.	September 2007	Genomics R&D ADM Coordinating Committee with support from the Working Group

[1] Members on the Working Group are responsible for implementing aspects of the Management Action Plan on behalf of their respective departments / agencies. These include program representatives from AAFC, EC, DFO, HC/PHAC, NRC and NRCan.

Recommendation	Management Action Plan	Forecast Completion	Action By
5. The Interdepartmental Genomics R&D ADM Coordinating Committee should clarify the rules on how the funds are used with respect to program management and other overheads and ensure that those rules are enforced.	Agreed. The rules surrounding program management and other overhead costs will be clarified.	December 2007	Genomics R&D ADM Coordinating Committee with support from the Working Group
6. The summative [impact] evaluation needs to address the issue of cost-effectiveness in a way to reliably conclude on the cost and effectiveness aspects of the Initiative. The departments should therefore ensure that improved cost information is available. The specific cost-effectiveness evaluation requirements will be outlined in the revised RMAF for the Initiative. This should include methods for a more thorough cost-effectiveness analysis at the time of the summative [impact] evaluation.	Agreed. The revised RMAF for the initiative identifies evaluation requirements associated with cost-effectiveness and suggestions are provided on items that should be measured in order to address this evaluation criterion. These suggestions will be used as a guide to develop departmental systems that ensure that Initiative costs are captured in a manner that will permit a proper analysis in the impact evaluation.	December 2007	Genomics R&D Working Group
7. Similarly to the Canadian Regulatory System for Biotechnology, the Genomics R&D Initiative should become an ongoing initiative with dedicated A-base funding. This will provide stability to the Initiative while ensuring an ongoing focused funding source for genomics R&D.	Agreed. A consideration to move the Initiative to be funded with A-base will be included in the analysis used to support the business case development.	May 2007	Genomics R&D Working Group
8. In light of other recommendations, greater effort to strategically plan and to share the results of this Initiative will become important to its ongoing success. As such, horizontal management costs may increase but the benefits resulting from increased horizontal activity are expected to be greater.	Agreed. Strategic planning and results sharing will be used in the development of future phases of the Initiative and will be included in annual planning exercises by the participating departments.	Annual and ongoing	Genomics R&D ADM Coordinating Committee with support from the Working Group
9. As per Recommendation 8, due consideration should be given to exploring opportunities for better horizontal integration with other biotechnology programs. As a result, horizontal management costs may increase but the benefits associated with horizontal management could be important in terms of ensuring complementarity while avoiding overlap and duplication.	Agreed. Strategic planning activities and annual planning exercises by the participating departments will include elements that explore opportunities for improved horizontal integration and complementarity while avoiding duplication of effort.	Annual and ongoing	Genomics R&D ADM Coordinating Committee with support from the Working Group

Recommendation	Management Action Plan	Forecast Completion	Action By
10. Without adding unnecessary burden to the Interdepartmental Working Group, specific terms of reference need to be defined for this group in order to ensure that, with ongoing support for this Initiative, its roles and responsibilities are clear. These terms of reference should include responsibilities for defining how funds can / should be allocated for departmental overhead costs as well as common approaches to some of the departmental processes (e.g., project selection, reporting, etc.).	Agreed. Formal Terms of Reference (TOR) for the Genomics R&D Working group will be established, documented and distributed to all departments. NRC will take the lead in developing the TOR with input from the participating departments. The TOR will include aspects that will provide the Group with responsibility for making recommendations on items such as departmental overhead costs and the development of common approaches to activities such as project selection and reporting.	May 2007	Genomics R&D Working Group
11. The Interdepartmental Genomics R&D ADM Coordinating Committee should play a more active role in providing strategic direction for government wide genomics R&D priorities linking to other components of the Canadian Biotechnology Strategy.	Agreed. The Genomics R&D ADM Coordinating Committee will provide strategic direction to the Working Group as part of the development of future phases of the Initiative. Advice will focus on ensuring that government-wide priorities are addressed and that appropriate linkages are established with other components of the federal government S&T Strategy.	Periodic based on funding cycle	Genomics R&D ADM Coordinating Committee with support from the Working Group
12. Departments should continue to build on lessons learned and refine departmental processes as needed. The Interdepartmental Genomics R&D ADM Coordinating Committee should take steps to ensure that transparency and accountability continue as key elements in program proposal and approval processes, and that integrated performance reporting is formally implemented.	Agreed. Lessons learned will be integrated into strategic planning activities and annual planning exercises by the participating departments. Transparency and accountability will continue as key elements in program proposal and approval processes. Integrated performance reporting will be formally implemented.	Annual and ongoing June 2007	Genomics R&D ADM Coordinating Committee with support from the Working Group
13. The summative [impact] evaluation needs to address the issue of leveraging in a way to reliably conclude on this issue. Departments will need to ensure that they put in place the required systems to meet the specific leveraging evaluation requirements which will be outlined in the revised RMAF for the Initiative.	Agreed. Systems will be developed and implemented (in departments where they do not already exist) that capture leveraging evaluation requirements identified in the revised RMAF.	March 2008	Genomics R&D Working Group

Recommendation	Management Action Plan	Forecast Completion	Action By
14. The performance measurement system outlined in the upcoming revised horizontal RMAF for this Initiative needs to clearly define common performance measures and ensure that the appropriate tools are available to collect, analyze and report performance information without imposing undue burden or cost requirements to the departments.	Agreed. A performance measurement approach will be developed and implemented based on the revised RMAF. Appropriate tools will be used to collect, analyze and report performance information without imposing undue burden or cost requirements to the departments. Approaches will be developed based on existing individual departmental systems.	March 2008	Genomics R&D Working Group
15. The total funding for the Genomics R&D Initiative should be increased. First, funding should be increase to compensate for inflation. It is important for departments to, at least, be able to maintain previous levels of research. In addition, some of the additional budget should be used to re-balance departmental inequities. The funding for Phase 1 of this Initiative was initially allocated to the departments on the basis of existing capacity and it was expected that funding re-allocations would occur in later phases. This has not been the case. Nevertheless, the re-balancing cannot be done by reducing the existing funding levels of departments receiving a larger proportion of the total funding, as this could negatively affect the ability of these departments to undertake the genomics R&D required to support their departmental mandates. Finally, some of this additional funding could be pooled for interdepartmental projects. Assuming that a pooled fund is set aside, appropriate processes will need to be put in place including approval processes as well as performance monitoring and reporting processes.	Agreed. A consideration to request additional funding to re-balance departmental inequities will be included in the analysis used to support the business case development. A request for funding to compensate for inflation will be included in the TB renewal submission. Additional funding for the Initiative that could be pooled for interdepartmental projects will be considered as part of future phases for the Initiative.	May 2007 September 2007 March 2010	Genomics R&D Working Group

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Submitted by:

Performance Management Network Inc.

December 1, 2006

Table of Contents

Page #

List of Acronyms

AAFC – Agriculture and Agri-Food Canada
ACOA – Atlantic Canada Opportunities Agency
ACRDP – Aquaculture Collaborative Research and Development Program
ADM – Assistant Deputy Minister
AHFMR – Alberta Heritage Foundation for Medical Research
ASRA – Alberta Science and Research Authority

BAC – Bacterial Artificial Chromosome
BACC – Biotechnology ADM Coordinating Committee
BC – British Columbia
BDO – Business Development Office
BRI – Biotechnology Research Institute

CA – California
CBS – Canadian Biotechnology Strategy
CBSec – Canadian Biotechnology Secretariat
CCGI – Canadian Crop Genomics Initiative
CEAA – Canadian Environmental Assessment Act
CEPA – Canadian Environmental Protection Act
CFI – Canada Foundation for Innovation
CFIA – Canadian Food Inspection Agency
CFS – Canadian Forest Service
CIHR – Canadian Institutes of Health Research
CITES – Convention on International Trade of Endangered Species
CRC – Canada Research Chairs
CRSB – Canadian Regulatory System for Biotechnology
CWS – Canadian Wildlife Services

DBO – Departmental Biotechnology Office
DEC – Canada Economic Development for Quebec Regions
DFO – Fisheries and Oceans Canada
DNA – Deoxyribonucleic Acid
DOE – Department of the Environment (United States)
DPR – Departmental Performance Report
DSL – Designated Substances List

EBAD – Environmental Biotechnology Applications Division
EC – Environment Canada
ENGO – Environmental Non-Governmental Organization
EP – Environmental Protection

ERC – Expenditure Management Review Committee
ESTs – Expressed Sequence Tags
ETAD – Environmental Technology Advancement Directorate
ETC – Environmental Technology Centre

FRSQ – Fonds de la recherche en santé du Québec

GACC – Genomics R&D ADM Coordinating Committee
GELS – Genomics, Ethics, Law and Society
GFC – Gulf Fisheries Centre
GHI – Genomics and Health Initiative
GMF – Genetically Modified Food
GMO – Genetically Modified Organisms
GRASP – Genomics Research on Atlantic Salmon Project
GRI – Genomics Research Initiative

HC – Health Canada
HESCB – Healthy Environment and Consumer Safety Branch
HPFB – Health Products and Food Branch
HQ – Headquarters
HR – Human Resources
HQP – Highly Qualified Personnel

IBD – Institute for Biodiagnostics
IBS – Institute for Biological Sciences
ICES – International Council for the Exploration of the Sea
IEWG – Interdepartmental Evaluation Working Group
IFREMER – Institut Français de Recherche Pour l'Exploitation de la Mer
IIT – Institute for Information Technology
IMB – Institute for Marine Biosciences
IMD - Invasive meningococcal disease
IMI – Industrial Materials Institute
IMS – Institute for Microstructural Sciences
IMTI – Integrated Manufacturing Technologies Institute
INRA – Institut National de Recherche Agronomique

LOI – Letter of Intent

MA – Massachusetts
MII – Matching Investment Initiative
MOU – Memorandum of Understanding
MSF – Manitoba Science Foundation

NB – New Brunswick
NBAC – National Biotechnology Advisory Committee
NBCC – National Biotechnology Coordinators Committee
NCE – Network of Centres of Excellence
NFLD – Newfoundland
NIH – National Institutes of Health
NINT – National Institute for Nanotechnology
NMFS – National Marine Fisheries Service
NRC – National Research Council
NRCan – Natural Resources Canada
NS – Nova Scotia
NSERC – Natural Sciences and Engineering Research Council
NSNR – New Substances Notifications Regulations
NWRC – National Wildlife Research Centre
NWRI – National Water Research Centre

O&M – Operations and Maintenance
OAB – Office of Aquatic Biotechnology
OAG – Office of the Auditor General
OECD – Organisation for Economic Co-Operation and Development
OGDs – Other Government Departments
ON – Ontario
ORF – Ontario Research Foundation

P3G – Public Population Project in Genomics
PBI – Plant Biotechnology Institute
PCO – Privy Council Office
PCR – Polymerase Chain Reaction
PDF – Post Doctoral Fellow
PERD – Program for Energy Research and Development
PESC – Pacific Environmental Science Centre
PHAC – Public Health Agency of Canada
PMRA – Pest Management Review Agency
PWGSC – Public Works and Government Services Canada
PYLET – Pacific and Yukon Laboratory for Environmental Testing

QC – Québec
QPCR – Quantitative Polymerase Chain Reaction

R&D – Research and Development
RFP – Request for Proposal
RIVM - National Institute for Public Health and Environment
RMAF – Results-based Management and Accountability Framework

RNA – Ribonucleic Acid
RPP – Report on Plan and Priorities

SARA – Species at Risk Act
SBDA – Science Based Departments and Agencies
SETAC – Society for Environmental Toxicology and Chemistry
SGC – Structural Genomics Consortium
SIMS – Steacie Institute for Molecular Sciences
SSHRC – Social Sciences and Humanities Research Council
STAB – S&T Advisory Board
STAGE – Strategic Applications of Genomics in the Environment Program

TB – Treasury Board
TBS – Treasury Board of Canada Secretariat
TRC – Technical Review Committee

UBC – University of British Columbia
UK – United Kingdom
UNCLOS – United Nations Convention on the Law of the Sea
UNESCO – United Nations Educational, Scientific and Cultural Organization
USA – United States of America
USDA – United States Department of Agriculture
USEPA – United States Environmental Protection Agency
UVIC – University of Victoria

WA – Washington
WAPPRIITA – Wild Animal and Plant Protection and Regulation of International and Inter-provincial Trade Act
WD – Western Economic Diversification Canada
WHO – World Health Organization
WTC – Wastewater Technology Centre

Executive Summary

Description of the Genomics R&D Initiative

In March 1998, the National Biotechnology Advisory Committee (NBAC) released a report recommending ways to position Canada as a leading global player in biotechnology by the year 2005. During the same period, the National Research Council (NRC) and the Medical Research Council (now the Canadian Institutes of Health Research) held discussions with stakeholders as part of the Canadian Biotechnology consultations. Genome research was clearly identified as an important priority for Canadian biotechnology research and development (R&D).

The NBAC recommended that a top priority be placed on several actions, including political championship and increased funding to Canada's genome program. The February 1999 Budget provided $55 million in funding for genomics R&D in six departments and agencies under the Canadian Biotechnology Strategy (CBS).

The Genomics R&D Initiative was launched in 1999 and is currently in its third three-year phase:

- Phase 1 – 1999-2000 to 2001-2002
- Phase 2 – 2002-2003 to 2004-2005
- Phase 3 – 2005-2006 to 2007-2008

Its stated objective is:

> *"to build the capacity inside government laboratories to do ... biotechnology research (related to genome sciences), which will strengthen the regulatory system and bring the benefits of revolutionary advances in research and technology to a variety of Canadian industry sectors and regions. The new technologies are expected to have a dramatic impact on industrial competitiveness and economic growth. They are also expected to bring significant social benefits, e.g. better therapeutics, cleaner environment and better management of natural resources."*[1]

Six departments currently receive funding under this Initiative: Agriculture and Agri-Food Canada (AAFC), Environment Canada (EC), Fisheries and Oceans Canada (DFO), Health Canada (HC), NRC, and Natural Resources Canada (NRCan). It should be noted that throughout this report, that the Public Health Agency of Canada (PHAC), which was established as a separate agency in 2004, was considered to be part of HC. The administration of the Genomics

[1] Source: Treasury Board of Canada, Secretariat website (http://www.tbs-sct.gc.ca/rma/eppi-ibdrp/hrdb-rhbd/cbs-scb/description_e.asp)

R&D Initiative funds for both HC and PHAC was coordinated through HC's Departmental Biotechnology Office for Phases 1, 2 and 3.

Purpose of the Evaluation and its Intended Audience

It is the policy of the federal government of Canada that departments evaluate their key policies, programs, functions and initiatives strategically and cost-effectively and to use the findings in decision-making and reporting. The Phase III Program Framework (2005-2008) states that a targeted evaluation of the Initiative was to be conducted in 2005-2006. This interdepartmental, horizontal evaluation study focused on the Initiative's short-term outcomes given that it is too early to measure impacts and to address other longer term issues. The intended audience of this report includes:

- Treasury Board;
- the Interdepartmental Genomics Assistant Deputy Minister (ADM) Coordinating Committee;
- the Interdepartmental Working Group for the Genomics R&D Initiative;
- program managers in the six funded departments; and
- the Canadian public.

Methodology

The evaluation addressed issues related to the relevance of the Initiative, its early success, its cost-effectiveness or alternatives, and its design and delivery. The methodologies used for this evaluation included:

- a document review;
- 26 in-depth interviews with departmental managers;
- 61 in-depth interviews with researchers;
- 19 in-depth interviews with departmental stakeholders (including project partners, beneficiaries or others with an interest in the genomics R&D activities of specific departments); and
- 9 in-depth interviews with "horizontal" stakeholders (including representatives of central agencies, other biotechnology departments / programming, or others with an interest in genomics R&D).

While there are some imbedded strengths and weaknesses associated with each of these methodologies, overall, the approaches and sample sizes used for this evaluation resulted in a strong and reliable horizontal evaluation, which provided the evidence to conclude on all issues. Additionally, the overall evaluation methodology is strong because multiple lines of evidence were used for all issues.

For more details, please refer to Section 2.0 of the main evaluation report.

Main Evaluation Findings

The main evaluation findings are summarized according to the issue categories previously identified:

- ***Relevance:***

  The evidence from documents and from management, researcher and stakeholder interviewees revealed that there is an ongoing and ever evolving need for an initiative that supports capacity building inside government laboratories to do genomics R&D. While specific departmental needs differ and while the Initiative has increased the genomics R&D capacity of the funded departments, there is an ongoing need to maintain and grow that capacity and therefore support genomics R&D. Additionally, the evaluation revealed that there is a legitimate and necessary role for government in this area, particularly given the importance of genomics R&D in the context of the broader Canadian Biotechnology Strategy, and the need for credible research results to inform policy, regulation and other governmental decisions.

  For more details, please refer to Section 3.0 of the main evaluation report.

- ***Success:***

  The evidence from documents and management, researcher and stakeholder interviewee feedback indicates that the first phase of the Initiative was successful in building capacity inside government laboratories to carry out genomics research. It was uncovered that there was limited capacity in most of the six funded departments before the Initiative and that the labs now have the human resource capacity, as well as the tools, equipment, infrastructure and networks required to undertake genomics R&D. This capacity has helped labs benefit through the ability to undertake other genomics R&D projects using the capacity built in earlier phases. Additionally, it has helped strengthen other areas of research in departments. There was evidence of use of the research results in other (non-genomics) applications. Additionally, the labs continue to benefit from this capacity through ongoing projects, use of previous results in other projects, and ongoing involvement of the scientists in projects. Additionally, through the projects, the departments have established formal and information collaborations with Canadian and international organizations (governmental organizations, universities, non-governmental organizations and private sector organizations).

  The key facilitating factor, as identified by the wide range of interviewees (managers, researchers and stakeholders), is the additional focussed funding available to departments to do this type of research. This additional funding also facilitated the hiring and training of highly qualified personnel (HQP) and other technical staff.

However, there were also impediments to success. There was evidence that the money was insufficient to address the genomics research priorities in the departments, in particular in those departments where the funds are more limited. Additionally, the three-year funding cycles, caused a delay in the release of the funds in the first year of the first phase. This delay resulted in delays in the proposal approval process and in the release of funds. Since personnel needed to be hired for many of the Phase 1 projects, the delay in the release of funds was further impeded by the hiring process. This delay in the release of funds was, therefore, a major impediment as it did not allow enough time to complete the projects. Another impediment involved the uncertain nature of the funding (three-year funding cycles) which could lead to human resource challenges (i.e. attracting and retaining highly qualified personnel). Another major impediment was the result of a Treasury Board ruling (starting in April 2006) that, while federal labs may continue to participate in Genome Canada projects, they cannot receive Genome Canada funding, except in special circumstances. This has a major negative impact on the types of projects and collaborations that became possible in Phase 3.

While it is fairly early to report longer-term impacts, there is early evidence that the Initiative is successful. Since the evidence gathered in interviews shows that the Initiative is incremental (genomics programming would not likely be in place in departments, many of the projects would not have been undertaken, others would have been delayed, of smaller scopes or otherwise negatively affected), the success to date can be directly attributed to the Initiative.

For more details, please refer to Section 4.0 of the main evaluation report.

- ***Cost-Effectiveness / Alternatives***

A review of other genomics R&D programming in Canada revealed that the Genomics R&D Initiative complements rather than overlaps or duplicates other federal or provincial initiatives related to genomics or biotechnology. Other organizations involved in genomics R&D either have broader mandates than just genomics R&D, target different groups, and / or cover a narrower field of genomics R&D (such as just human genomics). Managers, researchers and stakeholders confirmed that they were unaware of other programs of a truly comparable nature. However, interviewees noted that it was important for the researchers in the departments to seek opportunities to work in collaboration with these other programs or initiatives and that there were many instances where such collaborations had taken place. However, during the third phase, the Treasury Board ruled that, according to government policy, government departments cannot receive funding directly from Genome Canada (except in special circumstances). This change greatly reduced the level of interaction and complementarity between the Genomics R&D Initiative and Genome Canada.

As a separate fund with specific allocations to each department, the funding structure was deemed appropriate. However, the amount allocated to some departments was noted to be inappropriate in the context of the needs and priorities of those departments. The cost-effectiveness of the Initiative was difficult to assess because most departments did not have specific information on the actual cost of the Initiative, especially during the first phase. Departments did not have systems set up to capture these costs. However, the costs associated with the interdepartmental nature of the Initiative were believed to be minimal (interdepartmental meetings, TB Submissions, horizontal planning and reporting requirements). Some noted the costs associated with program renewal every three years. Along the same vein, it was noted that the uncertainty about the longevity of the Initiative could affect the types of projects undertaken and, therefore, the possible effectiveness of the Initiative. While the three-year funding cycle for this Initiative was deemed appropriate at the project level, it was believed to have added burden and costs (preparations for next cycle, difficult for human resource management, writing proposals every three years, burden on external reviewers, etc.).

For more details, please refer to Section 5.0 of the main evaluation report.

- ***Design and Delivery***

Most managers, researchers and stakeholders interviewed noted that the position of the Initiative was appropriate within the larger government biotechnology strategy. Several noted that they did not believe that the Canadian Biotechnology Strategy could guide the Genomics R&D Initiative. The CBS is broader and was, therefore, not believed to be directly relevant. As a result, interviewees strongly believed that a separate fund was needed.

The interdepartmental governance model for the Genomics R&D Initiative includes an Interdepartmental Genomics R&D ADM Coordinating Committee and a Genomics R&D Initiative Working Group. In addition, the Initiative is part of the overall Canadian Biotechnology Strategy governance structure. Departmental managers believed that the Genomics R&D Initiative governance structure was effective, particularly in light of the fact that it was of limited burden to them. The role of NRC as the lead was also viewed positively. It was, however, noted that this was not viewed as a truly horizontal initiative and that it was, therefore, not "governed" as one. Nonetheless, concerns were expressed with the limited involvement of the ADM Coordinating Committee and with the lack of formal terms of reference for the working group.

Departmental processes have reportedly changed since the initial phase of this Initiative. In particular, the project approval processes have been deemed to have been greatly improved with the advent of more rigorous peer reviews of the proposals.

As noted previously, most departmental systems were not set up to capture detailed information on the costs associated with this Initiative, especially during the first phase. Additionally, most departments were not set up to keep track of the funds levered internally or externally. Nevertheless, there is evidence of leveraging through A-base matching funds, as well as through collaborations with other organizations on projects.

In addition to the limited information on costs and leveraging, there is also limited evidence of adequate systems to capture good and complete performance information. This is due in part to the evolution of the Initiative and thus to the types of projects (and possibly changing performance information requirements in Phase 1 than in Phase 2 or 3). The lack of adequate systems to collect and capture performance information is also in part due to the uncertainty of the Initiative (i.e. it would not have been cost-effective to invest resources in a performance measurement system for an Initiative that was funded for three years). Nevertheless, the Initiative is now at a stage in its evolution where enough is known on the Initiative to develop and implement better performance measurement systems in those departments with limited information. As a new Results-based Management Accountability Framework (RMAF) is being developed for the Initiative, this concern should be addressed.

There were several improvements suggested to the Initiative. These are reflected in the conclusions and recommendations which follow.

For more details, please refer to Section 6.0 of the main evaluation report.

Conclusions and Recommendations

The findings outlined above (and in the main evaluation report) support the following conclusions and recommendations.

Conclusions	Recommendations
Relevance	
Conclusion 1 The Genomics R&D Initiative is relevant as a critical element of the broader Canadian Biotechnology Strategy and is complementary to other elements of this broader Strategy such as the Canadian Regulatory System for Biotechnology. Given that genomics is still a relatively new and emerging technology, there is an ongoing need for government involvement in this field. Additionally the research results are required to support departmental mandates, the development of new regulations as well as to help enforce existing ones. As such, there is a legitimate and necessary role for government in this area.	**Recommendation 1** Federal support for the Genomic R&D Initiative as a separate initiative of the Canadian Biotechnology Strategy should continue. **Note: the rest of the recommendations in this report assume the continuation of the Genomics R&D Initiative.**
Success	
Conclusion 2 The primary objective of the Initiative was to build capacity in federal labs. There is extensive evidence that the Initiative has built capacity inside government labs to carry out genomics research. Phase 1 built basic capacity which continues to be strengthened. As such, while there has been much progress made in this regard, there continues to be a need to build and maintain capacity in federal labs.	**Recommendation 2** Support for capacity building should continue as there is an ongoing and ever evolving need for building and maintaining capacity in genomics R&D. The Interdepartmental Working Group should develop a strategy which identifies the mechanisms needed to ensure that new capacity will continue to be supported and that the existing capacity is maintained.
Conclusion 3 The capacity that was developed in Phase 1 has been used in Phase 2. There is extensive evidence of ongoing or continued projects, use of the tools developed or research results, and ongoing involvement of the same scientists. As such, Phase 1 translated into benefits for Phase 2. The increased capacity has also helped strengthen the research carried out in other areas of the departments.	No specific recommendation is required.

Conclusions	Recommendations
Conclusion 4 While there is some evidence of interdepartmental collaboration, it is limited. For example, different departments were initially at different stages of genomics research. In other cases, there was little commonality in the issues being explored. As such, there was limited opportunity for collaboration. However, as the capacity of departments has evolved, there may be increased opportunities for interdepartmental collaboration in future phases. There has, nonetheless, been extensive evidence of collaboration with other research entities. The research projects have involved collaborative efforts on a national and international level with universities, governmental organizations, non-governmental organizations as well as private sector organizations. As such, the Initiative has been successful in strengthening linkages with appropriate research institutions. Some departments participated in Genome Canada Competition I and II projects. Effective April 2006, federal labs cannot receive Genome Canada funding except in special circumstances (as a result of a Treasury Board ruling). As a result, projects are negatively affected, not only in their scope, but in the ability of the government labs to continue working with established collaborators. Therefore, while the Initiative has been successful in strengthening linkages with appropriate research institutions, its continued success in this regard has been hampered, particularly due to the impact of the TB ruling regarding Genome Canada.	**Recommendation 3** The Interdepartmental Genomics R&D ADM Coordinating Committee should explore specific ways in which interdepartmental projects could be encouraged to address government-wide genomics R&D priorities. This could include a pool of money set aside for interdepartmental projects as well as other options. This Committee should also precisely articulate these priorities and revisit them as needs evolve. **Recommendation 4** The Interdepartmental Genomics R&D ADM Coordinating Committee should also work with Treasury Board to investigate opportunities for federal scientists to participate more significantly in Genome Canada projects.

Conclusions	Recommendations
Conclusion 5 The main facilitating factor of the Genomics R&D Initiative has been that it is a focused funding source. However, there are other financial elements of the Initiative that have impeded its success. The total amount of money available has become an impediment not only because there have been no inflationary increases in funding, but also because there is a need to re-balance the funding envelope to ensure that all departments have sufficient funding to address strategic priorities. The three-year funding cycle has resulted in uncertainty. This has affected the scope of some of the projects as well as the ability to attract and retain highly qualified personnel. Finally, the timing of the funding (delays in year one of each phase) has led to delays in meeting project milestones and, for start-up projects, to delays in hiring the required people for the research teams.	**Note: There are several conclusions which can be addressed through more overarching recommendations. These recommendations are presented at the end of this section.** **One of these deals with financial elements of the Initiative. Recommendations linked to Conclusion 5 are therefore presented at the end of this section.**
Conclusion 6 There are significant differences in the way in which departments are allocating resources for program management and other overheads. As such, this has resulted in significant differences in the proportion of the funds which are available for the projects in different departments.	**Recommendation 5** The Interdepartmental Genomics R&D ADM Coordinating Committee should clarify the rules on how the funds are used with respect to program management and other overheads and ensure that those rules are enforced.
Conclusion 7 The Initiative is highly incremental. Specific genomics R&D departmental programming would not be in place in the absence of this Initiative. As such, the great majority of projects would not have taken place and / or would have been seriously negatively affected as a result of delays, changes in scope, less qualified teams or for some other reasons. Therefore, the impacts of the projects are highly attributable to the Initiative.	No specific recommendation is required.
Cost-Effectiveness / Alternatives	
Conclusion 8 The Initiative complements other federal or provincial initiatives related to genomics or biotechnology without undue overlap or duplication. However complementarity with Genome Canada has been reduced in the last few years as a result of a recent Treasury Board ruling.	See recommendations 1 and 4

Conclusions	Recommendations
Note: Conclusion 5 is also directly relevant to the cost-effectiveness issue dealing with the funding structure, in brief: The focused funding is a strength of this Initiative. Problems with the funding structure include the total amount of money available, its three-year funding cycle, and the timing of the funding.	**Recommendations linked to Conclusion 5 are presented at the end of this section.**
Conclusion 9 It is not possible to conclude on the Initiative's cost-effectiveness because there is insufficient information in most departments on the specific departmental and interdepartmental costs associated with this Initiative. This is no reflection on specific departmental performance as departments were not required to track costs (nor would it have been cost-effective for them to set up specific systems to do so for an initiative with three-year funding cycles).	**Recommendation 6** The summative evaluation needs to address the issue of cost-effectiveness in a way to reliably conclude on the cost and effectiveness aspects of the Initiative. The departments should therefore ensure that improved cost information is available. The specific cost-effectiveness evaluation requirements will be outlined in the revised RMAF for the Initiative. This should include methods for a more thorough cost-effectiveness analysis at the time of the summative evaluation.
Conclusion 10 The three year funding cycle is appropriate at the project level but not for the Initiative. Overall, the uncertainty associated with the three year cycle has negatively affected the flexibility of the Initiative and aspects of its cost-effectiveness (see conclusions under Design and Delivery section).	**Recommendation 7** Similarly to the Canadian Regulatory System for Biotechnology, the Genomics R&D Initiative should become an ongoing initiative with dedicated A-base funding. This will provide stability to the Initiative while ensuring an ongoing focused funding source for genomics R&D.
Conclusion 11 The benefits (sharing of information, communications with central agencies, etc.) resulting from the interdepartmental aspects of this Initiative, while limited, have outweighed the costs which have been minimal. The limited costs are, to a large extent, due to the fact that the Initiative is not structured as a truly horizontal initiative (nor was it intended to be).	**Recommendation 8** In light of other recommendations, greater effort to strategically plan and to share the results of this Initiative will become important to its ongoing success. As such, horizontal management costs may increase but the benefits resulting from increased horizontal activity are expected to be greater.
Design and Delivery	
Conclusion 12 It is appropriate to have this Initiative as a separate initiative within the larger federal government biotechnology strategy. Within departments, the Initiative is well integrated with other biotechnology programs (such as the Canadian Regulatory System for Biotechnology – CRSB, in the regulatory departments). However, there is limited integration with these programs from a horizontal perspective.	**Recommendation 9** As per Recommendation 8, due consideration should be given to exploring opportunities for better horizontal integration with other biotechnology programs. As a result, horizontal management costs may increase but the benefits associated with horizontal management could be important in terms of ensuring complementarity while avoiding overlap and duplication.

Conclusions	Recommendations
Conclusion 13 The governance structure currently in place for this Initiative is of limited complexity and burden. As such, it is appropriate. However, some of its elements need improvement. The Interdepartmental Genomics R&D ADM Coordinating Committee is not providing the required level of leadership. Additionally, the working group has no documented terms of reference and could play a more active role in identifying areas for horizontal coordination or more common interdepartmental processes.	**Recommendation 10** Without adding unnecessary burden to the Interdepartmental Working Group, specific terms of reference need to be defined for this group in order to ensure that, with ongoing support for this Initiative, its roles and responsibilities are clear. These terms of reference should include responsibilities for defining how funds can / should be allocated for departmental overhead costs as well as common approaches to some of the departmental processes (e.g., project selection, reporting, etc.). **Recommendation 11** The Interdepartmental Genomics R&D ADM Coordinating Committee should play a more active role in providing strategic direction for government wide genomics R&D priorities linking to other components of the Canadian Biotechnology Strategy.
Conclusion 14 Departmental processes (such as for project selection and approval) have evolved and improved over time.	**Recommendation 12** Departments should continue to build on lessons learned and refine departmental processes as needed. The Interdepartmental Genomics R&D ADM Coordinating Committee should take steps to ensure that transparency and accountability continue as key elements in program proposal and approval processes, and that integrated performance reporting is formally implemented.
Conclusion 15 There is insufficient information to reliably conclude on the extent to which most departments have been able to leverage the funds provided through the Genomics R&D Initiative. There is, nonetheless, evidence of internal leveraging as well as leveraging through partnerships with other research organizations.	**Recommendation 13** The summative evaluation needs to address the issue of leveraging in a way to reliably conclude on this issue. Departments will need to ensure that they put in place the required systems to meet the specific leveraging evaluation requirements which will be outlined in the revised RMAF for the Initiative.
Conclusion 16 There is currently no formal performance measurement system in place for this Initiative either horizontally or within the departments. As a result, there is limited performance information available. Recognizing that it is still fairly early to measure impacts, it is important to ensure that performance information available within departments is not limited to inputs and outputs measures.	**Recommendation 14** The performance measurement system outlined in the upcoming revised horizontal RMAF for this Initiative needs to clearly define common performance measures and ensure that the appropriate tools are available to collect, analyze and report performance information without imposing undue burden or cost requirements to the departments.

Several of the conclusions presented above helped lead the evaluation team to the following series of recommendations:

Recommendation 15

The total funding for the Genomics R&D Initiative should be increased.

First, funding should be increase to compensate for inflation. It is important for departments to, at least, be able to maintain previous levels of research.

In addition, some of the additional budget should be used to re-balance departmental inequities. The funding for Phase 1 of this Initiative was initially allocated to the departments on the basis of existing capacity and it was expected that funding re-allocations would occur in later phases. This has not been the case. Nevertheless, the re-balancing cannot be done by reducing the existing funding levels of departments receiving a larger proportion of the total funding, as this could negatively affect the ability of these departments to undertake the genomics R&D required to support their departmental mandates.

Finally, some of this additional funding could be pooled for interdepartmental projects. Assuming that a pooled fund is set aside, appropriate processes will need to be put in place including approval processes as well as performance monitoring and reporting processes.

1.0 Introduction

1.1 Background to the Study

The Genomics Research and Development (R&D) Initiative was launched in 1999 and is currently in its third three-year phase:

- Phase 1 – 1999-2000 to 2001-2002
- Phase 2 – 2002-2003 to 2004-2005
- Phase 3 – 2005-2006 to 2007-2008

Six departments currently receive funding under this Initiative: Agriculture and Agri-Food Canada (AAFC), Environment Canada (EC), Fisheries and Oceans Canada (DFO), Health Canada (HC), National Research Council Canada (NRC), and Natural Resources Canada (NRCan). It should be noted that throughout this report, that the Public Health Agency of Canada (PHAC), which was established as a separate agency in 2004, was considered to be part of HC. The administration of the Genomics R&D Initiative funds for both HC and PHAC was coordinated through HC's Departmental Biotechnology Office for Phases 1, 2 and 3.

It is the policy of the federal government of Canada that departments evaluate their key policies, programs, functions and initiatives strategically and cost-effectively and to use the findings in decision-making and reporting. The Phase III Program Framework (2005-2008) states that a targeted evaluation of the Initiative was to be conducted in 2005-2006.

The objective of this evaluation was to measure the genomics R&D capacity that has been established in federal labs and to evaluation its impact to date. Recommendations will be submitted to an Assistant Deputy Minister (ADM) level interdepartmental Genomics R&D Coordinating Committee and will be shared with the Treasury Board Secretariat. Overall, the evaluation is meant to assess how well the Initiative was implemented, what went right and what needs improvement.

This horizontal evaluation of the Initiative started in February 2006. It involved a planning phase and an evaluation phase. A third phase will involve preparing an updated Results-based Management and Accountability Framework (RMAF) for the Initiative based on evaluation findings as well as additional consultations with key representatives from the six departments.

This was meant to be a horizontal evaluation. However, in order to ensure that the findings were also meaningful to each department / agency, departmental analyses were performed and are included in Annex A of this report.

The scope of the evaluation was limited to Phases 1 and 2. However, given that the Initiative is already well into Phase 3, it was sometimes difficult to limit observations to the first two phases. Therefore some of the findings include aspects of Phase 3 implementation.

This report is limited to the evaluation methodology, findings, conclusions and recommendations. The RMAF will be presented in a separate document.

1.2 Brief Profile of the Initiative

1.2.1 Background

In March 1998, the National Biotechnology Advisory Committee (NBAC) released a report recommending ways to position Canada as a leading global player in biotechnology by the year 2005. During the same period, the NRC and the Medical Research Council (now the Canadian Institutes of Health Research (CHIR)) held discussions with stakeholders as part of the Canadian Biotechnology consultations. Genomics research was clearly identified as an important priority for Canadian biotechnology research and development.

The NBAC recommended that a top priority be placed on several actions, including political championship and increased funding to Canada's genomics program. Genomics was also identified as an important priority by a consultation led by the Canadian Agri-Food Research Council.

The February 1999 Budget provided $55 million in funding for genomics R&D in six departments and agencies under the Canadian Biotechnology Strategy (CBS). The CBS includes:

- the Genomics R&D Initiative – $19.9 million per year;
- the Canadian Regulatory System for Biotechnology (CRSB) – $34.6 million per year; and
- the CBS Program – $9.5 million per year.

Each of these initiatives focuses on a different aspect of Canada's biotechnology-related priorities, involving separate program management, resource allocations and profiling of initiatives that are ultimately linked through the CBS governance structures.

The Genomics R&D Initiative was recently renewed for a period of three years (2005-2008). Funding is provided to six departments and agencies:

- the National Research Council of Canada – $6 million per year;
- Agriculture and Agri-Food Canada – $6 million per year;

- Health Canada – $4 million per year;
- Natural Resources Canada – $2 million per year;
- Environment Canada – $1 million per year; and
- Fisheries and Oceans Canada – $900,000 per year.

The 2005-2008 renewal was for Phase 3 of the Initiative. The phases have been as follows:

- Phase 1 (1999-2002) – the purpose of Phase 1 was to build capacity (people and equipment) within federal laboratories in the areas of genomics research;

- Phase 2 (2002-2005) – this phase built on Phase 1 by using and developing procedures and tools needed for genomics research; and

- Phase 3 (2005-2008) – Phase 3 aims at applying these tools to make discoveries. This phase was not included in the scope of this evaluation.

1.2.2 Overview

The federal government has wide-ranging responsibilities related to genomics by:

- playing a key role in building and participating in local, national and international genomics R&D initiatives;
- supporting the development and application of the scientific knowledge base;
- advancing the principles of sustainable development and ethical uses of genomics;
- evaluating potential new and modified products to protect human health, safety and the environment; and
- facilitating Canadians' access to accurate and understandable information concerning genome sciences.

Genomics research (the study of genes and their interactions) will provide new methods for managing agriculture, forestry, fisheries and aquaculture, enhance stewardship and environmental conservation activities, and develop new methods of disease diagnosis, treatment and prevention. The objective of the Genomics R&D Initiative is to build the capacity inside government laboratories to do this new type of biotechnology research, which will strengthen the regulatory system and bring the benefits of revolutionary advances in research and technology to a variety of Canadian industrial sectors and regions. The new technologies are expected to have a dramatic impact on industrial competitiveness and economic growth.

Programs funded under the genomics R&D initiative are also used to augment human resources and help create partnerships among government-based science organizations, universities and other research institutes through the sharing of technology platforms and by collaborating in research areas that cut across traditional departmental sectors.

1.2.3 Governance

An interdepartmental Genomics R&D ADM Coordinating Committee has been established to oversee collective management and coordination of the federal Genomics R&D Initiative. This Coordinating Committee functions as a Subcommittee of the federal Biotechnology ADM Coordinating Committee (BACC) established under the Canadian Biotechnology Strategy. The Committee ensures that effective priority setting mechanisms are established within departments and, that government objectives and priorities are addressed.

The Committee also ensures that common management principles associated with R&D management are implemented and horizontal collaborations between organizations are pursued wherever relevant and possible. The committee includes members from each of the six organizations receiving funding, as well as the Canadian Biotechnology Secretariat (CBSec) and Industry Canada. An Interdepartmental Working Group supports the work of the committee. The National Research Council has been the lead agency in the development of the RMAF and Treasury Board (TB) submissions, and chairs the Coordinating Committee and the Working Group.

To ensure that the maximum possible benefit is derived from government investments in genomics R&D, each department uses an internal competitive program proposal and approval process, as well as scientific peer review to evaluate the quality and relevance of research programs. All departments have levered the government's investment in genomics R&D by providing additional (or matching) funds by allocating A-base (departmental base funding) to supplement genomics R&D funding. Resources in each department are directed towards fulfilling specific mandate requirements. Successful collaborations have also been established where relevant and appropriate.

1.2.4 Funding Allocation

Table 1 shows the funding allocation by department and program phase.

Table 1 – Funding Allocation by Department and Program Phase

Department/Agency	Phase 1 1999-2002	Phase 2 2002-2005	Phase 3 2005-2008
Agriculture and Agri-Food Canada	$ 17,000,000	$ 18,000,000	$ 18,000,000
Environment Canada	$ 3,000,000	$ 3,000,000	$ 3,000,000
Fisheries and Oceans Canada	$ 2,500,000	$ 2,700,000	$ 2,700,000
Health Canada	$ 10,000,000	$ 12,000,000	$ 12,000,000
National Research Council Canada	$ 17,000,000	$ 18,000,000	$ 18,000,000
Natural Resources Canada	$ 5,000,000	$ 6,000,000	$ 6,000,000
Medical Research Council*	$ 500,000		
Total	**$ 55,000,000**	**$ 59,700,000**	**$ 59,700,000**

* Precursor to the Canadian Institutes of Health Research (CIHR) – one time allocation in 1999-2000 to assist in the establishment and support of a Genome Canada Secretariat.

1.2.5 Departmental Delivery

A profile of the Genomics R&D Initiative in each of the six departments receiving funding is provided in Annex A. A broad overview is provided in Table 2.

1.3. Structure of this Report

This report is structured as per the core elements of an evaluation report, as outlined by the Treasury Board of Canada Secretariat (TBS).[2] As such, it includes the following:

The **Executive Summary** presented earlier provides a brief description of the Genomics R&D Initiative, the purpose of the evaluation, its intended audience and it presents the main evaluation findings, conclusions and recommendations.

This **Introductory** section provided a description of the Initiative and outlined the context for this evaluation.

[2] Source: Guide for the Review of Evaluation Reports, Centre of Excellence for Evaluation, Treasury Board of Canada Secretariat, January 2004.

Section 2.0 describes the **Evaluation Methodology**, identifies the evaluation issues and outlines how multiple lines of evidence were used to address these issues, discusses how data quality was ensured, and provides an overview of the strengths and limitations of the methodology.

The **Key Findings** are presented by issue in sections 3.0 to 6.0 according to the issue categories of:

- Relevance (Section 3.0);
- Success (Section 4.0);
- Cost-Effectiveness / Alternatives (Section 5.0): and
- Design and Delivery (Section 6.0).

In each section, the findings for each specific evaluation question are presented. To the extent feasible, the findings are summarized for the Initiative as a whole, not for each department / agency (see Annex A for findings by department). Nonetheless, there are cases where departmental / agency findings need to be discussed individually in order to appropriately address the issues.

Table 2 – Summary Profile by Department				
Focus / Themes	**Lead Centres / Organizations**	**Resources**		
		Phase 1	**Phase 2**	**Phase 3**
Agriculture and Agri-Food Canada – Canadian Crop Genomics Initiative (CCGI)				
Canola Wheat Soybean Corn	Saskatoon Research Centre Cereal Research Centre in Winnipeg Southern Crop Protection and Food Research Centre in London Eastern Cereal and Oilseed Research Centre in Ottawa	1999-2000 – $2.9 million 2000-2001 – $6.0 million 2001-2002 – $8.1 million **Total – $17.0 million**	$6.0 million per fiscal year **Total – $18.0 million**	$6.0 million per fiscal year **Total – $18.0 million**
Environment Canada – Strategic Applications of Genomics in the Environment (STAGE) program				
Genotyping Microarrays Test methodology development Environmental stewardship	Canadian Wildlife Service Wastewater Technology Centre Pacific Environmental Science Centre National Wildlife Research Centre National Water Research Institute Environmental Technology Centre Environmental Biotechnology Application Division	$1 million per fiscal year **Total – $3.0 million**	$1 million per fiscal year **Total – $3.0 million**	$1 million per fiscal year **Total – $3.0 million**

Table 2 – Summary Profile by Department				
Focus / Themes	**Lead Centres / Organizations**	**Resources**		
		Phase 1	**Phase 2**	**Phase 3**
Fisheries and Oceans Canada				
Biotechnology and Aquatic Resource Management Biotechnology and Aquatic Animal Health Biotechnology and Aquatic Ecosystem Integrity Novel Aquatic Animal Regulatory Science	Office of Aquatic Biotechnology	1999-2000 – $700,000 2000-2001 – $900,000 2001-2002 – $900,000 **Total – $2.5 million**	$900,000 per fiscal year **Total – $2.7 million**	$900,000 per fiscal year **Total – $2.7 million**
Health Canada				
Generation, use and societal impacts of human genetic information Health and safety of biotechnology products Human genomic applications and impacts related to diagnostics and diseases Microbial genomic applications and impacts related to diagnostics and diseases	Departmental Biotechnology Office	1999-2000 – $2.0 million 2000-2001 – $4.0 million 2001-2002 – $4.0 million **Total – $10.0 million**	$4.0 million per fiscal year **Total – $12.0 million**	$4.0 million per fiscal year **Total – $12.0 million**

Table 2 – Summary Profile by Department				
Focus / Themes	**Lead Centres / Organizations**	**Resources**		
		Phase 1	**Phase 2**	**Phase 3**
National Research Council – Genomics and Health Initiative[3]				
Advancing fundamental and applied research in the areas of genomics and health related to diagnosing, treating and preventing human disease, addressing environmental concerns, managing natural resources, and ensuring food safety	Institute for Marine Biosciences – Halifax Biotechnology Research Institute – Montreal Institute for Biological Sciences – Ottawa Institute for Biodiagnostics – Winnipeg Plant Biotechnology Institute – Saskatoon	1999-2000 – $5.0 million 2000-2001 – $6.0 million 2001-2002 – $6.0 million **Total – $17.0 million**	$6.0 million per fiscal year **Total – $18.0 million**	$6.0 million per fiscal year **Total – $18.0 million**

[3] Based on the $6 million per year received from the Genomics R&D Initiative, an additional $5 million in A-base funding received at about the same time from the new NRC-based allocations related to the creation of the CIHR, and additional A-base funding, NRC has created a Genomics and Health Initiative (GHI) with an annual budget of over $20 million.

Table 2 – Summary Profile by Department				
Focus / Themes	**Lead Centres / Organizations**	**Resources**		
		Phase 1	**Phase 2**	**Phase 3**
Natural Resources Canada – Genomics Research Initiative				
Molecular Genetics of Forest Tree Production and Protection Systems Molecular Markers for Diagnosis, Monitoring and Early Selection Production of Genetically Improved Trees Production of Environmentally Acceptable Forest Protection Methods	Atlantic Forestry Centre (Fredericton, NB) Laurentian Forestry Centre (Ste. Foy, QC) Great Lakes Forestry Centre (Sault Ste. Marie, ON) Pacific Forestry Centre (Victoria, BC)	1999-2000 – $1.0 million 2000-2001 – $2.0 million 2001-2002 – $2.0 million **Total – $5.0 million**	$2.0 million per fiscal year **Total – $6.0 million**	$2.0 million per fiscal year **Total – $6.0 million**

Finally, the **Conclusions** and **Recommendations** are discussed in Section 7.0 of this report. The conclusions are based on the findings presented throughout the report and are structured to address the evaluation issues and questions. The recommendations stem directly from the conclusions.

In order to limit the length of this report, details are provided through the following annexes:

- Annex A – Departmental Summaries (these include a profile of the delivery approach in each department as well as the findings for each issue and question);
- Annex B – List of Documents Reviewed (these were provided by departmental representatives);
- Annex C – List of Projects Approved (this lists all approved project by department and by phase);
- Annex D – List of Potential Interviewees (in order to minimize the risk that specific responses could be attributed to specific individuals, the annex provides a list of individuals from which interviewees were sampled, not the names of the specific individuals interviewed); and
- Annex E – Interview Guides (separate interview guides were developed for management interviewees, project leads and stakeholders).

2.0 Methodology

2.1 Detailed Methodology

The conduct of the evaluation consisted of two distinct phases: the planning phase and the data collection and analysis phase.

The planning phase, involved the following distinct tasks:

- a project kick off meeting to discuss the protocols, study requirements, required adjustment to the approach proposed and introduction of the entire study team;
- a series of six preliminary interviews, one in each department or agency, was completed to develop a better understanding of the specific way in which the Initiative was delivered in each department, obtain preliminary documents to help the evaluation team familiarize itself with various aspects of delivery in each department, obtain preliminary information on the number of projects and lead researchers involved in each phase, and introduce a lead evaluation team member to the department;
- refinement of the initially proposed approach to the data collection and analysis phase through a detailed work plan which included refined evaluation issues, sample sizes, sampling methodologies and data collection instruments; and
- a first meeting of the Interdepartmental Evaluation Working Group (IEWG) to finalize the issues and evaluation methodology.

Upon approval of the detailed work plan, the evaluation team proceeded to the actual data collection and analysis phase which consisted of a document review, the development of a project database, in-depth interviews and, analysis and reporting. These are discussed in more detail below.

2.1.1 Document Review

The document review involved documents relevant to the Initiative as a whole as well as department specific documents including available project summary reports. In addition, documents on the Canadian Biotechnology Strategy and its gamut of programming were reviewed. Finally, information on genomics initiatives in other jurisdictions was also reviewed.

It is important to note that the documents reviewed were limited to those provided by the various departmental leads as well as those known by the evaluation team. The study did not involve a thorough literature search and review.
A list of the documents reviewed is provided in Annex B.

2.1.2 Database Review

During the planning phase, the evaluation team was able to determine that there was a limited amount of consistent information available on the projects funded in each department. There was no database available on projects. The evaluation team therefore obtained as much information as was possible from each department on the funded projects and developed an Initiative project database. The information included in the database was fairly limited because of the inconsistent level of detail available across organizations. The information captured in the database was therefore limited to the following information:

- project title;
- project phase;
- $ value of project;
- department; and
- lead organization / laboratory.

A list of projects funded by department is provided in Annex C.

2.1.3 Interviews

Interviews were completed with the following four groups of individuals, either in person or by telephone:

- departmental managers – in each department, interviews were completed with managers involved in the Initiative;

- lead project scientists – in each department, interviews were completed with a sample of scientists who were identified as the lead in either a Phase 1 project, a Phase 2 project or both;

- departmental stakeholders – each department identified "other" individuals to interview either because they were partners on a project, beneficiaries of a project or because they had an interest in the genomics R&D activities of that department; and

- horizontal stakeholders – people with an interest in the Initiative as a whole (not necessarily in the delivery within a given department) were also identified and interviewed; these included representatives of Central Agencies, of other CBS departments, or those with an interest in genomics R&D but not receiving funding through this Initiative.

The specific number of interviews completed in each group and in each department was determined taking the following factors into consideration:

- the total number of potential interviewees in that group and across organizations;
- ensuring that a sufficient number of interviews were completed in each group and each department for analytical purposes as well as for purposes of confidentiality;
- attempting adequate coverage of different interests / knowledge; and
- ensuring that a sufficient number of knowledgeable interviewees were completed to address each of the evaluation issues and questions.

The majority of the interviews were completed by telephone. However, some were completed in person. All interviews were completed at a time most convenient to the respondent and in the official language of his / her choice. The appropriate interview guide was sent as soon as the interview was scheduled to give the interviewee time to prepare for the interview, as required. Some group interviews (with more than one individual) were completed upon request of some interviewees. The total number of individuals interviewed is as per Table 3 below.

Table 3 – Number of Individuals Interviewed by Type and Department

Department	# of Managers	# of Researchers	# of Stakeholders	Total #
Agriculture and Agri-Food Canada	4	15	5	**24**
Environment Canada	4	11	3	**18**
Fisheries and Oceans Canada	4	8	3	**15**
Health Canada	6	11	4	**21**
National Research Council	3	6	2	**11**
Natural Resources Canada	5	10	2	**17**
Horizontal / non-departmental	0	0	9	**9**
Total	**26**	**61**	**28**	**115**

The sampling methodology varied across organizations and depended on the interviewee type.

For example, all managers were interviewed (i.e. no sampling) in all departments except in NRC where only three managers were interviewed because NRC had recently completed its own evaluation and other managers had already been interviewed in the context of that evaluation (which was used extensively in the findings for NRC).

For researchers in departments where there were few researchers, all or almost all were interviewed. In departments where there were more researchers, they were sampled to ensure that researchers involved in only one phase as well as some involved in several phases were interviewed. It is important to note that a significant proportion (two-thirds) of researchers across departments was interviewed.
For the departmental stakeholders, close to all identified stakeholders were interviewed (19 out of 22) on a random basis.

Finally, for horizontal stakeholders, the individuals were selected to cover the range of organizations as well as based on their level of knowledge of the Genomics R&D Initiative. Most individuals not interviewed eliminated themselves from the sample because of limited knowledge or involvement.

The list of potential interviewees is provided in Annex D and the interview guides are included as Annex E.

It is important to note that, given the nature of the questions, the type of interaction with the initiative and thus the difference in perspective, each interviewee group was viewed as a different line of evidence.

2.2 Final Issues by Methodology Matrix

Table 4 over the next several pages identifies the list of final issues, questions and indicators. The table also identifies the extent to which each data collection method has contributed to each issue or question. In order to determine how to allocate high, medium or low, the following principles were used:

- High – the source contributed highly to this issue because of the extensive amount of information available through the source and / or the high reliability of the source for that issue;
- Medium – contribution of the source to this issue because of the medium amount of information available through the source and / or the medium reliability of the source for that issue; and
- Low – the source contributed minimally to this issue because of the low amount of information available through the source and / or the low reliability of the source for that issue.

Table 4 – Evaluation Issues and Questions by Method						
Issues / Questions	**Indicators**	**Document Review**	**Database Review**	**Interviews**		
				Managers	**Researchers**	**Stakeholders**
Rationale						
R1. Are the mandate and the strategic objectives of the Genomics R&D Initiative still relevant? What need was the Initiative intended to address? Does this need still exist?	Documented mandate, objectives, needs Opinions of various stakeholders	Medium		Medium		Medium
R2. Is there a legitimate and necessary role for government in this area?	Link to government-wide and departmental priorities Description of activities / programs undertaken under the Initiative Extent to which those activities / programs are better associated with mandates of provinces / private / voluntary sector Opinions of various stakeholders	High		Medium		
Success						
S1. Have the individual departments achieved, or made progress towards, their specific objectives / goals?	Evidence of progress made by departments Feedback from departments	Medium		High	High	Medium

Table 4 – Evaluation Issues and Questions by Method						
Issues / Questions	**Indicators**	**Document Review**	**Database Review**	**Interviews**		
				Managers	**Researchers**	**Stakeholders**
S2. To what extent did the projects funded under Phase 1 of the Genomics R&D Initiative build capacity inside government laboratories to carry out genomics research?	Evidence of change in capacity from Phase 1 projects Feedback from departments and other stakeholders	Medium	Low	High	High	Medium
S3. Did this increased capacity strengthen the research carried out in the departments?	Change in profile of research undertaken by the departments Feedback from departments Expert opinion	Medium		High	High	
S4. Did this increased capacity created in Phase 1 translate into the benefits of advances in research and technology in Phase 2 for department constituents?	Evidence of advances in research and technology in Phase 2 Extent to which results of Phase 2 are attributable to change in capacity created in Phase 1 Feedback from departments Expert opinion	Medium		High	High	
S5. To what extent has the Initiative strengthened coordination, cooperation and linkages among the appropriate research institutions?	Change in the number and type of collaborative projects Other evidence of coordination, cooperation and linkages Feedback from departments and other stakeholders	Medium		High	High	Medium

Table 4 – Evaluation Issues and Questions by Method						
Issues / Questions	**Indicators**	**Document Review**	**Database Review**	**Interviews**		
				Managers	**Researchers**	**Stakeholders**
S6. What have been the facilitating and impeding factors for the success of Phases 1 and 2 of the Initiative?	Evidence of facilitating and impeding factors in documents (e.g., minutes of meetings) Feedback from departments and others	Medium		Medium	High	Medium
S7. Are there other intended and unintended impacts resulting from the Initiative?	Evidence of unintended impacts (positive and negative) Feedback from departments and others			Medium	Medium	Low
S8. To what extent would the impacts have occurred without the Initiative?	Incremental impact of Initiative on the level of activity, the scope of activities and the success of the projects for each phase Contributing factors to this	Medium		Medium	High	
Cost-effectiveness / Alternatives						

Table 4 – Evaluation Issues and Questions by Method

Issues / Questions	Indicators	Document Review	Database Review	Interviews		
				Managers	Researchers	Stakeholders
C1. Does the Genomics R&D Initiative complement, overlap or duplicate other federal or provincial initiatives related to genomics or biotechnology?	Description of activities / programs undertaken under the Initiative Description of activities / programs undertaken by provinces / of current private / voluntary sector involvement / capacity Extent to which Initiative activities / program overlap with / complement those of the provinces / private / voluntary sector involvement / capacity	Medium		Medium	Medium	Medium
C2. Is the funding structure of the Genomics R&D Initiative the most appropriate mechanism for achieving the intended objectives? Are there more cost-effective alternative ways to achieve the Genomics R&D Initiative mandate?	Extent to which the various participants are satisfied with the funding structure / suggestions for improvement Evidence of problems with the funding structure Costs and benefits associated with the funding structure versus other possible alternatives Opinions of departments and stakeholders on alternatives	Medium		Medium	Medium	Low

Table 4 – Evaluation Issues and Questions by Method						
Issues / Questions	**Indicators**	**Document Review**	**Database Review**	**Interviews**		
				Managers	**Researchers**	**Stakeholders**
C3. Is the three year funding cycle appropriate for achieving intended outcomes?	Evidence of progress towards outcomes to date Cycle used for other programs Feedback from departments Expert opinion	Medium		High	High	High
C4. What has been the level of effort or cost required by departments / agency to participate in this horizontal initiative? What have been the benefits?	Departmental costs associated with horizontal initiative (i.e., costs that would not have been incurred if the departments had received their share of funding directly) Incremental benefits associated with horizontal initiative	Medium		Medium		

Table 4 – Evaluation Issues and Questions by Method						
Issues / Questions	**Indicators**	**Document Review**	**Database Review**	**Interviews**		
				Managers	**Researchers**	**Stakeholders**
Design and Delivery						
D1. Is the position of the Genomics R&D Initiative appropriate within the larger government biotechnology strategy? Is the level of integration with other federal government biotechnology programs appropriate?	Position of initiative within the CBS Opinions of all parties on appropriateness Evidence of integration Extent to which more integration is required / would increase the likelihood of success	Medium		High	Medium	High
D2. How effective is the overall governance structure for the Initiative and departmental processes (e.g., project approval process)? Are the roles and relationships clearly defined and appropriate?	Extent to which the various participants are satisfied with the governance structure and processes / suggestions for improvement Evidence of problems with the governance structure and departmental processes Evidence of defined roles and relationships Extent to which players understand their roles and relationships Evidence that players are adhering to their expected roles and relationships	Medium		High	Medium	

Table 4 – Evaluation Issues and Questions by Method

Issues / Questions	Indicators	Document Review	Database Review	Interviews		
				Managers	Researchers	Stakeholders
D3. To what extent have the departments been able to leverage the funds provided through the Genomics R&D Initiative? What are the pros and cons associated with the leveraging requirements?	Opinions of all parties on strengths and weaknesses Requirements used by others	Medium		Medium	Medium	
D4. How effective / appropriate is the Initiative's approach to performance measurement? What performance measures should be captured in the next phase and why?	Extent to which the performance measurement strategy outlined in the RMAF has been implemented Extent to which parties have the performance information they need for decision-making purposes Evidence of use of performance information Strengths and weaknesses of current performance strategy, in particular as it relates to what will be needed in Phase 3 Gaps in current measures, in particular as it relates to what will be needed in Phase 3	Medium	Low	High	Medium	
D5. How could the Genomics R&D Initiative be improved? What changes are required to make the Initiative more efficient?	Suggestions for improvement Other evidence from previous issues indicating a need for changes	Medium		High	High	High

The evaluation issues are based on the draft set of evaluation issues that were developed and included in the Statement of Work dated December 2005. They were adjusted in the planning phase of this study based on the preliminary interviews conducted as well as the input of the Interdepartmental Evaluation Working Group (IEWG). The issues, the study methodology and data collection instruments were approved by the IEWG before the start of data collection. It is noteworthy that cost-effectiveness was not really covered in this evaluation and it will be more fully addressed in the summative evaluation, based on the criteria outlined in the revised RMAF for the Initiative. It is also important to note that, in the context of the success issues, the links between activities, outputs, outcomes and objectives were not assessed. These linkages will be more clearly established in the revised RMAF for the Initiative and mechanisms to assess the strength of these linkages will also be identified in the revised RMAF.

The Treasury Board Secretariat Expenditure Review Committee (ERC) questions were included as per Table 5.

Table 5 – Link between ERC Questions and Evaluation Questions

ERC Questions	Evaluation Issues / Questions
Public Interest – Does the program area or activity continue to serve the public interest?	R1. Are the mandate and the strategic objectives of the Genomics R&D Initiative still relevant? What need was the Initiative intended to address? Does this need still exist?
Role of Government – Is there a legitimate and necessary role for government in this program area or activity?	R2. Is there a legitimate and necessary role for government in this area?
Federalism – Is the current role of the federal government appropriate, or is the program a candidate for realignment with the provinces?	
Partnership – What activities or programs should or could be transferred in whole or in part to the private / voluntary sector?	Partially addressed through: R2. Is there a legitimate and necessary role for government in this area? C1. Does the Genomics R&D Initiative complement, overlap or duplicate other federal or provincial initiatives related to genomics or biotechnology?

Table 5 – Link between ERC Questions and Evaluation Questions	
ERC Questions	**Evaluation Issues / Questions**
Value-For-Money – Are Canadians getting value for their tax dollars?	C1. Does the Genomics R&D Initiative complement, overlap or duplicate other federal or provincial initiatives related to genomics or biotechnology? C2. Is the funding structure of the Genomics R&D Initiative the most appropriate mechanism for achieving the intended objectives? Are there more cost-effective alternative ways to achieve the Genomics R&D Initiative mandate? C4. What has been the level of effort or cost required by departments / agency to participate in this horizontal initiative? What have been the benefits? D3. To what extent have the departments been able to leverage the funds provided through the Genomics R&D Initiative? What are the pros and cons associated with the leveraging requirements?
Efficiency – If the program or activity continues, how could its efficiency be improved?	C3. Is the three year funding cycle appropriate for achieving intended outcomes? D1. Is the position of the Genomics R&D Initiative appropriate within the larger government biotechnology strategy? Is the level of integration with other federal government biotechnology programs appropriate? D2. How effective is the overall governance structure for the Initiative and departmental processes (e.g., project approval process)? Are the roles and relationships clearly defined and appropriate? D4. How effective / appropriate is the Initiative's approach to performance measurement? What performance measures should be captured in the next phase and why? D5. How could the Genomics R&D Initiative be improved? What changes are required to make the Initiative more efficient?
Affordability – Is the resultant package of programs and activities affordable? If not, what programs or activities would be abandoned?	See Value-For-Money and Efficiency

2.3 Strengths and Weaknesses of Study Methodology

Overall, the approaches and sample sizes used for this evaluation resulted in a strong and reliable horizontal evaluation, which provided the evidence to conclude on all issues. Additionally, the overall evaluation methodology is strong because multiple lines of evidence were used to the extent possible. Some of the factors that contributed positively to the overall strength of the evaluation methodology included the following:

- the budget allocated to this evaluation was reasonable;
- the departmental representatives were very cooperative and played a major role in ensuring that the evaluation team had all the information it needed in a timely fashion; and
- there was a high level of interest in this evaluation and most people contacted were willing to participate in the study.

However, there were some key weaknesses with the evaluation some due to the timing of the evaluation, others due to the lack of consistent departmental information, and others still due to the fact that it was unfeasible to undertake other approaches in the context of this evaluation. More precisely:

- While this evaluation was undertaken in the eight years of the initiative, it was still more formative than summative in nature. In addition, given the nature of the initiative, which is to build capacity in federal labs, the parties with some familiarity with the program at this stage in its implementation are internal to the departments. There were few people outside the six departments who were knowledgeable enough about the initiative to be able to provide informed feedback on it at this time. As such, the consultations are more internal than external to the six departments. Nevertheless, important stakeholders outside the six departments were consulted during the evaluation.

- When this initiative was started, a very broad performance framework was developed and departments were left to implement their own performance measurement systems. Unfortunately, this resulted in limited information in departments of a quantitative nature. As a result, it was initially expected that an interdepartmental database could be prepared and analyzed to help address issues related to relevance, success and cost-effectiveness. Unfortunately, this was impossible because departments did not have this information. As a result, the evaluation relied extensively on qualitative approaches. Nevertheless, given the nature of the issues, this still resulted in the required evidence to conclude on the issues. In other cases where quantitative information should have been available but was not, this provided evidence to conclude on design and delivery issues.

- Finally, in some cases, possible evaluation approaches were excluded because they were unfeasible at this time, impractical or unrealistic. For example, while international benchmarking had been considered, within the budget it was deemed by the interdepartmental working group to be unfeasible. In order to appropriately benchmark the interdepartmental nature of this initiative, comparison to one other country would have been almost as resource intensive as the other evaluation approaches combined. As such, benchmarking was not included. As another example, interviews with a large number of external parties were deemed impractical as well as unrealistic for several reasons. First, as previously noted, a large number of external parties were not familiar enough with the initiative to provide informed input. Second, the burden of previous studies in the federal biotechnology community had to be taken into consideration. This evaluation was undertaken at the same time as an evaluation of the Canadian Regulatory System for Biotechnology; one year after an evaluation of three components of the CBS (i.e., the CBS Fund, the Canadian Biotechnology Advisory Board and the CBS Secretariat); and two years after the major Expenditure and Management Review of the Federal Government's Investments in Biotechnology. As such, respondent burden had to be taken into consideration. Additionally, some departments involved in this initiative were undertaking their own departmentally driven studies (e.g., Environment Canada's white paper) and others outside this initiative were completing studies which were to feed into this evaluation (e.g., Industry Canada's genomics study), but which were not made available during the timing of this evaluation.

These considerations resulted in an evaluation which was of a qualitative nature and which was heavily weighed to internal departmental sources. Table 6 which follows outlines the key strengths and weaknesses of each method.

Table 6 – Methodological Strengths and Weaknesses by Approach

Approaches	Strengths	Weaknesses
Review of Documents	A large number of documents were reviewed – these provided information which was useful in addressing most of the evaluation issues.	The review was limited to those documents directly identified by the consulting team as being required for the evaluation or to documents provided by representatives in each department because they were believed to be useful. As such, there is a risk that key documents could have been missed in the review. Nevertheless, this is not a major risk particularly given the wide range of sources used to collect the documents. For some of the issues, only background information was available. As such, the documents did not provide direct evidence for those issues but rather only helped provide background to the issues.
Data Review	This provides quantitative factual information on projects. In the case of this evaluation, due to the absence of departmental project databases, a combined database of projects in all departments was developed. This database provides limited information on the range of projects funded through the Initiative.	The project information was difficult to obtain from some departments because they did not have the systems in place to capture such data. As such, there was limited information that could consistently be captured on projects across departments. This information was limited to profile information and therefore provided very limited data in helping address success issues.
Interviews (overall)	This provides an opportunity to obtain in-depth, qualitative information on the program. All issues were covered through this method. Because a significant number of interviews were completed (115), and because there was a fair amount of consistency in the responses provided within and across groups of interviewees, the results yielded through the interviews are highly credible. Additionally, the level of participation was very high and there were few refusals. This increases the reliability of the sample of interviewees and reduces the potential for non-response bias.	The key limitation to this approach was that, while a large number of people were interviewed, many others could have been interviewed. However, there were budget and timing limitations as well as the fact that there have been many studies completed in recent years related to biotechnology that have involved the same people. It was therefore important to avoid overburden on some potential interviewees.

Table 6 – Methodological Strengths and Weaknesses by Approach

Approaches	Strengths	Weaknesses
Interviews with Managers	With 26 managers interviewed across six departments, a significant proportion of the managers involved in this initiative were interviewed. This results in a high level of confidence that information on the departmental and interdepartmental management of this initiative was well covered. The managers were able to provide well informed feedback on all issue categories.	This initiative has gone through a lot of management changes over the three phases. Therefore, in some departments, it was difficult to find managers who had been involved in all three phases and who could provide informed feedback on the earlier phases.
Interviews with Researchers	A total of 61 interviews were completed with researchers involved in one or more phases of the initiative. In some departments, all lead researchers were interviewed. Overall, a large number of researchers, with varying involvement (Phase 1 only, Phase 2 only, Phase 1 and 2, etc.) were interviewed. The researchers provided well informed feedback on most issue categories, and were particularly important for addressing the success issues.	Over 240 projects were approved in Phases 1, 2 and 3. While a large number of researchers were involved in more than one project, there are several researchers who could not be interviewed within the scope of this study.
Interviews with Stakeholders	Interviews were completed with 28 stakeholders. Since a limited number of potential stakeholder interviewees were identified, most of the ones who were familiar with the initiative were interviewed. These provided valuable, third party perspectives on the relevance issues as well as some input into all other issues.	No major weaknesses directly associated with this method are noteworthy.

2.4 Analysis

Since the interviews were qualitative in nature, it is difficult and possibly misleading to quantify the responses. The interview results were therefore not quantified for the purposes of reporting. Nevertheless, in reporting, the following guidelines were used:

- All – when everyone asked a particular question gave a similar answer;
- Most – when some respondents in all departments (unless otherwise noted) have made an observation of this nature and, overall across all departments, more than half did so;
- Several – when close to half the respondents gave a similar answer;
- Some – when less than half the respondents gave a similar answer; and
- Few – when less than five respondents asked the question gave a similar answer.

3.0 Findings – Relevance

3.1 R1. Are the mandate and the strategic objectives of the Genomics R&D Initiative still relevant? What need was the Initiative intended to address? Does this need still exist?

The original Genomics Research Initiative Framework, as well as the two subsequent ones, provided background on the rationale for the Initiative. The framework noted that the Genomics R&D Initiative is part of the broader Canadian Biotechnology Strategy developed in 1998. The CBS recognized that immediate increased investment in genomic R&D was necessary if Canada was to be able to participate in this important emerging field. The original strategic objectives of the broad Genomics R&D Initiative, as defined in the original Genomics Research Initiative – Program Framework (1999-2000 to 2001-2002) were to "address public policy concerns with social, economic and environmental outcomes".

The stated objective of the Genomics R&D Initiative is:

> *"to build the capacity inside government laboratories to do ... biotechnology research (related to genome sciences), which will strengthen the regulatory system and bring the benefits of revolutionary advances in research and technology to a variety of Canadian industry sectors and regions. The new technologies are expected to have a dramatic impact on industrial competitiveness and economic growth. They are also expected to bring significant social benefits, e.g. better therapeutics, cleaner environment and better management of natural resources."*[4]

The Initiative is structured to address the capacity building needs in each of the six funded departments. While the documented objectives and needs are different across departments (see Annex A for specific departmental objectives), the overall need was for building genomics R&D capacity.

As the Initiative evolved (through its three three-year funding cycles), the specific departmental needs evolved. Nevertheless, as outlined in Table 7, they are still related to building genomics R&D capacity.

[4] Source: Treasury Board of Canada, Secretariat website (http://www.tbs-sct.gc.ca/rma/eppi-ibdrp/hrdb-rhbd/cbs-scb/description_e.asp)

Table 7 – Phase 3 Departmental Objectives	
Department	**Objective**
Agriculture and Agri-Food Canada	To develop the infrastructure, highly qualified personnel and knowledge base required for the creation of new bio-based products.
Environment Canada	To facilitate the development of biotechnology applications that have the potential for significant environmental benefit as well as supporting key departmental priorities.
Fisheries and Oceans Canada	To develop genomic and biotechnology application for use in the management of aquatic resource and habitats.
Health Canada	To generate knowledge that is essential to the effective regulation of products and technologies produced in the field of genomics, including studying the societal impacts of genomics research, the long-term effects of products of biotechnology, and the interaction of humans with pathogens and the environment.
National Research Council	To advance the frontiers of scientific and technical knowledge within the area of genome sciences and to create and use new genomics technologies to support value for Canada in key industrial sectors such as aquaculture, agriculture, environment and health.
Natural Resources Canada	To improve forest generation and protection methods, while ensuring that environmental impact considerations are addressed.

Source: Genomics R&D Initiative: Phase III Program Framework (2005-06 to 2007-08).

Management interviewees noted that, while the need for the overall Initiative was to build capacity, the specific needs varied from one department to the next. This was due to the fact that some departments were already involved in genomics R&D at the time this Initiative started while others were just starting to be involved while others had no capacity whatsoever in this area. As such, some departments were building on what they had whereas others were just starting to build. This, therefore, resulted in different types of projects in Phase 1 in the various departments and thus in differing budgetary allocations. Nevertheless, the needs were (and still are):

- for people, in particular highly qualified personnel (HQP) – it is important for departments to be able to attract new personnel in this field, train existing personnel, and ensure the necessary financial commitment to retain the HQP they have attracted and trained;

- for equipment and facilities – it is critical to have the resources required to obtain, maintain and upgrade existing equipment and facilities; and

- for the funding to conduct research studies – there is an ongoing need to conduct research studies, in order to ensure appropriate use of the people, equipment and facilities identified in the two previous bullets.

Regardless of the initial need identified by the departments, managers, researchers and stakeholders agreed that the need still exists and that continued funding was required in order to, for example:

- keep up in this rapidly developing field and develop expertise in new applications, and thus ensure that Canada does not fall behind other countries;
- address enforcement issues;
- support national and international commitments;
- address human resource and infrastructure needs in labs;
- maintain the capacity that has been built to date in the early phases;
- use the knowledge and capability already developed; and
- expand the application of genomics tools and techniques.

Most interviewees (managers, researchers and stakeholders alike) felt that the need was greater than ever. In fact, some managers and researchers noted that, in Phase 1, the need may not have been recognized as much as it is now since departments were less aware of the importance and benefits of genomics R&D to their departmental mandates. Now that they have started to reap the benefits (see Section 4.0 – Success), managers and researchers feel that there is an even greater need for their involvement in this field.

Additionally, it was noted by some managers, researchers and stakeholders that the emerging "omics" areas within the genomics R&D field (e.g., transcriptomics, proteomics, metabolomics) mean that the need for this Initiative continues to grow.

3.2 R2. Is there a legitimate and necessary role for government in this area?

From 1998 to the present, several documents highlight the legitimate and necessary role for government in genomics R&D. Highlights of the 1998 Canadian Biotechnology Strategy which illustrate the importance of federal initiatives such as the Genomics R&D Initiative include:[5]

[5] Source: The 1998 Canadian Biotechnology Strategy: An Ongoing Renewal Process, Government of Canada, Cat. No. C21-22/5-1998, ISBN 0-662-63917-0.

- As a result of extensive consultations, proposed governmental actions were divided into 10 key themes – public confidence, communication and awareness; R&D; regulation to protect health, safety and the environment; biotechnology for public health advantage; intellectual property; commercialization; international issues; human resources; policy relevant data collection and analysis; and sector-specific strategies.

- Genomics R&D was identified as a possible priority under the R&D theme. Possible actions included the identification of key strategic choices in biotechnology platforms / domains in basic research, research to support the regulatory framework and the public good, and research related to wealth creation, innovation and commercialization. As such, the R&D theme is also expected to contribute to most of the other themes.

In 2003, the importance of federal initiatives such as the Genomics R&D Initiative was reinforced in a document produced by the Biotechnology Assistant Deputy Ministers' Coordinating Committee.[6] This Blueprint noted that:

> *"The government must integrate an aggressive economic agenda and effective stewardship that not only protects health, safety, and the environment, but is also responsive to issues of public confidence, awareness and consumer acceptance of biotechnology applications. Both effective stewardship and world-leading innovation are necessary to realize the potential of this technology."*

In this context, the document identifies the role of government as being one of:

- Catalyst for Innovation – this includes funding R&D and putting in place globally competitive economic and regulatory framework policies ***(which are informed by federal initiatives such as the Genomics R&D Initiative)***;

6 Source: Building the 21st Century Economy, A Government of Canada Blueprint for Biotechnology, Realizing Canada's Potential, Biotechnology Assistant Deputy Ministers' Coordinating Committee, Canadian Biotechnology Strategy, December 2003.

- Innovative Regulator – this responsibility is founded on effective, rigorous laws, regulations and policies that are transparent, aligned with international standards and best practices, and supported by fact-based dialogue with Canadians, investments in science, as well as research to close knowledge gaps ***(including as a result of the Genomics R&D Initiative)***, and foresight analyses;

- Engagement of Canadians; and

- Reflecting Canadian Values.

The February 2004 Speech from the Throne[7] reaffirmed the Government of Canada's commitment to seeing Canada as "a world leader in developing and applying the path-breaking technologies of the 21st century – biotechnology, environmental technology, information and communication technologies, health technologies, and nanotechnology".

Several departmental program managers interviewed noted that there is a very legitimate and necessary role for the federal government to be involved in undertaking genomics R&D particularly in light of the following:

- it is critically important in providing quality advice to Ministers;

- the research findings are important in order to support the regulatory mandate of some departments (i.e., HC, DFO and EC);

- the research findings are important in support of management (e.g. fisheries management, resource management) and sustainability issues; and

- some of the research can only be done by government because there is a need for credible and unbiased research which cannot be done by others or because the research requires access to commercial or confidential information.

However, it was noted by some of the stakeholders interviewed that, while there is a legitimate and necessary role for government in this area, it is important that the role of government in the context of the Genomics R&D Initiative be clearly defined in order to ensure that the research supports government priorities, informs the policies of other departments and agencies not funded through this initiative, and complements the research mandates of others involved in genomics R&D (such as Genome Canada, provincial governments, academia, and possibly the private sector). It was noted by

7 Source: Speech from the Throne to Open the Third Session of the 37th Parliament of Canada, February 2, 2004. (http://www.pco-bcp.gc.ca)

some stakeholders that there is a need to be more focused on government-wide needs rather than department-specific needs.

Nonetheless, most managers and stakeholders noted that the type of research and its application (e.g., to resource management or regulatory issues) undertaken was mandate-specific or mission-driven and therefore the federal government's role was needed. It was noted by several managers and stakeholders that university researchers were involved in more fundamental research and that the private sector was involved in later stage, pre-commercialization research. Finally, several managers and stakeholders noted that most provinces are not involved in genomics R&D to any great extent.

4.0 Findings – Success

4.1 S1. Have the individual departments achieved, or made progress towards, their specific objectives / goals?

Since this issue is specific to each individual department and their own objectives / goals, the reader is referred to the details provided in the relevant sections of Annex A for each department. Additionally, specific progress is described throughout the rest of Section 4.

As previously noted, the departmental objectives and needs varied extensively. The documentation also clearly shows that the specificity of the objectives also varied significantly. The existing RMAF[8] does not clearly define the objectives for the Initiative as a whole, or for the individual departments. The Phase 1 Framework also identified the departmental objectives, which differ. For example, NRC's objectives are at the program level (four programs are outlined), whereas Health Canada's objectives are at the project level. The Phase 2 Framework outlines planned activities rather than specific objectives / goals. Finally the Phase 3 Framework discusses departmental priorities for investment.

Regardless, the evidence in documents and observations resulting from the interviews with managers, researchers and stakeholders make it evident that individual departments have made progress towards their specific objectives / goals through, for example:

- the genomics R&D infrastructure that has been put in place to deliver this Initiative;
- the design and implementation of the research projects;
- hiring and training of people (researchers and technicians);
- purchasing of equipment / technical platforms;
- building databases and libraries;
- development of tools, protocols, guides;
- upgrades and renovations of labs;
- needs assessment; and
- knowledge gained.

8 Source: Genomics Performance Framework, Draft 5, November 24, 2000.

4.2 S2. To what extent did the projects funded under Phase 1 of the Genomics R&D Initiative build capacity inside government laboratories to carry out genomics research?

The Phase 2 Framework indicated that the primary focus of Phase 1 had been on planning and helping to build a basic capacity in genomics in the six federal departments receiving funding. This included establishing platforms for performing genomics research and transferring knowledge generated to industry and other partners. The Phase 2 Framework went on to note that the Initiative had brought the federal labs together by providing significant opportunities for collaboration on promising areas of genomics research. Some of the key capacity building achievements (based on the Phase 1 Performance Report and results reported by researchers, managers and stakeholders) are highlighted in Table 8.

Table 8 – Capacity Built in Phase 1

Element	Examples of Specific Results in Departments
Human resources	New hires (hundreds of new hires, as reported by some departments)[9]: ‣ 106 at NRC ‣ 52 at AAFC ‣ not reported for HC, NRCan, EC and DFO Establishment of genomics research teams (at NRC alone, there are close to 200 scientists and technical staff dedicated to its genomics programming). According to the Phase 2 Program Framework, "it is estimated that more than 1,000 employees are working on projects related to the genomics initiative in the funded departments". Personnel trained, for example: ‣ 54 at NRCan

9 Note: the exact number of new hires cannot be reported because this information was not consistently reported by departments in the Phase 1 Performance Report nor in the Phase 2 Program Framework. As such, when hundreds are reported, it is based on evidence provided by those departments who did provide this information. It would be erroneous to report an exact figure in this case because the number of new hires was not available from all departments.

Table 8 – Capacity Built in Phase 1	
Element	**Examples of Specific Results in Departments**
Equipment / technical platforms	Use of microarray technology, for example: ‣ at NRC, using the microarray facility developed at the Biotechnology Research Institute (BRI),Deoxyribonucleic Acid (DNA) chips have been provided to many GHI programs, and external university and industrial clients ‣ at AAFC, used the 5000 unigene maize microarray to define the genetic response of a susceptible maize inbred to the *Fusarium* pathogen ‣ at HC, comparative genomics, including the use of microarrays, has identified numerous genetic elements that may explain the great virulence of certain lineages of priority pathogens such as E. Coli and Salmonella ‣ at EC, microarrays were developed to identify pathogenic microorganisms in wastewater Development or acquisition of sequencing capability, for example: ‣ advancement of sequencing of the bacterial genome at NRC ‣ acquisition of the *A. Salmonicida* sequence at NRC ‣ identification of a molecular genetic sequence that differentiated the northern abalone from all other species tested (12) at DFO
Databases, libraries	Data produced made available to research scientists in the department and to research groups at public institutions Developed Bacterial Artificial Chromosome (BAC) and cDNA libraries, for example: ‣ AAFC obtained a complete set of 17,000 soybean unigenes and three soybean BAC libraries ‣ AAFC developed an ordered BAC library of *Brassica napus* of 64,000 cloned fragments ‣ DFO constructed a cDNA library from salmon pigmenting muscle ‣ at NRC, subtracted libraries have been made from lung tumour cells to identify genes that are differentially expressed

Table 8 – Capacity Built in Phase 1	
Element	**Examples of Specific Results in Departments**
Tools, protocols, guides	Tools / methods developed for future use, for example: ‣ at NRCan, development of molecular tools to screen for resistance factors in spruce trees conferring reduced reproduction in white pine weevil ‣ at NRC, *In vivo* bacterial culture techniques have been developed adaptable for studies of other pathogenic bacteria ‣ at HC, methods for rapid diagnosis of invasive meningococcal disease (IMD) were developed and applied to identify correctly the serogroup nature of miningococci recovered from patients with IMD ‣ at DFO, test protocols to identify changes in specific bacterial members in oil-contaminated environments were developed, in collaboration with EC and NRC, to monitor the efficacy of bio-remediation technologies and habitat recovery ‣ at HC, research activities have led to the launch of full toxicogenomics gene array techniques and experiments, pathogenomics and more emphasis on bioinformatics support and applications Guides for the application of genomic techniques and tools for example: ‣ diagnostic kits for forest pathogens (NRCan) Research protocols developed for example: ‣ at HC, genotyping of deer mice which are hosts of hantaviruses
Labs	Lab facilities updated with new analytical equipment and genomics tools, for example: ‣ largest, high throughput DNA sequencing facility in the Maritime region, second largest in Canada (NRC) ‣ high throughput DNA sequencing laboratory which operates a Dell Precision 610 server and a SunEnterprise E450 Ultra with full BLAST capability, sequence look-up and retrieval, an microarray analysis capability (AAFC) ‣ renovations to house a toxicology laboratory for continued research on test methodologies required for identification of Designated Substances List (DSL) listed soil fungi (EC)
Publications, presentations, etc.	Hundreds of articles published; hundreds of reports produced for example: ‣ 77 refereed articles, 6 reviews and 11 book chapters (NRC) ‣ 5 background papers (HC) ‣ 82 refereed articles, 5 reviews and 11 book chapters (NRCan) Hundreds of presentations at conferences and other events, for example: ‣ 71 invited presentations at international conferences (NRC) ‣ 61 invited presentations at international conferences (NRCan)

Table 8 – Capacity Built in Phase 1	
Element	**Examples of Specific Results in Departments**
Collaborations	Interactions established and growing with: ‣ Canadian universities ‣ provincial ministries ‣ universities in other countries ‣ governmental organizations in other countries ‣ Genome Canada ‣ local and international not-for-profit science and technology organizations ‣ private sector organizations
Others	Draft national policies to manage intellectual property development by genomics activities Knowledge base established for the development and implementation of regulations, for example: ‣ recommendations for listing of enzymes under *Food and Drug Regulation* were proposed (HC) ‣ the development of a primer for scientists on "Ethical Issues of Environmental Biotechnology Research", for use by researchers, managers and regulators (EC) ‣ a state of knowledge paper on the genetic control of growth in domesticated strains of salmon (DFO) ‣ extensive advice concerning regulatory aspects of triploid shellfish and a sequence list for future development and policies related to Genetically Modified Organisms (GMO) (DFO) Patents filed / patents granted, for example: ‣ 18 patents filed (NRC) ‣ 11 disclosures and 6 patent filings (AAFC) ‣ 2 US patents granted, 1 Worldwide patent granted (NRCan) Contracts signed, for example: ‣ 8 contracts signed (NRC)

Researchers and managers interviewed were all in agreement that the Initiative had built significant capacity inside the six funded government departments to carry out genomics research. Most indicated that there was little or no capacity prior to the Initiative in several of the funded departments. Additionally, in several departments, researchers and managers noted that specific programming for genomics research would not exist without the Initiative and that much less ("little to no") progress would have been made in developing genomics capability.

4.3 S3. Did this increased capacity strengthen the research carried out in the departments?

The managers and researchers interviewed were in agreement that the capacity built in Phase 1 (as well as in Phase 2) strengthened the research carried out in their department. Some managers and researchers noted that the genomics research findings were applied to other aspects of the research work carried out in the departments, such as diagnostic applications.

Other researchers and managers mentioned the fact that the tools developed are used in other applications. Additionally, in cases where facilities were updated, researchers noted that the facilities were used in other applications and, therefore, that all those making use of the facilities benefited.

It was also noted by some of the managers and researchers familiar with both initiatives that the Genomics R&D Initiative research projects have strengthened the research carried out for CRSB. For example, it was noted by one researcher that some CRSB research would have been contracted out if not for the capacity built through the Genomics R&D Initiative.

According to managers and researchers, another important benefit resulting from the genomics research is that departments are able to participate in national and international genomics research consortia. For example, AAFC is a member of the Natural Sciences and Engineering Research Council (NSERC) genomics network and has been able to participate in a number of Genome Canada research projects. Several other departments (managers and researchers) also noted their participation on Genome Canada research projects.

Collaborations are also evident within departments. For example, the genomics workshops that bring together researchers from across Environment Canada and NRCan have helped to identify areas of possible cooperation / collaboration and strengthen research programs within these departments. At NRC, the concept of large, multi-disciplinary teams was initially used for genomics projects but has since expanded beyond those projects. AAFC and NRC also hold annual scientific meetings to discuss the results of their research programs.

4.4 S4. Did this increased capacity created in Phase 1 translate into the benefits of advances in research and technology in Phase 2 for department constituents?

In approaching this issue, several factors were considered in terms of how Phase 2 benefits could be gained from Phase 1 capacity, including:

- the extent to which Phase 1 projects continued in Phase 2;

- the extent to which Phase 1 products or results (tools, techniques, equipment, facilities) were used in Phase 2;
- the extent to which the scientists involved in Phase 1 continued to be involved in Phase 2; and
- the extent to which the knowledge gained in Phase 1 resulted in an ability to take part in larger collaborative efforts in Phase 2 projects.

Phase 1 to Phase 2 Projects

A review of the project summaries, performance reports, and other documents provides evidence of several projects from Phase 1 that were continued in Phase 2 (and even Phase 3).

The project database that was developed by the evaluation team shows evidence of ongoing projects. Within the limitations of the information provided in support of this database (as identified in the methodology section), there is evidence of more than 10 projects that continued directly (e.g., no change in project objectives) from Phase 1 to Phase 2. Most of these were also ongoing in Phase 3.

The managers and researchers also noted the extent to which some of the projects continued from Phase 1 into Phase 2. The researchers mentioned that the work done in the three-year period for Phase 1 involved building libraries, microarrays, genome databases, bioinformatics software and other tools that needed continued or ongoing work. It was noted by several researchers that some of the work could not reasonably be expected to be completed in the three-year period and therefore it was important to support ongoing projects of this type. Finally, some managers and researchers noted that ongoing projects were critical to the success of an initiative that is aimed at building capacity.

Use of Phase 1 Products or Results

In most departments, the project summaries, performance reports and other documents illustrate that Phase 1 activity was used to:

- identify research needs and opportunities – these needs and opportunities were used to help develop, approve and implement Phase 2 projects;

- support the development of research capacity (hiring and training) – this is discussed later on in this section;

- support the development of infrastructure (equipment purchases and laboratory renovations) – this infrastructure was used in Phase 2 projects and ongoing, as

well as for the benefit of other research projects not directly related to this Initiative; and

- develop tools and techniques – these tools and techniques were applied in Phase 2 as well as in Phase 3 and in other applications.

Specific examples are provided in the departmental summaries in Annex A.

Most of the researchers interviewed confirmed that the majority of Phase 2 projects could not have been undertaken without the products or results from Phase 1 projects.

Continuity in Scientific Personnel

The information provided by departments for the conduct of the interviews provided some evidence that there was much continuity in the researchers from Phase 1 to Phase 2. Recognizing that information was only provided on lead researchers, rather than the entire research team, the evidence shows that a large number of scientists[10] involved in a Phase 1 project were also involved in Phase 2 and / or Phase 3 projects.

Some managers and researchers noted that the continuity in projects and scientists was important to the success of the Initiative. However, some researchers and managers reflected on the fact that this created a certain "barrier to entry" in Phase 2 and that researchers who may not have been ready for a Phase 1 project therefore had difficulty getting approved in later phases. It is important to note, however, that this is a reflection of program design (to build on Phase 1). This is discussed in Section 6.0 (Design and Delivery).

Collaborative Projects

There was evidence of this in the interviews as well as in the documents. However, details are provided in the next section.

4.5 S5. To what extent has the Initiative strengthened coordination, cooperation and linkages among the appropriate research institutions?

The Phase 1 Framework noted that the six funded departments planned to work together and with external partners on several projects. Examples of documented evidence of collaboration is summarized in Table 9.[11]

[10] Based on the information provided on lead researchers from three of the six departments, out of 29 researchers involved in Phase 1, 16 were also involved in Phase 2 and / or Phase 3 projects.

[11] Source: Genomics R&D Initiative: Performance Report (1999-00 to 2001-02).

Table 9 – Examples of Documented Evidence of Formal and Informal Collaboration
Agriculture and Agri-food Canada Collaborations
▸ NRC ▸ Genome Canada (Genome Prairie, Genome Alberta, Genome Quebec) ▸ Canadian Food Inspection Agency ▸ Plant Biotechnology Institute, National Research Council of Canada ▸ B.C. Genome Centre ▸ McGill University ▸ Stanford University ▸ U.S. Department of Agriculture ▸ UK Natural Environment Research Council ▸ UK Horticultural Research Institute ▸ Biotechnology and Biological Research Council (UK) ▸ Institut National de Recherche Agronomique, France ▸ GABI (Germany) ▸ RIKEN (Japan) ▸ Gibberella Zeae International Genomics Consortium
Environment Canada Collaborations
▸ AAFC ▸ DFO ▸ NRC ▸ Genome Canada ▸ University of British Columbia ▸ Carleton University ▸ University of Ottawa ▸ Queen's University ▸ USEPA ▸ US Fish and Wildlife Service ▸ British Biotechnology Scientific Research Branch ▸ Friends of the Earth ▸ Arctic Bird Joint Venture ▸ Society for Environmental Toxicology and Chemistry (SETAC) ▸ OECD International Panel on Chemical Safety

Table 9 – Examples of Documented Evidence of Formal and Informal Collaboration

Fisheries and Oceans Canada Collaborations

- Other DFO researchers
- EC
- NRC
- University of British Columbia
- University of Victoria
- Simon Fraser University
- Dalhousie University
- University of Prince Edward Island
- Oregon State University
- University of Idaho, Moscow
- Children's Hospital Oakland Research Centre, San Francisco, CA
- National Research Institute for Basic Biology, Japan
- US National Marine Fisheries Service, Seattle, Washington
- PanFish Canada (private sector)
- Cold Spring Harbour Laboratories

Health Canada Collaborations

- NRC
- CFIA
- DFO
- AAFC
- Dalhousie University
- University of Sherbrooke
- University of Ottawa
- University of Toronto
- University of Alberta
- University of Guelph
- RIVM, Netherlands
- University of Cincinnati
- University of Nebraska
- Institute of Food Safety, The Netherlands
- Veterinary Laboratories Agency, United Kingdom
- Centres for Disease Control and Prevention, Georgia, USA
- Sidney Kimmel Cancer Centre, California
- United States Department of Agriculture
- National Salmonella Reference Laboratory, Germany

Table 9 – Examples of Documented Evidence of Formal and Informal Collaboration
National Research Council Collaborations
▸ Canadian Institutes of Health Research (CIHR) ▸ HC ▸ AAFC ▸ EC ▸ University of Saskatchewan ▸ University of Toronto ▸ University of Ottawa ▸ Carleton University ▸ McGill University ▸ University of Waterloo ▸ Université Laval ▸ University of Aberdeen ▸ University of Arkansas ▸ Indian Institute of Science ▸ Genome Canada ▸ AquaNet ▸ Microtek International ▸ Ottawa General Hospital ▸ Ottawa Civic Hospital ▸ Novadaq Technologies ▸ Sunnybrook Hospital Burn Centre
Natural Resources Canada Collaborations
▸ AAFC ▸ EC ▸ Université Laval ▸ Carleton University ▸ University of British Columbia ▸ New York State University ▸ Genome Canada ▸ BC Ministry of Forests ▸ Ministère des ressources naturelle du Québec ▸ USDA ▸ Institut National de Recherche Agronomique (INRA), France ▸ TimberWest Forest Company ▸ J.D. Irving Lumber Ltd. ▸ Fraser Paper Inc. ▸ Sick Kids Hospital ▸ SilvaGen Ltd. ▸ Forest Protection Ltd. ▸ Chinese Academy of Sciences ▸ Japan Society for the Promotion of Science

The managers, researchers and stakeholders confirmed that Phase 1 and Phase 2 activities have resulted in a significant amount of coordination, cooperation and linkages with other research institutions. It was noted by researchers and managers that some of these

linkages could not have occurred without the Genomics R&D Initiative as evidenced, from their perspective, by the increased amount of collaboration in Phase 2 versus Phase 1. Researchers and managers noted that the research results were widely published and presented at relevant events and that, as such, departments had established the credibility required to become important players on collaborative genomics R&D projects.

The managers and researchers also mentioned a certain degree of collaboration with the other departments involved in this Initiative. It was noted by some managers and researchers that cooperative efforts with some departments were unlikely because the type of genomics research undertaken in other departments is not relevant to the research undertaken in theirs. Some researchers and managers noted that more cooperation was required but not encouraged, particularly in light of the allocation of the Initiative's budget directly to the various departments. One researcher and some managers suggested that a pool of money should be set aside for collaborative projects.

Finally, an issue impeding collaboration noted by several researchers, managers and stakeholders was the limited ability to be involved on Genome Canada projects as of April 2006. These researchers, managers and stakeholders noted that in Phases 1 and 2, researchers in departments could receive Genome Canada funding. As such, departments were able to undertake large scale projects and /or to be lead players on collaborative projects. With a Treasury Board decision that, under the *Federal Administration Act*, federal labs cannot receive Genome Canada funding except in special circumstances, the ability to be involved in large Genome Canada collaborative projects was negatively affected.

4.6 S6. What have been the facilitating and impeding factors for the success of Phases 1 and 2 of the Initiative?

The facilitating and impeding factors were identified only through the interviews. However, there is supporting evidence for many of these factors in the documents reviewed.

4.6.1 Financial Factors

Several managers, researchers and stakeholders noted that the money available to do this type of research had facilitated the success of Phases 1 and 2 particularly in light of the fact that many of the projects would not have been undertaken without the funding. Supplemented with A-base matching funds, this facilitated success in terms of:

- being able to undertake research that otherwise would not have been undertaken;

- being able to complete research projects earlier than they otherwise would have been completed; and
- being able to access the knowledge base required to complete the projects.

Another financial factor that was identified as positive by managers and researchers was the fact that this was a focused funding source (i.e., targeted to genomics and not a broader biotechnology program).

On the other hand, some financial factors were noted as impediments to success.

Issues raised by managers, researchers and stakeholders in this regard were generally related to the fact that the **money was insufficient** to address the genome research priorities in the departments. In some cases the issue was related to the fact that the money has been the same annually for the three phases. This was deemed an impediment particularly in the departments with the smallest allocations who noted that in the early years they could not spend a lot because they did not have the capacity to do so. However, as capacity developed in the first phase, these departments were able to undertake more, and also needed to maintain the progress they had made, and noted that there is now a greater demand for / need for Genomics R&D funding.

Additionally, it was noted by managers and researchers that with the amount of money available being the same over time, taking into account inflation costs, less research was possible.

Another financial element noted as an impediment by some was the **three-year funding cycle**. This is discussed in more detail in a later section (Section 5.3).

Other managers and researchers noted that the **timing of the funding** was an impediment as it did not leave enough time to complete the projects. That is, with the proposal submission, review and approval processes, a fair portion of the three-year cycle was already used up by the time the project funding was approved. Additionally, particularly in Phase 1 where hiring needed to take place, even less time was left for implementing the projects.

Managers and researchers in two departments also noted that they were subject to an **"overhead" charge**. This charge was inconsistently applied and directly reduced the dollars available for the projects.

4.6.2 Human Resource Factors

Human resource factors were also noted in a positive and negative light.

On the positive side, the availability of funds to hire and train Highly Qualified Personnel (HQP) and other technical staff was noted by some as a positive factor. However, a source of frustration (and an impediment to success) was related to the staffing procedures. It was noted by managers and researchers that when Post Doctoral Fellows (PDFs) were hired (using the NSERC process), it was fast and easy. However, for graduate and other staff where the Public Works and Government Services Canada (PWGSC) process had to be used, it was extremely time consuming, lengthy and tedious. While this factor is outside the sphere of control or even of influence of this Initiative, it is important to note because the delays in hiring had a negative impact on the ability to:

- start some projects on time and therefore meet milestones; and
- spend the money according to plan (i.e., in most cases, equal amounts each year).

Another major human resource constraint noted by a significant number of managers and researchers involved the impact of the uncertainty of funding on human resources. It was noted that, with three-year funding cycles, it was difficult to provide potential new hires with more than a three year guarantee of employment. Even if departments were able to provide indeterminate positions, without the assurance of ongoing genomics R&D programming, it was more difficult to attract people with specific expertise in the field.

4.6.3 Other Factors

Other facilitating factors mentioned by some managers, researchers and stakeholders included:

- the ability to link to CRSB given the timing of the Initiative;
- along the same vein, the fact that the Initiative is managed in conjunction with CRSB in regulatory departments; and
- the leveraging of funds gained through the partnerships established.

Another impediment noted during the interviews was regarding the reporting requirements. Concerns in this regard included the fact that reporting requirements were unclear (in some departments) at the time of project approvals (thus, the appropriate measurement systems were not necessarily in place for easy reporting), the fact that there was no standard reporting format (some noted that the reporting requirements should be more rigorous), and that ad hoc requirements for information were not uncommon. All other impediments are departmental specific and are discussed in Annex A.

4.7 S7. Are there other intended and unintended impacts resulting from Initiative?

The documents and interviews revealed no significant additional intended or unintended impacts, either positive or negative.

4.8 S8. To what extent would the impacts have occurred without the Initiative?

Sections 4.1 to 4.6 provide extensive evidence that the Initiative has, to date, been successful and that, while it is fairly early to report longer-term impacts there is evidence of such. (See Annex A for departmental impacts.) However, this issue deals with the question of incrementality. That is, if the departmental programs would have been implemented without the Initiative, the Initiative is not incremental. If the projects would have taken place without the Initiative, the impacts are not incremental and cannot be attributed to the Initiative.

The managers and researchers were in agreement that the Initiative is incremental. Many projects could not have been undertaken without the special funding. Others would have taken more time as fewer resources could have been allocated to those projects. Others still would have been delayed and as such, some departments would still be working towards Phase 1-type of objectives and goals and therefore at a much earlier stage of building and applying genomics R&D capacity.

In most departments, there would not be any specific genomics programming. Some genomics research projects would still have been undertaken. However, these would have been in competition with a gamut of other research priorities in departments.

Researchers and managers noted that departments would have been negatively impacted in their ability to realize success in the genomics field if the projects had not occurred, had been delayed, had taken more time to complete, and / or had been completed without the right human resource complement. For example:

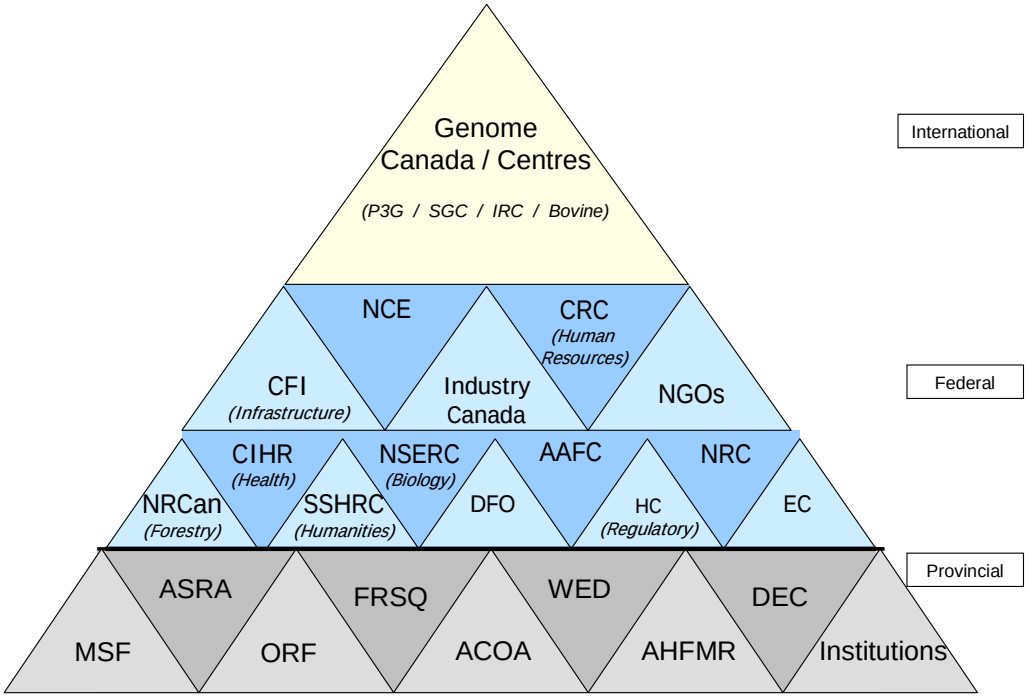
- some of the collaborations could not have taken place as the departments would not have had the capacity to participate on those projects;
- departments would not be able to make informed policy / regulatory decisions regarding genomics issues as the required research results would not necessarily be available; and
- Canada would lag behind other developed countries in its genomics R&D capacity.

5.0 Findings – Cost-Effectiveness / Alternatives

5.1 C1. Does the Genomics R&D Initiative complement, overlap or duplicate other federal or provincial initiatives related to genomics or biotechnology?

In a presentation to the Minister of Industry, the President of Genome Canada depicted the funding environment for genomics and proteomics as per Figure 1.[12] Some of the organizations depicted in the figure are briefly described in Table 10.[13]

Figure 1 – The Funding Environment Genomics & Proteomics



12 Source: Genome Canada, Survol des activités, Présentation à l'honorable Maxime Bernier, Ministre de l'Industrie, le 24 mai 2006.

13 Sources: The website of each organization was used to develop the brief descriptions provided in Table 9.

Table 10 – Canadian Genomics Programming

Organization	Description	Comparison to Genomics R&D Initiative
Genome Canada	Genome Canada is the primary funding and information resource relating to genomics and proteomics in Canada. It invests and manages large-scale research projects in key selected areas such as agriculture, environment, fisheries, forestry, health and new technology development. Genome Canada also supports research projects aimed at studying and analyzing the ethical, environmental, economic, legal and social issues related to genomics research.	Complementary – as federal labs cannot receive Genome Canada funding, except in special circumstances
Network of Centres of Excellence (NCE)	The tri-councils (CIHR, NSERC and SSHRC) and Industry Canada combine their efforts to support and oversee the NCE initiative. NCEs are unique partnerships among universities, industry, government and not-for-profit organizations aimed at turning Canada research and entrepreneurial talent into economic and social benefits for all Canadians. These nation-wide, multi-disciplinary and multi-sectoral research partnerships connect excellent research with industrial know-how and strategic investment. NCE has been involved in some genomic initiatives, particularly though the Canadian Protein Engineering Network (PENCE).	Complementary – NCE's mandate is much broader than genomics R&D
Canada Research Chairs (CRC)	The CRC Program was created to establish 2,000 research professorships in universities across the country by 2008. Some of the Chairs are involved in genomics R&D.	Complementary – CRC's mandate is much broader than genomics R&D and CRC's target groups are located in universities
Canada Foundation for Innovation (CFI)	The CFI is an independent corporation created by the Government of Canada to fund research infrastructure. The CFI's mandate is to strengthen the capacity of Canadian universities, colleges, research hospitals, and non-profit research institutions to carry out world-class research and technology development that benefits Canadians. The CFI has supported several genomics R&D projects and initiatives.	Complementary – broader mandate and different target group
Industry Canada	Industry Canada has a broad range of programs and initiatives designed to benefit a diverse client base across Canada. Collaborating extensively with partners at all levels of government, as well as within the private sector, the Department has become a leader in providing client-focused programs and initiatives. Its Innovation, Research, Science and Technology theme includes the following initiatives: Genome Canada, CFI, CRC, and NCE – see previous descriptions.	Complementary – see Genome Canada, CFI, CRC and NCE

Table 10 – Canadian Genomics Programming

Organization	Description	Comparison to Genomics R&D Initiative
Canadian Institutes of Health Research (CIHR)	CIHR is the major federal agency responsible for funding health research in Canada. It is comprised of 13 institutes, one of which is the Institute of Genetics (IG). IG supports research on the human and model genomes and on all aspects of genetics, basic biochemistry and cell biology related to health and disease, including the translation of knowledge into health policy and practice, and the societal implications of genetic discoveries. CIHR's Genomics Research Program has as its objective the analysis of the human and other selected genomes, including the development of related technologies and bioinformatics, and the study of corresponding medical, ethical, legal and social issues.	Complementary – broader mandate, narrower field and different target group
National Sciences and Engineering Research Council (NSERC)	NSERC is the national instrument for making strategic investments in Canada's capability in science and technology. NSERC supports both basic university research through discovery grants and project research through partnerships among universities, government and the private sector, as well as the advanced training of highly qualified people. Support has included funding of genomics R&D to these target groups.	Complementary – broader mandate and different target group
Social Sciences and Humanities Research Council (SSHRC)	SSHRC is an arm's-length federal agency that promotes and supports university-based research and training in the social sciences and humanities. SSHRC-funded research fuels innovative thinking on issues such as the economy, education, health care, the environment, immigration, globalization, language, ethics, peace, security, human rights, law, poverty, mass communication, politics, literature, addiction, pop culture, sexuality, religion, Aboriginal rights, the past, our future. In this broad context, it has supported some initiatives related to genomics.	Complementary – broader mandate and different target group
Alberta Science and Research Authority (ASRA)	The ASRA is an independent board of members from Alberta's academic, business and research communities, appointed by provincial Cabinet. ASRA was established to maximize the effectiveness of science and research as an integral component to the success of the province in the global economy. ASRA's three strategic priorities are: Information and Communications Technology, Energy, and Life Sciences. Its website has no specific information on its work in genomics R&D.	Complementary – broader mandate and different target group
Fonds de le recherche en santé du Québec (FRSQ)	FRSQ is a non-profit funding agency reporting to the Minister in charge of Québec's department of economic development, innovation and exportation. Its mandate is to implement government strategy with respect to human health research. It deals with 12 research fields. Its genomics activities are undertaken under one of these fields.	Complementary – broader mandate, narrower field

Table 10 – Canadian Genomics Programming

Organization	Description	Comparison to Genomics R&D Initiative
Western Economic Diversification Canada (WD)	WD works to strengthen western innovation, entrepreneurship and community economic development. Through its innovation programming, it has funded a limited number of genomics R&D projects. Additionally, WD's Canada Foundation for Innovation Support Program is designed to enhance western institutions' rates of participation in the CFI.	Complementary – broader mandate and different target group
Canada Economic Development for Quebec Regions (DEC)	DEC is Canada's regional development agency for Quebec. Through its innovation programming, it could fund genomics R&D projects. However, its website has no specific information on its work in genomics R&D.	Complementary – broader mandate and different target group
Manitoba Energy, Science and Technology – Manitoba Science Foundation (MSF)	The Life Science Branch of the Manitoba Energy, Science and Technology Department was established in response to the provincial government's recognition of the importance of science innovation to future economic growth. Its role is to profile Manitoba's life sciences capabilities and expertise, develop and implement economic development strategies aimed at growing Manitoba's life sciences sector, and work with public and private research institutions and people to support and enhance new research and development capacities within the province. Biotechnology (which includes genomics) is one of the areas of activity of the Branch.	Complementary – broader mandate and different target group
Ministry of Research & Innovation – Ontario Research Foundation (ORF)	ORF's Research Infrastructure (ORF-RI) program supports the modernization, development and / or acquisition or new research infrastructure at Ontario's universities, colleges and hospitals. The program provides matching funds toward projects that have been awarded a grant from the CFI. Since the CFI has supported several genomics R&D projects and initiatives, ORF-RI has supported some.	Complementary – broader mandate and different target group
Atlantic Canada Opportunities Agency (ACOA)	ACOA's support for genomics R&D is provided through the Atlantic Innovation Fund (AIF). The AIF is a program designed to strengthen the economy of Atlantic Canada by accelerating the development of knowledge-based industry. AIF has funded a limited number of projects related to genomics.	Complementary – broader mandate and different target group
Alberta Heritage Foundation for Medical Research (AHFMR)	AHFMR supports a community of researchers who generate knowledge, the application of which improves the health and quality of life of Albertans and people throughout the world. Its long-term commitment is to fund health research based on international standards of excellence and carried out by new and established investigators and researchers in training. It has funded a number of genomics studies.	Complementary – broader mandate, narrower field and different target group

In addition to the information outlined in Table 10, it is important to note that the Genomics R&D Initiative is one element in the broader Canadian Biotechnology Strategy, which included several other initiatives. These include the Canadian Regulatory System for Biotechnology and the Canadian Biotechnology Strategy Fund. Coordination is provided through the Canadian Biotechnology Strategy Secretariat. Together these three initiatives support R&D, regulations and policy. The Phase 3 Program Framework states that "Good complementarity and linkages have been established between federal departments receiving intramural Genomics R&D Initiative funding and Genome Canada", and gives examples of collaboration.

The managers, researchers and stakeholders interviewed were in agreement that the Genomics R&D Initiative does not overlap or duplicate other federal or provincial initiatives related to genomics or biotechnology. Rather, interviewees believed that the Initiative complemented other initiatives. Examples provided by interviewees included:

- Genome Canada supports primarily university-based research as another funded genomics initiative. Until recently, during the first two rounds of funding, there were several cases where government capability developed through the Genomics R&D Initiative was utilized as part of a Genome Canada funded project. Interviewees in AAFC and EC noted that Genome Canada has relatively little funding devoted to agriculture and environment (5% to 7% and 3% respectively), but rather focuses on human health and genomics. However, there were examples of cooperation and complementarity between federal government and university scientists. As discussed previously, during the third phase, Treasury Board has ruled that, according to government policy, federal labs cannot receive funding directly from Genome Canada, except in special circumstances. This change has greatly reduced the level of interaction and complementarity between the two programs. Many interviewees (managers, researchers and stakeholders alike) considered this change to be a major impediment to cooperation and collaboration with the university sector through Genome Canada.

- Some interviewees mentioned CFI as a complementary program that provides funding for capital equipment and facilities for non-government labs.[14]

- One person mentioned NSERC Strategic Grants, which fund university based research, as a complementary program with overlap in some project areas.

[14] It should be noted that CFI infrastructure investments are not available to government labs. In addition, the value of the government input is not large enough to steer CFI-funded projects.

- In terms of provincial programs, few interviewees were aware of any overlaps or duplication. A few mentioned that the provincial labs have limited capacity for genomics research in the areas of federal interest (e.g. agriculture, fish, forestry).

- CRSB funding was also seen as complementary. However, one interviewee observed that, in departments such as Health Canada and Environment Canada, there is some overlap with the regulatory funding and objectives.

- Some researchers, stakeholders and managers noted that there is some similar work being done at universities.

5.2 C2. Is the funding structure of the Genomics R&D Initiative the most appropriate mechanism for achieving the intended objectives? Are there more cost-effective alternative ways to achieve the Genomics R&D Initiative mandate?

For the purposes of this section, the funding structure was defined as a separate fund with specific allocations to each department as per Table 11. It also included the structure surrounding the allocation of those funds including three-year funding cycles (which is discussed in more detail in Section 5.3).

Table 11 – Genomics R&D Initiative Resource Allocation

Organization	Phase 1	Phase 2	Phase 3
AAFC	$17.0 million	$18.0 million	$18.0 million
EC	$3.0 million	$3.0 million	$3.0 million
DFO	$2.5 million	$2.7 million	$2.7 million
HC	$10.0 million	$12.0 million	$12.0 million
NRC	$17.0 million	$18.0 million	$18.0 million
NRCan	$5.0 million	$6.0 million	$6.0 million
Medical Research Council (Phase 1 only)	$0.5 million		
Total	**$55.0 million**	**$59.7 million**	**$59.7 million**

Note: The Medical Research Council was the precursor to CIHR and received a one-time allocation in 1999-2000 to assist in the establishment and support of a Genome Canada Secretariat. This was excluded from the scope of this evaluation study.

For the purposes of this section, the intended objectives were broadly defined as to build genomics R&D capacity and to support the development and application of the scientific knowledge base in federal laboratories. Costs were interpreted as the costs involved in implementing the Initiative, that is the horizontal and departmental costs associated with

program management and implementation. Effectiveness was defined as the best way to achieve the stated objectives.[15]

In terms of the funding structure, some managers and researchers felt that it was important to keep the Genomics R&D Initiative fund separate and not integrate it with the department A-base. However, several interviewees noted that there were some problems associated with the direct allocation / distribution of all funds to the departments in that:

- there was no formal mechanism to encourage interdepartmental collaboration or horizontal projects across departments; and
- some departments (in particular DFO and EC) had very small allocations.

As a result, projects were selected according to the priorities of individual departments rather than to address government-wide priorities, according to some stakeholders, researchers and managers.

Some managers and researchers noted that the allocation may have been appropriate for Phase 1 but that it needed to be revisited now that individual departments were more capable of undertaking genomics R&D aligned with their needs. Other managers and researchers noted that in order to encourage horizontal projects, a pool of money should be set aside for interdepartmental projects.

In terms of the costs associated with this Initiative, a review of the database developed for this evaluation revealed that some departments have set aside some Initiative money for "program management" projects. More precisely,

- Health Canada – $40,000 in Phase 1 (Fund Management); $428,932 in Phase 2 (Fund Administration); $200,000 in Phase 3 (Office of Biotechnology and Science, Administration and Management of Genomics R&D Fund);

- NRCan – nothing in Phase 1; $300,000 in Phase 2 (Coordination of the genomics program and communication to the general public); $29,000 in Phase 3 (Coordination of the genomics program); and

- NRC – $900,000 in each phase to support a Coordination Office that serves as a central secretariat for the $22 million per year GHI program as well as to

[15] It should be noted that, within the scope of this study and with the factual information available, a thorough cost-effectiveness analysis for the Initiative could not be performed. Means of improving information (possibly through the RMAF) and for including methods for a more thorough cost-effectiveness analysis at the time of the summative evaluation should be considered.

undertake activities associated with being the lead department on the Genomics R&D Initiative as a whole.

Similar information was not available from the other departments. It should be noted that some of the higher program administration cost for NRC is, to a large extent, due to its role as lead department for this Initiative (from a horizontal perspective).

Most management interviewees noted that the costs associated with the horizontal or interdepartmental aspects of this Initiative were minimal (see Section 5.4). Nevertheless, some noted that the costs with program renewal every three years (e.g. planning, administrative tasks, TB Submissions, etc.) needed to be considered in the context of the effectiveness of extending the funding period. Along the same vein, but in the context of effectiveness, it was noted that uncertainty about the longevity of this Initiative could affect the types of projects undertaken, particularly now that the Initiative is in its third phase.

Nevertheless, most management interviewees had no other suggestions on ways to either reduce the costs or improve the effectiveness of this Initiative, and thereby felt that there were limited opportunities for making it more cost-effective.

5.3 C3. Is the three year funding cycle appropriate for achieving intended outcomes?

The findings related to this issue were limited to interviews and responses from the interviewees were mixed. On the one hand, there were those who believed that the three-year funding cycle was appropriate for one or more of the following reasons:

- this is long enough to achieve significant research progress;
- allows refocusing or changing program direction easier than with longer term funding;
- three years is standard for federal R&D programs; and
- given the pace at which technology is changing, three years is appropriate

On the other hand, those who believed that the funding cycle should be longer than three years noted problems such as:

- there is the burden of writing a new proposal every three years, a burden placed on external reviewers, as well as increased internal costs associated with the selection process;
- three years is not long enough to make good progress in the case of start-up projects;
- the lack of A-base funding to support staff retention on a longer-term basis;
- the delay in the release of funds at the beginning of each phase limits the time for the research projects to less than three years;

- allows limited time for reporting / publishing research results; and
- the lack of continuity affects the types of projects undertaken, thereby changing the long-term success of the Initiative.

From a program management perspective, managers noted the workload associated with the three-year cycle in that they had to prepare for the next cycle almost as soon as the last one begins. Other managers indicated that a three year cycle was appropriate for the research projects, but not effective for human resource management. Nevertheless, managers, researchers and stakeholders who wanted the cycle to be longer than three years still noted that it should not be too long as there was a need to assure discipline, accountability and focus. No one felt that the funding cycle should be shorter.

5.4 C4. What has been the level of effort or cost required by departments / agency to participate in this horizontal initiative? What have been the benefits?

Before addressing this issue, it is important to reflect on the type of horizontal initiative this is. Management interviewees indicated that they did not view the Genomics R&D Initiative as a horizontal initiative. The TBS defines horizontal initiatives as follows:

> *"A horizontal initiative is an initiative in which partners, from two or more organizations, have agreed under a* ***formal funding agreement*** *(e.g. Memorandum to Cabinet, Treasury Board Submission, federal / provincial agreement) to work towards the achievement of shared outcomes."*[16]

According to this definition, the Genomics R&D Initiative is a horizontal initiative. Additionally, TBS has developed a Horizontal Results Database. The Canadian Biotechnology Strategy and its components (including the Genomics R&D Initiative) are identified in this database.[17]

There was no information available in the documents regarding the level of effort or costs required by departments / agency to participate in this horizontal initiative, nor on its benefits. As previously noted, some departments had funds set aside for program management; however, no data on horizontal costs were available.

Management interviewees in all departments except NRC noted that the costs were very limited. They were noted to include:

- the time, effort and travel expenses associated with participation in the Genomics R&D Working Group and other joint meetings;

[16] Source: Reporting on Horizontal Initiatives, Treasury Board of Canada Secretariat, Presentation made by Tom Fitzpatrick, April 30, 2004.

[17] Source: http://www.tbs-sct.gc.ca/rma/eppi-ibdrp/hrdb-rhbd/profil_e.asp

- the time and effort associated with development of TB Submissions, preparation of departmental contribution to CBS Horizontal Report on Plans and Priorities (RPP), Departmental Performance Report (DPR) (some managers noted that the time and effort associated with this was not any different than for internal RPP, DPR requirements);

- the development of the strategic three year plan, the preparation of Requests for Proposals (RFP), the preparation of proposals, selection of projects (peer review, etc.); and

- the required A-base contribution.

The costs were higher in NRC because it has subsidized much of the cost of coordinating departmental involvement through the Working Group, taken a lead in the TB Submissions, etc. This informal secretariat role was estimated to be about 30% of a professional's time, plus administrative support.

Management interviewees felt that the benefits outweighed the minimal costs. However, those benefits were not clearly outlined except for the benefits associated with sharing of information, identification of potential collaborations and opportunities to avoid duplication.

6.0 Findings – Design and Delivery

6.1 D1. Is the position of the Genomics R&D Initiative appropriate within the larger government biotechnology strategy? Is the level of integration with other federal government biotechnology programs appropriate?

The position of the Genomics R&D Initiative is described in the Phase 2 Program Framework which reported that the Initiative is one element within the larger Canadian Biotechnology Strategy. Other funding elements include the Canadian Biotechnology Regulatory Strategy which supports regulatory issues and the Canadian Biotechnology Strategy Fund which focuses on policy development.

The Phase 3 Program Framework states that "The continuation of intramural genomics R&D funding directed to federal laboratories is vitally important to complement and link the other key government investments in biotechnology" (e.g., ongoing funding for the Canadian Regulatory System for Biotechnology and major investments in Genome Canada, Canadian Institutes of Health Research and other university research funding organizations).

Most managers, researchers and stakeholders interviewed noted that the position of the Initiative was appropriate within the larger government biotechnology strategy. Several noted that they did not believe that the Canadian Biotechnology Strategy could guide the Genomics R&D Initiative. The CBS is broader and was therefore not believed to be directly relevant. Therefore, interviewees strongly believed that a separate fund was needed.

Managers and researchers noted that, within departments, the Initiative was well integrated with other programming such as CRSB and the CBS Fund.

However, some researchers, stakeholders and managers felt that there could be some benefit to greater coordination / integration with Genome Canada from a strategic point of view. In an earlier section (Section 5.1), it was noted that Genome Canada complements the Genomics R&D Initiative. However, Genome Canada recently undertook a wide range of consultations to help define its strategic priorities which are:[18]

- Public Population Project in Genomics (P3G);
- Regulome Consortium;

[18] Source: Genome Canada, Survol des activités, Présentation à l'honorable Maxime Bernier, Ministre de l'Industrie, le 24 mai 2006.

- Structural Genomics Consortium (SGC);
- Nutrigenomics;
- BioDefense; and
- Cancer Genomics Initiative.

It is unclear if the departments involved in the Genomics R&D Initiative were consulted in setting the priorities as important ones may have been missed.

6.2 D2. How effective is the overall governance structure for the Initiative and departmental processes (e.g., project approval process)? Are the roles and relationships clearly defined and appropriate?

6.2.1 Governance Structure

The interdepartmental governance model for the Genomics R&D Initiative[19] covers areas of program management, accountability, performance measurement, coordination and funding leverage. The model builds on the jointly developed RMAF prepared in November 2000. Its overarching governance principles have evolved over time, however, its key elements (as described below) have remained unchanged.

An inter-departmental Genomics R&D ADM Coordinating Committee oversees the collective management and coordination of the federal Genomics R&D initiative. This Coordinating Committee functions as a Subcommittee of BACC established under the Canadian Biotechnology Strategy. The R&D ADM Committee ensures that the government objectives and priorities are addressed, common management principles associated with R&D management are implemented, and collaborations between organizations are pursued wherever relevant and possible. The committee includes members from each of the six organizations receiving funding, as well as the Canadian Biotechnology Secretariat and Industry Canada.

Management interviewees were asked to comment on the effectiveness of this governance structure. Most believed that this structure was effective, particularly in light of the fact that it was of limited burden to them. The role of NRC as the lead was also viewed positively. It was, however, noted that this was not a truly horizontal initiative and that it was therefore not "governed" as one.

[19] Source: Genomics R&D Initiative – Interdepartmental Governance. Most recent version (last modified March 22, 2006).

Nonetheless, some management interviewees had concerns with aspects of the governance structure. These were at the working group level and at the ADM Committee level:

- the fact that the Genomics R&D Initiative Working Group has no formal terms of reference; and
- involvement by senior management at the higher level was limited.

Additionally, it was noted that, if the funding levels are increased in the future, it may be appropriate to revisit the overall governance structure.

6.2.2 Departmental Processes

Processes differed not only from one department to the next, but also from one phase to the next. The key processes are described in Annex A.

Managers and researchers commented significantly on the project selection process (including proposal requirements) as well as on the reporting requirements.

Comments on the project selection process were generally positive, notwithstanding some suggestions for improvements. It was noted by managers and researchers that these had evolved from phase to phase and that the changes had resulted in improvements, particularly the addition (in several departments) of a peer review process. Concerns were expressed by some (not necessarily in all departments) with respect to specific departmental processes including:

- the lack of clarity as to what needs to go into proposals and how they will be assessed;
- the lack of detail currently required for proposals to ensure that the peer reviewers have the information needed to assess the quality of the proposed research; and
- the added rigor to the process which has also added administrative burden.

Reporting requirements are addressed in more detail in Section 6.4.

6.2.3 Roles and Responsibilities

The NRC-GHI roles and responsibilities are defined in its Governance Framework, approved by NRC Senior Executive Committee in April 2005 (as part of the transition to GHI Phase III). However, there was limited evidence in the documents received that other departmental roles and responsibilities were clearly defined. Nevertheless, managers and researchers noted that the departmental roles and responsibilities were clear and appropriate.

6.3 D3. To what extent have the departments been able to leverage the funds provided through the Genomics R&D Initiative? What are the pros and cons associated with the leveraging requirements?

Regarding this issue, leveraging was interpreted to include internal departmental leveraging (through A-base funding) as well as external leverage (through project partnering).

The Phase 3 Program Framework notes that "Many departments have been able to lever additional funds with their allocation, stretching the federal government's investment even further. Moreover, industrial partnerships are being established, which may lead to revenue generation in the future."

The Phase 3 Program Framework states that "All departments have levered the government's investment in genomics R&D by providing additional (or matching) funds by allocating A-base to supplement genomics R&D funding".

Specific details on the extent of internal and external leveraging was not available from the departments except for NRC.[20] Table 12 provides an overview of departmental leveraging based on the input of interviewees as well as documents.

[20] Again, it should be noted that means of improving access to leveraging information (possibly through the RMAF) and for including methods for a more thorough analysis of levered dollars at the time of the summative evaluation should be considered.

Table 12 – Estimated Departmental Leveraging	
Department	**Type and Amount of Leveraging**
AAFC	In-kind resources from the departmental A-base in the form of salaries of scientists and technicians and funding of physical facilities – estimated at $7 million
EC	In-kind support they receive from research partners at universities and other research organizations – estimated at $2.4 million over three years (Phase 1) Significant amount of A-base – estimated at $983,000 (Phase 1); $1,623,000 (Phase 2)
DFO	In-kind and Operations and Maintenance (O&M) contributions to this project from within and outside DFO – estimated at $900,000 per year
HC	Salaries and operational costs for facilities are supported through A-base
NRC	Commitment to match funds received with A-base funding ($11 million – $6 million from Genomics R&D Initiative and $5 million new funding from NRC received at the time of the creation of CIHR) A-base funding – beginning in 1999-2000 with A-base funding of about 35% (or $11 million) to a present level at least equal to or higher than the $11 million
NRCan	In-kind and financial contributions from a number of sources – estimated at $11.75 million over three years (Phase 1)

When asked about the pros and cons associated with leveraging requirements, managers and researchers were more positive than negative in this regard. The identified advantages and disadvantages are identified in Table 13.

Table 13 – Pros and Cons Associated with Leveraging Requirements	
Pros	**Cons**
Leads to good team work and collaborative arrangements Helped to improve credibility with lab management, increase the visibility of genomics, and in turn lever additional funding for equipment purchases (from the capital pool) and hiring Access to required expertise, equipment and facilities	Inability to bring as much to the table because of the limited funding available through the Genomics R&D Initiative Additional workload associated with establishing formal agreements with other parties

6.4 D4. How effective / appropriate is the Initiative's approach to performance measurement? What performance measures should be captured in the next phase and why?

The Genomics Performance Framework (November 24, 2000) required participating departments to develop RMAFs and monitor genomics related R&D activities using performance indicators established for those activities. Annex A of the Performance Framework describes in summary form the various indicators and measurement approaches that could be used to measure and report on the performance of the Initiative. This annex identified the possible indicators and measurement approaches as per Table 14.

Table 14 – Possible Performance Indicators and Measurement Approaches

Indicators	Examples of Measurement Approaches
Stewardship	
Critical mass established and strengthening of national genomic program through excellence in federal research programs	Number of scientific papers, refereed articles, reviews, book chapters (# & quality), invited presentations and technical service reports, bibliometric studies, collaborative research projects
Economic Benefits	
Extent to which key Canadian business indicators have changed (for example: return on investment, increased sales by Canadian firms and companies)	Analysis and surveys indicating royalties, patents, licenses, spin-offs, technology transfer
Citizen Engagement	
Changes in awareness, understanding of genomics research and its potential impacts	Undertake surveys; review media comments; feedback received from the public; website feedback; etc.

Source: Genomics Performance Framework, Draft 5, November 24, 2000.

The evidence collected during this evaluation shows that departments are at various stages of development regarding performance measurement:

- The original Genomics Research Program Framework identified a number of indicators to measure **Agriculture and Agri-food Canada** achievement of objectives. These included number of genes identified for target traits; number of new technologies developed for genetic modification; insertion or operation of genes in plants; number of patents applied for; number of scientific publications; and, number of scientists and technicians developed with specific skills in genomic research.

- No RMAF was developed for the STAGE program at **Environment Canada**. The project managers provide a progress report at mid-year and year end. CWS collects reports from its project managers and submits a summary when required. A standardized reporting template has evolved and now includes: Project Description, Status of Deliverables (including a list of publications and presentations), Report on Budget, and a Report Against STAGE Objectives.

- An RMAF for **Fisheries and Ocean Canada**'s Aquatic Biotechnology Program has been recently developed. The RMAF covers activities related to DFO's involvement in the CBS, the CRSB and the Genomics R&D Initiative. In order to support ongoing monitoring, DFO has developed a project database to track project and financial information. At the project level, the database captures the following output and outcome measures: new and improved research knowledge, tools, technologies, methods and / or protocols; risk factors identified; evidence of application of biotechnology tools for aquatic resource management; evidence of research progress with respect to diagnosis of aquatic animal diseases; evidence of the development and / or application of biotechnology tools to enhance aquatic ecosystem health; evidence of development of biotechnology techniques to prevent or manage disease outbreaks; and evidence of use of information by resource managers and other stakeholders.

- At **Health Canada** the DBO is currently in the process of developing an electronic Performance Information Tracking System for Genomics R&D Initiative, CRSB and CBS Fund projects in consultation with researchers. A detailed logic model and output and outcome performance indicators have been developed for biotechnology within HC. The plan is that each initiative (CRSB, CBS Fund and Genomics R&D) will select indicators that are most relevant to them.

- At the **National Research Council**, performance reporting for Genomics and Health Initiative-2 (GHI) was completed on an annual basis with each Program submitting a summary of results for the previous fiscal year to the Coordination Office. The Coordination Office then used this information to complete an overall integrated performance report for the initiative. However, the annual performance reporting was based on the NRC-DPR requirements. GHI therefore produced performance reports in a manner similar to those prepared by NRC research institutes and they were written under the headings of NRC's Vision 2006 rather than against individual Program objectives. The lack of clearly stated objectives in the GHI-2 Charters meant that there was little to effectively report performance against. The GHI Evaluation therefore reported that the approach to performance reporting for GHI-2 was not considered to be effective and was not generally supported by interviewees. The evaluation also noted that GHI has not developed specific performance measures.

- At **Natural Resources Canada,** a standard template for progress reports has been used since Phase 1 and addresses major accomplishments, performance against milestones, and provides a listing of outputs and outcomes (e.g., peer reviewed articles, conference presentations, invited presentation, interviews, stakeholder or client recognition, alliances, patents, etc.).

The GHI Evaluation reported that, while individual departments provided input to the annual CBS Horizontal DPR and RPP concerning their Genomics R&D Initiative funded programs, a specific report for the Genomics R&D Initiative has never been developed. The evaluation cited an OAG report that "the federal organizations we examined have not adequately reported on results". [21]

Some of the management interviewees indicated that they are satisfied that the performance measurement and reporting systems that have been developed will meet their needs. Other managers indicated that the approach to performance measurement and information tracking requires improvement.

Similarly, some of the researchers indicated that the performance reporting requirements were clear, simple and based on traditional indicators that were readily available. However, other researchers noted that performance measurement and reporting requirements have not been clearly defined for the Initiative, and resulted in a lack of consistent reporting formats and ad hoc requests for project information. According to some researchers, non-standardized reporting formats and multiple reporting requirements has led to duplication of effort and inefficiency. Some researchers noted that they do not have systematic access (e.g., through a website) to information on projects in their department or the Genomics R&D Initiative more broadly. Several noted that the annual reports focus on outputs (deliverables) but that there is no formal system for tracking results (outcomes).

However, some of the departmental practices used to share performance information were noted positively by researchers and / or managers. For example:

- At NRCan, performance is assessed through annual reports, provided by researchers, and also at various workshops and meetings. Regular meetings of the CFS genomics researchers and ad-hoc meetings (e.g., the Workshop on Forest Genomics [co-hosted with Genome Canada and attended by approximately 70 people]) are used to review project performance and identify future research directions.

[21] Source: Report of the Auditor General of Canada to the House of Commons, Chapter 4: Managing Horizontal Initiatives, P. 19, November 2005.

- At DFO and HC, workshops were held to bring researchers together to discuss research results and refine research themes.

- At AAFC, annual meetings are held during which scientists provide abstracts and report on results obtained over the past year.

- At NRC, the Genomics and Health Initiative hosts an Annual General Meeting (AGM). The GHI-AGM is a scientific conference that provides a forum for GHI-supported research to be presented and discussed. The meeting is hosted on a rotational basis by the NRC research institutes participating in the GHI programs. The Conference typically attracts approximately 200 participants and includes NRC scientists involved in the various NRC-GHI research programs, as well as a number of external speakers and participants from universities, other government departments and agencies, and the private sector.

- At EC, regular dialogue between the STAGE community and headquarters (HQ) management is achieved through tri-annual meetings. This provides an opportunity for all EC scientists and departmental stakeholder (enforcement and regulation) to discuss the results they have obtained over the past year.

6.5 D5. How could the Genomics R&D Initiative be improved? What changes are required to make the Initiative more efficient?

Throughout the findings sections of this evaluation report, suggestions for improvements or required changes were identified as they pertained to specific issues. These led to the conclusions and recommendations outlined in Section 7.0. This section provides some of the other suggestions provided by managers, researchers and stakeholders. (See Annex A for a more complete discussion of the suggestions made by interviewees for each department.)

It should be noted that most interviewees felt that the Initiative was working reasonably well. Additionally, some of the suggestions made below have already been discussed in previous sections, but were important enough to the interviewees to be repeated in this section:

- ***Funding:***

  A number of managers and researchers commented on the fact that the amount of funding has been fixed, and has not increased to keep up with salary increases or inflation. Since 1999, the increased cost of salaries has been significant

(estimated 40% by some researchers). Interviewees believed that this should be corrected in future funding. It was noted that more consistent and stable funding is required to ensure that the capacity developed to date can be maintained (to attract and retain skilled human resources) and that the level of funding allocated to some departments needs to increase. It was suggested to allocate some fraction of the funding to interdepartmental projects. It was also noted that there was a need to ensure timely communication to researchers about access to funds as early as possible in the first year of the cycle.

- ***Project Approval:***

  With respect to the project approval process, one suggestion made by researchers was to provide (e.g, a standardized program-wide) an improved RFP, including a clear description of criteria for project selection and resource allocation, provide longer notice and a more substantive peer review process.

- ***Human Resources:***

  One researcher spoke of the difficulties in accessing graduate students through the bureaucratic PWGSC process as something that needs improving (access to PDFs is fine through NSERC). It was also noted by managers and researchers that there was a need to address human resource issues (recruitment, staffing process, retention of highly skilled personnel, training) associated with the three year funding cycle (e.g., establish consistent departmental guidance with respect to covering staff salaries caused by funding delays).

- ***Clear / Standardized Guidelines:***

  It was suggested by managers and researchers in two departments that clear guidelines (at the program level) to address the issue of departmental taxes that reduce the available funds to support actual research activities were required. Another suggestion made by managers and researchers was to establish a set of guiding principles for peer review processes that would benefit all departments (e.g., conflict of interest guidelines).

- ***Performance Measurement:***

  It was noted by managers and researchers that there was a need to establish a reasonable and cost-effective approach for performance measurement and communicate the mandatory reporting requirements to researchers at the time of the request for full proposals. Where necessary, timely instruction and training in preparation of reports should be provided.

- ***Networking Opportunities:***

  It was noted by researchers, managers and stakeholders that more opportunities to share research results with other departments to enhance knowledge, future research opportunities and networks should be provided. Another suggestion made by researchers, stakeholders and managers was to establish closer linkages with Genome Canada to increase departmental influence on research priorities and to provide opportunities for greater collaboration on projects. Also regarding Genome Canada, it was noted by researchers, stakeholders and managers that there was a need to revisit Genome Canada eligibility requirements to open up funding and collaboration opportunities for federal researchers.

- ***Strategic Issues:***

  At a more fundamental level, one person spoke of the need to connect the departmental strategy, objectives and project selection with overall government strategy and to focus on applying the genomics capability already developed on particular critical applications.

  A senior manager noted that, at this point in the program, it would be beneficial to introduce a mechanism that would meet regularly to identify government-wide priorities and support horizontal accountability for the research.

  One stakeholder noted that, because biotechnology is an enabling technology that cuts across many government departments, stronger horizontal management is needed to ensure that all relevant issues are addressed.

7.0 Conclusions and Recommendations

The conclusions and recommendations stemming from the findings presented in this report are outlined in Table 15.

Table 15 – Conclusions and Recommendations

Conclusions	Recommendations
Relevance	
Conclusion 1 The Genomics R&D Initiative is relevant as a critical element of the broader Canadian Biotechnology Strategy and is complementary to other elements of this broader Strategy such as the Canadian Regulatory System for Biotechnology. Given that genomics is still a relatively new and emerging technology, there is an ongoing need for government involvement in this field. Additionally the research results are required to support departmental mandates, the development of new regulations as well as to help enforce existing ones. As such, there is a legitimate and necessary role for government in this area.	**Recommendation 1** Federal support for the Genomic R&D Initiative as a separate initiative of the Canadian Biotechnology Strategy should continue. **Note: the rest of the recommendations in this report assume the continuation of the Genomics R&D Initiative.**
Success	
Conclusion 2 The primary objective of the Initiative was to build capacity in federal labs. There is extensive evidence that the Initiative has built capacity inside government labs to carry out genomics research. Phase 1 built basic capacity which continues to be strengthened. As such, while there has been much progress made in this regard, there continues to be a need to build and maintain capacity in federal labs.	**Recommendation 2** Support for capacity building should continue as there is an ongoing and ever evolving need for building and maintaining capacity in genomics R&D. The Interdepartmental Working Group should develop a strategy which identifies the mechanisms needed to ensure that new capacity will continue to be supported and that the existing capacity is maintained.
Conclusion 3 The capacity that was developed in Phase 1 has been used in Phase 2. There is extensive evidence of ongoing or continued projects, use of the tools developed or research results, and ongoing involvement of the same scientists. As such, Phase 1 translated into benefits for Phase 2. The increased capacity has also helped strengthen the research carried out in other areas of the departments.	No specific recommendation is required.

Table 15 – Conclusions and Recommendations	
Conclusions	**Recommendations**
Conclusion 4 While there is some evidence of interdepartmental collaboration, it is limited. For example, different departments were initially at different stages of genomics research. In other cases, there was little commonality in the issues being explored. As such, there was limited opportunity for collaboration. However, as the capacity of departments has evolved, there may be increased opportunities for interdepartmental collaboration in future phases. There has, nonetheless, been extensive evidence of collaboration with other research entities. The research projects have involved collaborative efforts on a national and international level with universities, governmental organizations, non-governmental organizations as well as private sector organizations. As such, the Initiative has been successful in strengthening linkages with appropriate research institutions. Some departments participated in Genome Canada Competition I and II projects. Effective April 2006, federal labs cannot receive Genome Canada funding except in special circumstances (as a result of a Treasury Board ruling). As a result, projects are negatively affected, not only in their scope, but in the ability of the government labs to continue working with established collaborators. Therefore, while the Initiative has been successful in strengthening linkages with appropriate research institutions, its continued success in this regard has been hampered, particularly due to the impact of the TB ruling regarding Genome Canada.	**Recommendation 3** The Interdepartmental Genomics R&D ADM Coordinating Committee should explore specific ways in which interdepartmental projects could be encouraged to address government-wide genomics R&D priorities. This could include a pool of money set aside for interdepartmental projects as well as other options. This Committee should also precisely articulate these priorities and revisit them as needs evolve. **Recommendation 4** The Interdepartmental Genomics R&D ADM Coordinating Committee should also work with Treasury Board to investigate opportunities for federal scientists to participate more significantly in Genome Canada projects.

Table 15 – Conclusions and Recommendations	
Conclusions	**Recommendations**
Conclusion 5 The main facilitating factor of the Genomics R&D Initiative has been that it is a focused funding source. However, there are other financial elements of the Initiative that have impeded its success. The total amount of money available has become an impediment not only because there have been no inflationary increases in funding, but also because there is a need to re-balance the funding envelope to ensure that all departments have sufficient funding to address strategic priorities. The three-year funding cycle has resulted in uncertainty. This has affected the scope of some of the projects as well as the ability to attract and retain highly qualified personnel. Finally, the timing of the funding (delays in year one of each phase) has led to delays in meeting project milestones and, for start-up projects, to delays in hiring the required people for the research teams.	**Note: There are several conclusions which can be addressed through more overarching recommendations. These recommendations are presented at the end of this section.** **One of these deals with financial elements of the Initiative. Recommendations linked to Conclusion 5 are therefore presented at the end of this section.**
Conclusion 6 There are significant differences in the way in which departments are allocating resources for program management and other overheads. As such, this has resulted in significant differences in the proportion of the funds which are available for the projects in different departments.	**Recommendation 5** The Interdepartmental Genomics R&D ADM Coordinating Committee should clarify the rules on how the funds are used with respect to program management and other overheads and ensure that those rules are enforced.
Conclusion 7 The Initiative is highly incremental. Specific genomics R&D departmental programming would not be in place in the absence of this Initiative. As such, the great majority of projects would not have taken place and / or would have been seriously negatively affected as a result of delays, changes in scope, less qualified teams or for some other reasons. Therefore, the impacts of the projects are highly attributable to the Initiative.	No specific recommendation is required.

Table 15 – Conclusions and Recommendations	
Conclusions	**Recommendations**
Cost-Effectiveness / Alternatives	
Conclusion 8 The Initiative complements other federal or provincial initiatives related to genomics or biotechnology without undue overlap or duplication. However complementarity with Genome Canada has been reduced in the last few years as a result of a recent Treasury Board ruling.	See recommendations 1 and 4
Note: Conclusion 5 is also directly relevant to the cost-effectiveness issue dealing with the funding structure, in brief: The focused funding is a strength of this Initiative. Problems with the funding structure include the total amount of money available, its three-year funding cycle, and the timing of the funding.	**Recommendations linked to Conclusion 5 are presented at the end of this section.**
Conclusion 9 It is not possible to conclude on the Initiative's cost-effectiveness because there is insufficient information in most departments on the specific departmental and interdepartmental costs associated with this Initiative. This is no reflection on specific departmental performance as departments were not required to track costs (nor would it have been cost-effective for them to set up specific systems to do so for an initiative with three-year funding cycles).	**Recommendation 6** The summative evaluation needs to address the issue of cost-effectiveness in a way to reliably conclude on the cost and effectiveness aspects of the Initiative. The departments should therefore ensure that improved cost information is available. The specific cost-effectiveness evaluation requirements will be outlined in the revised RMAF for the Initiative. This should include methods for a more thorough cost-effectiveness analysis at the time of the summative evaluation.
Conclusion 10 The three year funding cycle is appropriate at the project level but not for the Initiative. Overall, the uncertainty associated with the three year cycle has negatively affected the flexibility of the Initiative and aspects of its cost-effectiveness (see conclusions under Design and Delivery section).	**Recommendation 7** Similarly to the Canadian Regulatory System for Biotechnology, the Genomics R&D Initiative should become an ongoing initiative with dedicated A-base funding. This will provide stability to the Initiative while ensuring an ongoing focused funding source for genomics R&D.
Conclusion 11 The benefits (sharing of information, communications with central agencies, etc.) resulting from the interdepartmental aspects of this Initiative, while limited, have outweighed the costs which have been minimal. The limited costs are, to a large extent, due to the fact that the Initiative is not structured as a truly horizontal initiative (nor was it intended to be).	**Recommendation 8** In light of other recommendations, greater effort to strategically plan and to share the results of this Initiative will become important to its ongoing success. As such, horizontal management costs may increase but the benefits resulting from increased horizontal activity are expected to be greater.

Table 15 – Conclusions and Recommendations	
Conclusions	**Recommendations**
Design and Delivery	
Conclusion 12 It is appropriate to have this Initiative as a separate initiative within the larger federal government biotechnology strategy. Within departments, the Initiative is well integrated with other biotechnology programs (such as the Canadian Regulatory System for Biotechnology – CRSB, in the regulatory departments). However, there is limited integration with these programs from a horizontal perspective.	**Recommendation 9** As per Recommendation 8, due consideration should be given to exploring opportunities for better horizontal integration with other biotechnology programs. As a result, horizontal management costs may increase but the benefits associated with horizontal management could be important in terms of ensuring complementarity while avoiding overlap and duplication.
Conclusion 13 The governance structure currently in place for this Initiative is of limited complexity and burden. As such, it is appropriate. However, some of its elements need improvement. The Interdepartmental Genomics R&D ADM Coordinating Committee is not providing the required level of leadership. Additionally, the working group has no documented terms of reference and could play a more active role in identifying areas for horizontal coordination or more common interdepartmental processes.	**Recommendation 10** Without adding unnecessary burden to the Interdepartmental Working Group, specific terms of reference need to be defined for this group in order to ensure that, with ongoing support for this Initiative, its roles and responsibilities are clear. These terms of reference should include responsibilities for defining how funds can / should be allocated for departmental overhead costs as well as common approaches to some of the departmental processes (e.g., project selection, reporting, etc.). **Recommendation 11** The Interdepartmental Genomics R&D ADM Coordinating Committee should play a more active role in providing strategic direction for government wide genomics R&D priorities linking to other components of the Canadian Biotechnology Strategy.
Conclusion 14 Departmental processes (such as for project selection and approval) have evolved and improved over time.	**Recommendation 12** Departments should continue to build on lessons learned and refine departmental processes as needed. The Interdepartmental Genomics R&D ADM Coordinating Committee should take steps to ensure that transparency and accountability continue as key elements in program proposal and approval processes, and that integrated performance reporting is formally implemented.

Table 15 – Conclusions and Recommendations	
Conclusions	**Recommendations**
Conclusion 15 There is insufficient information to reliably conclude on the extent to which most departments have been able to leverage the funds provided through the Genomics R&D Initiative. There is, nonetheless, evidence of internal leveraging as well as leveraging through partnerships with other research organizations.	**Recommendation 13** The summative evaluation needs to address the issue of leveraging in a way to reliably conclude on this issue. Departments will need to ensure that they put in place the required systems to meet the specific leveraging evaluation requirements which will be outlined in the revised RMAF for the Initiative.
Conclusion 16 There is currently no formal performance measurement system in place for this Initiative either horizontally or within the departments. As a result, there is limited performance information available. Recognizing that it is still fairly early to measure impacts, it is important to ensure that performance information available within departments is not limited to inputs and outputs measures.	**Recommendation 14** The performance measurement system outlined in the upcoming revised horizontal RMAF for this Initiative needs to clearly define common performance measures and ensure that the appropriate tools are available to collect, analyze and report performance information without imposing undue burden or cost requirements to the departments.

There are several conclusions presented in Table 15 which, together, helped lead the evaluation team to the following series of recommendations:

Recommendation 15

The total funding for the Genomics R&D Initiative should be increased.

First, funding should be increase to compensate for inflation. It is important for departments to, at least, be able to maintain previous levels of research.

In addition, some of the additional budget should be used to re-balance departmental inequities. The funding for Phase 1 of this Initiative was initially allocated to the departments on the basis of existing capacity and it was expected that funding re-allocations would occur in later phases. This has not been the case. Nevertheless, the re-balancing cannot be done by reducing the existing funding levels of departments receiving a larger proportion of the total funding, as this could negatively affect the ability of these departments to undertake the genomics R&D required to support their departmental mandates.

Finally, some of this additional funding could be pooled for interdepartmental projects. Assuming that a pooled fund is set aside, appropriate processes will need to be put in place including approval processes as well as performance monitoring and reporting processes.

Annex A – Departmental Summaries

A.1 Agriculture and Agri-Food Canada

The following is a supplementary report to the main report on the Evaluation of Genomics R&D Initiative that describes those aspects of the evaluation specific to AAFC. This report is based on information collected in a review of program and other related documentation as well as 24 in-depth interviews – four with program management, fifteen with project leads / researchers (drawn from the research groups involved in the three phases of the program) and five with stakeholders.

A.1.1 Profile

Strategic Approach

Agriculture and Agri-Food Canada decided that the Genomics R&D Initiative funding would be most effectively employed if it were directed to supporting a dedicated program, the Canadian Crop Genomics Initiative (CCGI), focusing research on the four most important Canadian crops in terms of economic value. These crops (canola, wheat, corn and soybeans) were also considered to have the best potential for employing genetic research to improve crop performance and create increased benefit.

The initial Genomics R&D Initiative funding (Phase 1) was for three years, April 1, 1999-March 31, 2002. There have been two successive renewals of the funding (Phase 2 and Phase 3), each for three years. The current Phase 3 funding is for the period April 1, 2005-March 31, 2008.

Theme / Research Priority

The research priorities for Phase 1 of the CCGI focused on the development of genomics research infrastructure, including equipment, trained staff, bioinformatics and databases. In addition, CCGI conducted research projects in the four selected crop areas linked to improving seed traits related to cold tolerance, disease and insect resistance (input traits) and seed quality (output traits).

To a large extent, the research priorities in Phase 2 were a continuation of those in Phase 1. Infrastructure funding supported development of technology platforms and construction of DNA microarrays. As in Phase 1, research priorities included improving seed input traits such as disease resistance through research on host pathogens, as well as improving seed output traits, such as oil or protein content through research on plant metabolism.

Again in Phase 3, most research was a continuation of that conducted in Phase 2. Increased priority was given to research on seed output traits, in order to improve seed characteristics in order to increase the economic value of the target crops. The long term goal is to increase the value of some of the crops above commodity level. Funding for research related to corn was reduced in Phase 3.

How Initiative is Delivered in Department

The Canadian Crop Genomics Initiative has been delivered primarily through four research centres, each focusing on one of the four crops. The original allocation for Phase 1 is shown below:

- Canola and brassicas – Saskatoon Research Centre
- Wheat – Cereal Research Centre (Winnipeg)
- Soybeans – Southern Crop Protection and Food Research Centre (London)
- Corn – Eastern Cereal and Oilseed Research Centre (Ottawa)

The Director of the relevant centre was responsible for overall management of the research on each crop.

In 2002, shortly after Phase 2 began, AAFC reorganized the delivery of scientific programs into four National Science Programs. A number of genomics related programs were grouped together to form a Genomics and Biotechnology Theme within the Bioproducts and Bioprocesses National Science Program. Originally, the group included CCGI and a Livestock Genomics Strategy (including rumen metagenomics), focusing on beef, with dairy and swine to follow. More recently, a Potato Genomics Strategy is being implemented and another strategy in Nutrigenomics is being developed.

While there has always been a small contribution from researchers in other research centres with particularly relevant expertise, this has increased in Phase 3, as proposals were solicited from all research centres for the first time. With the decreased focus on corn related research in the third phase, some of the capabilities of the Eastern Cereal and Oilseed Research Centre have been redirected to support the programs for the other three crops.

Resources

In each phase of the program, funding has been provided to each department for three years. In Phase 1, AAFC was allocated $5 million for 1999-2000, and $6 million for each of 2000-2001 and 2001-2002, for a total of $17 million. Because of the late start to the program, it was not possible to utilize the full amount of the funds in the first year, and the unused funds were reprofiled to the third year. The actual allocation of resources to each of the centres is shown in Table A1 on the following page.

Table A1: Resource Allocation for Phase 1 (in thousands of dollars)						
Crop	**Centre**	**1999-2000**	**2000-2001**	**2001-2002**	**Total**	**Percentage**
Canola	Saskatoon	$ 1,250	$ 2,100	$ 2,600	$ 5,950	35
Wheat	Winnipeg	$ 750	$ 1,800	$ 2,550	$ 5,100	30
Soybeans	London	$ 500	$ 1,260	$ 1,810	$ 3,570	21
Corn	Ottawa	$ 400	$ 840	$ 1,140	$ 2,380	14
Total		**$ 2,900**	**$ 6,000**	**$ 8,100**	**$ 17,000**	**100**

In Phase 2, AAFC received $6 million per year for each of the three years from 2002-2003 to 2004-2005. As shown in Table A2 below, the funds were allocated in the same proportion as in Phase 1.

Table A2: Resource Allocation for Phase 2 (in thousands of dollars)						
Crop	**Centre**	**2002-2003**	**2003-2004**	**2004-2005**	**Total**	**Percentage**
Canola	Saskatoon	$ 2,100	$ 2,100	$ 2,100	$ 6,300	35
Wheat	Winnipeg	$ 1,800	$ 1,800	$ 1,800	$ 5,400	30
Soybeans	London	$ 1,260	$ 1,260	$ 1,260	$ 3,780	21
Corn	Ottawa	$ 840	$ 840	$ 840	$ 2,520	14
Total		**$ 6,000**	**$ 6,000**	**$ 6,000**	**$ 18,000**	**100**

Phase 3 has just begun. AAFC has again received $6 million in annual funding for the three years of Phase 3. In addition to funding of $ 3.4 million for continuation of some ongoing projects related to input and output traits, $1.6 million was assigned to new initiatives focused on output traits for the four crops. Table A3 below provides a summary of the Phase 3 funding allocations for the first year of Phase 3, indicating the major research centres involved and the funding allocation by crop. As noted previously, funding for corn research has decreased.

Table A3: Resource Allocation for Phase 3 (in thousands of dollars)			
Crop	**Centres**	**2005-2006**	**Percentage**
Canola	Saskatoon, Ottawa, London	$ 2,040	34
Wheat	Winnipeg, Ottawa, Summerland	$ 1,920	32
Soybeans	London, Ottawa	$ 1,500	25
Corn	Ottawa	$ 540	9
Total		**$ 6,000**	**100**

Note: at the time of the evaluation the resources for 2006-2007 and 2007-2008 were not available.

As discussed previously, CCGI resources have been used to fund the development of both infrastructure and discovery research. Much of Phase 1 funding was used to develop infrastructure, hire staff and develop expertise and genomics capability. In Phases 2 and 3, there was increased funding of research projects that could take advantage of the infrastructure and expertise developed earlier. In some cases, research projects continued from Phase 1 to Phase 2 and into Phase 3, developing increased knowledge and moving closer to application. Table A4 shows the changing allocation of resources from Phase 1 to Phase 3. As can be seen, the percentage of funding for infrastructure has been reduced and funding for projects directly linked to crop improvement has increased. Table A4 also shows the allocation of research for improving crop input traits such as cold and disease resistance associated with increased yields and output traits associated with characteristics such as protein level and oil content. In some cases, such as *Fusarium* fungus, the research is linked to both input and output traits, as this fungus produces toxins that harm the crop and can render it unsuitable for sale.

Table A4: Changing Allocation of Resources			
Category	**Percentage of Total Funding**		
	Phase 1	**Phase 2**	**Phase 3***
Infrastructure Development and Support	72%	49%	24%
Development of Improved Input Traits	21%	27%	43%
Development of Improved Output Traits	7%	24%	33%
Total	**100%**	**100%**	**100%**

* Planned based on funded projects

Project Approval Process

As discussed previously, the Genomics R&D Initiative funding for AAFC was used to create the CCGI. For Phase 1, because of the lack of time to prepare for the funding, the process of project selection was somewhat informal. The high level funding allocations were made based on the value of the four crops being supported. Each centre was responsible for one of the four crops. Knowing their funding allocation, which had been made previously, management in each centre met with senior staff and discussed what projects were feasible, given existing capabilities, opportunities and objectives. In general, funding decisions were made very quickly, following a consensus process. Funding was allocated in three broad categories. One involved developing and building the necessary infrastructure and technical expertise in gene sequencing and bioinformatics. The second focused on developing a molecular tool box and databases consisting of microarrays, expressed sequence tags (ESTs) and libraries. The third category included specific genomics related research projects in such areas as gene discovery, molecular and computational technology development and enhanced plant performance. The majority of research was undertaken by researchers in the four centres, with a few scientists from other centres with specific expertise participating on project teams. Because of the three year funding envelop, funding was allocated for the full three year period 1999-2000 to 2001-2002.

For Phase 2, researchers in each of the four centres were asked to submit project proposals for the next three year funding cycle. Once again, each centre received its funding allocation and decisions were made by each centre management about which projects to fund.

There were significant changes to the project selection process for Phase 3. For this phase, researchers from all research centres were invited to submit proposals. Also, a peer review process was instituted to help select research projects. One page descriptions of each proposed project were reviewed by international and Canadian reviewers. The peer review was used to help select projects, however management included other considerations in making final selections. Project funding was notionally allocated to three categories in the following percentages:

- infrastructure (bioinformatics, etc.) – 20%;
- improving crop input traits (resistance to stress, etc.) – 40%, and
- improving output traits (seed quality, value) – 40%.

The infrastructure projects were not peer reviewed.

A.1.2 Rationale

R1. Are the mandate and the strategic objectives of the Genomics R&D Initiative still relevant? What need was the Initiative intended to address? Does this need still exist?

Document Review

A number of documents provided background on the rationale for the initiative. As outlined in the Phase 1 program documentation, the Genomics R&D Initiative is part of the broader Canadian Biotechnology Strategy, developed in 1998. The Strategy recognized the low level of genomics R&D capacity in Canada and that immediate increased investment in genomics R&D was necessary if Canada was to be able to participate in this important emerging field. The original strategic objectives of the broad Genomics R&D Initiative as defined in the Phase 1 documentation were to contribute to social, economic and environmental outcomes through the enhancement of genomics-based research and development programs in several federal government departments. The Phase 3 Program Framework noted that the action plan "will involve building on current core federal capabilities in genomics R&D".

The original Canadian Crop Genetics Initiative plan, developed by AAFC in 1998, was entitled "Investing in Life's Basic Building Blocks to Secure Canada's Future Food Supply". The plan cited several recent industry, parliamentary and departmental reports that identified the importance of genomics as an emerging scientific field of major importance to many sectors, including agriculture and agri-food. Based on these reports, the plan noted that both public and private institutions have significant roles to play. Recommendations from two of the reports most significant to AAFC follow.

The Canadian Agri-Food Research Council conducted consultations in 1998 and produced a report entitled "Opportunities and Challenges for Application of Biotechnology in the Canadian Agri-Food Sector". The report recommended that:

> *"public institutions play a leadership role in a number of basic areas of research, including genomics technologies for specific projects of relevance to Canada's major agricultural commodities and for increased R&D in support of agri-food regulation."*

The report also emphasized the principle of building on strengths and previous investments.

The CCGI plan also noted that Parliament's Standing Committee on Agriculture and Agri-Food had produced a report in 1998 entitled "Capturing the Advantage: Agricultural Biotechnology in the New Millenium" that recommended that funding for

long term basic research within AAFC be increased. Emphasis was placed on projects of major international potential and research to build on Canadian strengths and commercial possibilities through partnerships.

Consistent with the recommendation of the Canadian Agri-Food Research Council, the plan focused on applying genomics to improve farmed crops which account for a large portion of Canada's agri-food exports. The plan provided an outline of program elements and research topics for a 10 year period, a time frame that was considered appropriate to build genomics capacity and then apply it to improve crop production and quality. It should be noted that the program is now in its seventh year and is making progress. The need is larger than ever, as genomics is becoming recognized as an important enabling technology in agri-food research. Other developed countries are putting in place major agricultural genomics programs.

Interviews

According to several interviewees, Canada's lack of participation in the Human Genome Project in the late 1990s was a signal that the country was falling behind in this important new scientific field and failing to keep up with international developments. There was a recognized need for Canada to catch up. A number of federal departments and agencies including AAFC produced reports or plans at about the same time in the late 1990s outlining the need to develop genomics capability to address national problems. It was also pointed out that the cuts to federal R&D from Program Review in 1995 severely reduced government laboratories' research capacity and ability to embark on new initiatives. The new Phase 1 Genomics R&D Initiative funding was focused on developing genomics research capacity in government laboratories to enable them to participate both within Canada and internationally.

This general situation applied to AAFC. One interviewee estimated that Program Review in 1995 took about 20% of the budget of the AAFC Research Branch. In Ottawa, the number of research personnel was reduced from 900 to about 300. While AAFC had begun to put some limited A-base resources into genomics in response to the new opportunities, there was limited ability to move forward within existing resources. The Genomics R&D Initiative funding was kept separate from A-base funding and was directed towards crop genetics, which was seen as the sector with the greatest economic impact and where some genomics capability already existed.

The need still exists. One interviewee noted that the field of genomics has changed greatly since 1999, with major increases in knowledge about genes and technology to support genetic research. With the focused funding, AAFC has been able to develop world class capability and to participate in major international consortia and lead in some areas. Continued funding is needed to be able to keep up in this rapidly developing field and develop expertise in new applications.

R2. Is there a legitimate and necessary role for government in this area?

Document Review

The previously cited recommendation from the Canadian Agri-Food Research Council acknowledged the important role played by public institutions like AAFC in conducting basic genomics research and technology development relevant to Canadian agricultural commodities. Similarly, the Standing Committee on Agriculture and Agri-Food recommended increased funding for long term basic research in areas of international and commercial potential.

The Phase 1 documentation noted that the funding for genomics research in the six departments, each operating in different sectors was expected to have both economic and social benefits, including industrial competitiveness, economic growth, a cleaner environment, better management of natural resources and improved therapeutics. These are all areas in which government funding of basic research is considered appropriate. Furthermore, the Phase 3 Program Framework noted that the federal government has wide ranging responsibilities related to genomics including: playing a key role in building and participating in local, national and international genomics R&D initiatives; and supporting the development and application of the scientific knowledge base. The Framework went on to note that "the continuation of intramural genomics R&D funding directed to federal departments is vitally important to complement and link to other key government investments in biotechnology ..."

Interviews

One interviewee noted that the long term legacy of federal support for agricultural research in Canada was modeled on policies in other countries like the U.S. and Germany.

A.1.3 Success

S1. Have the individual departments achieved, or made progress towards, their specific objectives / goals?

Document Review

As noted in the original Phase 1 Program Framework, for AAFC, the funding was provided to "enhance its strength in plant breeding and plant biology through identification of the structure and function of important genes." Furthermore, the funding was expected to "lay the basis for the development of Canadian crops that are resistant to disease and insects, can better withstand stress such as cold and heat, and have better yield qualities."

A June 2003 AAFC report entitled "Bringing Genes to Life" described the success that CCGI had achieved in the first three years. In addition to establishing the program infrastructure, hiring key scientific and technical staff and Post Doctorate Fellows (PDFs), and purchasing specialized equipment such as sequencers, the program has been developing tools and databases such as ESTs, Deoxyribonucleic acid micro-arrays, bioinformatics systems and reference mapping populations related to the four target crops.

Specific achievements are discussed in more detail in the following sections.

S2. To what extent did the projects funded under Phase 1 of the Genomics R&D Initiative build capacity inside government laboratories to carry out genomics research?

Document Review

The AAFC section of the Phase 1 Performance Report described the results achieved by the Department in Phase 1 of the Genomics R&D Initiative. The report stated that "the key objectives of the first phase of the CCGI were first to develop a genomics research infrastructure that included both highly trained staff and equipment and critical biological and informational resources in four key crop / model systems" and to then "initiate discovery programs that addressed both improved crop value and constraints to production". The report went on to note that as a result of CCGI, over 50 scientists and technicians have new skills in genomics and are actively engaged in research projects. CCGI has also developed DNA sequencing capability, bioinformatics systems and libraries.

A separate AAFC report lists the many scientific publications that were written in this period, which represent the creation of scientific knowledge.

Interviews

Many interviewees reported that the main results of the Phase 1 projects were the building of genomics capacity in the four centres. In particular, the hiring of young talented people with the related skills in genomics R&D was a major contributor to improved R&D capacity. In addition, the acquisition of sequencing equipment and development of technology platforms such as DNA microarrays and EST libraries were important results.

Interviewees all stated that without the Genomics R&D Initiative funding, a major focused crop genomics program would not have existed, and much less progress would have been made in developing genomics capability. Some interviewees reported that the

funding allowed the establishment of a genomics laboratory with up-to-date equipment and trained PDFs and technicians. Various researchers reported that they had developed thousands of EST libraries and microarrays for the four crop types during Phase 1. Several interviewees reported that in 1999 some A-base funding was already being used to conduct genomics research. It was also noted that AAFC matched the $6 million in Genomics R&D Initiative funding annually with an equal or slightly greater amount of A-base funding. One researcher commented that some research groups had already established some genomics research capability and had "limped along" until Phase 1 funding arrived. Another interviewee estimated that the Department would have been able to do less than half as much genomics research (estimated 40%). Other interviewees stated that little genomics related research would have been done on crops without the focused funding that led to the CCGI.

In terms of specific results of genomics research, one group had identified gene markers for increased protein content in soybeans, and was working with crop breeders to use those markers to analyze seeds obtained by cross breeding to determine if they had the protein gene markers. In this way, the genetic marker capability was able to reduce the time to test conventional cross breeding for the desired characteristics dramatically.

S3. Did this increased capacity strengthen the research carried out in the departments?

Document Review

In the early 2000s, the contribution of genomics and biotechnology to many sectors became more widespread both within Canada and internationally. Within AAFC, the success of CCGI in developing genomics expertise and potential applications related to crops demonstrated the potential application of genomics to other agricultural sectors. As mentioned previously, in 2005, AAFC reorganized the research programs and created a Genomics and Bioproducts Theme within the newly formed Bioproducts and Bioprocesses National Sciences Program. In addition to CCGI, the Theme included a Livestock Genomics Strategy focused on beef. Other elements continue to be added to the Genomics and Bioproducts Theme, including a Potato Genomics Strategy (currently being implemented) and a Nutrigenomics Strategy for animals and humans (currently under development).

Interviews

Some interviewees reported that the capacity in genomics R&D developed in Phase 1 has led to AAFC participation in a number of national and international genomics research consortia. For example, AAFC is a member of the Natural Sciences and Engineering Research Council (NSERC) genomics network and has been able to participate in a number of Genome Canada research projects. AAFC researchers with CCGI funding

have been able to develop other research collaborations based on the expertise and capability acquired through the initiative.

Interviewees noted that other AAFC research groups such as crop breeders and animal researchers, as well as university researchers were able to make use of the genomics infrastructure developed in Phase 1, including the sequencing and bioinformatics capability. More generally, bioinformatics is now recognized as very useful in many research areas, partially as a result of its successful application in genomics research. Molecular genetics capability has been used to support crop breeders' ability to identify genetic traits in cross breeding studies.

As noted previously, several researchers commented that the genomics research led to linkages with other AAFC scientists working in applied areas, such as seed breeders, who are now able to use gene markers to identify desired characteristics in seeds produced by their conventional breeding program.

S4. Did this increased capacity created in Phase 1 translate into the benefits of advances in research and technology in Phase 2 for department constituents?

Document Review

The Canadian Biotechnology Strategy Horizontal DPRs for the three fiscal years 2002-2003, 2003-2004 and 2004-2005 provide summaries of the results achieved for all departments participating in the Genomics R&D Initiative. The report for 2003-2004 noted that, through the CCGI, AAFC had constructed a wheat library covering every wheat gene, one of only two in the world and the only one containing an elite wheat type of relevance to Canada. *Fusarium graminearum* is a fungus found in wheat and corn which produces mytotoxins which are toxic and reduce the value of the crop or, in extreme cases, make it unsaleable and unsuitable for on-farm use as livestock feed. The report indicated that corn and wheat *Fusarium* microarrays produced have been used to identify pathways in the corn *Fusarium* interaction. In addition, research in legume genomics has helped identify genes involved in development of seed protein and nitrogen fixation, areas that affect both crop value and growth. AAFC researchers have also identified genes involved in disease development in target crops, resulting in genes for resistance to blackleg fungus in canola being released to industry. The report also noted that other research has resulted in nutritional improvements to plants that are used for feed for the aquaculture industry.

Interviews

Interviewees reported that, in many cases, the research in Phase 2 continued projects begun in Phase 1. There was still a need to continue to build libraries, microarrays, genome databases and bioinformatics software in target areas. As Phase 2 projects built

on the infrastructure and knowledge developed in Phase 1, little or none of the work would have been possible without Phase 1. Much research focused on functional genomics involving both input and output characteristics. Some specific results noted were the characterization of genetic populations for *Fusarium* resistance (wheat and corn) and protein content (soybeans). Some of the research on legumes consisted of building a genomic map of the interactions of legumes with microbes that produce nitrogen and phosphate, important factors linked to plant growth and reduced use of commercial fertilizers. One researcher was able to isolate the gene for leaf rust resistance in wheat and to map the genes responsible for hardness and gluten. In addition to research focused on applications of knowledge, some projects are addressing fundamental questions in biology that are needed for further innovation.

More generally, the research expertise and capacity developed in Phase 1 increased the credibility of AAFC researchers working in this field and led to interest by other researchers in collaborating with CCGI researchers. Many collaborations within Canada and internationally have developed. A number of collaborations with partners on Genome Canada projects have taken place. It should be noted that for Phase 3, direct funding from Genome Canada is no longer available to federal scientists.

S5. To what extent has the Initiative strengthened coordination, cooperation and linkages between the appropriate research institutions?

Document Review

Several documents describe intended and actual linkages between AAFC and other organizations. The original Phase 1 Program Framework described AAFC's plan to collaborate with NRC's Plant Biotechnology Institute (PBI) on the functional genomics of canola and other *Brassica* species.

The Phase 2 Program Framework reported that "the data produced and tools developed (in Phase 1) have been made available to research scientists throughout AAFC as well as research groups at public institutions funded through, for example, Genome Canada."

The Phase 3 Program Framework referred to the role of the Genomics R&D ADM Coordinating Committee in ensuring that horizontal collaborations between organizations are pursued wherever appropriate. The framework also noted that AAFC and NRC were collaborating in leading a Genome Prairie funded project on "Enhancing Canola Through Genomics". and reported that the Initiative has helped create new research partnerships among government-based science organizations, as well as between government researchers and those in universities and other research institutions through both the sharing of technology platforms and by collaborating in research areas.

The Framework also noted that new models for future collaborations between federal organizations and Genome Canada were being developed and were to be reviewed with the Treasury Board Secretariat."

Interviews

A number of interviewees reported that the funding provided through the Initiative has led to projects that have strengthened collaborations both within the four centres and between AAFC research centres. Collaboration between centres have grown, particularly for Phase 3, when proposals were solicited from all research centres. Centres are trying to build an integrated approach where it is warranted, however, there is a limit to integration since the four plant systems have different problems and specific solutions are required for each. Bioinformatics capability and software developed through CCGI has been transferred to other AAFC research centres outside CCGI.

In canola research, there is extensive collaboration between the AAFC Saskatoon Research Centre and Plant Biotechnology Institute (PBI). In fact, the two laboratories signed a Memorandum of Cooperation soon after the beginning of Phase 1.

The Initiative has also developed capability in a number of government departments to address emerging issues. For example, senior managers from AAFC, NRCan and Environment Canada are discussing ways to develop and utilize biomass for production of renewable energy. Genomics is expected to make an important contribution to this initiative.

One interviewee identified collaborations with NRCan's Canadian Forest Service and the University of British Columbia as well as PBI as a result of the increased genomics expertise in AAFC. Other interviewees reported collaborations with Canadian university researchers and those in other countries (Denmark, Japan, Scotland, Australia, U.S.) as well as the US Department of Agriculture. In particular, AAFC is seen internationally as being a major centre of expertise in wheat genomics.

Several interviewees spoke of the value of annual meetings among the CCGI researchers in facilitating cooperation and collaboration within the Initiative. To encourage collaboration and sharing of information, AAFC has also sponsored several Plant Genomics Workshops with participants from AAFC, relevant federal Departments, Canadian and international universities and industry.

Several interviewees reported on collaborations with universities and other organizations fostered through funding from the various Genome Canada centres during Phase 1 and Phase 2. Unfortunately, since Phase 3 began, Treasury Board has ruled that federal laboratories cannot receive Genome Canada funding directly to participate in research

projects. Some groups have continued to find ways of working with Genome Canada, but overall, the ruling has greatly reduced the level of interaction.

S6. What have been the facilitating and impeding factors for the success of Phases 1 and 2 of the Initiative?

Interviews

For Phase 1, interviewees noted that the departmental commitment to a focused approach and use of the funds and the plan at the beginning helped guide the delivery of the initiative and limit competition between the centres. One person reported that the 1998 CCGI plan also helped people plan ahead, allowing anticipatory staffing, which helped get the Phase 1 program off to as good a start as possible. Some interviewees reported that the targeted use of resources, rather than spreading them widely "like peanut butter", was a critical success factor. Another facilitating factor mentioned by several people was the annual meetings where all research groups presented their results. This was deemed to have facilitated communication, increased awareness and helped build collaborations. Others reported that the focused funding helped build collaborations among AAFC researchers within each centre.

Factors impeding success in Phase 1 that were reported included difficulties in reaching consensus among managers over the distribution of Genomics R&D funding and program definition. Some reported an early sense of entitlement to the funding at the four centres. Another problem identified was the lack of a single manager for the CCGI. It was noted that each research centre director had control over the funding to that centre, which limited co-operation among the centres.

S7. Are there other intended and unintended impacts resulting from Initiative?

Document Review

The Program Framework for Phase 3 (2005-2006 to 2007-2008) noted that the February 2004 Speech from the Throne indicated that the government wants "a Canada that is a world leader in developing and applying the path breaking technologies of the 21st Century", and "creating high quality jobs that will meet the ambitions of young Canadians".

The AAFC section of the Phase 2 Performance Report noted that AAFC had hired 12 new scientists and 40 new technical and support staff, and had 12 PDFs as a result of Phase 1 funding. This development of highly qualified personnel is an important contribution to new genomics capability in crops.

Interviews

Most impacts have already been reported. As previously noted, several interviewees reported that the capability developed as a result of the initiative helped AAFC become a participant in Genome Canada funded projects. Others identified the HQP developed, some of whom are still at AAFC while others, particularly the graduate students and PDFs, have moved on to universities and industry, contributing their knowledge and expertise to genomics research in Canada and other countries.

S8. To what extent would the impacts have occurred without the Initiative?

Document Review

The Phase 3 Program Framework noted that "AAFC A-base will be used to augment the selected projects and the funds would be used to lever external funds from collaborative partners".

Interviews

Most interviewees stated that, since the CCGI program was begun as a result of the Genomics R&D Initiative funding and the project funding was provided from the external funding, any genomics projects undertaken would have been carried out at a much lower level of funding and in a much less focused way. Some interviewees noted that AAFC is contributing A-base resources and therefore would have been carrying out some genomics related research in any case, but much less. However, most consider that a significantly lower amount of genomics research would have been carried out. Some interviewees noted the high cost of purchasing sequencing and other genomics equipment, which the Department would not likely have been able to purchase without the external funding. Others noted that without the external funding, AAFC would not likely have created a focused crop genomics research program, and the sector would have had to compete with other research areas for scarce funding. It was also pointed out that, more recently, animal based genomics research is now being funded with AAFC resources.

A.1.4 Cost-Effectiveness / Alternatives

C1. Does the Genomics R&D Initiative complement, overlap or duplicate other federal or provincial initiatives related to genomics or biotechnology?

Document Review

The Genomics R&D Phase 3 Program Framework noted that the Genomics R&D Initiative is one element within in a broader Canadian Biotechnology Strategy, which

includes several other initiatives. These include the Canadian Regulatory System for Biotechnology and the Canadian Biotechnology Strategy Fund. Coordination is provided through the Canadian Biotechnology Strategy Secretariat. Together these three initiatives support R&D, regulations and policy. The Phase 3 Framework also stated that "Good complementarity and linkages have been established between federal departments receiving intramural genomics R&D funding and Genome Canada", and gives examples of collaboration with external partners funded through the five Genome Canada Centres and international Genome Canada initiatives. The Genomics R&D is one of the three initiatives under CBS. The other two are the CRSB and the Canadian Biotechnology Strategy Fund. The Phase 2 Program Framework section describing AAFC initiatives noted that "the data and tools developed have been made available to research groups at public institutions funded through, for example, Genome Canada".

The Phase 2 Program Framework also observed that good complementarity had been developed with Genome Canada, and that "Departments collaborate with partners in projects applying for funding from the five regional Genome Canada Centres." and that "There is ongoing consultation between the Departments and Genome Canada regarding priorities and progress of genomics research. Similar comments were made in the Phase 3 documents, with the additional mention of international Genome Canada initiatives.

As mentioned previously, the Phase 3 documents noted that new models for future collaborations between federal organizations and Genome Canada were being developed.

Interviews

A number of interviewees identified the Genome Canada Foundation that supports primarily university-based research as another federally funded genomics initiative. Until recently, during the first two rounds of funding, there were several cases where government capability developed through the Genomics R&D Initiative was utilized as part of a Genome Canada funded project. (As mentioned previously, CCGI and NRC's PBI were co-leaders of a Genome Prairie project on canola.) Other interviewees noted that Genome Canada has relatively little funding devoted to agriculture (estimated 5% to 7%), but rather focuses on human health and genomics. Genome Prairie has the most agricultural funding while Genome Ontario has practically none. However, there were examples of cooperation and complementarity between federal government and university scientists. More recently, during the third phase, Treasury Board has reminded Genome Canada that, according to government policy, no government department can receive funding directly from Genome Canada. This change has greatly reduced the level of interaction and complementarity between the two programs. Many interviewees considered this change to be a major impediment to cooperation and collaboration with the university sector through Genome Canada.

A few interviewees mentioned the CFI as a complementary program in that it provides funding for capital equipment and facilities. One person mentioned NSERC Strategic Grants, which fund university based research, as a complementary program with overlap in some project areas. However, it was noted that little NSERC funding goes to agriculture.

In terms of provincial programs, one interviewee noted that Manitoba has no wheat research at the provincial level to complement the wheat research program at the AAFC Cereal Crop Research Centre in Winnipeg.
As mentioned previously, there is a degree of complementarity between CCGI and other AAFC genomics programs within the Genomics and Biotechnology Theme of the Bioproducts and Bioprocesses National Science Program, primarily in terms of sharing expertise in bioinformatics and genomics infrastructure.

C2. Is the funding structure of the Genomics R&D Initiative the most appropriate mechanism for achieving the intended objectives? Are there more cost-effective alternative ways to achieve the Genomics R&D Initiative mandate?

Interviews

Some interviewees felt that it was important to keep the Genomics R&D Initiative funds separate and not integrate them with the departmental A-base, where they could be diverted to other purposes.

In terms of alternatives, most interviewees who provided input to this question could not identify better alternatives, as they considered the use of the funds to support focused crop genetics research to be appropriate. Some interviewees commented that improving the linkages with those that apply genomics R&D, such as seed breeders, would improve effectiveness. Several others suggested that improving the linkages between Genome Canada and this program would also improve effectiveness. Others wanted an improved peer reviewed project selection system where researchers compete for funding. Another suggestion was to provide some dedicated funding for interdepartmental projects to encourage cooperation and collaboration among Departments.

C3. Is the three year funding cycle appropriate for achieving intended outcomes?

Document Review

During the first year of a new program or project, there is little that can be done in terms of actually using a substantial amount of available funds, as there is a need to hire staff, order and purchase equipment and so on. As shown in Table A1, the department did not spend the full amount of the allocated funding in the first year of the Phase 1 program ($2,900,000 out of $5,000,000), but reprofiled the unused funds into year three.

Interviews

Most interviewees considered the three-year funding cycle to be appropriate. On the positive side, this is long enough to achieve significant research progress. However, on the negative side, there is the burden of writing a new proposal every three years. Many researchers interviewed would prefer a longer cycle, but some other interviewees felt that it should not be too long to assure discipline, accountability and focus, and also pointed out that three years allows refocusing or changing program direction more easily than would be the case with longer term funding. One person recommended five-year funding with project milestones identified and annual review. It was pointed out that NSERC discovery funding is for five years and strategic funding for three years. Managers spoke of the workload associated with the three-year cycle. They have to begin to prepare for the next cycle almost as soon as the last one begins.

Some interviewees spoke of the time it takes to start up a new project, in terms of finding and hiring PDFs and new staff, and purchasing equipment. For a new project, it often takes six months or almost a year before the project actually begins, making the actual project time less than three years. Renewal of the next three year phase of an ongoing project does not have this problem.

C4. What has been the level of effort or cost required by departments / agency to participate in this horizontal initiative? What have been the benefits?

Interviews

This question was addressed by the AAFC managers. There are a number of different activities involved in departmental input to the program. These include:

- the time, effort and travel expenses associated with participation in the Genomics R&D Working Group and other joint meetings;
- the time and effort associated with development of TB Submissions, preparation of departmental contribution to the CBS Horizontal RPP, DPR; and
- the development of the strategic three year plan, the preparation of RFPs, the preparation of proposals, selection of projects (peer review, etc.).

The National Science Program Co-ordinator / Working Committee Representative shoulders the majority of the effort associated with the first two items. The effort associated with the third bullet is periodic, every three years, and involves managers involved in genomics and related disciplines.

The A-base contribution of six to seven million dollars was also identified by some as a cost of participation, as money received by AAFC from the Genomics R&D is "matched" by AAFC internal funds.

In general, the managers did not consider the workload associated with participation to be onerous. One person noted that the AAFC financial systems are not fully capable of handling a complex funding situation like this program.

Benefits were not mentioned by interviewees.

A.1.5 Design and Delivery

D1. Is the position of the Genomics R&D Initiative appropriate within the larger government biotechnology strategy? Is the level of integration with other federal government biotechnology programs appropriate?

Document Review

As mentioned previously, the position of the Genomics R&D Initiative is described in the Phase 3 Program Framework which observed that the initiative is one element within the larger Canadian Biotechnology Strategy. Other funding elements include the Canadian Biotechnology Regulatory Strategy which supports regulatory issues and the Canadian Biotechnology Strategy Fund which focuses on policy developments

The documentation associated with renewal of funding for Phase 3 described the importance of the continuation of intramural genomics R&D funding directed to federal laboratories in order to complement and link with the other key government investments in biotechnology (i.e ongoing funding for the Canadian Regulatory System for Biotechnology and major investments in Genome Canada, Canadian Institutes of Health Research (CIHR) and other university research funding organizations). The Phase 1 Program Framework notes that AAFC works with NRC's PBI on the functional genomics of canola and other brassica species.

Interviews

Not many interviewees provided input to this question. Those that did considered the initiative to be appropriately positioned. One interviewee mentioned CIHR and NSERC as two biotechnology related programs that coexist with the Genomics R&D Initiative, and occasionally cooperate. While AAFC has a limited regulatory role, some research is done on behalf of the regulatory role of CFIA.

A few interviewees spoke about integration among Departments. As mentioned previously, AAFC has an agreement with NRC's PBI to share research on canola. There is little interaction with other Departments.

D2. How effective is the overall governance structure for the Initiative and departmental processes (e.g., project approval process)? Are the roles and relationships clearly defined and appropriate?

Document Review

The project selection process was described in Section A.1.1. The Phase 3 Program Framework states that "In response to the recent Expenditure and Management Review of Biotechnology by the TB Secretariat, an interdepartmental Genomics R&D ADM Coordinating Committee (GACC) has been established to oversee collective management and coordination of the federal Genomics R&D Initiative." Overall coordination of the Canadian Biotechnology Strategy is the responsibility of the Biotechnology Ministerial Coordinating Committee supported by the BACC. GACC is a subcommittee of BACC. GACC is supported by the Genomics R&D Working Group made up of representatives of each of the six funded Departments, the Canadian Biotechnology Strategy Secretariat and other stakeholders.

The Phase 3 Program Framework also states that "Each department uses an internal competitive program proposal and approval process, as well as scientific peer review to evaluate the quality and relevance of research programs."

Interviews

Most interviewees addressed the project approval process. For Phase 1, the project approval process was quite informal, with decisions being made by consensus by each of the four research centre managers and their senior scientists based on financial allocations, scientific capability and priorities identified in the CCGI Strategic Plan. Almost all funding went to projects within the four centres. For Phases 2 and 3, the project selection process became more formal, with peer review being introduced for the third phase. For Phase 3, proposals were solicited from all AAFC research centres, not just the four principal crop centres, with 40% of funding notionally allocated to research on input traits, 40% on output traits and 20% on infrastructure. All research project proposals for input and output traits were rated by peer review, followed by management review to choose projects for funding based on peer review plus alignment and distribution with priorities and effective use of personnel. Even for Phase 3, almost all funding went to the four research centres, although it was somewhat more widely distributed. Many interviewees expressed a desire to have the selection process be more rigorous, with full scale proposals (not one page as for Phase 3) and indepth peer review undertaken following the NSERC process, with reviewers actually meeting. Some

indicated that they would like the peer review to be the deciding factor, others recognized that management needed to make the final decisions. A manager suggested that larger team projects should be solicited to focus resources on larger, high priority areas.

Only managers were asked to comment on the governance structure and roles and responsibilities. At the program level, one interviewee stated that the program was working well at the Working Group level, but there had been less involvement by senior AAFC management, perhaps due to Departmental reorganization.

D3. To what extent have the departments been able to leverage the funds provided through the Genomics R&D Initiative? What are the pros and cons associated with the leveraging requirements?

Document Review

The Phase 2 Program Framework noted that "many departments have been able to lever additional funds, stretching the federal government's investment even further. In addition, industrial partnerships are being established, which may lead to revenue generation in the future." The Framework also noted that $7 million of AAFC's A-base has been reallocated to the AAFC's Canadian Crop Genomics Initiative.

The Phase 3 Program Framework observed that "All departments have levered the government's investment in genomics R&D by providing additional (or matching) A-base to supplement genomics R&D funding". The documentation noted that "AAFC A-base will be used to augment the selected projects and the funds will be used to lever external funds from collaborative partners."

Interviews

Several interviewees noted that AAFC provides a significant level of in-kind resources from the departmental A-base in the form of salaries of scientists and technicians and funding of physical facilities to complement the funding provided from the Genomics R&D Initiative. The official estimate is that AAFC provides approximately $7 million in A-base resources to complement the $6 million from the Genomics R&D Initiative (see Document Review.) One researcher estimated an even greater 2:1 ratio of A-base in-kind resources to Genomics R&D Initiative funding. It was noted that matching funds are not required in proposals, other than the work of the researcher paid from AAFC A-base resources. Other interviewees identified external funding from Genome Canada and NSERC as leveraging CCGI investments. Industry also provides some funding for crop genomics projects through other AAFC programs such as the Matching Investment Initiative (MII).

One manager spoke of the fact that the influence of genomics research now extends throughout the crop and other research programs. As genomics research is integrated into various crop innovation programs, the Departmental financial system is challenged to track AAFC investments in crop genomics research.

D4. How effective / appropriate is the Initiative's approach to performance measurement? What performance measures should be captured in the next phase and why?

Document Review

The Phase 1 documentation identified a number of indicators to measure AAFC achievement of objectives. These included the number of genes identified for target traits; number of new technologies developed for genetic modification; insertion or operation of genes in plants; number of patents applied for; number of scientific publications; and number of scientists and technicians developed with specific skills in genomic research.

Interviews

Most interviewees mentioned that traditional indicators of performance are used, based on information already available. These include peer reviewed and industrial publications, invitations to speak, patents, licenses, collaborations, partnerships and training of students, PDFs and other HQPs. One person mentioned that annual meetings are held during which scientists provide abstracts and report on results obtained over the past year. Others mentioned that reporting on the utilization and application of knowledge developed within CCGI linked to the AAFC mandate was another important performance indicator.

One person said that there was a need to develop a new approach to performance measurement that was more appropriate and useful.

D5. How could the Genomics R&D Initiative be improved? What changes are required to make the Initiative more efficient?

Interviews

Most interviewees felt that the initiative was working reasonably well at the present time, but could be improved. A number of interviewees commented on the fact that the amount of funding has been fixed, and has not increased to keep up with salary increases or inflation. Since 1999, the increased cost of salaries has been significant (estimated 40%). Many felt that this should be corrected in future funding.

Several interviewees commented that there has been a recent tendency within the CCGI to spread the funding more widely and fund a larger number of smaller projects. According to interviewees, this tendency should be resisted, as much of the success of the initiative has been due to the focusing of funding on major projects. The focus should remain on the original crop systems. Some felt that even fewer but larger projects should be encouraged.

With respect to the project approval process, one suggestion was to provide an improved RFP, including a clear description of criteria for project selection (such as the relevance of the proposal to CCGI objectives) and resource allocation (input, output traits), provide longer notice and a more substantive peer review process.

One person spoke of the difficulties in accessing graduate students through the bureaucratic PWGSC process as something that needs improving (access to PDFs is satisfactory through NSERC).

At a more fundamental level, one person spoke of the need to connect the CCGI strategy, objectives and project selection with overall government strategy and to focus on applying the genomics capability already developed on specific critical applications.

There was also a suggestion to allocate some fraction of the Genomics R&D Initiative funding to horizontal, interdepartmental projects. AAFC could potentially collaborate with CFS, universities and, of course, continue to collaborate with NRC.

A.2 Environment Canada

Genomics is the science that decodes the genes of all living organisms and uses that knowledge to develop new techniques, therapies and technologies.

The following is based on an extensive review of program documentation provided by Environment Canada and NRC (see Annex B). In addition, 18 in-depth interviews were conducted – four with program management, 11 with project leads / researchers (representing all research organizations involved in the program) and three with stakeholders.

Environmental Genomics can be defined as the application of knowledge for[22]:

- Gene identification;
- Gene and whole organism structure and function;
- Ecosystem structure and function for environmental conservation, protection and management; and
- Determining the toxic effects of contaminants on wildlife ('toxicogenomics').

A.2.1 Brief Profile

Strategic Approach

Environment Canada delivers its Genomics R&D funding through the *Strategic Applications of Genomics in the Environment (STAGE)* program. The Department has focused its STAGE funding on projects that examine how genomics tools and methods can be used to support their regulatory decision making and enforcement mandates. More specifically, projects address the following Departmental priorities:

- Risk Identification (e.g., the effects of environmental contaminants on the biodiversity and function of microbial communities);

- Risk Assessment / Management (e.g., genomics-based procedures to ensure more accurate data for submission under the New Substances Notifications Regulations [NSNR]; use of toxicogenomics techniques [i.e., finding out why and how difference species respond to differently to pollutants / contaminants] to link observed effects of toxics to specific environmental exposures thereby providing improved 'early warning' signals to industry regulators);

[22] STAGE Presentation to the Environmental Protection Board, July 22, 2005.

- Conservation Biology and Wildlife Management (e.g., development and application of genetic markers to address conservation management and protection issues); and

- Improved Enforcement and Compliance.

In addition to the STAGE program, the Department has allocated some Genomics R&D Initiative funds to research in support of stewardship issues, including GELS (genomics, ethics, law and society), mechanisms to determine the sustainability of genomics techniques and improved citizen engagement and outreach. These projects are delivered by the Environmental Biotechnology Applications Division (EBAD).

The Department is developing a White Paper on Genomics that will make recommendations for future environmental genomics research at Environment Canada.

Theme / Research Priority

In an effort to understand the Department's genomics capacity and R&D needs / opportunities, a call for proposals was released in 1999. The call asked for proposals for the first year of STAGE funding only. A total of 78 proposals were received, of which 23 were funded. The projects fell into one of six areas:

- Applications of Environmental Genomics: Opportunities and Responsibilities;
- Using Genomics to Assess Environmental Effects;
- Using Genomics for Remediation;
- DNA Microarrays and Other Technology Applications for the Environment;
- Genotyping for Assessment and Recovery of Species at Risk; and
- Genotyping for Monitoring and Management of Migratory Birds.

An evaluation of the first year's results was conducted by an internal working group. Findings were discussed at a departmental workshop in April 2000 and were used to re-define program directions in years 2 and 3 of Phase 1. The program themes, which have remained consistent throughout Phase 2 and 3 of the Genomics R&D Initiative funding, are:

- Theme 1: Genotyping – for improved understanding of conservation biology and wildlife management, with particular focus on endangered species and migratory birds, in support of wildlife conservation and management and enforcement of Canadian Environmental Protection Act (CEPA), Species at Risk Act (SARA),

the Convention on International Trade of Endangered Species (CITES), and the Wild Animal and Plant Protection and Regulation of International and Inter-provincial Trade Act (WAPPRIITA).

- Theme 2: Microarrays – for detection and monitoring of pathogens, toxic substances and environmental effects, in support of pollution prevention, ecosystem effects monitoring and conservation of biodiversity.

- Theme 3: Test Methodology Development – soil methods development and use of genomics-based methods for monitoring genetically engineered microbes, in support of the Department's regulatory, environmental assessment, stewardship and enforcement functions (e.g., CEPA).

- Theme 4: Environmental Stewardship Research – includes research involving GELS, identification of next generation genomics research, public outreach and information dissemination.

Phase 1 focused on identifying the needs and opportunities within Environment Canada for genomics research and capacity building (including training, equipment purchase, and laboratory infrastructure). In most cases, Phase 2 projects built directly on the Phase 1 activity and involved the same researchers.

How Initiative is Delivered in Department

The STAGE program is managed by the Environmental Biotechnology Applications Division (EBAD) within the Technology Strategies Division (formerly the Environmental Technology Advancement Directorate [ETAD]). The Program Manager is supported by a senior project officer and one other staff member.

The program activities are spread across Canada. The three themes are delivered by the Canadian Wildlife Service (CWS) and five national labs or research / technology centres (see Table A5). WTC leads the microarray research area and is responsible for building a workplan that integrates the research plans of the four labs, and reporting for this theme. Each lab's STAGE activity is overseen by a principal investigator.

Table A5: STAGE Research Themes and Participating Labs / Organizations	
STAGE Theme	**Organization**
Genotyping	Canadian Wildlife Service (CWS), Canada-wide participation
Microarrays	Wastewater Technology Centre (WTC) – lead Pacific Environmental Science Centre (PESC)* National Wildlife Research Centre (NWRC) National Water Research Institute (NWRI)
Test Methodology Development	Environmental Technology Centre (ETC)
Environmental Stewardship	Environmental Biotechnology Applications Division (EBAD)

* PESC has recently been renamed and is now called PYLET – the Pacific and Yukon Laboratory for Environmental Testing. The acronym PESC is used throughout this report.

Beginning in 2000, annual workplans have been developed for each of the three primary themes; the work at EBAD evolves as needs emerge (e.g., funding is spent on workshops, meetings, etc). The research focus of the labs is described in Table A6.

Table A6: Research Focus of Participating Labs / Organizations	
Lab / Organization	**Research Focus**
Canadian Wildlife Service (CWS)	Genomics R&D activities that address wildlife conservation and include the use of genomics / genetics to investigate the population structures of wildlife and impacts of harvesting practices. The activities support a number of departmental mandates (e.g., SARA, WAPPRIITA).
Environment Canada Research Labs	
Wastewater Technology Centre (WTC)	As the lead on the Microarray theme, WTC established an on-site DNA microarray printing and is using the capacity to detect different types of microbial pathogens in wastewater and characterize the microbial populations that are present in wastewater treatment facilities.
Pacific Environmental Science Centre (PESC)	The objective of PESC's toxicogenomics group is to develop capacity within the Department to use genomics-based tools and genomic end-point measurements (e.g., induction or repression of genes associated with toxic effects) for aquatic ecotoxicity testing.
National Wildlife Research Centre (NWRC)	The toxicogenomics team at NWRC is developing and applying genomics methods and analysis of gene expression to examine the toxic effects of environmental contaminants on wildlife (i.e., to discover how and why species differ in sensitivity and response to environmental contaminants.
National Water Research Institute (NWRI)	NWRI is developing and applying genomics methods to investigate the effects of environmental contaminants on microbial communities. The overall objective is to develop tools / approaches to better assess the environmental effects of priority substances and emerging contaminants (e.g., in support of CEPA, NSNR).
Environmental Technology Centre (ETC)	ETC is using genomic methods to predict the eco-toxicological impacts of individual substances and contaminant mixtures on soil systems. These methods are more reliable and faster than the existing methods, and findings will be used to develop guidance documents for regulatory assessors and industry notifiers.

Source: Draft White Paper on Genomics, Environment Canada.

Reporting is done on a semi-annual basis, and STAGE workshops are also held twice each year.

Resources

Environment Canada has received $1 million per year since the inception of the Genomics R&D Initiative in 1999. The allocation of resources, by theme, is shown in Table A7.

Table A7: Allocation of STAGE Funding to Research Themes			
Theme	**Phase (Years 2 & 3)[1]**	**Phase 2**	**Phase 3 (Year 1 only)**
Genotyping (CWS)	$133,000	$330,000	$165,000
Microarrays	$615,000	WTC – $450,000 PESC – $150,000 NWRC – $150,000 NWRI – $150,000	WTC – $150,000 PESC – $50,000 NWRC – $44,000 NWRI – $50,000
Test Methodology Development (ETC)	$400,000	$600,000	$200,000
EBAD (HQ) (including taxes, one staff salary)	$852,000	$1,170,000	n/a

[1] Year 1 of Phase 1 funding was used to support 23 projects (within the Department and externally). Results were used to refine research priorities and identify theme areas for Years 2 and 3 and subsequent Phases.

The allocation of Phase 1 among capacity building and research activity is shown in Table A8.

Table A8: Allocation of Phase 1 STAGE Funding by Activity			
Theme	**HR Capacity**	**Lab Infrastructure**	**Research Advancement**
Genotyping (CWS)	100%	–	–
Microarrays (WTC, PESC, NWRI, NWRC)	39%	46%	15%
Test Methodology Development (ETC)	42%	58%	–

Estimates provided to the recent Industry Canada review of departmental genomics funding and goals, identified A-base contributions to genomics projects as shown in Table A9.

Table A9: Environment Canada's A-base Contributions to Genomics Projects						
2000/01	**2001/02**	**Phase 1 Total**	**2002/03**	**2003/04**	**2004/05**	**Phase 2 Total**
$484,000	$499,000	**$983,000**	$750,000	$434,000	$439,000	**$1,623,000**

Project Approval Process

Prior to Genomics R&D funding, there was little physical infrastructure and capacity to support genomics research within Environment Canada. The focus of the first year was on the identification of internal capacity, needs identification and planning for a focused program of activity.

After the first year of funding, an analysis of the STAGE-funded activities was completed by Environment Canada researchers. Three research themes emerged, and within two themes (Microarrays and Test Methodology Development) lead researchers in each of the five key labs were identified. Under the guidance of the STAGE program manager, these scientists were responsible for defining the direction of their lab's genomics research and developing workplans. The Microarray workplan was coordinated by WTC and integrated the research plans developed by each of the supporting labs (NWRC, NWRI, PESC). The Test Methodology workplan involved ETC only.

At CWS, a call for proposals went out to CWS researchers. The proposals that came forward were first reviewed at the Regional Director level and then integrated into a single CWS proposal that was submitted to EBAD. The workplans were reviewed by the S&T Advisory Board (STAB) Biotechnology Panel who provided guidance on the overall direction of the program and the distribution of funds. Once the funding levels were identified, the workplans for each theme were finalized.

In Phase 2, EBAD allocated approximately $550,000 per year to the three STAGE workplan areas. No new proposals were considered for funding and it was decided that an even split among the three workplans was equitable. (The balance of the funding was allocated to HQ [$275,000 for communications, GELS, etc.] and a program tax [$175,000]). Research activities were decided upon by the respective lab leads and / or coordinating committee. The requirements placed on STAGE Phase 2 projects were that they:

- continue to enhance Environment Canada's capacity and understanding of the application of genomics;
- explore the potential for responsible application of these advances in fulfilling departmental priorities and improved decision making; and
- prepare the Department to participate in rapidly evolving genomics initiatives.

The funding cycle was two years, with the option of requesting a third year of funding, at the same level, with supporting rationale.

Prior to Phase 3 renewal a meeting of the STAGE community, CEPA New Substances Branch, and Environment Canada Enforcement groups was convened to refine the

Department's biotechnology priorities and determine how genomics tools can play a role. Based on this, and an ADM level discussion of STAGE, the status quo was selected as the path forward (i.e., continue funding as per Phase 2).

A.2.2 Rationale

R1. Are the mandate and the strategic objectives of the Genomics R&D Initiative still relevant? What need was the Initiative intended to address? Does this need still exist?

Document Review

Documents show that the objectives of Environment Canada's STAGE activity have been as follows:

> *"Environment Canada will explore the use of genomic applications to improve techniques for pollution remediation, abatement and prevention; enhance knowledge of ecosystem structure and function; address important problems in conservation biology and wildlife management; and enhance environmental assessment techniques in the application of new molecular tools."*

Presentations to Environment Canada's S&T Advisory Board (STAB) Biotechnology Panel (April 2004) and to the Environmental Protection (EP) Board (September 2005) illustrate strong links between genomics research activities and specific departmental priorities. The presentation to the EP Board was to seek guidance on the next steps of STAGE. The EP Board, while recognizing the potential for genomics, felt that additional context was required before decisions could be reached regarding future Environment Canada investment and activities in environmental genomics. As a result a White Paper, presenting recommendations for environmental genomics at Environment Canada, is being developed. The (draft) White Paper on Genomics outlines the need for environmental genomics research in toxicogenomics (to better understand and apply genomics as a tool for assessing the risks posed by contaminants) and wildlife conservation.

Interviews

The interview findings reinforce the document review findings. Managers and researchers alike indicated that the mandate and objectives of the STAGE program have continued relevance for the Department and see a need for continued investment in this area. Environmental genomics is at the early stages of development and there is a concern that Canada not fall behind other countries in this area. Interviewees see that capacity has been built and directions identified. All managers and most researchers

commented on the need for a larger program, with A-base support, to sustain the capacity developed to date.

A new Environment Canada S&T Strategy is being developed and it is hoped that the conclusions of the White Paper on Genomics and STAGE efforts to date will be reflected (i.e., that the visibility of genomics will be raised and genomics will be better integrated with the broad science strategy).

R2. Is there a legitimate and necessary role for government in this area?

Document Review

Genomics presents an opportunity for the Department to develop new approaches to support its mandated regulatory, enforcement and conservation activities. The public good benefits provide a strong rationale for federal investment in this area.

Genomics research can support an enhanced understanding of biosphere function, improved ability to manage natural systems, effective techniques to rehabilitate and restore contaminated ecosystems, enhanced regulatory capacity, and improvements in wildlife management techniques.

There are a number of specific Departmental priorities towards which genomics research has been targeted, including:

- Remediation and restoration of contaminated sites;
- Toxics reductions;
- Pollution prevention, abatement and detection;
- Regulatory compliance and enforcement (e.g., CEPA, obligations under the Convention on Biological Diversity, the Biosafety Protocol, and the Pest Management Review Agency's [PMRA] Pest Control Products Act);
- Wildlife management;
- Conservation biology and wildlife genetics; and
- Genomics, ethics, law and society (GELS).

Environmental genomics is at a fairly early stage of development, and whole genome sequences for microorganisms of environmental relevance are only now beginning to be published. The knowledge can improve remediation techniques as well as the ability to predict adverse environmental impacts before they happen. To effectively address environmental effects monitoring and emerging issues such as the effect of genetically modified organisms, further research is required.

Environment Canada's White Paper on Genomics states that "genomics will change the way in which Environment Canada and other agencies tasked with protecting the environment and wildlife execute their mandate. Genomics will impact the process by which ecological risks are assessed and managed, wildlife conservation is conducted and regulatory decisions are reached".

Interviews

As noted by several management interviewees, Environment Canada has a unique mandate as compared to the other five departments involved in the Genomics R&D Initiative. There are a number of regulatory and enforcement obligations under CEPA, Canadian Environmental Assessment Act (CEAA) and other Acts that genomics techniques can support. As explained by one manager: "We can improve the 'smartness' of our existing oversight by developing new (genomics) tools. For example, we may see a transition from taking a total population approach to one that identifies specific cohorts. With this new capacity, we can refine our regulations to focus on the specific areas / populations that are the most vulnerable." The promise of environmental genomics is faster, more precise and more efficient measurement techniques that do not depend on animal testing. (Several interviewees mentioned that concerns with animal testing are driving the development of a number of alternative genomics-based research tools in Europe.)

Several managers and researchers noted the competing roles that Environment Canada plays in the biotechnology / genomics areas; that is, there is a need to develop both applications and regulations. According to one manager, this balance has at times been difficult to attain and this may have slowed progress in both areas.

Stakeholder interviewees responsible for the assessment of new substances view the need for in-house genomics capacity as critical to effectively meeting Environment Canada's mandate: "This kind of research cannot be sub-contracted to university researchers or the private sector". For example, the work at ETC (to use genomic methods to predict the eco-toxicological impacts of individual substances and contaminant mixtures on soil systems) has focused on the detection of DSL substances and project outcomes will directly support Environment Canada's regulatory program.

One researcher noted that: "A lot of the research has the potential to support regulation development, but this has yet to happen. The microarray work is getting close to application, while the toxicogenomics work will require more development (five to ten years away from application). CWS is closest in terms of application, using findings to support conservation planning." Within CWS, researchers noted the importance of understanding the genetic structure of species (possible through the application of genomics tools) to be able to differentiate between species, map their geographic range,

and to know what to preserve. This information guides management strategies and recovery plans.

A number of researchers felt that Environment Canada could play a role in bringing environmental genomics researchers together. To date there have been limited efforts to do this and the impact has been a low profile for environmental genomics.

Several managers and researchers commented on the role played by international governments in this field. The UK, Holland, Germany and France are viewed as world leaders with respect to funding programs, the application of genomics tools and techniques and bioinformatics.

A.2.3 Success

S1. Have the individual departments achieved, or made progress towards, their specific objectives / goals?

Document Review

The objectives and goals of the STAGE program are to: (1) explore the use of genomic applications to improve techniques for pollution remediation, abatement and prevention; (2) enhance knowledge of ecosystem structure and function; (3) address important problems in conservation biology and wildlife management; and (4) enhance environmental assessment techniques in the application of new molecular tools.

The three research theme areas address these objectives: the Microarray Theme addresses Objective 1; the Genotyping Theme addresses Objectives 2 and 3; and the Test Methodology Theme addresses Objectives 2 and 4.

Based on a review of project progress reports there is evidence that projects have met their specific objectives and are aligned with the above themes.

Interviews

All managers interviewed believe that STAGE funds were allocated to the three core areas in direct support of departmental priorities. Specific goals were set by the three workplan managers and progress towards project milestones is reviewed semi-annually. The STAGE program manager believes that 'the objectives have absolutely been met'. All researcher interviewees described progress towards their projects' goals.

Examples of progress to date can be found under Issues S2 through S5.

S2. To what extent did the projects funded under Phase 1 of the Genomics R&D Initiative build capacity inside government laboratories to carry out genomics research?

Document Review

The focus in Phase 1 was on identifying needs and opportunities, and planning and building capacity within Environment Canada organizations. Select Phase 1 outputs / outcomes, as reported in annual reports, are summarized in Table A10.

Table A10: Phase 1 Example Outputs and Impacts on Capacity

Research Program	Organization	Funding (2000/01-2001/02)	Outputs / Impact on Capacity
Genotyping Tools	Canadian Wildlife Service	STAGE: $133k Levered: $666k	▸ Identified knowledge gaps and the long-term need for genetic tools within CWS. ▸ Completed a report detailing a review of projects and the need for genomics research within CWS to aid in wildlife management, conservation and protection. ▸ Identified the need for a 'CWS Wildlife Genetics Primer' to orient researchers to the range of uses of genomics tools. (This is now available on-line.) ▸ Identified the need for a DNA / Tissue Bank to manage samples over the long-term.
Microarray Development	WTC (PESC, NWRI, NWRC)	STAGE: $615k Levered: $533k	▸ Supported the development of biosensors by five different Environment Canada laboratory research groups, each comprising two to five researchers. ▸ Developed knowledge on the use of DNA microarrays for the detection of pathogens in municipal wastewater, the potential of endocrine disruptors to affect the early life stages of amphibian and salmon, avian wildlife toxicology and, environmental effects monitoring. ▸ Developed knowledge used to develop new ways to assess environmental contamination, the effect of endocrine disruptors, and ecomonitoring. ▸ Purchased equipment, including a DNA Microarray Reader and -80^{o}C freezer (WTC).

Table A10: Phase 1 Example Outputs and Impacts on Capacity			
Research Program	**Organization**	**Funding (2000/01-2001/02)**	**Outputs / Impact on Capacity**
Test Methodology Development	ETC	STAGE: $400k Levered: $180k	▸ Completed a report on the state of soil microcosm testing internationally and a comparison of the degree of standardization of various test methodologies. ▸ Completed the renovations necessary to house a toxicology lab for continued research on test methodology required for identification of DSL (Domestic Substance List) listed soil fungi. ▸ Purchased lab equipment, including a plant growth chamber and temperature-gradient Polymerase Chain Reaction (PCR).
Environmental Impacts of Genomics GELS Citizen Engagement and Public Outreach	HQ		▸ Completed a detailed literature review. ▸ Initiated a formal dialogue with the United States Environmental Protection Agency (USEPA) and the British Biotechnology Scientific Research Branch on complementary environmental genomics R&D. ▸ Convened a meeting of Genome Canada GELS centres. ▸ Convened a workshop with university scientists. ▸ Developed a primer for scientists on 'Ethical Issues of Environmental Biotechnology Research'. ▸ Prepared a series of fact sheets outlining how genomics can address environmental protection, biodiversity conservation and wildlife management issues.

Interviews

All interviewees noted that prior to STAGE funding there was little genomics capacity within the Department; as a result, they view the program as fully incremental. Managers and researchers alike agreed that Phase 1 objectives were achieved to the extent that capacity and needs were identified; Phase 2 allocated more funding to capacity building and developing research projects. In Phase 3, a more solid connection between researchers and end-users (e.g., regulatory and enforcement groups) is being made. According to one interviewee, as a result of STAGE "people within the Department now know what genomics is". Others felt that more could be done to communicate what the Department is doing, both inside and outside the organization.

One research centre manager noted that Phase 1 helped identify those scientists best able to explore the use of microarrays and other sequencing projects to enhance their research directions. This led to the identification of lead researchers for each lab, all of whom continue to receive funding.

Within CWS the Genotyping program of activity exposed biologists to the application of genetic tools to resolve conservation issues. (Table A8 shows that 100% of CWS Phase 1 funding was used to support the development of human resources capacity.) New capacity supports legislated responsibilities under the Migratory Birds Convention Act and the Canada Wildlife Act. The projects have helped to build partnerships among the regions and with biologists in the US and researchers of hemispheric and circumpolar nations sharing species.

With respect to physical infrastructure, the STAGE funding was used to build a Level 2 security soil lab (for the measurement of micro-organisms) at ETC. (In fact, 60% of ETC Phase 1 funding was spent on infrastructure, and the balance on human resources development.) Prior to this, Environment Canada had several projects with Carleton University's soil microbiology lab (a Level 1 facility).

Within the microarray research theme, 40% of Phase 1 funding was spend on human resources capacity development, 45% on infrastructure and 15% on research. At PESC, funding was used to develop the capacity and infrastructure to undertake environmental genomics for salmonids. Prior to STAGE, there was no departmental capacity for this work. Now the only aspect of microarray work not done at PESC is the printing of gene arrays, which is done at the British Columbia Cancer Research Institute. The Centre now has three staff dedicated to genomics, two of whom are new hires. With the capacity developed under Phase 1, the lab was able to access funding ($175,000 per year for five years) from the Georgia Basin Action Plan to examine the impact of chemical and pharmaceuticals on fish species.

STAGE (Phase 1 and 2) also supported a number of post-graduate and post-doctoral researchers, and helped develop new skills and expertise within the federal system. However, the capacity is threatened by a lack of A-base support for Genomics. As one interviewee explained, "people can't be managed on a three year basis".

S3. Did this increased capacity strengthen the research carried out in the departments?

Interviews

Researchers and management interviewees felt that the genomics workshops at Environment Canada that bring together researchers from across the Department have helped to identify areas of possible cooperation / collaboration and strengthen research

programs within the Department. Several researchers noted that with enhanced capacity, greater connections between the end-users (e.g., regulatory, enforcement) and researchers are now possible. These new connections can inform / strengthen the research conducted within the labs and by CWS.

According to one lab researcher, the new genomics capacity will allow the labs to compete for new sources of funding, such as those available through the Pesticides and Emergency Preparedness programs.

A stakeholder noted the importance of microarray facilities to the work of Environment Canada, given the limitations of other techniques for detecting micro-organisms (e.g. pathogens) in the Environment. "For compliance promotion and enforcement, we need tools that demonstrate with certainty the levels of micro-organisms."

Another stakeholder noted that, without STAGE, the CRSB program would not be working as well as it is and that the development of test methodologies and tools would have to have been contracted out.

Within CWS, the availability of STAGE funding led the researchers to use new tools in their work. The STAGE funding is used to lever funds from other sources (e.g., US Fish and Wildlife Service, Arctic Bird Joint Venture). The 'genomics work' (i.e., genetic testing) is done outside CWS (either within Environment Canada labs, universities, or US organizations). As stated by one wildlife biologist: "The new perspective provided by genetic studies changes the way we will approach wildlife management."

Researcher interviewees gave numerous examples of how STAGE projects have led to new international linkages / partnerships, a better understanding of the international genomics R&D situation, and expanded the scope of their research.

S4. Did this increased capacity created in Phase 1 translate into the benefits of advances in research and technology in Phase 2 for department constituents?

Document Review

Phase 1 activity (see Annex D for a list of projects) was used to identify research needs and opportunities, support the development of research capacity (hiring and training) and infrastructure (equipment purchases and laboratory renovations). Phase 1 led to some progress on the development of tools and techniques; however, it was not until Phase 2 that the labs began to apply microarrays and test methods. Some examples of how capacity from Phase 1 led to advances in technology in Phase 2 follow.

Genotyping

- CWS is developing and applying genetic markers to help with the delineation of discrete population units for migratory species and species at risk, the investigation of the effects of harvesting on specific populations and the development of DNA-based identification system for a number of species (e.g., Brant Geese, Canada Geese, Polar bears, Common Eiders). These projects support a number of Acts and international conventions, including SARA, Migratory Birds Convention Act, the CITES and the Convention for the Conservation of Biological Diversity.

Microarrays

- At WTC the development of DNA microarrays are being used for the detection of pathogens in municipal wastewater. The WTC also developed a DNA microarray tool to allow for faster aquatic chemical toxicity monitoring, faster evaluation of CEPA chemical categorization and environmental effects monitoring.

- NWRI is developing and applying genomic methods for environmental effects monitoring and examining the effects of single and multiple stresses on microbial community diversity and function. NWRI is also applying microarrays to assess effectiveness for ecosystem restoration monitoring.

- PESC is applying genomic techniques to produce a better understanding of the potential deleterious effects of endocrine disruptors associated with effluents from pulp and paper mills and municipal wastewater (on salmonids and amphibians). This information can be used to improve 'early warning' signals to industry and regulators. PESC is the only federal lab with the capability / infrastructure to undertake environmental genomics for salmonids. (Salmonids are a sentinel indicator species used to assess the effect of stressors on commercially important species of fish.)

Test Methodology Development

- At ETC the development and standardization of genomics-based procedures are being used to ensure more accurate data under the New Substances Notifications Regulations.

- ETC has developed an in-house capability to conduct pathogenicity and toxicity testing of microbial substances in soil. The Centre is generating data on the potential toxicity, pathogenicity, survival and persistence of DSL microbial substances in soil. This data is needed for the screening level risk assessment required for all DSL substances, a CEPA 1999 obligation.

Interviews

According to one senior manager: "The research is meeting the needs of the Department, is well leveraged and has built good partnerships (nationally and internationally)."

The lab scientists (at ETC, WTC, etc.) all noted the importance of Phase 1 support for capacity building to the Phase 2 projects. The CWS researchers involved in Phase 1 used this funding to establish the foundation for research that followed in Phase 2. Some examples follow.

- A CWS researcher described how Phase 1 led to the development of techniques for genetic analysis, supported the development of a database of samples going back 100 years, and led to a strategic partnership with Queen's University. The project expanded the understanding of population dynamics, population connectivity, genetic diversity and population viability. This increased capacity helped focus research activities and led researchers to take a more proactive and science-based approach to conservation strategies / recovery plans.

- A scientist at PESC explained how each Phase of funding built on the previous Phase's results. Phase 1 focused on the development of the microarray, Phase 2 on quality control and verification, and Phase 3 on the application of the array to improve the quality of gene expressions. With this new capacity, the Centre was able to participate in Georgia Basin Action Plan and helped a collaborator access NSERC funding. In addition, the Emergencies Division of the Department is interested in the use of the array for spill response planning. "Because the type of toxics that we are now seeing are not easy to measure, we will need to re-tool and find better ways to support the *Fisheries Act* and other regulations."

Funding for genomics has helped to increase the international visibility of Environment Canada's work. Two STAGE researchers have been invited to write a chapter on environmental genomics by the Society for Environmental Toxicology and Chemistry (SETAC), an international effort. Environment Canada has also participated in the Pellston series of workshops sponsored by SETAC.

One researcher noted that NWRI's microarray research (the application and optimization of DNA microarrays for environmental effects monitoring conducted in partnership with BRI) has raised the profile of genomics within the Department. The project has been well-regarded internationally and the lab has received a number of requests for information, speaking invitations, etc. NWRI is now developing applications and using the tool to work with the Department of National Defence on an arctic contaminated site, with Health Canada on toxic substances and pharmaceutical research, and within Environment Canada on CEPA samples.

S5. To what extent has the Initiative strengthened coordination, cooperation and linkages between the appropriate research institutions?

Document Review

As noted in the 2000 STAGE Workshop Report and re-stated in the 2006 (draft) Environment Canada White Paper on Genomics, there is no focal point within Canadian academia, industry or the Environmental Non-Governmental Organization (ENGO) community to champion a national network on environmental genomics within and beyond the Genome Canada context. According to the 2000 Report, "Canada needs to develop a vehicle in environmental genomics that will allow for coordination of efforts within the scope of domestic and international commitments to the environment and its protection." A Canadian Environmental Genomics Network, to provide an umbrella for Canadian environmental genomics research and researchers inside and outside government in Canada and internationally, was proposed. The Environmental Technology Advancement Directorate (ETAD) was to champion and coordinate the development of the Network, which would, in part, help the community to secure external funding (e.g., through Genome Canada). This has not yet happened.

The proposals, workplans and reports provide evidence of coordination, cooperation and linkages between Environment Canada labs and researchers and other organizations.

A review of the STAGE workplans and reports identified a number of research partnerships for each project.

Interviews

Researcher interviewees provided many examples of research linkages established to access expertise and lever STAGE funding. Most projects involve collaboration with universities (e.g., PESC with University of British Columbia, ETC with Carleton University, WTC with University of Guelph and NRC's Biotechnology Research Institute [BRI], NWRC with University of Ottawa, and NWRI with BRI). Some involve collaboration with international labs, other government departments' labs and other programs (e.g. CRSB). No research partnerships with industry were identified.

According to a management interviewee, while there is evidence of inter-departmental cooperation at the working level, there is no evidence that the Genomics R&D Initiative helped to build higher-level strategies or that there is a systematic approach to identifying opportunities for collaboration. At the working level, one researcher is sharing ideas on genomics methods with Health Canada researchers and another has developed research linkages with the principal investigators on Genome BC's Genomics Research on Atlantic Salmon Project (GRASP) and exposure testing results are shared across the two

programs. A PESC researcher has linkages with DFO's West Vancouver Lab (fish genetics). A number of researchers saw the potential for future partnerships, once test methodologies and tools have been developed and validated, specifically with AAFC, DFO and NRC.

One researcher noted that his work has led to a number of new linkages, within Environment Canada (among researchers and with policy groups) and externally. For example, a presentation was made to the Department of Justice to demonstrate the use of new technologies to measure the impact of endocrine disruptors at the gene level. This new approach would replace traditional testing methods that assess impacts at a much higher level (e.g. death and reproduction rates).

A three-day workshop with Genome Canada was conducted in 2004 to bring environmental genomics practitioners together. Opportunities for better partnerships with Genome Canada have been explored but have not been successful to date. Several management and researcher interviewees felt that a more complete genomics vision needs to be developed, one that "recognizes the importance and complexity of the file and has effective accountability mechanisms for the work". There is some frustration with the level of Genome Canada support for environmental projects to date, estimated to be approximately 3% of Genome Canada's total budget.

The Department has established linkages, at the management level, with the USEPA and the ERC. These are used to stay current with international activities. (The United Kingdom is seen to be a world-leader in environmental genomics.)

One researcher noted that STAGE funding has helped to establish international credibility of the Department's work on toxicogenomics (i.e. finding out why and how difference species respond to differently to pollutants / contaminants). With STAGE funding, he organized a workshop on toxicogenomics and the application to wildlife toxicology in Michigan, was able to attend an OECD meeting on toxicogenomics in Japan, and made lab visits to the US and Europe. The researcher believes that without STAGE funding progress would have proceeded at less than one-half the rate that is has.

S6. What have been the facilitating and impeding factors for the success of Phases 1 and 2 of the Initiative?

Interviews

Factors facilitating the success of Phase 1 and 2 identified by interviewees include:

- Strong leaders at each lab, and well-respected researchers, have helped to lever funds and build partnerships in support of STAGE projects.

- STAGE funding pushed the research agenda and facilitated collaborations with university labs and others (e.g. PESC with University of British Columbia, ETC with Carleton University, WTC with University of Guelph and NRC's Biotechnology Research Institute (BRI), NWRC with University of Ottawa, and NWRI (Saskatoon) with BRI). These research partnerships have been critical to the success of STAGE projects.

Factors impeding success include:

- The level of funding allocated to Environment Canada (and the 19% tax faced by STAGE – 13% to ADM, 6% to Biotechnology Secretariat) has limited the size of the program. The Department expected to receive more funding in Phase 2 (based on its Phase 1 performance and the identification of environmental genomics opportunities). However, Phase 2 (and Phase 3) funding levels have remained unchanged from Phase 1. As noted by program management, the STAGE program has been over-subscribed from the beginning.

- The timing of fund distribution is problematic; because funding is not available until well after April 1, filling Post Doctoral Fellows and other graduate positions can be difficult. This has been an annual issue.

- NRC leads the intramural program, while Industry Canada and Genome Canada have a parallel planning process. This is seen to cause barriers to integration of research efforts and result in an imbalance in funding available for environmental genomics.

- The complexity of the file presents management challenges – both in terms of identifying priorities and communicating the role of genomics research to senior management and the public. Management turnover and reorganization at Environment Canada has complicated the management of the program as new managers have to be brought up to speed.

- There is no critical mass of environmental genomics resources across Canada (within either the federal government, academia or the private sector) upon which to build larger projects.

- The lack of a departmental vision or strategy for genomics is seen as a barrier. For example, several researchers felt that an integrated departmental strategy may have led to the creation of a centre of expertise for genotyping within the Department. Without this, much of CWS's genetic testing has been done by universities and other labs, sometimes outside Canada. The administrative costs of working with universities is estimated at 25% to 40% of the total project value.

- Several researchers felt that the program could benefit from more rigorous proposal review. However, others felt that external peer review would be cost-effective only if the program was larger.

S7. Are there other intended and unintended impacts resulting from Initiative?

Interviews

The STAGE program has improved linkages across the Department, through semi-annual STAGE meetings and meetings of sub-groups (e.g., CWS, Microarray sub-group). For example:

- Within the microarray research theme, communications among the four labs has been strengthened. As most of the capital investment for microarray research was allocated to WTC, this lab has developed the capacity for printing and is providing this service to the others (NWRI, NWRC, PESC).

- There has been some exchange of personnel involved in STAGE among the labs which has facilitated greater interaction among the labs.

- The Phase 2 workshop (held in September 2003) was attended by 17 people from across the Department. Participants reviewed research efforts underway, discussed priorities and allocations for the final year of Phase 2 and identified opportunities for the STAGE community to collaborate with other initiatives in the area of environmental genomics.

S8. To what extent would the impacts have occurred without the Initiative?

Interviews

All interviewees agreed that without the Genomics R&D Initiative the capacity building of Phase 1 would not have been possible. While there is some A-base contribution to this technology area (see Table A8), researchers report that this support was leveraged by the STAGE funds (i.e., without the initial STAGE investment, the A-base investment would not have occurred). Without the capacity building of Phase 1, the application of microarrays, genomics test methods and, especially, genomics techniques to wildlife conservation seen in Phase 2 would not have been possible.

No other sources of funding were identified by the lead researchers or managers. There was consensus that the STAGE program is unique and without it the progress described in previous sections (see S2 and S4) would not have occurred within the time frame that it did.

A.2.4 Cost-Effectiveness / Alternatives

C1. Does the Genomics R&D Initiative complement, overlap or duplicate other federal or provincial initiatives related to genomics or biotechnology?

Interviews

Those researchers aware of the various initiatives that support biotechnology R&D and management interviewees view the STAGE funding as (mainly) complementary to the other investments in biotechnology, within the federal government (e.g. CRSB, CBS), in universities and by Genome Canada. According to management interviewees, the processes for managing CRSB and STAGE have been aligned to ensure complementarity across the two programs. Generally, the two programs' activities / projects are seen as complementary, with STAGE building genomics-based capacity and tools while CRSB projects address the broader application of biotechnology to regulatory needs. However, one stakeholder interviewee noted that some researchers (within the labs) have submitted similar proposals to, and received funding from, both STAGE and CRSB.

According to one researcher STAGE has found a niche: Genome Canada's projects focus on commercialization, while Environment Canada uses its genomics capacity for enforcement and regulation (areas where academia and industry will not do the work). While the techniques and tools may be similar, the applications are different. Most interviewees (managers and researchers) felt that there is a disconnect between the federal genomics efforts and those of Genome Canada.

No provincial initiatives were mentioned by the interviewees.

C2. Is the funding structure of the Genomics R&D Initiative the most appropriate mechanism for achieving the intended objectives? Are there more cost-effective alternative ways to achieve the Genomics R&D Initiative mandate?

Interviews

In general, management interviewees did not take issue with the funding mechanism and did not suggest more cost-effective ways to achieve the Initiative's mandate. However, there was frustration on the part of managers and researchers that the *level* of Genomics R&D Initiative funding allocated to each department was not re-visited prior to the start of each phase. Management and researcher interviewees felt that, as the Department's capacity to undertake environmental genomics grew and needs were identified, the annual allocation would be increased (from $1 million).

Several researchers in particular were frustrated by the low level of funding allocated by Genome Canada to environmental genomics; only 3% of total funding although environment was intended to be an area of focus. In an effort to address this, Environment Canada and Genome Canada co-hosted a workshop in October 2003 to discuss opportunities for environmental genomics. (A management interviewee felt that resources may have been better spent organizing the environmental genomics R&D community across Canada so it would have been better positioned to respond to a Genome Canada RFP.)

A stakeholder noted that, by giving the funding directly to the six departments, there was no requirement for departments to coordinate with each other. (Unlike the approach used by CBS, which requires greater cooperation among departments.) It was suggested that two departments could undertake similar work and not be aware of it.

C3. Is the three year funding cycle appropriate for achieving intended outcomes?

Interviews

Three years is seen as a standard funding cycle for federal R&D programs and, other than a few comments by researchers that a five-year cycle would allow for longer-term research projects, there was no real concern with respect to the funding cycle. Several noted that, given the pace at which the technology is changing, three years is an appropriate time frame for projects.

As noted above, the more significant issues associated with funding were:

- Timing of funds: funds are not released until well after April 1. Last year, several CWS projects did not proceed because the funding came after the field work was to have started.
- Amount of funding: the annual allocation to Environment Canada has remained constant since the beginning of the Genomics R&D Initiative. It was hoped that, as more was learned about the application of genomics tools and techniques to environmental issues, that the amount of funding would be increased.
- Taxes: 19% of the Genomics R&D funding to Environment Canada is taxed, dropping the annual research budget to just over $800,000.
- Lack of A-base: there is no secure source of funds to support the capacity that has been developed under STAGE or to undertake long-term projects (e.g. monitoring). While STAGE funding supports capacity development, “people can’t be managed on a three-year basis” and equipment and lab facilities need to be maintained.

C4. What has been the level of effort or cost required by departments / agency to participate in this horizontal initiative? What have been the benefits?

Interviews

Most managers commented that the Genomics R&D Initiative is not truly a horizontal initiative as no entity was created to manage the program (e.g., a Secretariat that would ensure coordination [by design] on an on-going basis). A management interviewee felt that the various committees set up to oversee and coordinate the work across the departments have been inactive and / or ineffective: "We could have benefited from a shared vision, but each department went their own way."

Generally managers felt that the level of effort to participate in the Initiative was not significant, and that the program was well managed by NRC. One interviewee noted that it was useful to meet with other departments to identify areas of potential collaboration and avoid duplication. (Note: It is not clear how often these meetings take place.)

A.2.5 Design and Delivery

D1. Is the position of the Genomics R&D Initiative appropriate within the larger government biotechnology strategy? Is the level of integration with other federal government biotechnology programs appropriate?

Document Review

Environment Canada also receives funding from the CBS ($925,000 in 2004-2005) and the CRSB ($1.6 million in 2004-2005), bringing the total biotechnology program to approximately $3.8 million.

Interviews

Most who were aware of the broader biotechnology strategy and programs felt that the Genomics R&D Initiative was well integrated with other funds. (At Environment Canada, the Initiative is integrated with the Bio-based Economy Program, as well as CRSB and CBS.) In the absence of A-base support, the need for a separate fund for genomics research was mentioned by a number of researchers and managers. STAGE is viewed by the lab researchers as a unique program in that it allowed them to address capacity (human resources and equipment) needs; most programs focus on answering specific research questions and providing deliverables.

D2. How effective is the overall governance structure for the Initiative and departmental processes (e.g., project approval process)? Are the roles and relationships clearly defined and appropriate?

Document Review

The STAGE program was established to manage the genomics R&D allocation. A committee of senior scientists from the Department's regulatory, ecosystems science, wildlife and environmental technology advancement groups was struck to oversee project selection and program delivery. This committee reports directly to an Environment Canada Core Director General Biotechnology Management Committee.

Interviews

The process for identifying and approving projects has evolved from Phase 1. In the first year, 'a wide net was cast to find projects'. Twenty-three projects were funded in Year 1 and an internal committee was used to refine the focus of the research activities to three areas. Two mechanisms were used to help set research priorities: the Science Advisor to the Deputy and the STAB Biotechnology Panel. (Note: Both these groups were disbanded in 2004. The program now receives some direction from the Environmental Protection Board.) The workplans developed in Phase 2 have carried over to Phase 3; that is, there has been no significant change to the research programs. Semi-annual meetings of the research community are held to review progress and refine directions.

All interviewees felt that the roles and responsibilities are clear, and that the process for distributing funds was well-understood. This may be attributed to the fact that the key principal investigators involved in STAGE have been involved from the beginning.

Some researchers felt that it may be difficult for new researchers to become involved in the STAGE program and that a competitive process may lead to better projects. To date, the funding has been allocated within the themes on a 'consensus basis'. Some researchers felt that this approach has led to a 'cementing' of funds that makes it difficult for new projects / researchers to secure funding.

Reporting is done on a semi-annual basis, using a standardized format (see D5 for more detail).

D3. To what extent have the departments been able to leverage the funds provided through the Genomics R&D Initiative? What are the pros and cons associated with the leveraging requirements?

Document Review

Documents show that Environment Canada was able to lever its $3 million STAGE funding with an additional $2.4 million over three years (Phase 1). These funds were used to create the Environmental Biotechnology Applications Division.

Estimates provided to the Industry Canada review of genomics funding and goals, estimated A-base contributions to genomics projects in Phase 1 at $983,000 and in Phase 2 at $1,623,000 (see Table A9).

Interviews

All researchers mentioned the in-kind support they receive from research partners at universities and other research organizations. Researchers at the five laboratories involved in STAGE levered a significant amount of A-base and other funding. For example, WTC received $150,000 per year from STAGE and the new soil lab that was built cost $1.2 million.

Several researchers noted that the STAGE funding helped to improve their credibility with lab management and increase the visibility of genomics. This in turn helped lever additional funding for equipment purchases (from the Department's capital pool) and hiring.

D4. How effective / appropriate is the Initiative's approach to performance measurement? What performance measures should be captured in the next phase and why?

Document Review

No performance framework (e.g. a Results-based Management and Accountability Framework or RMAF) was developed for the STAGE program. (Note: The Genomics Performance Framework (November 24, 2000) required participating departments to develop RMAFs and monitor genomics related R&D activities using performance indicators established for those activities.)

The project managers provide a progress report at mid-year and year end. CWS collects reports from its project managers and submits a summary when required.

A standardized reporting template has evolved and now includes: Project Description, Status of Deliverables (including a list of publications and presentations), Report on Budget, and Report Against STAGE Objectives. The objectives are:

- Enhancing HR Capacity;
- Investment in Laboratory Infrastructure / Methodology Development;
- Advancement of Genomics Applied Research in Support of Environment Canada's Priorities; and
- Complementary Initiatives, Partnerships and Leverage.

Interviews

Researchers noted that they do not have systematic access (e.g., through a website) to information on STAGE projects or the Genomics R&D Initiative more broadly. Several noted that the annual reports focus on outputs (deliverables) but that there is no formal system for tracking results (outcomes).

There were no suggestions made with respect to the performance information that should be collected in the next phase.

D5. How could the Genomics R&D Initiative be improved? What changes are required to make the Initiative more efficient?

Interviews

Management interviewees felt that the Initiative was well-administered; however, more consistent and stable funding is required to ensure that the capacity developed to date can be maintained.

A senior manager noted that, at this point in the program, it would be beneficial to introduce an organization that would meet regularly to identify government-wide priorities and support horizontal accountability for the research. This issue of coordination is seen to be a problem across the biotechnology area. One stakeholder noted that, because biotechnology is an enabling technology that cuts across many government departments, stronger horizontal management is needed to ensure that all relevant issues are addressed. There are a number of examples of this kind of horizontal management (e.g., delivery of CEPA) from which best practices could be drawn.

Several managers and stakeholders noted that Environment Canada also needs to 'get its own house in order'. The White Paper on Genomics, upcoming S&T Strategy and re-organization are steps in this process. A-base support would provide a more secure basis upon which the Genomics R&D Initiative could build. A number of researchers felt that a barrier to a greater commitment to genomics research is the lack of understanding by

senior managers of its potential. As one noted: "We need an overall Departmental science strategy that brings together these funding programs. Funding cycles and reporting (for STAGE, CRSB) should be better aligned".

A.3 Fisheries and Oceans Canada

The following is a supplementary report to the main report on the Evaluation of Genomics R&D Initiative that describes those aspects of the evaluation specific to the Fisheries and Oceans Canada. This report is based on information collected in a review of program and other related documentation. In addition, 15 in-depth interviews were conducted – four with program management, eight with project leads / researchers (representing all research organizations involved in the program) and three with stakeholders.

A.3.1 Brief Profile

Strategic Approach

DFO has recently developed an *Aquatic Biotechnology and Genomics Research and Development Strategy* that aims to foster strong linkages among science, policy development and decision makers. The strategy is designed to support DFO's regulatory responsibilities, healthy and productive aquatic ecosystems, and sustainable fisheries and aquaculture. DFO's strategic vision for 2015 is to have:

> *"A successful, innovative, dynamic biotechnology and genomics program to enhance the sustainability of our aquatic resources and ecological health of our aquatic ecosystems, that is characterized by strong partnerships and stakeholder involvement; innovative research programs; the application of effective biotechnology and genomics tools and products; and funding to maintain required expertise."*[23]

Theme / Research Priority

The strategy has four priority research themes which are each supported by a number of specific objectives.

[23] Aquatic Biotechnology and Genomics Research and Development Strategy: Shaping the Future, draft May 25, 2006.

Table A11: Theme / Research Priorities	
Research Themes	**Objectives**
Biotechnology and Aquatic Resource Management	▸ Identify genetic markers to improve species, strain and stock identification for fisheries management and to allow for the protection and enhancement of biodiversity and aquatic fish habitat, including species at risk. ▸ Improve biotechnology knowledge base for enhanced sustainability of aquaculture production; increase strain development and enhance biotechnology tools for identification and control of aquaculture species. ▸ Enhance and apply research on population genetics and genomics to identify and monitor response of aquatic organisms due to environmental factors.
Biotechnology and Aquatic Animal Health	▸ Develop, validate and employ molecular techniques to detect and identify endemic and exotic pathogens. ▸ Incorporate molecular techniques in studies on epidemiology and transmission of aquatic pathogens for disease management. ▸ Apply biotechnology-based techniques for the treatment and prevention of aquatic animal diseases. ▸ Integrate biotechnology and other technologies in assessing the impact of disease in aquatic animals through risk analysis.
Biotechnology and Aquatic Ecosystem Integrity	▸ Develop and apply genomic indicators to detect and monitor environmental stress in aquatic ecosystems. ▸ Develop genomic tools to understand biological processes for mediating natural recovery in contaminated sites, and for development of bio-remediation technologies for mitigation. ▸ Develop sensitive tools based on genetic methods to detect and monitor invasive species and assess potential impacts. ▸ Improve measures of ecosystem health using meta-genomics and other biotechnology and genomics tools.
Novel Aquatic Animal Regulatory Science	▸ Enable risk assessment science through the identification, development and evaluation of appropriate novel aquatic animal models. ▸ Conduct studies in support of risk assessment methodology and the design and implementation of regulations. ▸ Develop and evaluate the efficacy of preventative and mitigative measures to prevent interaction between wild and novel aquatic animal strains (containment strategies). ▸ Assess potential ecosystem impacts of transgenic aquatic animals.

How Initiative is Delivered in Department

DFO's Office of Aquatic Biotechnology (OAB) is the lead organization for coordinating the Department's biotechnology efforts. The OAB, through the National Biotechnology Coordinators Committee (NBCC) and in conjunction with Department sectors, coordinates the Aquatic Biotechnology Program and will oversee the strategy's implementation. In addition to the Genomics R&D Initiative, the OAB also coordinates DFO's activities with respect to the CBS and CRSB funds.

Resources

DFO has received approximately $900,000 per year since the inception of the Genomics R&D Initiative in 1999. Under the initial Genomics R&D Initiative investment of $2.5 million (FY 1999-2000 to 2001-2002), eight projects were funded to develop genomic and biotechnology applications in support of an integrated wild fishery and aquaculture research program. Under Phase 2, DFO expanded its applications to other species and broadened the scope of its work by additional technological refinements. Seven projects were funded under the $2.7 million Phase 2 investment and a further eight projects have been selected for Phase 3 of the Genomics R&D Initiative.

Project Approval Process

The project approval process within DFO has evolved since 1999. Genomics funding allocations are based on the four DFO priority research areas identified above. A call for letter of intent is distributed to principle investigators through the NBCC. A review panel at DFO National Headquarters determines which projects should be further developed into full proposals based on: the letter of intent describing the project; current departmental and science priorities; existing capacity and expertise; track record of meeting previously funded project deliverables; and the available funding envelope. Once the initial project allocations have been determined, full proposals are submitted to the National Coordinator and evaluated through anonymous peer review for technical and scientific robustness. Approved and funded projects are entered into the recently developed the Aquatic Biotechnology Research Tracking Application. There is a requirement for primary researchers to up-load project details and maintain project information on a bi-annual basis and submit a final project report upon completion of the project.

A.3.2 Rationale

R1. Are the mandate and the strategic objectives of the Genomics R&D Initiative still relevant? What need was the Initiative intended to address? Does this need still exist?

Document Review

Program documentation for Phase 1 of the Genomics R&D Initiative stated that Fisheries and Oceans would use genomics for the aquaculture industry and in the management of the wild fishery, leading to better disease identification and control, and better fish movement policies; develop techniques to accurately determine the population structure of wild marine fish; and identify endangered species and minimize illegal or inadvertent harvesting.

DFO was to also work with NRC and EC to develop molecular bio-test for oil spill remediation. It was also stated that DFO would work with the province of British Columbia to map the Y chromosome for Atlantic salmon to facilitate the use of all-female stocks for aquaculture. In addition, international collaborations with US and Korean researchers were also identified.

The documentation reviewed indicates that the mandate and strategic objectives of the Genomics R&D Initiative continues to be relevant to DFO priorities. Key departmental priorities are outlined in the *2005-2010 Strategic Plan: Our Waters, Our Future.* Biotechnology and genomics tools and products contribute to the three inter-related DFO priority outcomes:

- **Healthy and Productive Aquatic Ecosystems –** refers to the sustainable development and integrated management of resources in and around Canada's aquatic environment through oceans and fish habitat management, and the critical science activities that support these two programs.

- **Sustainable Fisheries and Aquaculture –** refers to an integrated fisheries and aquaculture program that is credible, science-based, affordable and effective, and contributes to sustained wealth for Canadians.

- **Safe and Accessible Waterways –** is about providing access to Canadian waterways, and ensuring the overall safety and integrity of Canada's marine infrastructure for the benefit of all Canadians.

DFO's recently developed *Aquatic Biotechnology and Genomics R&D Strategy* (May 25 2006 Draft) identifies the need for continued support of biotechnology and genomics R&D within DFO. Some of the needs / challenges reflected in the strategic plan include:

- the incremental costs associated with ongoing research and its application are challenging the Department to regularly seek additional funds to meet the increasing capacity needs and maximize the application of these tools for sustainable development;

- the speed and accuracy of using biotechnology and genomics tools far outweighs more traditional methods of species identification, contaminated site remediation and disease diagnosis;

- biotechnology research also provides information that supports Canada's national and international commitments in aquatic animal health, stock management and assessment of risks associated with biotechnology derived products; and

- genetic tools to 'genetically fingerprint' fish as individuals and populations, enable attribution of fish stocks that straddle international boundaries to country of origin thereby supporting the management of the international fishery.

Interviews

Management and researcher interviews indicated that the mandate and objectives of the Genomics R&D Initiative have continued relevance. Interviewees suggested that, although progress has been made, there is still a lot more work to be done to raise Canadian capabilities in biotechnology and genomics. Interviewees felt that capacity in the area of biotechnology and genomics is critical to addressing enforcement issues within DFO and to support national and international commitments. Management stressed the importance of establishing longer-term stability to address human resource and infrastructure needs in DFO labs.

Stakeholders also felt that support for the Genomics R&D Initiative is very relevant, indicating a lack of research money within Canada necessitates coordination and collaboration between federal laboratories, academia and the private sector. For example, one stakeholder commented on the importance of the yet untapped potential of genomics tools and techniques and stressed that establishment of labs with the capacity for genomics R&D requires some capital investments for specialized equipment and machines.

R2. Is there a legitimate and necessary role for government in this area?

Document Review

DFO's regulatory mandate creates a legitimate and necessary role for government in this area. DFO has a responsibility to support Canada's national and international commitments in aquatic animal health, stock management and assessment of risks associated with biotechnology-derived products. DFO's role in the protection of Canada's interests in complex international fisheries and oceans management issues is both a legitimate and necessary role in the area of aquatic biotechnology and genomics R&D. For example, one of the key challenges for the management of the international fishery is the establishment of appropriate fishing quotas. Genomics R&D Initiative provides critical support for DFO in this area.

> *"With the development of genetic tools to 'genetically fingerprint' fish as individuals and populations, new information can be generated that enables the attribution of fish stocks that straddle international boundaries to country of origin. This additional information can be used by the Department, and the international community, to develop and propose quotas that are more reflective of migratory patterns and the*

> *need to maintain the health of fish stocks. Through the development of sensitive, accurate and rapid tests that provide valuable information to fisheries and oceans managers, Canada is contributing to the international knowledge and tool base for addressing the challenge of managing international fisheries, thereby supporting and contributing to our responsibilities under the United Nations Convention on the Law of the Sea (UNCLOS), the International Council for the Exploration of the Sea (ICES), the Pacific Salmon Commission, the North Pacific Anadromous Fisheries Commission, and the North Atlantic Fisheries Organization."*[24]

Interviews

Interviews with management indicated that there is a legitimate and necessary role for DFO and the federal government in the area of biotechnology and genomics R&D. Management felt that DFO capacity in the area of biotechnology and genomics is critically important in providing quality advice to the Minister. The focus of genomics R&D activities has been specifically targeted towards supporting DFO's regulatory mandate and issues related to fisheries management and sustainability. The department is concerned with issues such as risk assessment and quality assurance. The regulatory mandate requires a certain degree of independence of federal scientists. By enhancing DFO's in-house capacity, the Department is better positioned to ensure that research funds may be targeted to specifically address national priorities as stipulated by its mandate and strategic goals.

A.3.3 Success

S1. Have the individual departments achieved, or made progress towards, their specific objectives / goals?

Document Review

A review of project summaries and workshop proceedings provides evidence that DFO has achieved and made progress towards their specific objectives and goals as stated in program documentation.

A total of eight projects were carried out in Phase 1 of the Genomics R&D Initiative. Notable achievements from the Phase 1 projects include the following:

[24] Source: Aquatic Biotechnology and Genomics Research and Development Strategy, Draft May 25 2006, p. 8.

- DNA libraries to assist in determining the optimum / ecological size of Marine Protected Areas to protect vulnerable fish populations were developed;

- basic technology for fish DNA-based vaccines and knowledge of the genetic structure of fish pathogens provide scientific support for the development of new regulations governing the movement of fish;

- in collaboration with EC and NRC, test protocols to identify changes in specific bacterial members in oil-contaminated environments to monitor the efficacy of bio-remediation technologies and habitat recovery;

- genomic technology was used to develop the technology to enhance the uptake of pigments used to colour the flesh of salmonoids, thereby reducing production costs for the aquaculture industry;

- the development of the technology to reliably determine the sex of Atlantic salmon by non-lethal means will lead to assurances that all-female stocks, developed for aquaculture, will not establish reproducing populations in the wild even if salmon escape netpens; and

- through the development and use of technology to 'fingerprint' the various stocks of abalone, anti-poaching efforts to protect this species are supported. Subsequent to the completion of Phase 1, in a March 2006 news release, DFO announced that a Vancouver man was fined $10,000 after pleading guilty for unlawful possession of abalone. During a routine inspection of his store, fisheries officers found abalone which were seized and sent to the DFO Molecular Genetics Laboratory for DNA testing. Results from testing confirmed that the seized abalone was wild Northern Pinto abalone, a threatened species which is illegal for harvest and possession.

In Phase 2, a total of six projects were undertaken. The following table provides highlights of success as reported in project summary reports.

Table A12: Highlights of Phase 2 Success	
Project Name	**Reported Progress / Success**
Regulatory Science	
Genomic characterization of the salmon Y chromosome and sex determination	**Partially (largely) achieved expected results**. 3 manuscripts in preparation for publication 9 articles published 4 presentations at international conferences (Japan, Korea, France and Portugal) Advice on the regulatory implications of growth control in fish is provided to Aquaculture Science Branch, DFO, Ottawa. A State of Knowledge paper on the genetic control of growth in domesticated strains was prepared in part during this grant cycle. Advice is provided to Health Canada and Canadian Food Inspection Agency on GH expression and testing for transgenic fish. Both departments have programs for developing tools for examining risk assessment of transgenic fish. Regulatory research advice to DFO Ottawa and St. Andrew's Biological Station.
Aquatic Resource Profiling and Aquatic Animal Health	
Physiological Effects of Changing Environmental Conditions on Sockeye Salmon	**Fully achieved expected results.** 10 manuscripts in preparation for publication 19 articles published 2 papers, technical reports and articles (unpublished) 10 presentations delivered to external parties (American Fisheries Society – 2003 and 2005, Pacific Salmon Commission, Coastwide Salmon Genetics Workshop, the International Council for the Exploration of the Sea Conference, International Developmental and Comparative Immunology Conference, Lund University) 3 presentations delivered within DFO "This work is considered promising enough that the Pacific Salmon Commission has now funded a joint $1.35 million project with DFO, UBC and Carleton University to develop biomarkers for entry timing and further elucidate environmental and physiological cues for entry timing." The partnership between DFO and University physiologists has yielded highly useful co-validation of microarray data with the directed physiological assays. Worked with Panfish, an aquaculture company, to develop methods to quantify *Kudoa thyrocites* infection levels in Atlantic Salmon. Also worked with Microteck and the University of Victoria (UVIC) to isolate the Cathepsin L sequence used in the quantitative assay, which they intend to use as a vaccine candidate and patent.

Table A12: Highlights of Phase 2 Success	
Project Name	**Reported Progress / Success**
Aquatic Resource Profiling and Aquatic Environmental Health and Remediation	
Genomic characterization of growth in fish	**Partially to fully achieved expected results**. 8 publications 3 manuscripts in preparation for publication 1 presentation (IMBC, Japan – 2003) Provision of regulatory advice on the efficacy of monosex strategies for containment purposes provided to Aquaculture Science Branch, DFO Ottawa. Advice on the stability of sex determination in salmon providing, relating to potential sex reversal effects noted in chinook populations in the Columbia River (National Marine Fisheries Service, Seattle, WA). Provided extensive advice to aquaculture producer Target Marine Hatcheries, BC, as well as assistance in the development of their monosex coho salmon technology (also supported by Aquaculture Collaborative Research and Development Program [ACRDP]). Application of this technology pays for the initial research costs several fold over each year of its use in production. Research results used by DFO – 50 wild populations of chinook salmon have been examined for sex reversal effects in BC. University of Idaho and National Marine Fisheries Service (NMFS) in Seattle have used our genetic sexing technology.
Aquatic Resource Profiling	
A Scientifically-based approach to the Development of Aquaculture Broodstock and Fisheries Management	**Partially achieved expected results with good success.** On-going data analysis will result in publications over the next 2 years. 2 presentations (American Fisheries Society – 2003, International Marine Biotechnology Conference – 2005) 1 citation (Molecular Ecology Notes – 2005)

Table A12: Highlights of Phase 2 Success	
Project Name	**Reported Progress / Success**
Regulatory Science	
The Development of Triploid and Tetraploid Shellfish for Aquaculture	**Fully achieved expected results** 2 citations (Canadian Technical Report for Fisheries and Aquatic Science) 3 presentations (Aquaculture Association of Canada – 2004, International Marine Biotechnology Conference – 2005, Aquaculture Biotechnology Workshop – 2004) Extensive advice provided to DFO Ottawa concerning regulatory aspects of triploid shellfish. A reference list was prepared and sent for future development of regulations and policies related to GMO. International interest in our induction technologies and results has been heavily used by Institut Français de Recherche Pour l'Exploitation de la Mer (IFREMER) and New Zealand and will be the basis of a European Union project lead in the Netherlands. Mallet Research Services has induced their own bay scallops and is planning to market them.
Aquatic Animal Health	
Comparison of viral pathogens in aquatic animals to ascertain similarities and differences between geographic zones in support of the new Canadian Aquatic Animal Health Program (Phase 2 of Like-2-Like)	**Partially achieved expected results.** 2 manuscripts in preparation for publication 4 publications 3 presentations (Aquaculture Association of Canada) 1 presentation (DFO) The improved diagnostic tools developed during the project are directly applied for current diagnostic work. The sequence database of virus isolates is consulted whenever new isolates are obtained and partially sequenced. Research methods are also used by graduate students and private laboratories.

Interviews

Management indicated that the Genomics R&D Initiative funds were distributed to support core research priorities. Interviewees explained that science activities within the Department are operational so the Genomics R&D Initiative funds helped target developmental types of research.

Stakeholders agreed that progress had been made in increasing the capacity within federal labs and indicated that technology such as microarrays and genomics screens are still relatively new.

DFO researchers provided numerous examples of how they have achieved or made progress towards specific objectives and goals of the Initiative as evident in the review of project reports provided.

S2. To what extent did the projects funded under Phase 1 of the Genomics R&D Initiative build capacity inside government laboratories to carry out genomics research?

Document Review

Capacity building requires increased knowledge and skills of researchers and technicians, improved equipment and facilities, tools and techniques. A review of Phase 1 and 2 project summaries provides evidence that projects funded under Phase 1 led to a strengthened capacity within DFO labs to carry out genomics research. For example:

- recruitment, hiring and training of new staff;
- lab facilities were updated with new analytical equipment and genomics tools;
- use of microarray technology;
- development of BAC library;
- development and application of Quantitative Polymerase Chain Reaction (QPCR) technology;
- reduced processing time for analysis (e.g., tissue samples);
- improved techniques to better diagnose disease agents (e.g., the genotypic analysis of selected virus pathogens of finfish provided an enhanced ability to determine whether subtle differences between strains of the same pathogens from various parts of Canada are of biological significance);
- development of new Y chromosome markers and refinement of existing tests into more rapid quantitative PCR assays and tools for sex identification:
- applied genetic techniques leading to enhanced management strategies for the conservation of genetic biodiversity criteria for the sustainability of renewable marine fisheries resources; and
- development and improvement of genomic manipulation technologies (triploidy induction was performed for the benefit of the Canadian aquaculture shellfish industry).

Interviews

Interviewees identified several elements of improved capacity within DFO labs. Due to the relatively small amount of funding provided through the Genomics R&D Initiative, DFO made a strategic decision to develop informal centres of expertise across the country. There is also evidence that DFO has capitalized on external resources in other government departments, academia and industry to enhance its programs and mission critical science and technological innovation. A researcher commented that they had a

lot of interest from policy makers and industry with respect to the development of genetic markers for certain species. The researcher stressed how difficult it is to get funding for applied research. The Genomics R&D Initiative fund allowed the lab to acquire the initial tools needed to build necessary infrastructure and capacity. The funding allowed researchers to develop the technology to isolate the markers, and provided the necessary training for technicians that is required to do work in this area.

Stakeholders commented that the capacity of federal labs has increased substantially in the area of biotechnology and genomics. For example, one stakeholder commented that there has been a dramatic reduction in processing time for analysis of tissue samples.

S3. Did this increased capacity strengthen the research carried out in the departments?

Interviews

Management interviews indicated that the increased capacity has raised the credibility and profile of DFO. Staff have acquired new skills in using the genomics tools that provide new and innovative ways of looking at problems. Genomics tools have many uses and applications. For example, genetics tools can be used for diagnostic applications used to comply with international regulations regarding disease free status. The genomics tools support the development of international standards.

Researchers commented that the increased capacity has strengthened the scope of research (e.g., to look beyond salmon to other varieties of marine species, a shift from monitoring to using biotechnology for remediation techniques). Genomics was described as being a new tool that researchers did not have before.

S4. Did this increased capacity created in Phase 1 translate into the benefits of advances in research and technology in Phase 2 for department constituents?

Document Review

A review of the Phase 2 project summaries provides evidence that some projects are a follow-on to previous DFO research projects (e.g., Like-2-Like, the Development of Triploid and Tetraploid Scallops for Aquaculture, and the DFO / NSERC Partnership for Enhanced Development and Application of Genetic Biotechnology to Atlantic Fisheries and Aquaculture).

Interviews

Researchers indicated that the increased capacity developed in Phase 1 has translated into the benefits of advances in research and technology in Phase 2. For example, one researcher described a shift in focus towards examining changes in physiology based on environmental conditions.

S5. To what extent has the Initiative strengthened coordination, cooperation and linkages between the appropriate research institutions?

Document Review

The summary reports for Phase 2 projects provide evidence of coordination, cooperation and linkages between DFO and other research institutions. The following table identifies the list of collaborators and linkages to other research institutions that were identified.

Table A13: Phase 2 Collaborations / Linkages	
Phase 2 Projects	**Collaborations / Linkages to other Research Institutions**
Genomic characterization of the salmon Y chromosome and sex determination	▸ Children's Hospital Oakland Research Centre, San Francisco, CA ▸ University of Idaho, Moscow ▸ National Research Institute for Basic Biology, Japan ▸ Pacific Region Habitat Enhancement Branch, DFO ▸ US National Marine Fisheries Service, Seattle, Washington
Physiological effects of changing environmental conditions on sockeye salmon	▸ University of British Columbia ▸ University of Victoria ▸ PanFish Canada (private sector) ▸ Other DFO researchers ▸ Animal Health Centre, Ministry of Agriculture, Fisheries and Food
Genomic characterization of growth in fish	▸ University of Victoria ▸ Simon Fraser University ▸ Great Lakes Water Institute, Wisconsin ▸ Institute for Marine Biology, NRC (Halifax) ▸ Woods Hole Marine Biology Laboratories, Maine ▸ Cold Spring Harbour Laboratories ▸ New Brunswick Research and Productivity Council (private sector) ▸ St. Andrew's Biological Stations, DFO
A scientifically-based approach to the development of aquaculture broodstock and fisheries management	▸ Dalhousie University ▸ DFO Researchers in New Brunswick (NB), Nova Scotia (NS) and Newfoundland (NFLD)
The development of triploid and tetraploid shellfish for aquaculture	▸ AquaPrime Mussel Ranch, Ship Harbour, NS ▸ AquaDelights Seafood Ltd, Pictou Co., NS ▸ Lunenburg Shellfish Ltd ▸ Fish Health Unit, DFO, Gulf Fisheries Centre (GFC), Moncton ▸ Shippegan Hatchery, Shippegan, NB ▸ IFREMER-La Tremblade, France ▸ Cawthorn Institute, New Zealand ▸ New Zealand National Institute of Water and Atmospheric Research
Comparison of viral pathogens in aquatic animals to ascertain similarities and differences between geographic zones in support for the new Canadian Aquatic Animal Health Program (Phase 2 of Like-2-Like)	▸ Atlantic Veterinary College ▸ University of Prince Edward Island ▸ University of Victoria ▸ Oregon State University ▸ Institute Marine Biosciences, NRC, Halifax ▸ Nova Scotia Department of Agriculture and Fisheries ▸ US Western Fisheries Research Centre, Seattle, Washington

Interviews

Management interviewees indicated that DFO has a culture of joint venture in working with others. This is evident by examining the scope and breadth of collaborative partners identified above. In terms of collaboration with other federal departments, collaboration with the NRC has been greatest.

In general, stakeholders indicated that good linkages exist between DFO and university and NRC research institutions on projects they have been involved with.

DFO researchers indicated that the Genomics R&D Initiative has led to strengthened coordination, cooperation and linkages with other research institutions. One researcher indicated that they were also involved in co-writing aspects of the Genome Canada GRASP in conjunction with the University of Victoria. Another researcher also discussed DFO's collaborative relationships with the Canadian Food Inspection Agency (CFIA) with respect to the Aquatic Animal Health Program. DFO also works closely with EC and NRC in the area of bio-remediation for the treatment of environmental contamination (e.g., from toxic spills).

S6. What have been the facilitating and impeding factors for the success of Phases 1 and 2 of the Initiative?

Interviews

Management and staff expressed pride in what they have been able to accomplish with a relatively small amount of funding dedicated to Genomics R&D Initiative within DFO ($900,000 per year for the past six years). Interviewees indicated that the following factors facilitated success within Phase 1 and 2 of the Initiative:

- DFO Headquarters agreed to risk manage some of the staff salary costs so key researchers could be retained beyond the three year cycle;
- CRSB and Genomics R&D Initiative funds have been managed closely allowing greater flexibility;
- DFO's decision to develop centres of expertise in the area of genomics R&D to build core capacity and acquire new equipment (e.g., DNA sequencers); and
- recognition by external peers of DFO's strengthened capacity has led to increased credibility, which in turn makes DFO a more attractive research partner for others both within Canada and internationally.

The greatest impediments towards achieving success were identified as follows:

- DFO has lost staff that were hired and trained as a result of the Genomics R&D Initiative to organizations with more stable funding;
- delays in getting access to the funding at the beginning of the cycle impacted ability to initiate research activities and hire necessary staff;

- the level of DFO funding is seen to be too small which limits the amount of work that can be done;
- the gap between Genome Canada and funding support to federal labs is too wide;
- no access to intermediate-level funding sources;
- lack of continuity of funding between cycles has caused DFO to lose valuable staff resources;
- federal researchers do not have access to Genome Canada funding which favors international partnerships; and
- it is difficult for DFO to influence international researchers to focus on species of interest that are unique to Canada.

Stakeholders identified the collaborative approach / attitude of DFO researchers as being a major success factor. The following factors were identified as impediments by stakeholders:

- federal labs take a longer term perspective on strategic priorities, however, it was felt that this longer-term view is threatened by the inherent constraints imposed by a three year funding cycle; and
- horizontal initiatives can cause hierarchy problems because communication lines tend to by-pass the internal hierarchy within departments. It was suggested that this reduces the influence and contribution of more senior management (e.g., Director Generals).

S7. Are there other intended and unintended impacts resulting from Initiative?

Interviews

Management commented that the potential benefits for fisheries management have been greater than originally anticipated. For example, one researcher indicated that, because the funding for the Genomics R&D Initiative is coordinated out of Ottawa, it has helped raise the profile of their lab and strengthened linkages with other scientists across the Department. Stakeholders did not identify any intended or unintended impacts resulting from the Initiative.

S8. To what extent would the impacts have occurred without the Initiative?

Interviews

Researchers indicated that the progress achieved to date would not have occurred without the Genomics R&D Initiative, as there is really no other source of funding. The funds were used to build capacity within labs and provide critical training and experience for scientists and technicians. One interviewee explained that, in the late 1990s, researchers were using regular molecular biology techniques. Due to the Genomics R&D Initiative they now have BAC library, use mircroarray technology, and medium scale genotyping. This has helped DFO researchers maintain links to academia through increased credibility and capacity in genomics and biotechnology.

A.3.4 Cost-Effectiveness / Alternatives

C1. Does the Genomics R&D Initiative complement, overlap or duplicate other federal or provincial initiatives related to genomics or biotechnology?

Interviews

Management did not express any concerns with respect to overlap and duplication with any other programs. However, it was suggested that DFO should find ways to influence the types of projects supported by Genome Canada.

DFO researchers were not aware of any overlaps or duplication with other federal or provincial initiatives related to genomics or biotechnology. A few mentioned that the provincial labs do not have capacity for research in the area of fish genomics. No other sources of funding were identified. Researchers commented that it was good to have access to a fund such as the Genomics R&D Initiative that was specifically aimed at strengthening capacity of federal labs in this area.

Comments from DFO researchers with respect to Genome Canada were mixed. Some suggested that the Genome Canada projects were very large and that there were very few projects that were specifically related to DFO work. One person stated that "the disproportionately large amount of funding going to Genome Canada versus funding available for federal labs has created two solitudes between federal researchers and academia". It was suggested that there should be an intermediate level of funding available to address this gap. However, a few researchers offered a different perspective by commenting that the Initiative complements Genome Canada and has allowed them to participate in other projects (e.g., DFO is a partner on a Genome Canada project that is being led by the University of Victoria that has developed a microarray for salmon).

Stakeholders were not aware of any areas of overlap or duplication. One stakeholder commented that, because "the doors are closed for federal researchers at Genome Canada, there is a need for opportunities to access more funding". The interviewee indicated that

some funding is available through US organizations such as the Department of the Environment (DOE).

C2. Is the funding structure of the Genomics R&D Initiative the most appropriate mechanism for achieving the intended objectives? Are there more cost-effective alternative ways to achieve the Genomics R&D Initiative mandate?

Interviews

DFO management felt that its portion of the overall funding is too low and that an A-base component is required to sustain capacity that has been built through its strategic decision to create Centres of Excellence. It was suggested that a cost-benefit analysis of its genomics tools would demonstrate a significant return on investment.

One stakeholder indicated that the Genomics R&D Initiative has been a good approach for capacity building, but federal researchers would benefit from participation in Genome Canada technology platforms.

DFO researchers did not identify any other more cost-effective alternative ways of achieving the Genomics R&D Initiative mandate. In general, they were satisfied that the funds are being well-managed within DFO. However, researchers felt that the amount of funding should be increased. The stability of funding beyond the three-year time frame was also raised as being an issue of concern.

C3. Is the three-year funding cycle appropriate for achieving intended outcomes?

Interviews

Management indicated that the three-year funding cycle is appropriate from a research project perspective, but it has not been good from a human resources management perspective because the department has had to risk-manage staff costs. One interviewee commented that there is a limited pool of expertise to draw from, so risk-managing staff costs create issues around the ability to attract and retain qualified staff.

Stakeholders felt that a three-year funding cycle is appropriate, indicating that three years is long enough to get research off the ground and show early results. One stakeholder commented that "the suitability of the time frame depends on the nature of R&D objectives, indicating that ground-breaking science requires a longer time frame and that it takes several years to establish yourself in a new field." Another stakeholder commented that "a three year cycle promotes enhancements to existing research, not the development of new programs."

In general, researchers felt that the three-year funding cycle was appropriate and a good compromise. No one felt that the cycle should be any shorter; while some felt there were benefits to a longer cycle (up to five years). The most significant shortcomings identified by researchers were the lack of A-base funding to support staff retention on a longer-term basis. This was highlighted as a serious issue that requires attention. The Genomics funding has been used to pay salaries of technicians and to acquire necessary equipment. Now that capacity has been strengthened there is a need for more secure financial support to protect these initial investments. One researcher suggested that, as the Genomics program matures, a longer-term funding cycle may become more appropriate. Another researcher felt that a four-year cycle would allow more time for reporting / publishing of research results.

C4. What has been the level of effort or cost required by departments / agency to participate in this horizontal initiative? What have been the benefits?

Interviews

Management commented that the Genomics R&D Initiative was not designed to be a horizontal initiative. There is a horizontal DPR and RPP as well as a joint TB Submission. However, there is no central secretariat function. The ADM committee that was established is not seen as a decision making body. DFO has set its own priorities internally. The administrative costs associated with the initiative have been focused on internal planning, priority setting and development of an RMAF and project reporting mechanisms.

A.3.5 Design and Delivery

D1. Is the position of the Genomics R&D Initiative appropriate within the larger government biotechnology strategy? Is the level of integration with other federal government biotechnology programs appropriate?

Document Review

In addition to $900,000 Genomics R&D Initiative funding, DFO also receives funding from the CBS ($125,000 in 2004-2005) and the CRSB ($1,495,000 in 2004-2005), bringing the total biotechnology program to $2,250,000 annually.

Interviews

Management agreed that the position of the Genomics R&D Initiative is appropriate within the larger government biotechnology strategy. It was suggested that there may be some benefit to greater integration with Genome Canada from a strategic point of view, recognizing that DFO has its own mission-specific priorities to address.

Only one stakeholder provided comments on this issue, indicating that there could be better priority setting across departments. The interviewee commented that "the allocation of funds across departments does not seem equitable".

DFO researchers generally agreed that the position of the Genomics R&D Initiative is appropriate. However, they did comment on the lack of availability of other funding sources.

D2. How effective is the overall governance structure for the Initiative and departmental processes (e.g., project approval process)? Are the roles and relationships clearly defined and appropriate?

Interviews

DFO management described the Genomics R&D Initiative as a interdepartmental fund, not a true horizontal initiative. DFO has taken steps to develop its own internal processes for planning, project approval and performance monitoring / reporting. Management indicated that their processes work well for the amount of money being invested ($900,000 per year). Due to the limited amount of funding, research priorities are set before the call for proposals. The proposals are submitted to fit within certain envelopes in order to ensure that the department is well positioned to build on previous investments. In Phase 3, the proposals were taken to Science Managers within DFO for priority review. The proposals were also sent out for anonymous peer-review by external scientists. DFO indicated that researchers have worked well together to support the four research areas and two Centres of Excellence within the Department and that due to the relatively small amount of funding the department has had to be very focused on its research projects. Management indicated that departmental roles and responsibilities are clearly defined and understood.

Interviews with researchers indicated that they were very satisfied with the project approval process and did not have any significant suggestions for improvement. They were satisfied that roles and responsibilities were clearly defined and appropriate. Most commented that the workshop sessions provided the opportunity to share research results and develop future projects on a collaborative basis. Positive comments were made concerning the project approval and peer review process that has evolved over time, as well as with respect to the role played by OAB.

D3. To what extent have the departments been able to leverage the funds provided through the Genomics R&D Initiative? What are the pros and cons associated with the leveraging requirements?

Document Review

Although a review of summary reports for Phase 2 projects provides evidence of leveraging of funds provided through the Genomics R&D Initiative, the format in which details were provided was inconsistent. The instructions on the project reporting template for Phase II indicate that researchers provide the "Amount Levered" (includes in-kind and O&M contributions to this project from within and outside DFO). In most cases, a dollar amount was provided ranging anywhere from $0 to $480,000 per year. A detailed breakdown of leveraging sources was provided for only one project. On this particular project, the funding sources included British Columbia Aquaculture Research and Development Committee (BC Ministry of Agriculture and Lands), Aquaculture Collaborative Research and Development Program (ACRDP), an equipment grant from the Northern Endowment Fund, the Pacific Salmon Commission and microarrays from Genome Canada funded GRASP project.

Interviews

Interviews with management indicated that the leveraging of funds provided through the Genomics R&D Initiative has not been closely monitored. However, it was felt that the department has at least matched the $900,000 per year. In terms of pros and cons of leveraging, some researchers indicated that the requirement for leveraging leads to good team work and collaborative arrangements. However, short term funding sources (e.g. ACRDP) that require demonstration of results within a one year time period and industry contributions are difficult. Another disadvantage identified was the additional workload associated with establishing formal agreements with other parties. Lastly, a potential drawback is DFO's ability to bring as much to the table because of the limited funding available through the Genomics R&D Initiative.

D4. How effective / appropriate is the Initiative's approach to performance measurement? What performance measures should be captured in the next phase and why?

Document Review

A draft RMAF for DFO's Aquatic Biotechnology Program has been recently developed. The draft RMAF covers activities related to DFO's involvement in the CBS, the CRSB and the Intramural Genomics R&D Initiative. In order to support ongoing monitoring, DFO has developed a project database to track project and financial information. At the project level, the database captures the following output and outcome measures:

- new and improved research knowledge, tools, technologies, methods and / or protocols;
- risk factors identified;
- evidence of application of biotechnology tools for aquatic resource management;

- evidence of research progress with respect to diagnosis of aquatic animal diseases;
- evidence of the development and / or application of biotechnology tools to enhance aquatic ecosystem health;
- evidence of development of biotechnology techniques to prevent or manage disease outbreaks; and
- evidence of use of information by resource managers and other stakeholders.

Interviews

Management indicated that they are satisfied that performance measurement and reporting system that has been developed will meet their needs. In addition to project tracking, a workshop was held to bring researchers together to discuss research results. In general, interviewees felt that performance measurement processes were adequate within DFO, but questioned how the Initiative was being monitored as a whole if it is not being managed horizontally. Some concern was also expressed about over-complicating the current level of reporting if a decision were to be made that would increase reporting requirements on an inter-departmental basis. It was felt that DFO would not have the resources to meet any additional administrative and reporting requirements beyond the current level.

DFO researchers were involved in the development of the draft RMAF and new project reporting system and are satisfied that performance measurement requirements are being met. No new suggestions were provided with respect to other types of performance indicators beyond what is identified in the draft RMAF. In general, the project reporting requirements are seen to be reasonable. Researchers are appreciative of the efforts that have been made to streamline processes and minimize the 'bureaucratic burden' associated with the Initiative.

D5. How could the Genomics R&D Initiative be improved? What changes are required to make the Initiative more efficient?

Interviews

Suggestions for improvement from management and researchers include:

- increasing the level of funding to DFO (two or three times the current level);
- ensuring greater stability of funding beyond the three year cycle to attract and retain skilled human resources;
- ensuring timely communication to researchers about access to funds as early as possible in the first year of the cycle;
- providing more opportunities to share research results with other departments to enhance knowledge, future research opportunities and networks; and

- establishing closer linkages with Genome Canada to increase DFO influence on research priorities and provide opportunities for greater collaboration on projects.

Stakeholders commented that the Initiative could be improved by increasing the emphasis on scientific merits of projects and by encouraging team partnerships with academics to focus on bigger research questions in the future.

A.4 Health Canada

The following is a supplementary report to the main report on the Evaluation of the Genomics R&D Initiative that describes those aspects of the evaluation specific to HC. It should be noted that throughout this report, that PHAC, which was established as a separate agency in 2004, was considered to be part of HC. The administration of the Genomics R&D Initiative funds for both HC and PHAC was coordinated through HC's Departmental Biotechnology Office for Phases 1, 2 and 3.

This report is based on information collected in a review of program and other related documentation, as well as 21 in-depth interviews – six with program management, 11 with project leads / researchers (drawn from the research groups involved in the three phases of the program) and four with stakeholders. The purpose of this annex is to report findings from the document review and interviews. Given the purpose of this study is to conduct an evaluation of the Genomics R&D Initiative from a horizontal perspective, it is not the intent to draw conclusions or make recommendations that are specific to any one department. Nevertheless, a number of suggestions for improvement are noted throughout this annex (see D5 for specific suggestions raised by interviewees) as well as in the main evaluation report (see conclusions and recommendations Section 7, Table 14).

Limitations with respect to the overall methodology are discussed in detail in Section 2, Table 5 of the main evaluation report. As noted in the following sections, one of the limitations specific to HC is that a complete database of project summary reports for Phases 1 and 2 projects was not available for the evaluation. There is also a limitation with respect to corporate memory regarding the implementation of the Initiative within HC due to staff turnover over Phase 1, 2 and 3. These limitations may have resulted in some possible information gaps.

The reader should note that in addressing some of the evaluation issues, there is a discussion of findings from the review of available documentation provided by HC as well as from interviews. In addressing some of the evaluation issues, interview findings are the only available source (i.e, S4, S7, C1, C2, C3, C4, D2 and D5). In dealing with some of the success issues, the findings were based on a combination of interviews which were supplemented with specific information reported by researchers in written project reports (see sub-heading called *Document Review and Interviews* for evaluation issues S2, S3, S6, and S8).

A.4.1 Brief Profile

Strategic Approach

HC's mission is to help Canadians maintain and improve their health. In keeping with this mandate, HC has developed a Departmental Framework for Biotechnology that is rooted in the federal government's biotechnology policy as outlined in the CBS. In the area of biotechnology HC is responsible for:

- providing leadership in policy development and regulation;
- informing and engaging the public;
- ensuring an international positioning for Canada; and
- applying the benefits of biotechnology to HC's mandate.[25]

Research activities supported through the Genomics R&D Initiative in the last few years focused on utilizing genomics to better understand:

- how infectious pathogens and food / water-borne pathogens interact with their human / animal hosts;
- the effect of biotherapeutics on humans;
- how toxins trigger changes in gene expression;
- the potential for microbes used in environmental biotechnology applications to pose a health risk;
- how to detect and monitor any long-term effects of genetically modified foods; and
- how to maintain and improve the quality of genetic testing and services.

Though the fund was originally set up for genomics research, the scope of the fund has been expanded to include research on proteomics and metabolomics as well. [26]

25 HC Departmental Framework for Biotechnology (Executive Summary).

26 www.hc-sc.gc.ca/sr-sr/biotech/role/finance/index-e.html#3

Theme / Research Priority

Within each funding cycle, HC established key themes to guide its research efforts. At a Departmental workshop, held in Ottawa in December 2004, the themes for Phase 3, as well as the selection process and the criteria for the letters of intent and the proposals were determined by representatives of the branches which undertake genomics research. The four themes, which are largely a continuation of the themes from Phases 1 and 2, are as follows:

Table A14: Theme / Research Priorities

Research Themes	Objectives
Generation, use and societal impacts of human genetic information	▸ research such as the quality management of genetic testing laboratories, international harmonization of bioinformatics databases, as well as policy research and communication aspects in areas such as the ethical, legal and social issues of genomics, including genetic privacy
Health and safety of biotechnology products	▸ research that furthers the understanding of both the positive and negative impacts of biotechnology products (such as genetically modified foods, biopesticides, bioremediation, biotherapeutics) on human, animal and environmental health
Human genomic applications and impacts related to diagnostics and diseases	▸ research such as identification of genomics markers, including diagnostic targets; study of gene-gene, gene-drug and gene-environment interactions, use of animal models and genomic and proteomic basis of infectious and chronic diseases, pharmacogenomics and toxicogenomics
Microbial genomic applications and impacts related to diagnostics and diseases	▸ research such as the study of antibiotic resistance, host-parasite interactions, infection and immunity and control measures against bioterrorism

How Initiative is Delivered in Department

The Departmental Biotechnology Office (DBO) works in collaboration with the other branches of HC to coordinate the biotechnology activities of the department, including the Genomics R&D Initiative. The DBO is responsible to:

- provide a visible, integrative focal point for biotechnology in HC, within the federal government and with external stakeholders;
- provide intelligence and to forecast applications and potential impacts of biotechnology in the health sector;
- increase awareness of biotechnology internally and externally;
- coordinate departmental and interdepartmental efforts;
- increase awareness of health biotechnology and issues internally and externally;

- forecast and provide intelligence on health biotechnology;
- facilitate HC biotechnology activities and identify gaps; and
- position HC biotechnology externally.

Genomics research activities are carried out within the Healthy Environment and Consumer Safety Branch (HECSB), Health Products and Food Branch (HPFB), Health Sciences and Policy Branch, PMRA as well as PHAC facilities located in Winnipeg and Guelph. Genomics R&D Initiative funding continues to support research activities in both HC and PHAC (which was established as a separate agency in 2004). A memorandum of understanding is being developed to define administrative matters pertaining to biotechnology and genomics.

Resources

HC has received $4 million per year through the Genomics R&D Initiative since its creation (except $2 million in 1999). A total of 16 projects were approved in Phase 1. Sixteen projects were funded in Phase 2 and 11 were approved for Phase 3.

Project Approval Process

The project approval process has evolved since the establishment of the fund in 1999. The first step in the selection process is a call for Letter of Intent (LOI) followed by an RFP from the Principal Investigators of the successful LOIs. Funds are allocated based on a competitive peer review process coordinated by DBO. Each proposal is sent to two external reviewers for comment. The scientific peer review process (external) uses the Federal Granting Council Proposal Format (used by CIHR) as a guideline for project proposals submitted under this fund and for their evaluation. The Genomics R&D Technical Review Committee (TRC) ranks the research proposals according to scientific merit and tables recommendations for the approval of the ADM HPFB. Membership on the TRC includes federal research scientists from HC, EC, NRCan and a University of Ottawa biology professor.

A.4.2 Rationale

R1. Are the mandate and the strategic objectives of the Genomics R&D Initiative still relevant? What need was the Initiative intended to address? Does this need still exist?

Document Review

Program documents show that, although the objectives of the Initiative have evolved since the inception of the program, the fundamental need to enhance internal capacity for genomics research has continued relevance. This is highlighted in this section.

Program documentation for Phase 1 of the Genomics R&D Initiative show that HC's genomics research activities were intended to contribute "to expanding the knowledge capacity required in the efficient regulation of biotechnology derived products and services." [27] The following objectives identified for Phase 1 include:

- development of molecular detection technologies;
- development of new, safe and efficient vaccines;
- implementation of surveillance strategies for diseases using molecular technologies;
- screening populations for disease markers; and
- evaluation of the safety of new technology and new products used by Canadians.

The scope of research areas were expanded in Phase 2. The following themes were selected to target HC research activities:

- generation, use and societal impacts of human genetic information;
- long-term effects on health and safety of genetically modified foods and other biotechnology products;
- human genomics; and
- microbial genomics.

The above themes were further refined for Phase 3 of the Genomics R&D Initiative. Phase 3 program documents indicated that these inter-linked research areas support the objectives of the Health Canada Framework for Biotechnology (developed in 2004) and are vital to strengthening HC's regulatory, policy and scientific capacity in the fast moving field of genomics, with the view of maturing these projects into programs should further funding become ongoing.

[27] Health Canada Performance Report (1999-00 to 2001-02), Appendix B.

Having sufficient capacity and expertise within HC to fulfill its roles and responsibilities has been identified a key challenge facing the Department. For example, the HC Biotechnology Framework identifies that workload and demand for expertise in this area is increasing exponentially. This is due to a proliferation of new biotechnology applications in areas such as nanotechnology for drug delivery, the use of plants and animals as factories (e.g., drug, vaccine and antibody, and bio-material production), the development of personalized medicines (e.g., pharmacogemonics), and the development of multi-functional products (e.g., functional foods and nutraceuticals).[28]

Interviews

Management indicated that the mandate and objectives of the Genomics R&D Initiative have continued relevance as it provides financial support for capacity building and new areas of research that are necessary in supporting evolving Departmental needs in this area. It was noted that HC is the lead department for the stewardship pillar of Canada's Biotechnology Strategy. Stewardship is focused on "the preservation of public good through ensuring that the social and ethical issues related to biotechnology are addressed, and that the federal government has an effective regulatory regime as well as the science capacity to protect human health and the environment."[29] In addition, interviewees commented on the need for a larger program, with A-base support, to sustain the capacity developed to date in support of HC's mandate.

R2. Is there a legitimate and necessary role for government in this area?

Document Review

HC has an important leadership role in supporting Canada's Biotechnology Strategy, particularly in ensuring the safety of Canadians and their environment. HC's mandate creates a legitimate and necessary role for government in this area. HC's role is to provide national leadership to develop health policy and enforce health regulations. HC has total or partial responsibility for nineteen Acts including:

- *Canada Health Act*;
- *Canadian Environmental Protection Act;*
- *Controlled Drugs and Substances Act*;
- *Food and Drugs Act*;
- *Hazardous Products Act*; and

28 HC Departmental Framework for Biotechnology (p. 10)

29 HC Departmental Framework for Biotechnology (p. 2)

- *Pest Control Products Act*.

In addition, the policy and regulatory framework for HC activities in biotechnology are also guided by:

- HC Biotechnology Framework;
- HC Biotechnology Communication Plan;
- Canadian Biotechnology Strategy;
- HC's Decision Making Framework;
- HC's Framework for Science;
- Values and Ethics of the Public Service; and
- Federal Government Sustainable Development Strategy.

The HC Departmental Biotechnology Framework[30] outlines some of the key biotechnology related roles and responsibilities of the Department. Specific examples are highlighted in the following table.

30 HC Departmental Framework for Biotechnology (p. 5-6)

Table A15: HC Biotechnology Roles and Responsibilities	
Roles and Responsibilities	**Examples**
Providing leadership in the development of policy and regulations	▸ HC leads or participates in the development of evidence-based public policies as well as the "internal administrative" policies at the government-wide level or within HC. These policies may, for example, be required with respect to assessing products for regulatory approval, in collaboration with other countries, or they may look at the impact of the health care cost of biotechnology tools and products for Canadians that would impact availability. ▸ HC is mandated to regulate health products, food and pesticides, including those that rely on biotechnology in any way, under the Food and Drugs Act and the Pest Control Products Act. The Department is also responsible for administering the health-related aspects of the CEPA 1999. Risk management and the public's values are important considerations in fulfilling the regulatory role.
Informing and engaging the public	▸ To fulfill its role as regulator and policy maker, HC needs to ensure that the public has access to objective information about biotechnology and that Canadians are engaged in the discussions on biotechnology leading to decision making. The Canadian public requires information on biotechnology and on how the government regulates biotechnology to make informed decisions on products that could affect their health.
Ensuring an international position for Canada	▸ HC's role at the international level is multi-faceted. To be a responsible world leader in biotechnology, HC needs to: participate in the development of international policies and standards; seek opportunities to collaborate in areas of research, information exchange and product assessment; and where appropriate, harmonize Canadian regulations and standards with those of other countries.
Applying the benefits of biotechnology to HC's mandate	▸ To apply the benefits, HC must have state-of-the-art knowledge and facilities, and it must have extensive partnerships and networks. For example, regulations must be supported by scientific research to ensure effectiveness and timeliness. Two examples of this are the development of new analytical tools to verify the structure and purity of biotechnology health products and biologicals and the development of methodologies to assess adverse immunological events associated with biotechnology-derived therapies.

Program documentation for Phase 2 of the Genomics R&D Initiative also emphasizes the importance of capacity building in support of HC's regulatory role by expanding the knowledge required in the efficient regulation of biotechnology derived products and services (e.g., genetically modified foods, new types of vaccines derived from non-traditional sources such as plants, and diagnostic kits based on detection of sensitive genomic and proteomic elements associated with target organisms).

Since the Genomics R&D Initiative was first established, PHAC was created in response to growing concerns about the capacity of Canada's public health system to anticipate and respond effectively to public health threats. PHAC is focused on emergency preparedness and response, infectious and chronic disease prevention and control, and injury prevention and promoting good health, supported by a collaborative, pan-Canadian network.

Interviews

Interviews with management and stakeholders indicated that there is a legitimate and necessary role for HC and PHAC in the area of biotechnology and genomics R&D. The focus of genomics R&D activities has been specifically targeted towards areas of human health protection, and is a matter of public interest. It was stated that HC's unique regulatory mandate means that this type of work could not be done by the provinces, universities or private sector. Another interviewee commented that the regulatory needs in areas such as biotechnology-derived food and drugs and personalized medicine will have huge policy impacts on health care. One researcher explained that there are also strict confidentiality requirements to consider in fulfilling some of HC's regulatory responsibilities that would make it inappropriate for certain research to be conducted by either universities or the private sector. As an example, HC researchers have access to commercially sensitive or other proprietary information such as drug formulations.

A.4.3 Success

S1. Have the individual departments achieved, or made progress towards, their specific objectives / goals?

Document Review

The 1999-2000 to 2001-2002 HC Performance Report provides examples of progress achieved as a result of Phase 1 projects:

- successful development of several protocols to enhance surveillance (e.g., genotyping of deer mice which are hosts of hantaviruses, identified specific DNA mutations in measles virus which allows for differentiation of the 18 known measles virus genotypes, initiated development of a viral gene expression array);
- genomic candidates were identified that may be involved in host genetic susceptibility to persistent Chlamydial infection by using a tissue culture model;
- using biosensor technology, methods for rapid diagnosis of invasive meningococcal disease were developed;

- human herpes virus, influenza A virus, Marburg virus, Ebola virus and Hantaan hantavirus Sin Nombre hantavirus genes were cloned, expressed and viral specific proteins were purified in high throughput chromatographic systems;

- congenic mouse strains were developed by isolating specific chromosomal segments onto a common genetic background for the purpose of identifying complex genetic interactions underlying variations in drug metabolism;

- the role of tyrosine phosphatase SHP-1 in mediatric malignancies was studied;

- the toxicogenomics project delivered expert training, a new database, external partnerships and participation in several international fora; and

- several projects within the Food Directorate were carried out to address emerging needs and research gaps. A few of the gaps in research and regulatory framework include: lack of animal models that can reliably predict the allergenic potential of novel proteins that may be present in the Genetically Modified Food (GMF) as a result of genetic modification, lack of regulatory requirement for toxicity testing to assess long-term health effects, and lack of HC guidelines to address foods derived from genetically modified livestock animals and fish.

Highlights of progress achieved in Phase 2 were provided in the Departmental Performance Reports (FY 2001-2002 to 2003-2004). It was reported that the primary objective of HC's Genomics R&D funds was to generate knowledge that is essential to the effective regulation of products and technologies produced in the field of genomics, including studying the societal impacts of genomics research, the long-term effects of products of biotechnology, and the interaction of humans with pathogens and the environment. Examples provided in the report include the following:

- the pioneering development of a Benefit Sharing of Best Practices for Genetic Research through a series of workshops designed to promote dialogue between providers (communities providing DNA samples) and the users (researchers both academic and private using the samples for research), has already attracted interest by the United Nations Educational, Scientific and Cultural Organization (UNESCO) in taking the Best Practices scheme to the international level;

- genomics R&D research has provided efficient and sensitive tools to enhance understanding of the mechanism of action of toxicants and new biomarkers for toxicity which allow better extrapolation between experimental animals, animal and human *in vitro* models and the human situation in the context of hazard identification in the long-term use of genetically modified foods or biotechnology-derived drugs;

- a centralized DNA microarray facility has been established and gene arrays, which examine not only the host response to infection but also the gene expression of several pathogenic organisms such as herpes and Staphyloccocus, have been developed;

- diagnostic and surveillance arrays for influenza and other viral encephalitis pathogens are currently in the testing stage;

- several proteomic platforms have been validated and used in protein biomarker discovery, leading to the identification of a series of potential biomarkers of exposure to airborne particulates, allowing HC researchers to become involved in collaborations such as with the European Centre for the Validation of Alternative Methods and the Organization for Economic Co-Operation and Development (OECD) on the validation of toxicogenomics technology for regulatory use;

- comparative genomics, including the use of microarrays, has identified numerous genetic elements that may explain the great virulence of certain lineages of priority pathogens such as *E. coli* and *Salmonella*, how virulent versus non-virulent strains of *E. coli* might interact with host tissues, and the mechanisms behind antimicrobial and multi-drug resistance in *Salmonella*; and

- research has enabled Canada to take the lead in standardizing methods for identifying strains of *Bordetella pertussis* (whooping cough) through collaborations with the Swedish Institute for Infectious Disease Control (the World Health Organization (WHO) International Laboratory for Biological Standards), and participating in an international multi-centre study on pertussis surveillance.

Interviews

Management, stakeholders and researchers indicated that progress has been made with respect to the goals of capacity building and research objectives of specific projects as a result of the Initiative. More specific comments from interviewees with respect to success of the Initiative are provided in the following sections.

S2. To what extent did the projects funded under Phase 1 of the Genomics R&D Initiative build capacity inside government laboratories to carry out genomics research?

Document Review and Interviews

Capacity building requires increased knowledge and skills of researchers and technicians, improved equipment and facilities, tools and techniques. Researchers identified several elements of improved capacity within HC and PHAC labs. It is difficult to make a

distinction between the extents to which capacity was built between Phase 1, versus Phase 2, projects due to limited information available on Phase 1 specifically. However, a review of the available information for Phase 1 and 2 projects, along with interviews with researchers provides evidence that projects carried out have led to a strengthened capacity to carry out genomics research. Some examples include:

- recruitment and hiring of new staff (post-doctoral fellows, technicians and term co-op students);
- advanced training in new tools and techniques in genomics and molecular biology (including microarray development and analysis, comparative genomic hybridization, subtractive hybridization and bioinformatics);
- development of bioinformatics resources including data storage capacity, software and expertise;
- development of multivariate approaches to the identification of biomarkers from gene expression profiles;
- development of microarrays (e.g., 17K mouse cDNA microarray that is used as a core resource for work on prion pathogenesis and HSV-1 hose interactions); and
- access to, or purchase of, microarray scanners, an automated hybridization system, PCR machines and software packages for DNA sequence analysis and mircroarray data analysis.

As a spin-off benefit, one researcher remarked, that the investment in genomics has also led to the opening up of new career path options for researchers within government labs, creating important new opportunities for recruitment and retention incentives for highly qualified personnel.

S3. Did this increased capacity strengthen the research carried out in the departments?

Document Review and Interviews

Several examples of how increased capacity has strengthened research carried out in departments was evident through a review of Phase 2 project summary reports and interviews with researchers (highlights are discussed in Section S1). As an example, a principal investigator reported that:

> *"Genomics funding has been tremendously important to our lab and the Bureau of Nutritional Sciences. It has permitted our lab to develop cutting edge molecular biological techniques and evaluate their performance using real biological samples. In addition, it has allowed us to branch into new research areas that will greatly increase the Food Directorate's ability to evaluate future industry submissions as well as develop policies that will make the Canadian government a leading player world-wide."*

Management interviews indicated that the increased capacity has raised the credibility and profile of HC. Staff have acquired new skills in using the genomics tools that provide new and innovative ways of looking at problems. Researchers from PHAC commented that the Initiative has strengthened research in the area of safe food and water and provided support for emergency response planning (bioterrorism). Linkages with the NRC have been strengthened as well in areas such as proteomics and bioinformatics. Researchers also commented on the success of various training sessions and symposiums for sharing information.

S4. Did this increased capacity created in Phase 1 translate into the benefits of advances in research and technology in Phase 2 for department constituents?

Interviews

Researchers stressed that the Genomics R&D Initiative funding has been critical to building capacity within their labs and that Phase 2 projects could not have been undertaken without Phase 1 project results. Phase 1 laid the foundation to use mircroarray platform and trained staff for future projects. The equipment that has been acquired has also been crucial for supporting research carried out under A-base projects. It has also led to strengthened collaboration in mircroarray work. Some of the staff brought into the Department through Phase 1 are now full time. This reduced the learning curve for Phase 2 projects. One researcher also commented that the increased knowledge that has been gained also helps scientists to interpret the data in the literature. It was also noted that the funding has led to opportunities for researchers in securing grants through CIHR.

One researcher described that the core investments made in Phase 1 were "translated into skills / tools that could be shared with others (at least 2.5 times as many staff). While the four themes remained similar, actual research topics were more complex and in-depth in quality and quantity and involved more partnerships." Research activities have led to the launch of full toxicogenomics gene array techniques and experiments (also standardization methods) and pathogenomics (applications of gene array methods to classify and compare the genomes of microbial pathogens), more emphasis on bioinformatics support and applications, as well as the recruitment of highly qualified experts. "The fund allowed

specific research / science methods to be developed that would not have occurred or very little at all."

S5. To what extent has the Initiative strengthened coordination, cooperation and linkages between the appropriate research institutions?

Document Review

The project summary reports for Phase 1 and 2 projects provide evidence of coordination, cooperation and linkages between HC and other research institutions within Canada and internationally. Examples of research partners identified are as follows:

Table A16: Research Partners Identified in Phase 1 and 2 Project Summary Reports

Canadian Universities: ‣ Dalhousie University ‣ University of Sherbrooke ‣ University of Ottawa ‣ University of Toronto ‣ University of Alberta ‣ University of Guelph ‣ University of Calgary ‣ University of Montreal ‣ University of Manitoba ‣ University of British Columbia	Other Federal Departments and Agencies: ‣ National Research Council ‣ Canadian Food Inspection Agency ‣ Department of Fisheries and Oceans ‣ Agriculture and Agri-food Canada
International Universities: ‣ University of Cincinnati ‣ University of Nebraska	International Organizations: ‣ Institute of Food Safety, The Netherlands ‣ Veterinary Laboratories Agency, United Kingdom ‣ Centres for Disease Control and Prevention, Georgia, USA ‣ National Institute for Public Health and Environment (RIVM), Netherlands ‣ Sidney Kimmel Cancer Centre, California ‣ United States Department of Agriculture ‣ National Salmonella Reference Laboratory, Germany

Interviews

Management interviewees felt that collaboration has been very strong at the researcher level. However, it was noted that the limited funding amounts have an impact on the extent to which collaboration is possible.

Stakeholders agreed that the Initiative strengthened coordination, cooperation and linkages both internally and externally. One stakeholder specifically commented on linkages with the NRC in the area of bioinformatics and microarray facilities, joint research projects between PHAC labs in Winnipeg and Guelph, and collaboration with university labs through CIHR (e.g., Safe Food and Water Initiative). Stakeholders also

indicated that the Initiative has also resulted in increased credibility of federal labs and stressed the importance of having federal researchers remaining current within their fields of expertise.
Researchers also emphasized that there has been strong cooperation from scientists across HC Branches. Another scientist indicated that the increased capacity has led to work in areas such as tobacco smoke, fuel emissions (through the Program for Energy Research and Development (PERD)), radio frequency and airborne particulates. PHAC also indicated that linkages with AAFC, CFIA and the NRC have also been strengthened. It was also noted that"our profile in the scientific community has been raised and we are now up-to-speed with similar research being conducted by colleagues in the US".

Another researcher noted that:

> *"the collaborative nature of the thematic approach of the 2002-2005 cycle has fostered invaluable interactions with scientists and staff engaged in infectious disease across Canada and internationally. The benefits of this collaborative venture are invaluable for the future. As just one example, interactions in this project have led to several new projects with collaborators, funded by NSERC and CIHR. In addition, the two subprojects on Salmonella are continuing as components of one project funded by the HC Genomics program in the 2005-2008 cycle."*

S6. What have been the facilitating and impeding factors for the success of Phases 1 and 2 of the Initiative?

Document Review and Interviews

The key facilitating factors identified in project summary reports and by interviewees are:

- the support from senior management in recognizing the importance of studying biotechnology and genomics;
- the willingness of scientists to work together in a collaborative manner; and
- the competitive peer review process for encouraging excellence and raising the credibility of federal researchers with academia and industry.

A number factors were consistently identified with respect to impediments to success of the Initiative. They are:

- *Delays in Funding:* researchers reported that funds (especially in the first year of a funding cycle) were received six to nine months after the beginning of the fiscal year. As a result, research was delayed, staff could not be hired (including short term and casual help) and the achievement of project results was adversely

affected. It was noted in two Phase 2 projects that there is a substantial difference between the total allocation and actual expenditures for some projects. For example, in Phase 2, $2,251,500 was allocated for the project entitled "Genomics approaches to reducing the public health risks associated with foodborne and waterborne enteric pathogens" (which included five subprojects). The total expenditure reported was $1,454,534 (which represents a difference of $796,966). The project report states that "the lower than anticipated expenditures largely reflect the fact that funding was not received until October in the first year of the project". A difference of $348,000 between total allocation and total expenditure was also noted on another Phase 2 project.

- *Internal Transfer of Funds within A-base Allocation:* researchers indicated that the funds for the project were transferred as operating dollars and were therefore included in the A-base allocation. It was noted that the inclusion of the funds in the A-base allocation meant that they were subject to departmental and organizational pressures.

- *Departmental Taxes by HC Branches*: several researchers reported that a significant portion of project funds were lost due to taxation at the Directorate and Branch level. Practices concerning departmental taxes were not consistently applied across the department, nor were the amounts communicated at the outset of the project. Interviewees were unaware of any TB or departmental guidelines concerning the issue of corporate levies / taxes.

- *Unclear Reporting Requirements:* the reporting requirements were not made clear before proposals were submitted or approved. Researchers noted that requests for reports and information on the project were made by DBO in numerous formats, often with very different terms of reference or reporting parameters. In addition, performance measurement criteria were unfamiliar to many of the participating scientists. A researcher stated that "although funding had been significantly reduced, researchers were expected to report progress and spending as if the entire amount awarded was received and used for the intended purpose".

- *Lengthy Staffing Procedures:* several researchers reported that due to the regular public service staffing process, the proposed human resources were often not available until the end of the first of the three years of the project. Delays in hiring the required staff resources negatively impacted the achievement of planned deliverables.

- *Re-allocation of Funds:* several interviewees commented that a re-allocation of funds occurred in the early stages of the Initiative towards activities that were not originally supported through the technical review process. It was reported that this adversely impacted the work of researchers in other areas and contributed to strained relations across branches in subsequent phases of the Initiative.

S7. Are there other intended and unintended impacts resulting from Initiative?

Interviews

Interviewees (management, researchers and stakeholders) were unable to identify any significant intended or unintended impacts resulting from the Initiative given the objective was primarily aimed at internal capacity building. It was noted by one researcher that, given this is a relatively new field of science, some research was more difficult and time consuming than was originally anticipated.

S8. To what extent would the impacts have occurred without the Initiative?

Document Review and Interviews

Interviewees indicated that the new opportunities derived from this investment have greatly accelerated the adaptation and development of genomics technologies and that this would not have been possible otherwise. No other sources of funding to support the types of research that have been carried out were identified. One researcher indicated that "the Genomics R&D Initiative filled a gap that was created when the CBS fund shifted from funding a mix of regulatory bench science and policy projects to only policy and communications activities. This enabled us to expand into gene arrays for use in the fledgling field of toxicogenomics."

Another principal investigator, responsible for the oversight of several sub-projects, reported that "the HC Genomics program has greatly accelerated our capacity and ability to detect emerging pathogens more rapidly, assess and predict their relative virulence and risks to human health, and thus to enhance surveillance, response capacity, and development of more effective public health policies. Notably, the impact of the 2002-2005 program has been much more than generation of traditional research outputs. In our organization, and amongst our collaborators, it has generated enthusiasm, interaction and collaboration, and a sense of realization of a vision for the future that would not occurred otherwise. This sense of commonality of purpose and involvement arose largely from the thematic approach used in the 2002-2005 cycle, which helped to focus federal scientists in different organizations on common public health goals. ...This approach is a much more effective use of our limited federal resources than approaches that encourage individual projects that do not promote this kind of interaction and involvement."

A.4.4 Cost-Effectiveness / Alternatives

C1. Does the Genomics R&D Initiative complement, overlap or duplicate other federal or provincial initiatives related to genomics or biotechnology?

Interviews

Management, stakeholders and researchers did not express any concerns with respect to overlap and duplication with any other programs. Interviewees were not aware of any overlaps or duplication with other federal or provincial initiatives related to genomics or biotechnology.[31] The interviewees indicated that objective of building capacity within federal labs would not be met if the fund had specific requirements for matching and partnering with other parties. CRSB funding is seen as complementary. In addition, it was felt that the Genome Canada efforts are complementary and that federal labs benefit from their work. One stakeholder commented that it is very important for the federal departments to have direct control of funds to ensure their own priorities can be effectively addressed. It was also felt that the broad mandate of Genome Canada does not address immediate public health issues and regulatory requirements of HC directly.

C2. Is the funding structure of the Genomics R&D Initiative the most appropriate mechanism for achieving the intended objectives? Are there more cost-effective alternative ways to achieve the Genomics R&D Initiative mandate?

Interviews

At the broader program level, interviewees felt that a separate fund for Genomics R&D Initiative made sense within the larger government biotechnology strategy. However, the requirement for a TB submission on a three year basis is burdensome and leads to delays in accessing funding (i.e., as a result, departments have to cash manage). Management interviewees indicated that the relatively small amounts available through the Genomics R&D Initiative do not warrant the implementation of more complex management processes. It was suggested that there may be opportunities for improved interdepartmental coordination. However, a centralized peer review process was not seen as being necessary or desirable. The current funding structure, with minimal administrative burden at the program level is seen to be cost-effective.

[31] Note: a detailed analysis of other federal and provincial initiatives is included in the main evaluation report.

C3. Is the three year funding cycle appropriate for achieving intended outcomes?

Interviews

Management suggested that the requirement for renewing approval of the Genomics R&D Initiative every three years has created problems, particularly with delays in funding. As a result, the Department has had to risk manage salaries and delay starting projects. It was felt that A-base funding brings stability regarding staffing, but makes the funds more vulnerable to compete against other operational priorities.

Stakeholders commented that a four or five-year cycle might be better given the time it takes to prepare a TB submission every three years. The interviewees also felt the planning and review process for selecting projects should be expanded to reflect the time it takes for peer review. A longer cycle would also help to ease the burden on external reviewers. If a five-year cycle were to be implemented, a process for mid-term review would be required to make necessary adjustments for changes in priorities and allow renewals based on performance.

C4. What has been the level of effort or cost required by departments / agency to participate in this horizontal initiative? What have been the benefits?

Interviews

Management indicated that $200,000 per year has gone towards administrative costs associated with the coordination and communication (e.g. workshop). This was seen to be reasonable amount and administrative requirements are covered within existing resources. The main benefit was seen to be networking opportunities and minimal administrative burden associated with participation in the interdepartmental Initiative.

A.4.5 Design and Delivery

D1. Is the position of the Genomics R&D Initiative appropriate within the larger government biotechnology strategy? Is the level of integration with other federal government biotechnology programs appropriate?

Document Review

The Genomics R&D Phase 3 Program Framework noted that the Genomics R&D Initiative is one element within in a broader Canadian Biotechnology Strategy, which includes several other initiatives. These include the Canadian Regulatory System for Biotechnology and the Canadian Biotechnology Strategy Fund. Coordination is provided through the Canadian Biotechnology Strategy Secretariat. Together these three initiatives support R&D, regulations and policy. In addition to $4 million Genomics R&D Initiative

funding, HC also receives funding from the CBS Fund ($865,000 in 2004-2005) and the CRSB (approximately $18.948 million in 2004-2005), bringing the total biotechnology program to approximately $23.3 million annually.[32]

Interviews

Management and researchers agreed that the position of the Genomics R&D Initiative is appropriate within the larger government biotechnology strategy. However, there was some concern with the balance of funding available through Genome Canada versus funding to support federal research. One interviewee stated that "the situation puts federal regulators in the position of having to play catch-up. The federal government is making a huge investment in biotechnology, but only a minimal investment to address regulatory needs." It was suggested that there should be more formal mechanisms in place for departments to be more aware of, and to influence, Genome Canada priorities.

Stakeholders agreed that the position of the Genomics R&D Initiative is appropriate within the larger biotechnology strategy. One stakeholder commented that it made sense to maintain a separate fund from CRSB and CBS because these funds have a different emphasis. The stakeholders felt that Genome Canada has a very different purpose within the broader government strategy and has a much heavier focus on commercialization. One interviewee commented that there may be some overlap from a science perspective in terms of tools and techniques, but that the mandate of the Genomics R&D Initiative and Genome Canada research projects are very different, emphasizing the need for science to support ethical and social policy issues.

D2. How effective is the overall governance structure for the Initiative and departmental processes (e.g., project approval process)? Are the roles and relationships clearly defined and appropriate?

Interviews

Management felt that there has not been any deliberate attempt to manage the Initiative on a horizontal basis. Interviewees indicated that the focus of interdepartmental governance has been on seeking TB renewal. Apart from the TB submission, and input to the horizontal RPP and DPR, there is very little coordination across departments. If the funding levels are increased in the future it may be appropriate to re-visit the overall governance structure.

Within HC, roles and relationships are generally seen to be appropriate. Most researchers were satisfied with the peer review and project approval process and felt that it has

[32] Canadian Biotechnology Strategy Horizontal DPR 2004-05 (p. 3)

improved with each phase. Researchers also emphasized the importance of using an external review process and suggested that membership on the Technical Review Committee (TRC) should have a stronger representation from external parties to avoid potential conflicts of interest. As a caution, some researchers indicated that external reviewers may not fully appreciate the regulatory requirements that need to be addressed and their implications. It was also suggested that the role, membership and terms of reference of the TRC for reviewing project proposals should be revisited well in advance of the next funding cycle.

D3. To what extent have the departments been able to leverage the funds provided through the Genomics R&D Initiative? What are the pros and cons associated with the leveraging requirements?

Document Review

Although a review of summary reports for Phase 2 projects provides evidence of leveraging of funds, the format and degree of detail provided was inconsistent. In most cases, funds leveraged from either A-base or other sources were not provided. For example, several researchers reported that leveraged funds are very difficult to estimate and more difficult to track. Some of the funding sources identified in project summaries include the following:

- Canadian Institutes of Health Research;
- HC Office of the Chief Scientist; and
- Food Directorate (A-base funding to cover supplies).

Interviews

Management and researchers indicated that leveraging of funds has not been a large thrust due to the regulatory mandate of HC which limits direct collaboration with industry in research activities. Salaries and operational costs for facilities are supported through A-base. One researcher commented that is not easy to attract external funding sources.

D4. How effective / appropriate is the Initiative's approach to performance measurement? What performance measures should be captured in the next phase and why?

Document Review

HC does not have a complete database of project summary reports for Phase 1 and 2. A special request for project information was sent to researchers on May 3, 2006 (at the time of writing of this report, 4 Phase 1 reports and 12 of 16 Phase 2 reports had been submitted). The DBO is currently in the process of developing an electronic Performance

Information Tracking System for Genomics R&D Initiative, CRSB and CBS Fund projects in consultation with researchers. A detailed logic model and output and outcome performance indicators have been developed for biotechnology within HC. The plan is that each initiative (CRSB, CBS Fund and Genomics R&D) will select indicators that are most relevant to them.

Interviews

Management indicated that the approach to performance measurement and information tracking requires improvement. Researchers stated that performance measurement and reporting requirements have not been clearly defined for the Initiative, and indicated a lack of consistent reporting formats and ad hoc requests for project information. Researchers have to report on their projects vertically within their own organizations, as well as reporting horizontally to meet departmental reporting needs. Non-standardized reporting formats and multiple reporting requirements has led to duplication of effort and inefficiency. On a horizontal basis, several researchers were unaware as to where the information they report goes to and how it is used. From the researchers' perspective, scientific achievement is based on peer reviewed publications, presentations at international conferences and whether they can exchange new knowledge and information with collaborators. It was suggested that the TRC should look at past project reports to guide decisions for project approval in subsequent funding cycles. Another interviewee suggested that there should be an external science advisory board to comment on the quality of the research being done.

D5. How could the Genomics R&D Initiative be improved? What changes are required to make the Initiative more efficient?

Interviews

Interviewees felt that the overall efficiency and effectiveness of the Initiative would be improved by:

- Improving the stability of funding on a longer-term basis to protect the investments that have been made to-date to build capacity. Suggestions varied from revising the project cycle so that approved projects have funds available at the proposed start date and / or moving to a five-year, rather than three-year, funding cycle.

- Establishing clear guidelines (at the program level) to address the issue of departmental taxes that reduce the available funds to support actual research activities. Interviewees stressed the importance of providing consistent corporate guidance with respect to the issue of "taxing" across HC and PHAC so that funds from the Genomics R&D Initiative are not diverted to addressing other A-base priorities at the discretion of different Branches.

- Addressing human resource issues (recruitment, staffing process, retention of highly skilled personnel, and training) associated with the three year funding cycle (e.g., establish consistent departmental guidance with respect to covering staff salaries caused by funding delays).

- Establishing a reasonable and cost-effective approach for performance measurement and communicate the mandatory reporting requirements to researchers at the time of the request for full proposals. Where necessary, provide timely instruction and training in preparation of reports.

- Establishing a set of guiding principles for peer review process that would benefit all departments (e.g., conflict of interest guidelines).

- Starting the project planning cycle earlier to provide more time for peer review and to maximize use of funds.

- Including a funding stream to support management priorities effectively broadening the scope of projects from a bench-science perspective. Such management priorities include the development of communications products, website development, fact sheets on genomics, and educational materials). In addition, if policy research is indeed a priority, the review criteria should be adjusted to be more than bench-science oriented.

- Clarifying the role and management information needs of ADM Sub-committee.

- Revisiting Genome Canada eligibility requirements to open up funding and collaboration opportunities for federal researchers.

A.5 National Research Council Canada

The following is a supplementary report to the main report on the Evaluation of Genomics R&D Initiative that describes those aspects of the evaluation specific to the National Research Council. This report is based on information collected in a review of program and other related documentation and the recent Evaluation of the Genomics and Health Initiative conducted by NRC[33], as well as 11 in-depth interviews – three with program management, six with project leads / researchers (drawn from the research groups involved in the three Phases of the program) and two with stakeholders.

A.5.1 Brief Profile

Strategic Approach

In the late 1990s, with $11 million in new, external funding consisting of $6 million per year received from the Genomics R&D Initiative plus an additional $5 million per year received at about the same time from new NRC-based allocations related to the creation of CIHR, NRC senior management decided to develop a major new, focused program, the Genomics and Health Initiative. To create GHI, NRC built on existing genomics and health related expertise in the five biotechnology research institutes, including:

- Institute for Marine Biosciences (NRC-IMB), Halifax;
- Biotechnology Research Institute (NRC-BRI), Montreal;
- Institute for Biological Sciences (NRC-IBS), Ottawa;
- Institute for Biodiagnostics (NRC-IBD), Winnipeg; and
- Plant Biotechnology Institute (NRC-PBI), Saskatoon.

The initial Genomics R&D Initiative funding (Phase 1) was for three years, April 1, 1999 to March 31, 2002. There have been two successive renewals of the funding (Phase 2 and Phase 3) each for three years. The current Phase 3 funding is for the period April 1, 2005-March 31, 2008.

Theme / Research Priority

GHI has been focused on advancing fundamental and applied research on genomics and health in areas of importance to Canadians, including the diagnosis and treatment of disease, aquaculture, agricultural crop enhancement and environmental bioremediation. As noted, GHI includes a component of health related research that is not genomics.

[33] Evaluation of the National Research Council's Genomics and Health Initiative (NRC-GHI), Final Report, March 2, 2006.

How Initiative is Delivered in Department / Agency

As discussed, GHI is a focused research program, managed and delivered separately from the regular NRC Institute research initiatives. From the start, GHI has built on the research capability in the five NRC biotechnology institutes, and for Phase 3, a number of other NRC institutes are participating. For all three phases, GHI has utilized a competitive process to select research programs, including an in-depth peer review process to support senior management decision making. For the first two phases, researchers in the five NRC biotechnology research Institutes were given the funding criteria and invited to submit proposals to be reviewed. Each program was funded at the million dollar level or higher, and includes a number of projects built around a central theme. In Phase 1, which lasted three years, from 1999-2000 to 2001-2002, GHI funded five programs involving all five biotechnology Institutes, as well as the development of three core genomics platforms. The table below provides a summary of the programs and platforms and research Institutes participating.

Table A16: Summary of Programs in GHI Phase 1

Phase 1 Research Programs	NRC-BRI	NRC-IBD	NRC-IBS	NRC-IMB	NRC-PBI
Genome Science in Agriculture					X
Genome Science in Aquaculture				X	
Prototyping of Biodiagnostics Devices[1]		X			
Genome Sciences in Age Related Diseases	X		X		
Genome Sciences in Infectious Diseases	X		X		
DNA Sequencing[2]	X				
DNA Microarray[2]				X	
Proteomics[2]			X		

[1] not genomics
[2] technology platforms

For Phase 2, many of the research programs were continuations of Phase 1 programs. The number of programs funded increased, however, each received less than requested. In some programs, researchers from other Institutes with relevant skills participated. The following table identifies the Phase 2 research programs and the participating institutes.

Table A17: Summary of Programs in GHI Phase 2						
Phase 2 Research Programs	**NRC-BRI**	**NRC-IBD**	**NRC-IBS**	**NRC-IMB**	**NRC-PBI**	**Other**
Enhancing Crop Performance and Value Through Genomics					X	
Genomics of Aquaculture			X	X		NRC-IMTI
A Genomics-based Approach to Enhancing Bioremediation through Microbial Identification and Community Profiling	X			X	X	
Cancer Genomics	X		X			
Genomics of Human Pathogens and their Host Interactions	X		X	X	X	NRC-SIMS
Multi modal Characterization of Disease[1]		X				
Structural Biology of Cellular Protein Assemblies	X				X	
Systems Biology of Brain Cell Interactions	X					NRC-SIMS NRC-IIT

[1] not genomics

For Phase 3, all NRC Institutes were invited to participate in the proposal process. As a result, there has been greater participation from non biotechnology Institutes in funded programs. Also, in Phase 3, the number of programs was reduced. Two new programs were funded, and only four proposals carrying on from Phase 2 funded programs were accepted. The following table describes the Phase 3 research programs and participating institutes.

Table A18: Summary of Programs in GHI Phase 3						
Phase 3 Research Programs	**NRC-BRI**	**NRC-IBD**	**NRC-IBS**	**NRC-IMB**	**NRC-PBI**	**Other**
Brassica Seed Development	X				X	
Aquatic Animal Disease Management			X	X		
Personalized Medicine for Cancer	X	X	X			NRC-IIT
Kinase Signaling Networks	X		X			
Chronic Cardiovascular Diseases[1]		X				NRC-IMI
Technologies for Pathogen Detection			X			NRC-SIMS NRC-IIT NRC-IMS NRC-NINT

[1] not genomics

Resources

In each phase of the Genomics R&D Initiative, funding has been provided to each department for three years. In Phase 1, NRC was allocated $5 million, $6 million and $6 million for each of the three years from 1999-2000 to 2001-2002 respectively, for a total of $17 million. As mentioned previously, NRC also received $5 million per year as part of allocations related to the creation of CIHR, which was folded into GHI. In Phases 2 and 3, NRC received $6 million per year from Genomics R&D Initiative, and continued to receive $5 million per year from the other source, for a total of $11 million annually. NRC is also contributing additional major A-base funding to GHI. This A-base funding ramped up from $3.5 million in 1999-2000 to a steady state level slightly above the $11 million in dedicated funding in recent years.

The following table shows the GHI dedicated funding allocations for each Phase 1 program for each of the three years.

Table A19: Funding Allocations in GHI Phase 1

GHI Phase 1 Research Programs	1999-2000	2000-2001	2001-2002	Total
Genome Sciences in Agriculture	$ 1,700,000	$ 1,900,000	$ 1,800,000	$ 5,400,000
Genome Sciences in Aquaculture	$ 1,700,000	$ 1,900,000	$ 1,800,000	$ 5,400,000
Prototyping of Biodiagnostics Devices[1]	$ 1,700,000	$ 1,900,000	$ 1,900,000	$ 5,400,000
Genome Sciences in Age Related Diseases	$ 1,600,000	$ 1,700,000	$ 1,700,000	$ 5,000,000
Genome Sciences in Infectious Diseases	$ 1,700,000	$ 1,900,000	$ 1,800,000	$ 5,400,000
Research Platform – DNA Sequencing	$ 500,000	$ 500,000	$ 600,000	$ 1,600,000
Research Platform – DNA Microarray	$ 600,000	$ 600,000	$ 700,000	$ 1,900,000
Research Platform – Proteomics	$ 300,000	$ 300,000	$ 400,000	$ 1,000,000
Program Administration / Networking.	$ 200,000	$ 300,000	$ 400,000	$ 900,000
Total	**$ 10,000,000**	**$ 11,000,000**	**$ 11,000,000**	**$ 32,000,000**

[1] not genomics

The allocation of dedicated GHI funding for Phase 2 programs and other activities is shown in the following table. The breakdown by year has not been included; however, in general, as seen for the table above, the funding was divided evenly across the three years.

Table A20: Funding Allocations in GHI Phase 2	
GHI Phase 2 Research Programs	**2002-2005 Total Funding**
Enhancing Crop Performance and Value Through Genomics	$ 4,800,000
Genomics of Aquaculture	$ 2,600,000
A Genomics-based Approach to Enhancing Bioremediation through Microbial Identification and Community Profiling	$ 750,000
Cancer Genomics	$ 4,950,000
Genomics of Human Pathogens and their Host Interactions	$ 8,400,000
Multi modal Characterization of Disease[1]	$ 4,300,000
Structural Biology of Cellular Protein Assemblies	$ 1,500,000
Systems Biology of Brain Cell Interactions	$ 4,200,000
Research Platform Support[2]	$ 0
Program Administration / Networking[2]	$ 1,500,000
Total	**$ 33,000,000**

[1] not genomics
[2] approximately $980,000 was provided from the research program budgets

The table which follows is for GHI Phase 3 funding. Funds have been allocated evenly across the three years.

Table A21: Funding Allocations in GHI Phase 3	
GHI Phase 3 Research Programs	**2005-2008 Total Funding**
Brassica Seed Development	$ 4,800,000
Aquatic Animal Disease Management	$ 3,750,000
Personalized Medicine for Cancer	$ 4,950,000
Kinase Signaling Networks	$ 1,500,000
Chronic Cardiovascular Diseases[1]	$ 7,200,000
Technologies for Pathogen Detection	$ 6,600,000
Research Platform Support[2]	$ 900,000
Program Administration / Networking[3]	$ 3,300,000
Total	**$ 33,000,000**

[1] not genomics
[2] an additional $300,000 has been planned to be provided from the research program budgets
[3] covers cost of program managers and a $300,000 per year reserve fund to be distributed to the research programs based on needs

It should be noted that the funding for non-genomics, health-related projects increased significantly in Phase 3.

Project Approval Process

As outlined in the GHI Evaluation Report, GHI has used a competitive process to select the major programs for all three phases. For Phase 1, because of the lack of lead time, the process was shortened and allocations were made to generic areas of research (i.e. aquaculture, agriculture). In addition, management decided to fund the development of three major research platforms for DNA sequencing, DNA microarray and proteomics as critical infrastructure to support the various research programs.

The process has become progressively more structured and complex for each of the phases, in order to make appropriate choices for such a major initiative. For Phase 2, the process involved a request for proposals, external peer review and management decision making. For Phase 3, a request for proposals was made, which identified the types of programs being solicited and the program criteria. Those wishing to submit a proposal first provided a Letter of Intent, which was reviewed by an external Panel of Experts, which provided feedback on all proposals. Successful proponents whose proposals were recommended to proceed then developed full proposals, which were evaluated by external technical reviewers for scientific excellence. The GHI Expert Panel then reviewed proposals and reviewer comments and discussed the proposals with the Scientific Leaders. Based on those sources of information, the Expert Panel then made recommendations to NRC senior management, who made final decisions as to which programs would be funded and at what level.

A.5.2 Rationale

R1. Are the mandate and the strategic objectives of the Genomics R&D Initiative still relevant? What need was the Initiative intended to address? Does this need still exist?

Document Review

A number of documents provided background on the rationale for the initiative. As outlined in the Phase 1 program documentation, the Genomics R&D Initiative is part of the broader Canadian Biotechnology Strategy, developed in 1998. The Strategy recognized the low level of genomics R&D capacity in Canada and that immediate increased investment in genomics R&D was necessary if Canada was to be able to participate in this important emerging field. The original strategic objectives of the broad Genomics R&D Initiative as defined in the Phase 1 documentation were to contribute to social, economic and environmental outcomes through the enhancement of genomics-

based research and development programs in several federal government departments. The Phase 3 Program Framework noted that the action plan "will involve building on current core federal capabilities in genomics R&D".

The 2005 GHI Evaluation Report cited the Prime Minister's Response to the 2004 Speech from the Throne, which identified health care as the top priority of Canadians, as demonstration of the continuing relevance of GHI health related objectives to government priorities. The report noted that GHI has been focused on advancing fundamental and applied research on genomics and health to address important Canadian needs, including the diagnosis and treatment of disease, aquaculture, agricultural crop enhancement and environmental bioremediation. Other GHI objectives related to food production are also relevant to government priorities. The Phase 1 documentation described the widespread support for developing federal genomics capacity to support agricultural policy development and production. This is relevant to NRC as well as AAFC, in so far as it applies to NRC's genomics research centered at PBI, which collaborates with AAFC in canola and other crop genomics research initiatives.

GHI objectives are also well aligned with the strategic directions identified in NRC's new five year strategic plan "Science at Work for Canada". For example, GHI's focus on genomics applications for human health and food are consistent with the plan's priorities related to health and wellness. The plan also identifies the need to leverage NRC competencies through collaborations with other Science-based Departments and Agencies (SBDAs), as GHI does.

Interviews

This issue was addressed in interviews with GHI managers and stakeholders, who reported that there remains a need to fund the Genomics R&D Initiative in order to maintain and further develop the technical and human capacity that has been built up in GHI Phases 1 and 2. Many of the Phase 3 projects will use this new enabling technology to help make progress towards achievement of NRC and government objectives in health, agriculture and other areas. Interviewees noted that the need for genomics research is stronger than ever, as genomics has become recognized as an important enabling technology in many sectors (forestry, fishing, agriculture and health). Now that capacity has been developed, it is time to make use of the knowledge and capability developed. It was noted that the program has been running for eight years, which is still relatively early in terms of moving from early stage basic and applied research to the achievement of longer term socio-economic impacts.

R2. Is there a legitimate and necessary role for government in this area?

Document Review

To a considerable extent, this issue was examined under R1, above; however, there are a number of additional documents that provide evidence on this issue. The GHI Evaluation Report discussed this issue. The evaluation cited a study by Lewis Branscome from Harvard University, who noted that "if the intended beneficiary of research is the greater public, then public investment in that research is appropriate, provided that the work is done under highly creative competitive conditions and the results are widely diffused and appreciated". This is clearly true of the Genomics R&D Initiative and GHI.

The 1999 Phase 1 Program Framework provided reasons why federal funding was appropriate. The National Biotechnology Advisory Committee released a report in 1998 that clearly identified genome research as the top priority for Canadian biotechnology and recommended increased federal funding for the genome program.

The Phase 1 documentation noted that the funding for genomics research is expected to have both economic and social benefits, including industrial competitiveness, economic growth, a cleaner environment, better management of natural resources and improved therapeutics. These are all areas which government has supported through research funding and in which GHI is participating. Furthermore, the Phase 3 Program Framework noted that the federal government has wide ranging responsibilities related to genomics by: playing a key role in building and participating in local, national and international genomics R&D initiatives; supporting the development and application of the scientific knowledge base; and evaluating potential new and modified products to protect human health, safety and the environment. The Framework went on to state that "the continuation of intramural Genomics R&D Initiative funding directed to federal departments is vitally important to complement and link to other key government investments in biotechnology...".

Interviews

This issue was addressed by only a few interviewees, one of whom commented that there is really no other place to undertake this work for the following reasons:

- provinces in general have limited research capacity to build on;
- large, expensive equipment and infrastructure are needed;
- multi-disciplinary teams are needed;
- voluntary sector does not have the required expertise;
- initiatives are early stage research, not immediately linked to products, sales and profit; and

- many of the outcomes need to be widely distributed as public good, not held by one organization as intellectual property.

Others pointed out that GHI supports the achievement of NRC's mandate in the areas of health and agriculture.

A.5.3 Success

S1. Has GHI achieved, or made progress towards, its specific objectives / goals?

Discussion under this issue will be general, with more detailed examination of specific aspects of success covered in following sections.

Document Review

There are several documents which describe GHI objectives. The Phase 1 Program Framework stated that NRC planned to develop technologies in three important areas of application: agriculture; pathogenesis; and human diseases related to aging. The Phase 1 Genomics R&D Initiative Performance Report prepared as part of the Phase 2 funding request described the GHI objectives at that time. These have remained substantially the same through all three phases, with minor word changes and additions for Phases 2 and 3. For Phase 3, GHI goals are to:

- advance science and technical knowledge within genome sciences and health related research which contributes to Canada's competitiveness in the 21st century;
- create and use genomics or health-related technologies to support value for Canada in industrial sectors such as aquaculture, agriculture, environment and health;
- support and participate in sectoral, national and international genomics and health-related innovation networks;
- foster cooperation and integration in genomics and health-related research and innovation programs across NRC, as well as with partners in federal departments and agencies, other levels of government, universities and the private sector; and
- foster excellence in horizontal research program management and accountability.

The GHI Evaluation Report noted that GHI was NRC's first large-scale internal horizontal research program, which "aims to encourage close collaboration between its research Institutes, and its partners in other government laboratories, the private sector and universities, both nationally and internationally". The report went on to say that GHI also

"focuses on transferring the knowledge developed in genomics and health to a variety of industrial sectors".

There are a number of documents which discuss GHI performance in terms of these goals. The GHI Phase 1 Performance Report described GHI progress in the achievement of objectives in terms of:

- contributions towards an expanded knowledge base through the publishing of 77 articles in refereed journals, 6 scientific reviews, 11 chapters in books and 71 invited presentations at International Conferences;
- progress towards the development of new technologies as indicated by the filing of 18 patents; and
- participation in a national genome innovation network as indicated by the signing of numerous formal collaborative agreements (MOUs) and contracts with Canadian and international universities, Canadian public and government organizations, and private sector firms.

The GHI Evaluation Report examined the issue of success thoroughly. It reported that:

- During Phase 2, GHI researchers had continued to publish extensively in peer-reviewed journals. Although each project had not been completely successful, "GHI has led to beneficial contributions to the advancement of scientific and technical knowledge in a number of research areas".
- GHI had developed three core technology platforms (DNA microarray, DNA sequencing and proteomics) that together provide world class infrastructure to support genomics research and technology development. By the end of the Phase 2 program, GHI had filed 132 patents, 29 issued and 20 licenses. The report noted that it was still too early to expect significant market level impacts, and these should become more apparent at the end of Phase 3 or even later.
- While Phases 1 and 2 had been successful in improving the interactions among NRC's biotechnology Institutes, there was a variable but overall lower level of networking with other government departments (OGD) compared to interactions within NRC.
- GHI had contributed towards a more integrated NRC, however, there had been little focus within NRC or GHI in becoming more entrepreneurial.

Interviews

Interviewees generally identified the main progress from Phase 1 as being related to building capacity (hiring people and building technical infrastructure and platform technologies). More specifically, for Phase 2, one interviewee identified the development of biological "homing agents" that can be used for diagnostics and therapeutic use to support physical treatment of disease, such as radiation. Other work was potentially useful for population screening through analysis of blood samples.

S2. To what extent did the projects funded under Phase 1 of the Genomics R&D Initiative build capacity inside NRC laboratories to carry out genomics research?

Document Review

A number of documents provided information to address this issue. The GHI section of the Phase 1 Genomics R&D Performance Report noted that 106 new staff were hired as a result of GHI. The GHI Evaluation Report also noted that in Phase 1, GHI "focused on building genomics infrastructure (three technology platforms) and research capacity". The other aspect of capacity building noted was in terms of team building, both within institutes and among institutes.

Interviews

NRC interviewees consistently commented that the specific results of Phase 1 were building capacity, and getting people started on working in larger teams on larger, more strategic projects. Capacity building included the purchase of equipment, development of technical infrastructure and hiring of more PDFs, young people with state of the art training, who helped advance NRC's overall capability in genomics rapidly. Capacity was also built in terms of developing processes and culture to manage and participate in very large, multi-institute, horizontal projects. One person interviewed said that Phase 1 has provided the foundation on which Phases 2 and 3 have been built.

S3. Did this increased capacity strengthen the research carried out in NRC?

Document Review

The GHI Evaluation Report noted that as a result of the capability and credibility developed during Phase 1, NRC's genome science researchers are being recognized internationally. In a number of cases, researchers are joining international collaborations based on expertise and knowledge developed during Phase 1.

Interviews

Most interviewees agreed that the increased capacity developed during Phase 1 strengthened and changed the research carried out in general. One example is the capability in bioinformatics that is being used much more broadly to support other research in NRC's biotechnology Institutes. The three research platforms created in Phase 1 are also used by other NRC researchers and external organizations such as universities. Other interviewees noted that the interdisciplinary, team approach used within GHI has spread to other NRC projects.

S4. Did this increased capacity created in Phase 1 translate into the benefits of advances in research and technology in Phase 2 for department constituents?

As discussed under S2, there is evidence that the work carried out under Phase 1 was critical for Phase 2 projects. There are additional sources of evidence as well.

Document Review

As can be seen by project titles in Section 5.1, and more specifically in project proposals, Phase 2 and to a large extent Phase 3 projects build on the work from Phase 1. The GHI Evaluation Report notes that "A widely held view, internally and externally, was that in GHI-1, NRC was putting in place the building blocks for genomics research; during GHI-2, researchers put those genomics approaches to work in their research".

Interviews

Interviewees also reported that for most projects, the research carried out in Phase 2 could not have been done without the research platforms, staff hiring and early research in Phase 1. The knowledge developed in Phase 1 was applied in Phase 2. In some cases, the milestones for Phase 1 projects were not completely achieved, and carried into Phase 2.

S5. To what extent has the Initiative strengthened coordination, cooperation and linkages between the appropriate research institutions?

There is considerable evidence that GHI Phases 1 and 2 have strengthened linkages within the NRC biotechnology Institutes and, for Phase 3, with other Institutes.

Document Review

The GHI Evaluation Report discussed this issue extensively. The report noted that "GHI-2 was successful in building a network of genomics researchers within NRC" and "biotech directors general are now more coordinated, (there is a) commonality of strategy – together we are stronger than apart". The report also noted that GHI has fostered greater

collaboration within participating institutes. However, the report noted that "GHI-2 made little progress in meeting this objective outside of NRC" and "there is little or no official interaction between federal organizations involved in genomics research at the senior management level". On the other hand, the report did take note that GHI researchers participated in a number of formal genomics related networks and that GHI researchers were connected to larger national efforts to exploit genome science, in particular Genome Canada funded projects.

The GHI section of the Phase 1 Genomics R&D Performance Report noted that "a network of interactions continues to grow, for example, collaborations have been established with several Canadian universities and companies and several GHI activities are now linked to the Genome Canada regional centres through agreements totaling in excess of $20 million".

The discussion in Section S1 on networks is also relevant to this issue, as it identified numerous Memoranda of Understanding (MOU) and contracts with public and private sector partners.

Interviews

Interviewees spoke about this issue at length, and provided a number of insights. There was a clear sense that GHI has strengthened collaboration among the biotechnology Institutes.

In the years before GHI began, NRC management had made program cuts based on perceived duplication among Institutes. This led to a reduction in collaboration between institutes, and a 'silo mentality' among managers. GHI, on the other hand, encouraged inter-institute collaboration, and has had a huge impact on changing NRC culture at the management level to support collaboration among Institutes.

In terms of working with other departments, an interviewee discussed the long standing relationship between NRC-PBI and AAFC, and emphasized that the Genomics R&D Initiative funding provided to NRC and AAFC had considerably strengthened the connection. An MOU was signed between NRC-PBI and the AAFC Saskatoon Research Centre soon after the beginning of Phase 1 to collaborate on genomics research on canola. Other relationships mentioned included those with the newly formed Public Health Agency of Canada, the linkages between NRC-IMB and DFO and CFIA with respect to aquaculture, and those between NRC-BRI and Environment Canada with respect to the bioremediation project in Phase 2. More generally, interviewees discussed the barriers responsible for difficulties in developing inter-departmental projects as being at the senior management level as well as difficulties in transferring funds among the different financial systems among departments. It was also pointed out that since the Genomics R&D Initiative funds are given to each department with no requirement for collaboration, there

is no financial incentive to do so. Others pointed out that some departments such as Health Canada and Environment Canada are primarily regulators with different research objectives than NRC. Another interviewee noted that there is a growing recognition that public policy issues defy departmental boundaries; however, the present system provides little ability to address national issues beyond the ability of any one department to solve. Several interviewees thought that Departments/Agencies should be working together on larger issues where there is complementarity of capability and mandate.

S6. What have been the facilitating and impeding factors for the success of Phases 1 and 2 of the Initiative?

Document Review

The GHI Evaluation Report identified a number of barriers to achieving maximum success for GHI. These included:

- burdensome and time consuming administrative procedures, such as the hiring process and the movement of funding both within a program and across Institute boundaries (these are not specific to GHI, but are more general across NRC and the federal government);
- physical distance, which was considered by some to be a challenge;
- a limited national talent pool with the desired experience and capabilities, considered by some to make attraction of personnel to the program difficult;
- federal IP rules, considered a barrier to interactions with firms; and
- the limited support available from the NRC Business Development Offices, considered by some to be a barrier to successful collaboration and technology transfer.

Other higher level barriers identified that affected industry's willingness to conduct research in Canada were the lack of clear national standards for clinical trials involving genomic or genetic testing and the lack of clear standards for genetic privacy. These high level barriers affect the likelihood that industry will invest in Canada and take up, and apply, GHI research.

There is also considerable evidence of the public acknowledgment of the benefits of linkages between the Genomics R&D Initiative and Genome Canada. For example, the Phase 2 program framework states that "Good complementarity has been developed with Genome Canada. Departments collaborate with partners in projects applying for funding from the five regional Genome Canada Centres. There is also ongoing consultation

between the departments and Genome Canada regarding priorities and progress of genomics research". The Phase 3 program framework also comments on the complementarity and linkages between the Genomics R&D Initiative and Genome Canada and describes several Genome Canada projects that departments participate in, or lead. The framework also notes that new models for future collaborations between federal organizations and Genome Canada are being developed and will be reviewed by the TB Secretariat.

The GHI section of the Phase 1 Genomics R&D Performance Report and the GHI Evaluation also reported examples of GHI participation in Genome Canada funded projects.

Interviews

The most important facilitating factor identified by several people was the large scale, dedicated funding available, which attracted interest and resulted in new people being hired, and new equipment and facilities being purchased and built. Another person interviewed noted that the self imposed requirement to match the $11 million from the Genomics R&D Initiative and new A based funding related to the creation of CIHR demonstrated a corporate commitment to emphasize genomics and manage on a strategic program basis. The use of peer review for project selection and buy in from scientists were also considered by some to facilitate success.

In terms of impediments, one interviewee noted that at the beginning of Phase 1, TBS wanted more documentation and funding was not received until September, 4 months after the start of the fiscal year, which delayed start up and the ability to achieve all Phase 1 milestones. Another person noted that for Phase 2, NRC tried to partially fund a larger number of programs by reducing their scope. This took additional time to redesign the programs and renegotiate funding and relationships, and was considered by the interviewee to be an error in judgment. In Phase 3, fewer projects were selected, and these were fully funded. Other impediments identified related to the radical nature of introducing a horizontal initiative to an Institute-based system. They included lack of support from institute management, access to A-base funding controlled by the Institutes, and willingness to develop inter-Institute projects. Another was the lack of skills and procedures to manage large projects within NRC. For Phase 3, some projects have engaged full or part time project managers to carry some of the administrative and reporting burden that the scientific leaders were previously responsible for. One person also identified difficulties in attracting and hiring good people. Another interviewee spoke of the limited visibility of the Genomics R&D Initiative in general as an impediment to success and credibility. The sense was that, in general, the funding "disappears into the departments", with little information about its impact. The interviewee commented that a sense of limited public accountability for the program as a whole comes from this low visibility. Another interviewee spoke about the visibility of

GHI specifically. It has its own external website, a separate section in the NRC Departmental Performance Report, and extensive coverage in presentations by the NRC President. GHI also has an Annual General Meeting and Scientific Conference, with presentations from GHI program participants and invited speakers from across Canada and internationally.

Several interviewees also spoke about the linkages with Genome Canada, including the sharing of facilities and platforms, and the participation in Genome Canada funded projects during Phases 1 and 2.[34] These were considered as an excellent way to interact with other players, including universities and industry.

A couple of interviewees identified the serious harm to the ability of government departments to collaborate with other national and international genomics R&D performers including universities caused by the recent TB decision with respect to access to Genome Canada funding.

S7. Are there other intended or unintended impacts resulting from GHI?

Document Review

The GHI Evaluation Report identified a number of other impacts. These include spill over to other research programs. For example, some of the knowledge and techniques gained on canola can be transferred to other crops such as flax, peas and lentils. GHI has also had a significant impact on training HQP, typically PDFs and technicians, some of whom stay at NRC, while others move on to other positions in Canada and elsewhere. They contribute to building genomics capability within NRC, the government, Canada and internationally.

Interviews

The approaches being used to deliver GHI have served as a model for NRC to follow for other work. Some mentioned that learning how to work together in teams was an unspecified benefit. However it was also noted that deciding on authorship for large teams was a problem. One interviewee said that the positive results of building an inter-Institute team under GHI had led to the development of another inter-institute team for a different initiative. Another interviewee said that GHI is seen within NRC as a successful management and governance model for large scale, strategically focused initiatives.

[34] Note: beginning with Phase 3, decisions by TBS have made it clear that government departments/agencies cannot receive Genome Canada funding directly.

The ability to work on other, non-GHI funded national and international genomics projects as a result of the expertise and credibility developed through GHI was identified by several interviewees.

S8. To what extent would the impacts have occurred without the Initiative?

Interviews

The opinions of interviewees varied to some extent. Some said that nothing would have been done, however, most consider that some of the A-base funding provided to GHI would have been spent on genomics R&D, but much less would have been done and whatever was done would have been fragmented and carried out at the Institute level without the large focused GHI program. Everyone interviewed considered the Genomics R&D Initiative funding to have been a major factor in whatever success has been achieved to date.

A.5.4 Cost-Effectiveness / Alternatives

C1. Does the Genomics R&D Initiative complement, overlap or duplicate other federal or provincial initiatives related to genomics or biotechnology?

Document Review

The Genomics R&D Phase 3 Program Framework noted that the Genomics R&D Initiative is one element within in a broader Canadian Biotechnology Strategy, which includes several other initiatives. These include the Canadian Regulatory System for Biotechnology and the Canadian Biotechnology Strategy Fund. Coordination is provided through the Canadian Biotechnology Strategy Secretariat. Together these three initiatives support R&D, regulations and policy. The Phase 3 Framework also stated that "Good complementarity and linkages have been established between federal departments receiving intramural genomics R&D funding and Genome Canada", and gives examples of collaboration with external partners funded through the five Genome Canada Centres and international Genome Canada initiatives.

The GHI Evaluation identified two additional sources of funding for biotechnology and genomics R&D beyond the four mentioned above. These include CIHR and the Canada Foundation for Innovation. The evaluation also noted the review underway led by Industry Canada, which is reviewing federal government involvement and investments in genomics R&D and examining the various institutions, roles and most appropriate support framework for the long term.

Interviews

Interviewees provided considerable input on the linkages between GHI, the Genomics R&D Initiative and other related federal initiatives such as Genome Canada.

One interviewee discussed the relationship between Genomics R&D Initiative funding and the Canadian Regulatory System for Biotechnology, and observed that in some departments such as Health Canada and Environmental Canada there is some overlap with the regulatory funding and objectives.

Interviewees noted that GHI has been involved in Genome Canada funded projects, as one of a number of partners. It was noted that the relationship with Genome Canada had been planned to be complementary, with some purposeful overlap, which is needed in order to collaborate. GHI's research platforms were intended to provide one means of partnering. (The GHI DNA Sequencing platform is recognized as a Genome Canada facility.) One person considered that Genome Canada funded work is often more fundamental and academic, often involving international partners, with publications as a major goal; whereas GHI is more focused on applications, using larger interdisciplinary teams, primarily within NRC. GHI researchers and those in other Government laboratories have been partners in a number of Genome Canada funded projects, where their expertise has been relevant. One interviewee spoke of the benefits of having a partnership between federal laboratories, universities and industry through a Genome Canada funded project, to form a larger critical mass. In discussing the relationship with Genome Canada, one interviewee said that there has not been much contact with the Ontario Genomics Institute, which was considered to be "Toronto-centric". One person interviewed spoke of the divide between government, universities and industry as a problem which needs to be overcome.

CIHR funded projects were also considered to be more fundamental than government ones.

Another interviewee noted that there is some similar work being done at universities.

One person commented that NRC has been able to develop some important infrastructure using CFI funding through partnerships with universities (i.e., IBS and Ottawa universities).

It was noted that the CBS Fund is focused on policy development, not R&D, although there was some limited funding of genomics R&D in the early years (before 2002).

C2. Is the funding structure of the Genomics R&D Initiative the most appropriate mechanism for achieving the intended objectives? Are there more cost-effective alternative ways to achieve the Genomics R&D Initiative mandate?

Document Review

As discussed in section R1, the mandate for the Genomics R&D Initiative is quite general, and focuses on improving capability, rather than specific outcomes of the use of that capability. The Phase 3 Program Framework states that "horizontal collaborations between (funded) organizations are pursued wherever relevant and possible". The Phase 1 Program Framework identified a number of projects in which funded Departments planned to work together and with external partners.

The GHI Evaluation noted the need to develop marketplace applications of the new knowledge created in the earlier phases. The evaluation recommended a portfolio approach in future phases, funding a balance of basic research and applied programs. For applied, "close to market" programs, market assessment studies should be performed as part of the selection process to maximize the likelihood of success. A number of other recommendations were made to improve the effectiveness of the management and delivery of GHI, including clear linkage of GHI programs with NRC priorities and continued improvements to the project selection process and use of external peer reviewers.

Interviews

GHI interviewees at the management level addressed this issue from the Genomics R&D Initiative perspective. Most would like to see a change. One person noted that there had been a missed opportunity in the late 1990s, at the start of Genomics R&D Initiative and Genome Canada to develop a truly integrated Government of Canada program. Instead the initiative was broken up into separate parts.

Several interviewees noted that each participating department receives its own financial allotment, which is used to support the achievement of the departmental mandate. Keeping some funding to support inter-departmental projects was suggested as a means of working on larger issues. It was also noted that some departments receive very little funding (i.e., DFO with less than $1 million), which limits their ability to contribute.

One person made a specific suggestion that was supported by others' more general observations. It was to increase funding by $20 million, with $10 million going to increase allocations for Environment Canada, DFO and NRCan, and the other $10 million going to fund inter-departmental projects that focus on truly national issues selected through a full peer review process. Another suggestion was to move the funding to dedicated A-base, to remove the risk of not being renewed every three years. Research

requires continuity and the need to manage longer term projects with the possibility of not renewing funding causes major problems (see next section on 3 year funding). However, it was recognized that major change of this nature may be difficult in the present political environment.

C3. Is the three year funding cycle appropriate for achieving intended outcomes?

Document Review

The GHI evaluation reported that researchers considered that, while the three year time frame is suitable for planning research and building capacity, it is not long enough to move from early research to achievement of marketplace outcomes. In Phase 2, all Phase 1 programs were successful in being continued for the next three years. In Phase 3, not all Phase 2 programs were continued. Two of the programs were new and four built on Phase 2 programs. The evaluation report discussed the difficulties caused by the ramping down of large Phase 2 programs that were not funded in the next phase and the impacts on staff, and relationships with partners. The report also discussed options for funding GHI programs for durations that did not align with the Genomics R&D Initiative three year funding cycle.

Interviews

A number of interviewees considered three years to be appropriate, particularly for a project that is continuing into the next Phase of the funding cycle. For a start-up project, three years is not long enough to make good progress, and it can be difficult to spend the allocated funding in the first year because of the time required to mobilize human and other resources for a new research project. Some commented on the major effort both at the management and the researcher levels in the selection process (many steps including developing proposals, peer review, management decisions). Others noted that the three year funding forces researchers to focus on getting early progress. One person noted that three years is short for staffing, including the time to hire (does not align with the five-year term for NRC Research Associates).

Most suggested that five years would be more appropriate, perhaps with a major review half way through. There was some discussion that NRC did not have to follow the same funding cycle as the Genomics R&D Initiative Fund, and could in fact, accept projects for a longer period, with the proviso that funding might be cut back to A-base levels if the Genomics R&D Initiative funding was not renewed. NRC management apparently decided not to follow this approach, which was considered more risky. Some interviewees noted that Canadian Regulatory System for Biotechnology (CRSB) funding is dedicated A-base and suggested that Genomics R&D Initiative funding also should be.

C4. What has been the level of effort or cost required by departments / agency to participate in this horizontal initiative? What have been the benefits?

Document Review

With respect to the issue of horizontality, the Phase 1 Program Framework reported that each funded organization will pursue their own research programs. The Framework noted that the six funded research organizations planned on working together and with external partners on several specific projects that were identified.

Interviews

This issue was addressed in management interviews. One person noted that the Genomics R&D Initiative is NOT an inter-departmental horizontal initiative and was never designed to be one. However, as noted in the GHI Evaluation Report, NRC does consider GHI to be an internal horizontal initiative linking Institutes.

One person noted that NRC has subsidized much of the cost of coordinating departmental involvement through the Working Group, by leading the development of Treasury Board Submissions, etc. This informal secretariat role was estimated to be about 30% of a professional's time, plus administrative support.

Some noted that NRC is providing 100% matching funding, so this could be considered a cost. Other than that, much of the ongoing cost is borne by the GHI Coordination Office, perhaps two person years. There has been some cost in managing this horizontal program, including project selection; however, most of those costs are required by the processes put in place by NRC to manage the initiative. The Genomics R&D Initiative Working Committee carries the majority of the burden in coordinating and managing this initiative at the inter-departmental level and liaising with the CBSec and TB. NRC senior managers play a minor role. There is considerable effort involved in the CBS relationship, consisting of meetings, and reporting, which is carried largely by the GHI Coordination Office.

A.5.5 Design and Delivery

D1. Is the position of the Genomics R&D Initiative appropriate within the larger government biotechnology strategy? Is the level of integration with other federal government biotechnology programs appropriate?

Document Review

The discussion under C1 is also relevant to this issue, particularly the reference to the broader review of federal genomics R&D presently being undertaken, led by Industry Canada.

Interviews

It was pointed out that some departments receiving Genomics funding (DFO, Health Canada and Environment Canada) also have a regulatory role and receive CRSB funding. Others, like NRC, receive only Genomics R&D Initiative funding. One person said that the major benefit of the CBS umbrella is that the size of the combined funding shows the importance of biotechnology.

Several people commented that there is minimal integration with other programs, and that there should be more. One person commented that federal departments conducting genomics R&D and Genome Canada have learned to live with each other and complement and benefit each other. (The contribution to Genome Canada funded projects made by government departments receiving Genomics R&D Initiative funding has been discussed previously in Sections S5 and S6.)

One person interviewed speculated on the value of having a single federal genomics agency (or at least a single federal genomics funding agency).

D2. How effective is the overall governance structure for the Initiative and departmental processes (e.g., project approval process)? Are the roles and relationships clearly defined and appropriate?

Document Review

The Phase 3 Program Framework addressed governance, and noted that an inter-departmental Genomics R&D Initiative ADM Co-ordinating Committee (GACC) had been established to oversee collective management and coordination of the federal genomics R&D initiative. This committee functions as a subcommittee of the federal Biotechnology ADM Coordinating Committee established under the CBS, and is responsible for ensuring that "government objectives and priorities are addressed, common management principles associated with R&D management are implemented and horizontal collaborations between organizations are pursued, wherever relevant and

possible". The Genomics R&D Working Committee supports GACC. The CBS Fund Program Evaluation and the GHI Evaluation both discussed the lack of effective decision making in the higher level CBS management structure that is supposed to oversee the three CBS funds. The highest level of active coordination with the other funds and CBS Secretariat is at the director general level.

The GHI Evaluation addressed both of these questions. In terms of the integration of Genomics R&D Initiative within the Canadian Biotechnology Strategy, the evaluation cited a recent report of the Office of the Auditor General[35] that noted that the Ministerial Coordinating Committee had not been "active in providing leadership to implement action plans to achieve the strategy's goals" and there had been a "lack of top-level leadership". Within GHI, while there were no major problems, there had been some concerns about varying understanding as to responsibilities of Program Scientific Leaders and institute directors general. To address these concerns, a Governance Accountabilities and Program Management Framework was created for Phase 3, which describes accountabilities and responsibilities for GHI as a whole and for the individual research programs.[36] The evaluation also examined the project approval process, which has evolved over the three phases. For Phase 3, the process was in general considered effective, but there were concerns about the high level of effort required to develop a proposal and the degree of transparency in the rationale for final funding decisions.

Interview

Interviewees said that at the organizational level, the Genomics R&D Initiative, CRSB and the CBS Fund communicate through the CBS Secretariat, which holds meetings and coordinates reporting through a CBS Horizontal DPR. However, there is no joint decision making. The Genomics R&D Initiative Working Group, the group providing coordination among those departments receiving Genomics R&D Initiative funding, has no formal terms of reference. At higher levels, above the GACC, there have been few meetings. While there may be reporting relationships in theory, they don't exist in reality. Within GHI, scientists approve of the in-depth project solicitation and approval process followed to select projects, as it is based on peer review and expert opinion. The process is complex, time consuming and costly, however it is considered by management and most researchers interviewed to be appropriate to spend significant time, effort and funds to make major multi-year financial decisions.

35 Report of the Auditor General to the House of Commons, Chapter 4, Managing Horizontal Initiatives, page 9, November 2005.

36 This Framework was approved by the NRC Senior Management Committee and recommended as a model for other horizontal research programs at NRC.

D3. To what extent have the departments been able to leverage the funds provided through the Genomics R&D Initiative? What are the pros and cons associated with the leveraging requirements?

Document Review

The Program Frameworks for Phases 2 and 3 address this issue. The Phase 3 Framework states that "All departments have levered the government's investment in genomics R&D by providing additional (or matching) funds by allocating A-base to supplement genomics R&D funding".

It is important to remember that NRC also received an additional $5 million per year in A-base funding related to the creation of CIHR, which management decided to combine with the Genomics R&D Initiative funding, for an annual total of $11 million. The annual financial reports show that NRC ramped up A-base funding, beginning in 1999-2000 with A-base funding of about $3.5 million, to a present level at least equal to or higher than the $11 million. The GHI Evaluation report noted that some of the smaller institutes found it difficult to free up matching A-base funding for GHI programs they were involved in.

Interviews

Several people stated that NRC made a commitment at the start of Genomics R&D Initiative Phase 1 to match funds received with A-base funding from the institutes performing the selected GHI projects. Some interviewees said that management's decision to develop and deliver a focused genomics initiative funded by the $11 million, together with matching A-base funding, separate from departmental programs, was a radical departure from NRC's usual practice, and signaled the importance placed on this Initiative.

It was also noted that it is not possible to expand this practice of providing matching A-base funding too far, as institutes, particularly small ones, have limited resources, and have little flexibility to direct funding to other research.

D4. How effective / appropriate is the Initiative's approach to performance measurement? What performance measures should be captured in the next phase and why?

Document Review

The Phase 2 Program Framework described initiatives associated with defining overall program performance and developing an accountability framework "for enhanced coordination, monitoring and reporting on activities". The Phase 3 Program Framework noted that "A key step to improve the reporting of genomics R&D investments across

departments will be the preparation of a single integrated annual performance report that documents research outcomes and impacts."

The GHI Evaluation reported that the approach to performance reporting for GHI-2 was not considered to be effective and was not generally supported by interviewees. The evaluation also reported that, while individual departments provided input to the annual CBS Horizontal DPR and RPP concerning their Genomics R&D Initiative funded programs, a specific report for the Genomics R&D Initiative has never been developed. The evaluation cited an Office of the Auditor General (OAG) report that noted that inadequate reporting and measurement of the impacts of horizontal programs is relatively common. The report found that "the federal organizations we examined have not adequately reported on results"[37]. The evaluation also noted that GHI has not developed specific performance measures.

Phase 3 funding approval was conditional on the funded departments and agencies providing an annual performance report for the Genomics R&D initiative in the future. The RMAF developed as part of the present evaluation will identify the appropriate performance measures for this report.

Interviews

It was noted that the Genomics R&D Initiative has no formal performance measurement system in place. There was an accountability framework developed in 2001 for the Genomics R&D Initiative, but was never used, as it was considered to be impractical. As discussed under document review, there is a CBS Horizontal Departmental Performance Report, which incorporates input from the Genomics R&D Initiative along with CRSB and the CBS Fund, and each department provides what is available from its own system. There is a need to develop an up-to-date integrated RMAF and performance measurement reporting system for the Genomics R&D Initiative. GHI is leading progress in this direction within the Working Group, and the RMAF developed as part of this study will provide the basis for reporting.

For GHI, many interviewees commented that most annual project level reporting is by achievement of milestones identified in the project proposal. There are multiple reporting requirements, at the institute level and for GHI. For Phase 2, scientific leaders used Institute reporting templates. In Phase 3, program Scientific Leaders report quarterly on progress. Interviewees commented that annual reporting uses traditional indicators of knowledge creation and distribution (i.e., publications, conferences and workshops), as well as indicators of networking (collaborations, partnering), and technology development

[37] Report of the Auditor General to the House of Commons, Chapter 4, Managing Horizontal Initiatives, page 19, November 2005.

(patents). Identification of soft skills such as teamwork and development of HQP is beginning.

D5. How could the Genomics R&D Initiative be improved? What changes are required to make the Initiative more efficient?

Document Review

At the Genomics R&D Initiative level, a number of problems have been identified. These include the lack of inter-departmental coordination among senior management above the Working Group level. The lack of a Genomics R&D Initiative accountability framework that identified common performance measures was identified as another problem.
For GHI, the recent evaluation provided a number of recommendations to improve the delivery of the initiative. These included the following:

- Need to ensure alignment of GHI objectives with those of NRC, as identified in the new five-year Strategic Plan;
- Introduce a portfolio approach in future phases, and fund a balance of basic and applied, closer to market programs. The selection process for applied programs should include a market assessment study to examine market opportunities;
- Efforts should continue to integrate activities among NRC Institutes and with other genomics and health research organizations across Canada;
- A GHI logic model and performance framework should be established to facilitate more effective performance measurement;
- The roles and responsibilities of the Business Development Offices (BDO) should be clarified so there is a common understanding of the activities that are part of the BDO function;
- The program selection process should be streamlined for future phases, and the rationale for funding decisions made more transparent; and
- Program plans should include strategies for phasing out in the event that funding does not continue after the three year period.

Interviews

Suggestions were made at two levels, at the higher Genomics R&D Initiative level and at the NRC GHI level.

Genomics R&D Initiative

At the higher level, examining opportunities for inter-departmental projects on larger issues was suggested, as the first step, adding an inter-departmental element to the initiative. Another suggestion related to departmental cooperation was to share information and equipment among departments. Other suggestions included lengthening the funding period to four years.

As mentioned previously, one change suggested was to seek additional funding and use it to provide additional funding to DFO, Environment Canada and NRCan, and to create a fund for inter-departmental projects chosen by an in-depth peer review process. Several interviewees have commented that part of the original rationale for the funding allocation among departments was to give it to those departments with the best existing genomics capability so they could effectively make use of the funds. Some have suggested that now other departments have developed improved capability, they can make effective use of increased funds.

One person interviewed said that the initiative needs to develop a higher profile and improved reporting so stakeholders and others not delivering the program are aware of it.

GHI

At the time of the interviews, the NRC Renewal initiative was underway, and interviewees noted that it would likely have some effect on delivery of GHI. At the GHI level, it was noted that in the first year of a new phase NRC takes several months to get GHI funding out to the research programs, and should develop ways to speed the transfer of funds. It was also pointed out that NRC has begun to develop management processes and individual skills to support the delivery of GHI, and needs to continue supporting the development of skills to manage large programs like GHI. In some projects, GHI programs have engaged a program manager to work with the program scientific leader to handle management and reporting responsibilities. This is similar to the approach taken by the National Centres of Excellence, each of which has a Scientific Leader and a Program Manager.

A.6 Natural Resources Canada

The following is based on an extensive review of program documentation provided by Natural Resources Canada and the National Research Council. In addition, 17 in-depth interviews were conducted – five with program management, 10 with project leads / researchers (representing all research organizations involved in the program) and two with stakeholders.

A.6.1 Brief Profile

Strategic Approach

The Canadian Forest Service (CFS) of NRCan established the Genomics Research Initiative (GRI) to improve forest generation and protection methods while ensuring that environmental considerations are addressed. In Phase 2, the scope was extended to include functional genomics and proteomics.

The key outcomes supported by the Initiative are enhanced timber production and protection of timber from pests. With respect to enhanced production of timber, the key question genomics research is to address:

- What are the appropriate technologies for and impacts of plantation forest management? (e.g., what genetics tools can be used to increase tree growth and quality, critical factors for the use of tree biomass for the purpose of bioenergy (e.g., genetics of short rotation species)

With respect to protection of timber from pests, the key questions are:

- What is the basic knowledge required for ecologically-based management of high-impact, high-risk pests? (e.g., enhance CFS DNA techniques to diagnose and monitor high-risk pests)
- What ecologically based approaches can be used effectively in pest management?
- What are the operational requirements / tools that must be in place to implement a range of pest management strategies?

These questions are addressed through four research themes / programs, as described in the following section.

Theme / Research Priority

The GRI comprises four research programs or themes. Table A22 describes the objectives in each program area.

Table A22: Research Programs and Phase 2 Objectives	
Program	**Objectives**
Molecular Genetics of Forest Tree Production and Protection Systems	The CFS will continue to lead a program on molecular biology in the following key areas, for trees and tree pests and pathogens: ‣ molecular analysis and mapping; ‣ study of gene structure and function within model systems; ‣ gene and regulatory sequence discover and characterization; ‣ genetic profiling of main pests and host defence mechanisms at the molecular level; and ‣ identification of genetic control for the production of bio-active molecules that could extend applications into the agriculture and health sectors.
Molecular Markers for Diagnosis, Monitoring and Early Selection	The CFS will continue to lead a program to develop molecular tools associated with quantitative traits to assist early selection of best tree materials, and accurate detection and monitoring of forest pathogens. The number of targets for DNA diagnostic assays will be broadened and the microarrays for the detection of exotic pests will be developed. The CFS will continue the mapping of genes that control quantitative traits of black and white spruce. As knowledge gets ready to attract commercial interest, the CFS will strengthen its technology transfer activities to the private sector.
Production of Genetically Improved Trees	The CFS will strengthen its program on tree genetic improvement through the introduction of genes for insect or disease tolerance, sterility, and through characterization of the transformed material. The CFS will continue its efforts towards the establishment of a national tree function genomics platform to facilitate collaborative scientific work.
Production of Environmentally Acceptable Forest Protection Methods	The CFS will continue to use DNA based technologies and genetic engineering to increase understanding, enhance the efficiency of biological control products, and develop innovative products and approaches: ‣ molecular biology of insect viruses; ‣ interference RNA strategies to enhance viruses against pests; ‣ structural and functional genomics of pests and bio-control organisms; ‣ optimization of recombinant viruses; and ‣ high-throughput and genome-wide approaches such as large-insert DNA clones, expressed sequence tags, and physical mapping.

Results of the Initiative will contribute to increased competitiveness of the Canadian forest sector by enhancing forest productivity. Technology transfer to the private sector is expected as forest managers are interested in the development of commercially viable and environmentally attractive products and processes. Thus the program is seen to support economic development and environmental protection.

The CFS now sees itself at the leading edge of unique technological platforms for tree and insect tissue culture, molecular diagnostics, population genetics, biological control products, and functional genomics.

How Initiative is Delivered in Department

Genomics projects are conducted in four of the five NRCan forest research centres:

- Atlantic Forestry Centre (Fredericton, NB)
- Laurentian Forestry Centre (Ste. Foy, QC)
- Great Lakes Forestry Centre (Sault Ste. Marie, ON)
- Pacific Forestry Centre (Victoria, BC).

The Laurentian and Great Lakes Centres are the largest centres for biotechnology within the CFS. The focus at Laurentian is on tree genomics, the focus at Great Lakes is on insects and viruses. The focus of the work at the Pacific Forestry Centre has been in two specific areas: white pine and blister rust fungus and conifer-host laminated root rot pathosystems. The Atlantic Forestry Centre has one project on functional genomics. Coordination and communication on forest genomics research is managed at CFS HQ.

Resources

With the exception of the first year of Phase 1, when $1 million in funding was allocated to the CFS Genomics Initiative, the annual budget has been $2 million.

The allocation of resources, by phase and research centre, is shown in Table A23.

Table A23: Allocation of GRI Resources

	Atlantic	Laurentian	Great Lakes	Pacific	HQ
Phase 1	4 projects $684,000	7 projects $1,849,000	6 projects $1,446,000	3 projects $544,000	$345,000
Phase 2	1 project $411,000	6 projects $2,372,000	6 projects $1,912,500	2 projects $576,000	$300,000
Phase 3[1] (Year 1 only)	1 project $160,000	5 projects $926,000	4 projects $584,000	2 projects 250,000	$29,000

[1] Phase 3 is based on a three-year cycle, and thus the recommended allocations may be extended for 2006-2007 and 2007-2008.

The allocation of resources, by theme area, in Phase 2 is shown in Table A24.

Table A24: Allocation of Phase 2 Resources by Theme Area	
Molecular Genetics of Forest Tree Production and Protection Systems	35%
Molecular Markers for Diagnosis, Monitoring and Early Selection	15%
Production of Genetically Improved Trees	25%
Production of Environmentally Acceptable Forest Protection Methods	25%

Project Approval Process

CFS uses a competitive request for proposal process to select its projects. The process has evolved from Phase 1 through to Phase 3.

In Phase 1, an RFP was sent out for one-year projects. The 28 proposals received, together, represented a request for $4.7 million. The proposals were assessed by the CFS Biotechnology Management Committee according to the following criteria:

- Relevance to the CFS Genomics Initiative;
- Relevance to the Canadian Forest Service;
- Significance of the opportunity / problem;
- Benefits from the outcomes (social, environmental, economic);
- Likelihood of success, capacity of the team; and
- Incrementality of the proposal and leverage.

A total of 12 projects were selected and, upon providing more detailed deliverables, received funding in the first year. For years 2 and 3, the already funded projects were asked to resubmit proposals and new proposals were sought. Project proponents had an opportunity to present their proposals to the CFS Canadian Biotechnology Strategy Meeting in March 2000.

Proposals are limited to three pages and provide a description of the project including: deliverables, relevance to the Genomics Program, funding, team capability, potential impacts and benefits, incrementality and training.

In Phase 3, peer review was added to the process. Letters of Intent were reviewed by the CFS Biotechnology Committee. Based on this review, 12 letters were selected for full project submission (maximum of five pages). The full proposals underwent a peer review process (three reviewers per project).

A.6.2 Rationale

R1. Are the mandate and the strategic objectives of the Genomics R&D Initiative still relevant? What need was the Initiative intended to address? Does this need still exist?

Document Review

Documents show that the focus of CFS involvement in the Initiative remained unchanged in Phase 1 and Phase 2:

> *"Natural Resources' Canadian Forest Service (CFS) will focus on the advancement of knowledge in forest genomics and the application of this knowledge to improve forest generation and protection methods, while ensuring that environmental impact considerations are addressed."*

The goal of the CFS Genomics Initiative is to balance productivity-oriented research with research aimed at resource conservation and protection of the environment.

There has been strong interest in this program from its beginning and it has been over-subscribed since Phase 1. As noted above, the RFP for the first year of Phase 1 netted 28 proposals which, together, represented a request for $4.7 million (as compared to the $1 million available). In Phase 2, a total of 41 proposals were received which represented, together a request for $16 million (as compared to the $6 million available). In Phase 3, a total of 27 Letters of Intent were received; 12 projects were selected for funding.

Interviews

According to a management interviewee, the launch of the Genomics R&D Initiative was an acknowledgment that Canada was lagging behind in the genomics field, especially when it came to internal government capacity. International developments in this area were outstripping Canada's; the Human Genome project was just being completed and Canada had not played a significant role in this project.

Researcher and management interviewees saw this Initiative as a means to help them catch up with what researchers needed and wanted to do. "The fit with CFS was very good." Prior to the GRI, CFS was unable to bring sufficient resources together. The Initiative allowed the CFS to "turn up the burner" in a number of critical, emerging areas.

Program managers, senior managers and researchers alike all felt the mandate of the Genomics R&D Initiative, and the objectives of the GRI more specifically, continue to make sense. One stakeholder stated that "The research at CFS is relevant. They are working on issues of high importance in a way that complements the projects at Genome

Canada." Most noted that the science has evolved very quickly: the scope of genomics is expanding to include other 'omics' research areas and using molecular techniques is changing the way research is being done. As a result, there is a need for continued and increased investment in this area, to maintain the capacity developed to date and expand the application of genomics tools and techniques.

As noted by one management interviewee, the need for continued CFS involvement in genomics research is clear. The three areas that the CFS is interested in (producing more fibre, producing species with an economic advantage, and protecting / conserving forests) are all supported by the enhanced biological information possible through genomics.

R2. Is there a legitimate and necessary role for government in this area?

Document Review

The context and justification for federal investment in this area was outlined in the background material to the Phase 2 RFP process. Two areas of public good are addressed by the research:

- One area of focus for CFS research is emerging *environmental issues*. Targeted research will address forestry concerns such as adaptation to environmental and climatic change, monitoring and response to pests and pathogens (with particular attention to invasive species that are new to Canada) and monitoring of genetic diversity.

- Another area of focus is *sustainable forestry and competitiveness*. The CFS will direct research towards targeted improvements of tree growth and wood quality characteristics. The development of environmentally acceptable methods to control forest pests is another key area of focus.

Interviews

The Genomics Research Initiative is linked to the 'Growing the Limits' component of the Department's Sustainable Development Initiative. According to management interviewees, the links between genomics research outcomes and the Department's SD objectives are very clear. The Department is concerned with plantation forestry management, pest control (diagnostics and control) and invasive species. The projects funded by the GRI directly address these areas.

Management and researcher interviewees agreed that provinces do not have the resources for this type of research. Paprican had a small research program, but it is no longer active. The private sector is not interested in this early-stage, novel research. Several management interviewees noted that this is not the case in other countries with a lot of

private ownership of land and plantation management (e.g., Brazil, where significant investment in genomics and biotechnology have been made by the private sector). Several researchers noted that this R&D is needed now to prepare Canada for the future. "At some point there will be a crisis in wood supply and we will need this genomics-related information and knowledge." A stakeholder noted that CFS's long-term mandate and funding provides important infrastructure to other forest researchers (in industry and university). For example, researchers are using trees established 30 years ago by CFS; academia can not support this type of investment.

A senior manager noted that genomics has broad horizontal implications and is a "good tool to have in the tool box" to understand forests, climate change and other environmental issues.

A.6.3 Success

S1. Have the individual departments achieved, or made progress towards, their specific objectives / goals?

Document Review

A review of project progress reports and input to the Canadian Biotechnology Strategy Horizontal Performance Reports illustrate progress towards the specific objectives and goals (as shown in Table A22 above). The 2004–2005 CBS Performance Report provides the following progress highlights to the end of Phase 2.

NRCan-CFS research scientists have developed several key technology platforms that allow strengthened collaborations with academia and international partners, and training of highly qualified personnel. Unique worldwide expertise, developed to fight the spruce budworm, has allowed the production of cloned spruce budworm cell lines starting with a single cell, as well as the optimized production of genetically engineered viruses to identify genes and understand their function. Other work has included the production of genetically engineered spruce and poplars to study specific candidate genes obtained from collaborators, and the development of high-throughput protocols for gene quantification. Landmark developments have been accomplished to describe viral and insect genome organization, their evolutionary development and history, and share this knowledge through a publicly available database. Scientists have gained enhanced understanding of conifer pathogen systems (e.g., Douglas fir and laminated root rots, western white pine and blister rust fungi) and poplar-rust interactions. This has led to the development of rapid techniques for early disease detection and for using molecular markers in breeding programs. The CFS was the first to develop a method to produce multiple embryogenic clones from vegetative tissues of mature white spruce, and has identified genes responsible for the successful induction of this type of cloning. The CFS genomics

research program is invaluable to design strategies for forest growth and protection, and to the formulation of sound trade policies for wood and wood products.

Interviews

The statement of broad GRI goals has been modified (slightly) every three years by the Biotechnology Committee. While there has been guidance provided at the higher-level, the program has evolved from the bottom-up; that is, individual researchers have identified the potential role for genomics tools / techniques in addressing CFS priorities.

There was concern expressed by one interviewee that the GRI supported only those areas with existing capacity, and was not allocated to those areas where capacity needed to be built. As the goal of Phase 1 was to build capacity, the interviewee felt that more could have been done to identify the areas where capacity was needed, rather than rely on a 'bottom-up' approach to identify projects.

Overall, interviewees (managers and researchers) felt that the GRI program objectives had been well met. Illustrative examples of project success in Phase 1 and 2 can be found in S2, S3 and S4.

S2. To what extent did the projects funded under Phase 1 of the Genomics R&D Initiative build capacity inside government laboratories to carry out genomics research?

Document Review

A review of Phase 1 project reports provides evidence that Phase 1 projects strengthened the Forest Centres' capacity to undertake genomics research. The key areas of capacity developed in Phase 1 are as follows:

- investigation of genes for tolerance to cold and white pine blister rust;
- work towards understanding the genome architecture of economically important conifer species;
- development of molecular tools to monitor forest pathogens and quarantine species;
- creation of a national tree functional genomics platform; and
- investigation of novel biological control products.

Table A25 lists key outputs from Phase 1.

Table A25: Phase 1 Outputs	
Number of scientific articles: Refereed articles Reviews Book chapters	 82 5 11
Number of invited presentations at international conferences	61
Number of technical reports	6
Formal collaborative agreements	BC Ministry of Forests Ministère des ressources naturelles du Québec New York State University USDA Forest Service Institut National de Recherche Agronomique (INRA) France
Private sector collaborative agreements	TimberWest Forest Company J.D. Irving Lumber Ltd. Fraser Paper Inc. Gene Vision Demegen (North Carolina)
Number of granted patents	2 US 1 Worldwide
Interviews to the media	22
Personnel trained	54

Source: NRCan Appendix to the Genomics R&D Initiative Performance Report (1999-2000 to 2001-2002).

Interviews

As stated by one management interviewee, the key result of Phase 1 was to "put CFS on the map as an important Canadian player; the capacity allowed us to get involved with Genome Canada projects". Because Genome Canada requires leveraging from its partners, without the Genomics R&D Initiative, the involvement in the two Genome Canada projects would most likely not have occurred.

Researchers and management interviewees noted that Phase 1 projects helped the CFS buy new equipment (e.g., DNA sequencers, real time PCR machines) and train highly qualified personnel. In addition to the CFS researchers involved in the projects, Phase 1 projects involved 54 students (masters, doctorate, post-doctorate). In addition, a number of new hires were made.

The Genomics research has led to the development of several technology platforms that have allowed for strengthened collaboration with academia and international partners, and training of highly qualified personnel.

Specific highlights include:

- The CFS Great Lakes Forest Centre generated new knowledge on the interaction between spruce budworm and its viruses and launched a program to address them. The Phase 1 project led to 15 peer reviewed articles and one world-wide patent (funded by industry). The unique expertise to fight the spruce budworm has allowed the production of cloned spruce budworm cell lines starting with a single cell, and the optimized production of genetically engineered viruses to identify genes and understand their function. The lead researcher was invited to be a member of the Board of Directors of the Joint European / Chinese Laboratory of Virology to advise on Research Programs and Directions, and invited by the Japan Society for the Promotion of Science to deliver 15 lectures at universities and research centres in Japan, and by the Chinese Academy of Sciences to deliver 14 lectures and seminars in China. The project involves collaborations with researchers in China, Argentina, the UK, Florida and at the University of Guelph, and has involved three or four post-docs or students each year. The funding available in Phase 1 helped to lever funds, including an NSERC Strategic Grant and a National Institutes of Health (NIH) grant through a collaborator in Florida. "The Genomics Research Initiative funding spawned a much bigger program for CFS, and the scientific impact and impact on our profile has been superb."

- An improved understanding of conifer pathogen systems (e.g., Douglas fir, western white pine) and poplar-rust interactions. This has led to the development of rapid techniques for early disease detection and for using molecular markers in breeding programs.

- In 1999, genome sequencing was expensive, difficult and time-consuming. With the GRI and Genome Canada, "we have seen a large ramp-up and a reduction in the time and money required for sequencing".

- A stakeholder interviewee would have had to re-model the project that CFS worked on with him had the CFS not been available. "We need the CFS's highly qualified personnel, greenhouse space and lab facilities." The interviewee felt that the CFS participation in his project was very important to the progress made.

- At the Laurentian Forestry Centre one interviewee felt that "the GRI allowed us to start running versus walking in this area". The Centre is now interacting with researchers in Norway, Sweden, and the US. The size of the team also increased. In 1999, there were approximately 10 people in his lab, by 2003-2004 the number had grown to 18 (including new post-docs and students). As a result, when Genome Canada was created, the Center was able to demonstrate that they could do genomics. "Genome Canada saw our expertise and couldn't ignore forestry.

> This expertise helped to get forestry on the list of Genome Canada technology areas."

According to a management interviewee: "The impact on the Laurentian and Great Lakes Forest Centres was huge. The program made CFS world-leaders in insect viruses and tree biotechnology."

S3. Did this increased capacity strengthen the research carried out in the departments?

Interviews

Interview findings show that the enhanced genomics capacity allows CFS to participate in new collaborative projects with industry, universities and international research organizations. The knowledge gained has helped to re-direct and strengthen research efforts at the Forestry Centres.

CFS researchers participated in two Genome Canada Competition II projects: Dr. Basil Arif (Great Lakes Forestry Centre) led the *Genomics of the Spruce Budworm and its Viral Pathogens* (Ontario Genomics Institute), an $8 million project over three years, and Dr. Armand Seguin (Laurentian Forest Centre) was a collaborator on the *Functional Genomics of Regulation in Forest Trees (Arborea Project)* (Genome Quebec). The Genome Quebec project was based at Laval and made use of the facilities and expertise at the Laurentian Forest Centre. As noted by one stakeholder interviewee: "There was a synergy that was very productive. This project was rated the best across Genome Canada." Federal scientists can no longer be Principal Investigators on Genome Canada projects (under Competition III rules); however, CFS researchers continue to use the platforms built by Genome Canada (Genome Quebec, Genome BC) and be involved in the projects. However, one Regional Director felt that the linkages between the CFS and Genome Canada are now "weaker than they've ever been"; this view is not the case at the corporate level or in all regions.

The new capacity has led to publications in areas where CFS scientists had not published before. This has increased the visibility of CFS (nationally and internationally). Among the scientists involved in GRI projects are several world-class researchers with strong international reputations. This has helped to establish international linkages which in turn strengthens CFS research.

S4. Did this increased capacity created in Phase 1 translate into the benefits of advances in research and technology in Phase 2 for department constituents?

. *Document Review*

A review of Phase 2 and Phase 3 projects shows that a number of projects have evolved from Phase 1, through to Phase 2 and 3. Of the 11 lead researchers participating in Phase 3 projects, all but three were involved in Phases 1 and 2.
The broad objectives for each program / theme area were identified in Table A22. Table A26 provides evidence of progress in each area (to the end of Phase 2).

Table A26: Phase 2 Outputs

Program	Progress / Outputs
Molecular Genetics of Forest Tree Production and Protection Systems	▸ Complete sequencing of entire genome of insect viruses ▸ The development of virus expression systems ▸ The elucidation of gene organization and major properties ▸ Development of a strong comparative genomics approach ▸ Commercialization potential of insecticidal delivery products is being pursued with the private sector
Molecular Markers for Diagnosis, Monitoring and Early Selection	▸ Identification of several candidate genes related to wood quality, defence mechanisms and somatic embryogenesis ▸ Development of a novel platform for the molecular diagnosis of forest pests, allowing the transfer of standard operation protocols to clients for quarantine application.
Production of Genetically Improved Trees	▸ Identification of genes for white pine resistance to blister rust ▸ The elucidation of molecular defence response mechanisms ▸ The demonstration of genetic control for somatic Embryogenesis induction in conifers ▸ Development of a tree functional genomics platform for testing of gene function
Production of Environmentally Acceptable Forest Protection Methods	▸ Promising work on juvenile hormone-based insect management tools ▸ Identification of key genes of interest ▸ Construction of high-throughput DNA chips ▸ Active participation in the International Lepidopteran Genome Consortium ▸ An international patent was obtained for transformation of insect viruses

Source: Annex B of Phase 3 Genomics R&D Initiative Treasury Board Submission.

Interviews

As in Phase 1, the key result of Phase 2 according to all management interviewees and some researchers, was increased national and international visibility and credibility. Canada is now recognized as a strong player in genomics and a world leader in some areas (e.g., insect genomics and fungal genomics). The International Union for Forest Research Organizations has a genomics working group and Canada is a well-respected participant.

Another benefit was the ability to partner and lever funds. Researchers noted that the approach to Phase 2 project development differed from Phase 1, in that, by Phase 2 there was the capacity to better leverage alternate sources of funding and partner (e.g., participation on two Genome Canada projects and new partnerships with researchers in China and France).

According to a researcher, CFS's genomics partnerships with university researchers (e.g., at University of British Columbia and Laval University) have helped universities demonstrate leadership and build credibility (nationally and internationally).

Specific examples provided by interviewees include:

- The work at the Pacific Forestry Centre improved the understanding of the interaction between a conifer host (Douglas Fir, the most economically important species in the area) and a root fungus. With this new knowledge, it may be possible to identify a diseased tree by its foliage (and not its roots). "We need to improve our knowledge of the susceptibility of fast growing trees to pests and disease. Our group worked with provincial tree growers to screen trees and identify those with increased resistance".

- Phase 2 funding allowed CFS (Laurentian Forestry Centre) to continue to be independent within the Genome Canada Arborea project and continue to influence the toolbox development.

- The main result of one interviewee's Phase 1 and 2 projects was the development of a kit to monitor sudden Oak death. The GRI allowed the CFS to develop the kit before the pathogen moved from the US into Canada. Being able to monitor disease is the first step in dealing with a threat (i.e., once the diseased area is identified it can be quarantined).

- At the Atlantic Forestry Centre, the GRI funded a project to address the Balsam Fir sawfly. The impact of the pest on the forests in Newfoundland has been significant. Prior to 1990, there was 2,500 hectares of infestation and by 2005 the area had grown to 330,000 hectares. The study helped to register a virus to control the outbreak. Genomics techniques helped to isolate and characterize the virus. It has since been registered and commercialized by Forest Protection Ltd. (Fredericton, NB). GRI funding supported two post-docs and four graduate students, and was used to purchase new equipment (e.g., centrifuges, PCR machines). (Note: In this case, as in many others, most of the genetic sequencing work is contracted out either within Canada or to Korea, China and other low-cost labs.) A new CRSB project, in collaboration with the Great Lakes Research Centre, will lead to increased linkages with Health Canada on the management of these new viruses.

S5. To what extent has the Initiative strengthened coordination, cooperation and linkages between the appropriate research institutions?

Document Review

Several program documents outlined a number of areas where the six funded departments planned to work together and with external partners. In the case of NRCan, partnerships were to be used to support work 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. Partners were to include universities, provinces, the private sector and other government departments.

Under Genome Canada Competition II projects, CFS led an Ontario Genomics Institute research project to study the genomics of the spruce budworm and its viral pathogens and was a key partner in a Genome Quebec project on functional genomics of regulation in forest trees. Genome Canada projects can no longer involve CFS due to a restriction on the participation of federal departments in projects.

Interviews

According to a management interviewee: "We do not have the programs in place to bring departments together, but scientists find others to work with." According to researchers, several have close links with Agriculture and Agri-Food Canada (e.g., CFS researchers used the collection of cultures at the Experimental Farm in Ottawa to generate the pathogen sequencing and develop assays) and some linkages with Environment Canada, Health Canada and the National Research Council (Biotechnology Research Institute [BRI]). One researcher noted a new collaboration with AAFC in Summerland, BC as a result of their genomics project.

A management interviewee noted that there are no requirements attached to the way in which funds were distributed that would promote collaboration among federal departments. Another noted that, given the early stages of development of these technologies and tools, requiring inter-departmental research linkages in Phases 1 and 2 may have caused more complexity than benefit.

Several workshops have been co-hosted by CFS, including:

- In September 2004, the CFS and Genome Canada co-hosted the Genomics for Future Forests Symposium to present key achievements and to provide a forum for discussion on future research. This meeting helped define the program for Phase 3 (for both CFS and Genome Canada). The report from the Symposium can be found in the CFS bookstore at http://bookstore.pfc.cfs.nrcan.gc.ca/default.htm (Genomics for Future Forests Symposium Report, A.C Bonfils and I. Gamache, eds.).

- In June 2005, the CFS organized a forest genomics session at the third Plant Genomics Workshop held in Saskatoon and co-organized by several departments and universities.

- In June 2006, the CFS sponsored a plant genomics workshop organized by AAFC and held in Ottawa to provide a forum for scientific exchange between Canadian government and academia research scientists.

Within the CFS, several researchers noted that the GRI benefits from the strong relationships among the 11 principal investigators involved at the four Forestry Centres. This group meets on a regular basis to identify areas of collaboration. One researcher also sees greater linkages now with policy groups.

Researcher interviewees all noted a number of new partnerships / collaborations that have been established as a result of the GRI. Because the equipment that is required to complete a lot of the analysis and sequencing work is very expensive, partnerships with those with the equipment have been developed (e.g., Sick Kids Hospital [protein / DNA sequencing], University of Guelph, Michael Smith Genome Centre [UBC], Bioinformatics Facility at the University of Calgary [established by Genome Canada]).

S6. What have been the facilitating and impeding factors for the success of Phases 1 and 2 of the Initiative?

Interviews

Interviewees identified the following factors facilitating success:

- **Timing of the funding**: The Genomics R&D Initiative came at virtually the same time as the CRSB and when the Department was looking for ways to move into genomics research.

- **Role of program coordinator**: Many Forestry Centre Directors and researchers mentioned the importance of a full-time program coordinator for the GRI and CRSB to the successful integration of the two funds and effective management of the biotechnology file.

- **Researchers' backgrounds in molecular biology**: Helped identify and focus potential areas for genomics research.

- **Leverage and partnerships**: The GRI funding allowed researchers to lever resources, work with new partners and develop more comprehensive programs.

Factors impeding success included:

- One management interviewee noted that they would have like to see a better covering of the innovation spectrum by the GRI to ensure that basic research goes through to the development phase. The interviewee believes that "some economic benefits are being missed". As the program matures in Phase 3, they would like to see increased support for the application of technology.

- A new issue in Phase 3 is that federal departments are no longer able to directly access Genome Canada funding. The participation of federal labs in larger, multi-player programs is seen by interviewees as important for building research networks and ensuring that integrated Canadian genomics / biotechnology strategies are developed. (This issue of access to these larger project funds has been raised by all departments and is being reviewed by Treasury Board.)

S7. Are there other intended and unintended impacts resulting from Initiative?

Interviews

There is concern that while the GRI is building capacity there are no strategies or long-term funding sources for using and maintaining the capacity. One interviewee noted that the more that is learned about genomics, the greater the opportunity for its application. Thus, the research is expanding the number of questions to be answered.

S8. To what extent would the impacts have occurred without the Initiative?

Interviews

All interviewees agreed that without Genomics R&D Initiative funding the GRI projects would not have occurred in the time period that they did. No alternative sources of funding were identified by principle investigators or managers. There was consensus that the program is unique and without it the progress described above (see S2, S3 and S4) would not have occurred. Several researchers noted that their research work was taking them in the direction of genomics tools and approaches; however, securing A-base resources for the required equipment and capacity building was made much easier with the GRI funding.

A.6.4 Cost-Effectiveness / Alternatives

C1. Does the Genomics R&D Initiative complement, overlap or duplicate other federal or provincial initiatives related to genomics or biotechnology?

Interviews

Researchers did not report any overlap between the federal genomics or biotechnology programs and felt that the GRI is complementary to CRSB and Genome Canada. According to one researcher, their participation in a Genome Canada project would not have happened had the GRI not been available to them first. "While the Genomics funding was relatively small, it was very complementary and beneficial to the Genome Canada project."

Several management and researcher interviewees attributed the complementarity of the biotechnology programs (including GRI) at CFS to the full-time biotechnology coordinator who has helped integrate program activity and avoid duplication.

The only provincial forestry genomics research and development program mentioned by researchers was that within BC. One interviewee noted that the specific provincial research priorities vary from year to year. With respect to university research, a large number of the academics that are involved in genomics participate in the Genome Canada projects; as a result, this research is viewed as complementary to that of CFS.

C2. Is the funding structure of the Genomics R&D Initiative the most appropriate mechanism for achieving the intended objectives? Are there more cost-effective alternative ways to achieve the Genomics R&D Initiative mandate?

Interviews

Management interviewees were generally satisfied with the funding structure and appreciated the existence of a program dedicated to capacity building for genomics. Some commented that it would be better to have an on-going program in order to sustain capacity and full-time, highly qualified personnel (Currently, NRCan's genomics research is 50% dependant on sunsetting funding.)

One suggestion for improving the cost-effectiveness of the Genomics R&D Initiative mandate was to provide more information to researchers on what OGDs are doing, what facilities and equipment are available, etc. As expressed by one researcher: "There is no single place to go to get this information. It would be nice to know what colleagues are doing in terms of research outcomes."

C3. Is the three year funding cycle appropriate for achieving intended outcomes?

Interviews

The program coordinator was satisfied with the three-year cycle and thinks it is good management practice to review science programs every three years. This review cycle has also been implemented for the CRSB.

As noted above, all interviewees (management and researchers) are concerned with the lack of on-going (A-base) support as B-base funding does not solve the long-term staffing issues. As one researcher stated: "The Initiative has increased opportunities but does not support long-term capacity in the way that CRSB does."

C4. What has been the level of effort or cost required by departments / agency to participate in this horizontal initiative? What have been the benefits?

Interviews

A percentage of the GRI budget is allocated to headquarters for program management activities (approximately 5% or $100,000 per year). The program coordinator and other managers do not see any additional costs as a result of the way the program is managed, as the reporting is no different than for a single department program. (It should be noted that a number of management interviewees felt that the Genomics R&D Initiative is not truly a horizontal initiative; while funding is allocated to a number of departments through the Initiative, there is no overarching strategy that sets federal priorities and integrates the research efforts of the various departments.)

A manager felt that there are now easier mechanisms for communicating as a result of the channels of communication created by this Initiative and others (e.g., CBS). Also, since all departments have genomics funding, it is possible to cost-share conferences and meetings.

The approach to genomics research is seen, by one interviewee, as part of the transformation that government is undergoing as it works to develop integrated strategies to address issue areas.

In summary, program management interviewees felt that the benefits outweighed the costs.

A.6.5 Design and Delivery

D1. Is the position of the Genomics R&D Initiative appropriate within the larger government biotechnology strategy? Is the level of integration with other federal government biotechnology programs appropriate?

Document Review

NRCan also receives funding from the CRSB (approximately $1.1 million in 2004-2005), bringing the total biotechnology program to $3.1 million (In 2004-2005 the Department did not receive CBS funding.)

There is on-going consultation between CFS and Genome Canada. In September 2004 the CFS and Genome Canada co-hosted a Forest Genomics Symposium to present key achievements and to provide a forum for discussion on future strategic research.

Interviews

Interviewees (managers and researchers) noted that each of the biotechnology programs have very specific objectives. A number of interviewees noted the importance of having a separate program dedicated to genomics as this has helped bring attention to this emerging technology. There is some integration across the two key programs – both are managed by the same Committee and some researchers are receiving funding from both the GRI and the CRSB. Several commented that the existence of two funds (CRSB and GRI) fits well with the CFS needs and overall strategy and came at a good time for CFS research.

At the overall management and reporting level, a management interviewee felt that regular reports from the CBSec on all three funds' activities would be useful. To-date, it was felt that the departments are not doing enough to promote / communicate their genomics research efforts to federal decision-makers.

A number of interviewees (management and researchers) expressed frustration with the inability to receive Genome Canada funding. This has effectively kept CFS researchers from accessing the only large genomics funding program. This is seen by all interviewees to be a lost opportunity to lever federal expertise and build / strengthen national research networks.

D2. How effective is the overall governance structure for the Initiative and departmental processes (e.g., project approval process)? Are the roles and relationships clearly defined and appropriate?

Document Review

The Initiative is managed through the Forest Science Division of the Science and Programs Branch of the CFS. The day-to-day operations of the GRI are managed by a program coordinator. The coordinator also chairs the CFS Biotechnology Committee, comprised of Regional Forestry Centre Directors and mandated to advise on strategic orientations for biotechnology programs at the CFS.

In Phase 2, the proposals were reviewed by the CFS Biotechnology Management Committee. A one-day meeting of the Committee was used to review the assessments and recommend projects for funding. The Committee also identified a number of issues that were to be addressed in subsequent phases:

- peer review was to be built into future project selection process;
- better-coordinated strategies are needed for key themes (e.g., spruce budworm, viruses, tree genomics, etc.);
- projects should reflect greater collaboration and relationships within CFS; and
- projects should have exit strategies for the third year.

The Phase 3 project approval process reflects these recommendations (e.g., peer review was used to select projects).

Interviews

According to program managers, the governance structure has worked well with NRC as the lead, supported by an inter-departmental working group. Regular communications are received by e-mail. No specific weaknesses were identified with respect to program management. However, one senior manager felt that biotechnology in government is over managed and that there are too many committees that are not effective. At the same time, there is a demand for greater inter-departmental coordination (on this and other 'horizontal' files). Departments need to find better ways to identify priorities and coordinate strategies.

Within the CFS, the allocation of Genomics and CRSB funding is overseen by the same CFS Biotechnology Management Committee (comprised of Regional Directors). This has helped to ensure that the funded projects were complementary. Management interviewees felt that this model has worked very well and that, within the Department, the Genomics Research Initiative is "horizontal".

The CFS project approval process has been competitive since Phase 1. External peer review was introduced in Phase 3. According to the program coordinator, the process works well, but is 'quite heavy' from an administration perspective. Overall, researchers and managers are satisfied with the process.

The funding structure used at CFS has encouraged intra-departmental linkages as preference was given to projects with multiple principle investigators from more than one centre. This has encouraged scientists to talk with each other more. The CFS National Biotechnology Committee is seen as a good model for communication by management interviewees. It allows all regions to share in the work done in other centres.

With respect to annual reviews, the regional directors meet via a conference call to discuss project renewal (within a phase). If the Director feels that the team is performing, and others do not object, then the project is renewed for another year. (The project selection process is described in detail in Section C6.1.)

One management interviewee noted that CFS is always working ahead of time to identify up-coming objectives and priorities. As a result, the Department was well prepared when the biotech programs were approved. This has also helped the transition from one phase to the next.

Researchers are happy that the program has moved to integrate peer review into the project selection process and include researcher curriculum vitae in proposal submissions.

All interviewees feel that the roles and responsibilities within CFS and NRCan are clear and well understood. With one person dedicated to coordinating the program, the program has run smoothly. Researchers appreciate the work done by CFS program coordinator and attribute much of the GRI's success to the effectiveness of the coordinator.

D3. To what extent have the departments been able to leverage the funds provided through the Genomics R&D Initiative? What are the pros and cons associated with the leveraging requirements?

Document Review

Documents show that in Phase 1 the $5 million allocation levered funds from other sources for a total investment of $11.75 million over three years. The funds were used to create the Genomics Research Initiative to improve forest generation and protection methods, while ensuring that environmental impact considerations are addressed.

In Phase 2, using the $6 million genomics allocation, the CFS levered funds from other sources for a total investment of close to $15 million.

Interviews

No interviewees mentioned any 'cons' associated with leveraging. Conversely, they noted the importance of partnerships to GRI projects, to access required expertise and the equipment and facilities. All projects have a number of significant research partnerships and report both in-kind and financial contributions from a number of sources.

Sources of additional funding mentioned by researchers include: NSERC, Biocontrol Network (funded by NSERC), Pest Management Program (CFS), CFIA, CRSB, provinces and industry.

D4. How effective / appropriate is the Initiative's approach to performance measurement? What performance measures should be captured in the next phase and why?

Document Review

A standard template for progress reports has been used since Phase 1 and addresses major accomplishments, performance against milestones, a provides a listing of outputs and outcomes (e.g., peer reviewed articles, conference presentations, invited presentation, interviews, stakeholder or client recognition, alliances, patents, etc.).

Interviews

Over the years, the reporting format used by CFS has been modified to capture more financial information (as required by Treasury Board).

Performance is assessed through annual reports, provided by researchers, and also at various workshops and meetings. Regular meetings of the CFS genomics researchers and ad-hoc meetings (e.g., the Workshop on Forest Genomics [co-hosted with Genome Canada and attended by approximately 70 people]) are used to review project performance and identify future research directions.

Management interviewees are satisfied with the information they receive through the CFS annual reports. One noted that in some cases, the performance reports have been used to justify decreasing funding to some projects. In other cases, information has been used to bring together groups to build a larger project or achieve economies of scale. One example given was increased cooperation between the Great Lakes Forest Centre and the Laurentian and Atlantic Centres on spruce budworm viruses.

With respect to what could be better measured, one management interviewee noted that the CFS needs to know if they are linked to the right people on projects. He noted that

"Because we have high performers and real innovators as lead scientists on these projects, and the projects are well-defined, we have not been as worried about performance measurement as we might have been."

Also, management interviewees feel that more needs to be done to integrate reporting for the Genomics R&D Initiative overall and develop a comprehensive picture of federal genomics activities and expertise.

Researchers felt that the number of papers produced and the impact factor (i.e., the average number of times a journal's papers are cited) are clear indicators of success. One noted that the CFS needs to develop better criteria to judge the scientific quality and impact of the research, which could also include the potential application in other fields (e.g., agriculture, environment).

D5. How could the Genomics R&D Initiative be improved? What changes are required to make the Initiative more efficient?

Interviews

Overall, the management and researcher interviewees felt that the program had worked very well for them. Some suggestions for improvement included:

- A more stable, long-term program would allow researcher to elevate the science, build international partnerships, and encourage scientists to build their careers within the CFS. Within CFS, researchers felt that a stronger commitment from NRCan to genomics research is needed.

- New resources are needed to push the science into proteomics and the other 'omics' areas.

- Better information on the government-wide initiative could be useful for increasing linkages and levering existing federal capacity and facilities. "We need to increase the visibility of federal genomics at the national level. A website would allow people to see what is going on."

- Opportunities for joint-projects with OGDs (e.g., AAFC, CFIA) should be explored.

Annex B – List of Documents Reviewed

List of Documents Reviewed

Agriculture and Agri-Food Canada

2004-2005 Departmental Performance Report for Agriculture and Agri-Food Canada

2003-2004 Departmental Performance Report for Agriculture and Agri-Food Canada

1999-2000 Departmental Performance Report for Agriculture and Agri-Food Canada

2005-2006 Report on Plans and Priorities for Agriculture and Agri-Food Canada

2004-2005 Report on Plans and Priorities for Agriculture and Agri-Food Canada

2003-2004 Report on Plans and Priorities for Agriculture and Agri-Food Canada

2002-2003 Report on Plans and Priorities for Agriculture and Agri-Food Canada

2001-2002 Report on Plans and Priorities for Agriculture and Agri-Food Canada

2000-2001 Report on Plans and Priorities for Agriculture and Agri-Food Canada

Agriculture and Agri-Food Canada Expenditure Management Review in Biotechnology, October 2003

Agriculture and Agri-Food Canada – Future Directions 2002-03 to 2004-05

Discovering Life's Building Blocks – An Update on the Canadian Crop Genomics Initiative (website printout)

Investing in life's basic building blocks to secure Canada's future food supply, Canadian Crop Genomics Initiative, AAFC, August 1998

AAFC Genomic Research Initiative, May 27, 1999

AAFC Genomics Implementation Plan, Draft 12/01/00

Canadian Crop Genomics Initiative, Draft, June 12, 2002

Agriculture and Agri-Food Canada, Canadian Crop Genomics Initiative, Annual Workshop, London, Ontario, June 13-14, 2002

AAFC Fifth Annual Genomics Meeting, Saskatoon, Saskatchewan, August 21-23, 2003

Agriculture and Agri-Food Canada, Sixth Annual Genomics Meeting, Ottawa, Ontario, June 2-4, 2004

Science and Innovation Bioproducts and Bioprocesses, Genomics and Proteomic Resources for Crop Improvement at CRC, Agriculture and Agri-Food Canada

AAFC Genomics Meeting notes, Winnipeg, Manitoba, June 22-23, 2005

Environment Canada

2004-2005 Departmental Performance Report for Environment Canada

2003-2004 Departmental Performance Report for Environment Canada

1999-2000 Departmental Performance Report for Environment Canada

2005-2006 Report on Plans and Priorities for Environment Canada

2004-2005 Report on Plans and Priorities for Environment Canada

2003-2004 Report on Plans and Priorities for Environment Canada

2002-2003 Report on Plans and Priorities for Environment Canada

2001-2002 Report on Plans and Priorities for Environment Canada

Environment Canada – Future Directions 2002-2003 to 2004-05

Environmental Protection Series, Strategic Applications of Genomics in the Environment (STAGE) on Results from Program Research Workshop, April 27-28, 2000

Questionnaire – Intramural Genomics Funding and Goals

STAGE Progress Report 2002-2005

Recommendations for environmental genomics research at Environment Canada – Draft Document

Strategic Technology Applications of Genomics for the Environment 2004-05 Progress Report (April 1, 2005-November 30, 2005)

Technology and Industry Branch Allocation of Genomics Funding for 2002-05 Departmental Research Proposals

Contributions of Strategic Technology Applications of Genomics to the Environment (STAGE) to Stewardship of Biotechnology

Recommendations for Environmental Genomics Research at Environment Canada, Draft Document

Draft White Paper on Genomics, Environment Canada

Fisheries and Oceans Canada

2004-2005 Departmental Performance Report for Fisheries and Oceans

2003-2004 Departmental Performance Report for Fisheries and Oceans

1999-2000 Departmental Performance Report for Fisheries and Oceans

2005-2006 Report on Plans and Priorities for Fisheries and Oceans

2004-2005 Report on Plans and Priorities for Fisheries and Oceans

2003-2004 Report on Plans and Priorities for Fisheries and Oceans

2002-2003 Report on Plans and Priorities for Fisheries and Oceans

2001-2002 Report on Plans and Priorities for Fisheries and Oceans

Project Template

CRSB Evaluation – RAO Survey

Fisheries and Oceans Canada – Future Directions 2002-03 to 2004-05

Formative Evaluation of the Canadian Regulatory System for Biotechnology (CRSB), Review Directorate, Project Number 60267, Final Report, Fisheries and Oceans Canada, April 2003

Expenditure Management Review Answers

Aquatic Biotechnology and Genomics Science: 2006 and Beyond, Aquatic Biotechnology Program, Synthesis of Workshop Proceedings, Department of Fisheries and Oceans, Synthesis of

Proceedings and Abstracts from a workshop held at the National Research Council of Canada's Biotechnology Research Institute, February 8, 9th, 2006, Montreal, Quebec, Draft April 3, 2006

Aquatic Biotechnology and Genomics Research and Development Strategy: Shaping the Future, Draft May 25, 2006
Aquatic Biotechnology & Genomics Research and Development Strategy, Shaping the Future, Aquatic Biotechnology Program, Draft March 2006

RMAF for DFO's Aquatic Biotechnology Program, Goss Gilroy, March 2006

DFO Program Activity Architecture (PAA), Revised January 2005

Aquatic Biotechnology and Genomics Science: 2006 and Beyond, Aquatic Biotechnology Program, Synthesis of Workshop Proceedings, Department of Fisheries and Oceans Canada, Draft April 11th, 2006

Project Reporting Template – Genomics Phase II project reports

News Release: "Man Fined $10,000 for Illegal Possession of Abalone", March 31, 2006

Article: "High-Speed DNA Analysis Changes Pacific-Salmon Management", not dated

Health Canada Document List

2004-2005 Departmental Performance Report for Health Canada

2003-2004 Departmental Performance Report for Health Canada

1999-2000 Departmental Performance Report for Health Canada

2005-2006 Report on Plans and Priorities for Health Canada

2003-2004 Report on Plans and Priorities for Health Canada

2002-2003 Report on Plans and Priorities for Health Canada

2001-2002 Report on Plans and Priorities for Health Canada

Overview of the two-step selection process

An Overview of the Office of Biotechnology and Science

Health Canada – Performance Report, 1999-00 to 2001-02

Discussion Document, December 2004

Data Collection Template

HC Departmental Framework for Biotechnology
Health Canada – Future Directions (2002-03 to 2004-05)

Expenditure Management Review in Biotechnology Information Collection Templates, September 12, 2003

Expenditure Management Review in Biotechnology, Information Collection Templates – Major Project / Initiative, September 2003

Expenditure Management Review Biotechnology, Health Canada, years 2000-2006

Phase 1 and 2 Project Summary Reports

Universal Declaration on Bioethics and Human Rights by United Nations Educational, Scientific and Cultural Organization (Adopted by acclamation on October 19th, 2005 by the 33rd session of the General Conference of UNESCO)

Health Canada Federal Genomics R&D Initiative for 2005-08 Project Allocations

Appendix 2: Performance Indicators for Health Portfolio Biotechnology Activities

Logic Models Health Portfolio (HP) Biotechnology, Health Canada

National Research Council

2004-2005 Departmental Performance Report for the National Research Council Canada

2003-2004 Departmental Performance Report for the National Research Council Canada

1999-2000 Departmental Performance Report for the National Research Council Canada

NRC Genomics and Health Initiative (GHI) Integrated Performance Report 2004-2005, June 2005

NRC Genomics and Health Initiative (GHI) Program Performance Report 2003-2004, July 2004

NRC Genomics and Health Initiative (GHI) Program Performance Report 2002-2003, July 2003

National Research Council – Future Directions (2002-03 to 2004-05)

NRC Genome Sciences and Health Related Research Initiative Phase 2 Research Program Proposal: Genomics of Aquaculture

NRC Genome Sciences and Health Related Research Initiative Phase 2 Research Program Proposal: Multimodal Characterisation of Disease

NRC Genome Sciences and Health Related Research Initiative Phase 2 Research Program Proposal: A Genomics-Based Approach to Enhancing Bioremediation through Microbial Identification and Community Profiling

NRC Genome Sciences and Health Related Research Initiative Phase 2 Research Program Proposal: NRC Cancer Genomics Program

NRC Genome Sciences and Health Related Research Initiative Phase 2 Research Program Proposal: Structural Biology of Cellular Protein Assemblies

NRC Genome Sciences and Health Related Research Initiative Phase 2 Research Program Proposal: Enhancing Crop Performance and Value Through Genomics

NRC Genome Sciences and Health Related Research Initiative Phase 2 Research Program Proposal: Genomics of Human Pathogens and Their Host Interactions

NRC Genome Sciences and Health Related Research Initiative Phase 2 Research Program Proposal: Towards Systems Biology of Brain Cell Interactions

NRC Evaluation of the Genomics and Health Initiative (GHI) Report

National Research Council Canada Program Charter: Linking Molecular Imaging / Diagnosis with Molecular Therapy: A Route to Personalized Medicine for Cancer, Scientific Leader: Dr. Maureen O'Connor, Biotechnology Research Institute, March 31, 2005

National Research Council Canada Program Charter: Genomic Approaches to Aquatic Animal Disease Management, Scientific Leader: Dr. Laura Brown, Institute for Marine Biosciences, March 24, 2005

National Research Council Canada Program Charter: Structure / Function Characterization of Kinase Signaling Networks, Scientific Leader: Dr. Mirek Cygler, Biotechnology Research Institute, March 30, 2005

National Research Council Canada Program Charter: Managing Chronic Cardiovascular Disease, Scientific Leader: Dr. Michael Sowa, Institute for Biodiagnostics, April 25, 2005

National Research Council Canada Program Charter: Transformational Technologies for Genomics Research and Pathogen Detection, Scientific Leader: Dr. John Pezacki, Steacie Institute for Molecular Sciences, April 5, 2005

National Research Council Canada Program Charter: Functional Genomics of Brassica Seed Development and Metabolism, Scientific Leader: Dr. Wilf Keller, Plant Biotechnology Institute, March 29, 2005

National Research Council Canada Evaluation of the Genomics and Health Initiative (GHI), Corporate Services, Strategy and Development Branch, Planning and Performance Management, February 8, 2006

Evaluation of the National Research Council's Genomics and Health Initiative (GHI), Planning and Performance Management Directorate, Strategy Development Branch, National Research Council Canada, March 2, 2006

NRC Genomics and Health Initiative GHI-3 Research Programs, National Research Council of Canada, April 2005 to March 2008

Natural Resources Canada

Departmental Performance Report 2004-2005 for Natural Resources Canada

Departmental Performance Report 2003-2004 for Natural Resources Canada

Departmental Performance Report 1999-2000 for Natural Resources Canada

Report on Plans and Priorities 2005-2006 for Natural Resources Canada

Report on Plans and Priorities 2003-2004 for Natural Resources Canada

Report on Plans and Priorities 2002-2003 for Natural Resources Canada

Report on Plans and Priorities 2001-2002 for Natural Resources Canada

Natural Resources Canada – Future Directions (2002-03 to 2004-05)

2005-08 Call for Genomics Letters of Intent

2005-08 Rating of Genomics Letters of Intent

2005-08 Invitations for full proposals

2005-08 Peer Reviews of full proposals

2005-06 Memo from Science DG advising of Fund Distribution

2005-06 Table – Fund distribution

2005-06 Call for progress reports

Nucleopolyhedrovirus functional and comparative genomics – Lucarotti
Functional genomics of CfMNPV: role of all the open reading frames in the infection process – Arif

Effects of the larval host on genomic variation and evolution of insect viruses: implications for pest control – Arif

Transcriptomics analysis of insect molting – Feng

Molecular tools for studies on the ecology and phylogeny of microsporidia in forest defoliators – K. van Frankenhuyzen

Association mapping of wood characters in white spruce – Beaulieu

Fungal genomics for protection and conservation – Hamelin

Genome-wide scan to reveal genes underlying growth productivity traits in white spruce (*Picea glauca*) – Isabel

Interacting genomes – A. Séguin

A tree functional genomic platform for gene function discovery – A. Séguin

Molecular analysis, elicitor activity, isolation of functional R genes and genetic engineering of white pine resistant to blister rust fungus – A. Ekramoddoullah

Molecular and genetic characterization of conifer host-laminated root rot (*Phellinus spp.*) pathosystems – Sturrock

2002-05 Call for Genomics Proposals

2002-05 Call for Ranking of Genomics Proposals

2002-05 Rating of Genomics Proposals

2002-05 Fund Distribution Meeting March 13-14, 2002

2002-05 Memo advising of Fund Distribution

2002-05 Table – Fund distribution

2004-05 Call for Progress Reports

2003-04 Call for Progress Reports

Sawfly Nucleopolyhedrovirus functional genomics – C. Lucarotti

Genomic sequencing of spruce budworm and its viruses: total sequencing, analyses and an expression vector of an entomopoxvirus; development of fusolin delivery and marketing of spin-off technologies by establishing proof of concept of fusolin and defensin – Arif

Expressed Sequence Tags (ESTs) of spruce budworm epidermis and midgut for analysis of global gene expression and identification of novel genes – Feng

Competition and gene flow among co-infecting transgenic and wild-type microorganisms: can engineered genes move into other organisms? – Feng

Development and pilot scale production of a recombinant virus for spruce budworm control: product development and optimization. Renamed in 04: Genetic engineering of viruses and insects for pest management and protein expression – Retnakaran/Arif

Microbial chitinases: potential agents to improve tree resistance to pests – Richards

Improving toxicity of Bt to spruce budworm by enhancing proteolytic stability of delta-endotoxins in the larval midgut – van Frankenhuyzen

Juvenile hormone-based pest management tools for forest insects; search for new bio-rational target sites – Cusson

Novel platform for molecular diagnostic of forest pests – Hamelin

Structural genomics of conifer species through functional genomics approaches – Isabel

Molecular approaches to understanding conifer somatic embryogenesis – Klimaszewska

Genomics of transcriptional factors involved in tree defense response – Séguin

A national tree functional genomics platform for collaborators in tree biotechnology – Séguin

Molecular analysis, elicitor activity, isolation of functional R gene and genetic engineering of resistance of white pine to blister rust fungus – Ekramoddoullah

Molecular and genetic characterization of conifer host-laminated root rot (Phellinus weirii) pathosystems – Sturrock

Coordination of the genomics program and communication on forest genomics research – Bonfils

1999-02 Call for Rating of Genomics Proposals 99-00

1999-02 Rating of Genomics Proposals 99-00

1999-02 Memo advising of Fund Distribution 99-00

1999-02 Call for Genomics Proposals 00-02

1999-02 Agenda – Funding Allocation Meeting March 6-8 2000, 00-02

1999-02 Table – Fund distribution

1999-00 Call for Progress Reports

Sawfly Nucleopolyhedrovirus functional genomics – Lucarotti

Bioinformatics for CBS genomics R&D programs – Martin

Somatic embryogenesis of conifers and its application in commercial plantation forestry – Park

Molecular markers to differentiate between native species of lps and exotic lps species, forest insects of quarantine significance – Smith

Genomic sequencing of spruce budworm and its viruses: Marketing of Spin-off technologies by establishing proof of concept of fusolin and defensin – Arif

Juvenile hormone-based pest management tools for forest insects (total funding 99K – between GLFC and LFC) – Cusson

Laboratory and field studies on the persistence of free DNA and bacterial transformation in forest litter and aquatic substrates – Holmes

Development and pilot scale production of a recombinant virus for spruce budworm control: Phase II – Establishment of control potential – Retnakaran

Hydrolytic enzymes: Potential agents to improve tree resistance to pests – Richards

Improving toxicity of Bt to spruce budworm by enhancing proteolytic stability of delta-endotoxins in the larval midgut – van Frankenhuyzen

Juvenile hormone-based pest management tools for forest insects (total funding 99K – between GLFC and LFC) – Cusson

Microarrays for the diagnosis of forest pathogens – Hamelin

Genome architecture of economically important conifers – Isabel
Molecular approaches to understanding conifer somatic embryogenesis – Klimaszewska

Gene stability and expression in transgenics and their potential impact on ecosystems – Séguin

Isolation and characterization of gene regulatory components (GREs) and anti-microbial peptides (AMPs) for use with crop plants and forest trees – Séguin

Creation of a national tree functional genomics platform for collaborators – Séguin

Molecular analysis and genetic engineering of resistance of while pine to blister rust fungus – Ekramoddoullah

Investigation of the cold protein gene – Ekramoddoullah

Development of molecular tools to screen for resistance factors in spruce trees conferring reduced reproduction in Pissodes strobe – White

Coordination of genomics program and gaining understanding and support in forest biotechnology – Bonfils

Other Documents Reviewed

Annex B of Phase 3 Genomics R&D Initiative Treasury Board Submission

Guide for the Review of Evaluation Reports, Centre of Excellence for Evaluation, Treasury Board of Canada Secretariat, January 2004

The 1998 Canadian Biotechnology Strategy: An Ongoing Renewal Process, Government of Canada, Cat. No. C21-22/5-1998, ISBN 0-662-63917-0

Building the 21st Century Economy, A Government of Canada Blueprint for Biotechnology,

Realizing Canada's Potential, Biotechnology Assistant Deputy Ministers' Coordinating Committee, Canadian Biotechnology Strategy, December 2003

Speech from the Throne to Open the Third Session of the 37th Parliament of Canada, February 2, 2004. (http://www.pco-bcp.gc.ca)

Reporting on Horizontal Initiatives, Treasury Board of Canada Secretariat, Presentation made by Tom Fitzpatrick, April 30, 2004.

Report of the Auditor General of Canada to the House of Commons, Chapter 4: Managing Horizontal Initiatives, P. 19, November 2005.

Genomics R&D Initiative – Interdepartmental Governance (last modified March 22, 2006) Service Bulletin, Science Statistics, Science, Innovation and Electronic Information Division, Statistics Canada, Vol. 28, No. 7

Costing Estimates, 2002-03 to 2004-05

Regional Distribution of Planned Spending, 2002-03 to 2004-05

Interim Evaluation of Genome Canada, Bearing Point, March 31, 2004

Ontario Genomics Institute Annual Report 2003-2004

Genomics Fund Distribution, 1999-2002

Genomics Fund Distribution, 2002-2005

International Organizational Review Study of Genomics R&D Programs Final Report, Industry Canada, Life Sciences Branch, by: Bearing Point, January 27, 2006

Genome Canada, Survol des activités, Présentation à l'honorable Maxime Bernier, Ministre de l'Industrie, le 24 mai 2006

Formative Evaluation of the Canadian Regulatory System for Biotechnology Horizontal Evaluation, prepared for the Canadian Food Inspection Agency, on behalf of the Canadian Biotechnology Strategy Working Group on Regulations, prepared by Performance Management Network, March 21, 2003

Documented weekly summaries of Genomics Biotechnology

Genomics Biotechnology Briefings

Genomics Biotechnology MOUs

Abstracts, Genomics Meeting, Quebec City, June 16-17, 2000

Communications Plan, Genomics Research

Canadian Science Departments Genomics Review, Radisson Hotel, Winnipeg, Manitoba, June 7, 2001

Abstracts, Genomics Meeting, Winnipeg, Manitoba, June 5-6, 2001

Canadian Biotechnology Strategy Horizontal DPR (2004-05)

Genomics Performance Framework, Draft 5, November 24, 2000
Genomics R&D Initiative Program Framework (1999-00 to 2001-02)

Genomics R&D Initiative Phase 2 Program Framework (2002-03 to 2004-05)

Genomics R&D Initiative Phase 3 Program Framework (2005-06 to 2007-08)

Genomics R&D Initiative Performance Report (1999-00 to 2001-02) November 2001

Genomics R&D Initiative Performance Report Phase 2 (2002-03 to 2004-05)

Miscellaneous websites

Annex C – List of Approved Projects

C.1 Agriculture and Agri-Food Canada[38]

C.1.1 Phase 1 Projects

Generating Saturated Mutagenized Populations of *Arabidopsis* for High Through Put Functional Genomics

Cloning of Resistance Genes and Characterization of Their Signal Transduction Pathways in *Arabidopsis thaliana*

Generation of an Ordered BAC Library of *Brassica napus*

Bioinformatics and Data Mining in *Brassica* Genomics

Brassica Microsatellite Markers

Developing Effective Gene Targeting Technology for Crop Plants

Maximizing Freedom-to-Operate: Construction of a Generic Binary Vector

Modifying the Biochemistry of DNA Recombination and Repair

Rapid Gene Discovery and Gene Function Analysis in DNA Recombination and Repair

A Functional Genomics Approach to Studying Cold Tolerance in Crucifers

Functional Genomics of Abiotic Stresses in Crop Plants

Genome Analysis and Reverse Genetics of Pathogenicity Genes in *Leptosphaeria maculans*

A Genomics Based Program for *Brassica* Crop Development

Mapping and Cloning of Resistance Genes to Pathogens in *Brassica*

Resistance to Flea Beetles

Developing a Selection Strategy for Plant Transformation Not Based on Antibiotic Resistance

[38] Note: A list of specific project titles was not available from AAFC.

A Proteomics Approach for Discovery of Novel Genes to Increase Oil Production in Canola

Development of 3400 F6 lines of AC Foremost X BW278

Generating an EST Database of the Wheat Leaf Rust Fungus, *Puccinia triticina*

Towards a Protocol for Transformation of Triticum Monococcum

ESTs and Leaf Resistance Gene *LR1*

Development of 1000 Double Haploid Lines from AC Majestix X Glenlea

Pathogen Mapping and Marker Development

Introducing *RescueMu* Gene Discovery Technology into Wheat

EST Sequencing of Glenlea Endosperm-Specific Libraries

EST Sequencing of Thatcher Lr1 Library (Leaf Rust Host)

Development of Fusarium Head Blight Resistance in Wheat Through an EST Approach at ECORC

Global Study of Host Signal Transduction Mechanisms in Resistance to Wheat Leaf Rust

Development of Bacterial Artificial Chromosome (BAC) library from wheat cultivar Glenlea

Bioinformatics at the Cereal Research Centre

Microarrayed biochip-based genomic expression of 10,000 ESTs and candidate Fusarium Head Blight (FHB) resistance genes

Molecular mapping and QTL analysis for FHB and marker development for LR

Wheat Genomics: Pathology, fusarium head blight (FHB)

Quality phenotypic analysis/protein

Starch and Fibre Analysis of Segregating Wheat Populations

Recent Developments in Bioinformatics at Southern Crop Protection and Food Research Centre

Maximizing Freedom-to-Operate: Construction of a Generic Binary Vector

Genomic Mapping and Map-based Cloning of *Rps* (939) Gene

Conditioning Resistance of Soybean to *Phytopthora* Root Rot

Development of a plant virus vector for Rapid expression and analysis of foreign genes in plants

Insect Pathogen Genomics: Complete Genome Analysis of three baculoviruses pathogenic for the Canola Pest, Bertha Armyworm (*Mamestra configurata*)

Construction of a Micro-Array of Soybean and *Phytophthora sojae* cDNAs, and BAC Library Pools for PCR Screening

Use of Transcription Factor Genes to Enhance Regeneration and Recovery of Transgenic Soybean

Physical mapping of *Avrla* in *Phytophthora sojae* and sequencing of co-segregating BAC clones

Functional genomics of cold tolerance in forage crops

Functional genomics of cold tolerance in soybeans

Functional genomics in the model legume *Lotus japonicus*

Characterization of a Class I Chitinase from Soybean Seed Coats

Gene Discovery in Plant Secondary Metabolism

Seed Quality Traits in Soybean: Genomic Approaches to Link Genes to Phenotypes

A Candidate Gene Approach to High Seed Protein in Soybeans

Development of Methods for Gene Function Testing in Legumes

Bioinformatics at ECORC

Novel Methods of mRNA and Genomic DNA Enrichment for Genomics Research

Fusarium Genomics at ECORC

Genomics of plant responses to low temperatures

Maize/*Fusarium* Genomics at ECORC

C.1.2 Phase 2 Projects

Brassica ESTs and molecular variation

BAC library and physical mapping in *B. napus*

Population development, Arabidopsis activation tagging and *B. napus* TILLING

Chromatin remodelling

Tolerance to abiotic stress

Resistance to white rust (*Albugo candida*)

Resistance to blackleg (*Leptosphaeria maculans*)

Resistance to flea beetles

Metabolite transport

B6/T2 DNA recombination and repair

Data Processing and Data Management Support for Biological Projects

Physical Mapping

Chromatin Immunoprecipitation

Genomic and proteomic analysis of the wheat – *Puccinia triticina* interaction

Development of resistance to *Fusarium graminearum* in wheat

Data Processing and Data Management Support for Biological Projects

Sequencing Support for Biological Projects

Legume Model Systems

Gene Function Testing in Legumes

The development and analysis of microarrays from soybean, *Lotus japonicus*

Functional genomics studies of the disease interactions

Pathogenicityof *Phytophthora sojae* on Soybean; A Functional Genomics Approach

Insect pathogen genomics: genome analysis of baculoviruses pathogenic for the canola pest, bertha armyworm (*Mamestra configurata*)

Genetic regulation of soybean storage protein genes

Isoflavone transport to developing soybean seeds

Gene discovery in secondary metabolism

Genomics of proteolysis in plants

Soybean allergic protein Glym1: Comparative genomic analysis of gene structure

Data Processing and Data Management Support for Biological Projects

Sequencing Support for Biological Projects

Cosmid library of Fusarium graminearum

The development and analysis of microarrays from soybean, Lotus japonicus

Large Scale Identification of Regulatory Sequences

Chromatin Immunoprecipitation

Chromatin remodelling

Development cold and drought tolerance in maize

B6/T2 DNA recombination and repair

Selection of peptide markers for proteins from full length cDNA libraries as a method of providing high-throughput tags

Development of resistance to *Fusarium graminearum* in maize

Development of resistance to *Fusarium graminearum* in wheat

A Candidate Gene Approach to High Seed Protein in Soybeans

C.1.3 Phase 3 Projects

Mining *Brassica/Arabidopsis* sequence data

Engineering DNA recombination frequency in plants

DNA repair interactome of *Arabidopsis*

SNPs in chickpea for ascochyta resistance

Resource for identifying novel variation

Brassica bioinformatics research and support

Brassica/Arabidopsis microarray resource

Brassica/Arabidopsis core sequencing facility

Mamestra configurata genomics and midgut proteomics

Arabidopsis/Albugo defence

Pathogenicity determinants of *Leptosphaeria maculans*

Developing enhanced freezing tolerance in plants

Role of the cytoskeleton in abiotic stress

Accumulation of modified proteins in seeds

Repressors for seed storage protein genes

Enhancing canola meal quality

Transporter specificity for sulphate and selenate

Arabidopsis proanthocyanidin and flavonoid biosynthesis

Sulphate transport in *Arabidopsis*

Affymetrix

Bioinformatics

Fine mapping of individual FHB resistance genes and correlation with changes in gene expression profiles in wheat

Characterization of the wheat leaf rust resistance gene *Lr1* and related family members

Gene expression of plant defense pathways of the leaf rust pathosystem using a wheat microarray and the Affymetrix wheat gene chip

Identification of phospho-signalling pathways and genomic changes resulting from an overexpressed MEK in wheat

Avirulence analysis in wheat leaf rust (*Puccinia triticina*)

Map-based cloning of the major FHB resistance gene on wheat chromosome 3BS

Bridging structural and functional genomics: expression level polymorphisms related to Quantitative Trait Loci (QTL) for seed quality in wheat

Physical mapping and genomic sequencing of important seed quality traits (*Glu-3, Ha* and *Glu-B1*): toward understanding evolution and genomic organization

Redox-signalling in germinating wheat seeds using disulfide-proteomics based approach

Sequencing, transformation and bioinformatics infrastructure

Development of Viral Vectors as an Efficient Gene-Expression System for Legume Genomics and Molecular Farming

Identification of genes and protein products from Phytophthora sojae that control virulence on soybean plants

Functional genomics of Baculovirus infection
Nitrogen use efficiency: Genetic and genomics of plant adaptation to low N and P in the model legume *Lotus japonicus*

Molecular biology of pathogenicity and survival in the broad host range phytopathogenic fungi *Sclerotinia sclerotiorum* and *Verticillium spp.*

Seed Lustre

Genetic regulation of seed storage protein genes in soybean and Arabidopsis

Functional genomics of diterpene metabolism

Functional genomics of soybean isoflavanoids

Sequencing and microarray facility

Fine mapping of individual FHB resistance genes and correlation with changes in gene expression profiles in wheat

Defining genes and regulatory networks required for pathogenicity in the cereal pathogen *Fusarium graminearum*

Identification, characterization and elimination of soybean seed allergens to create 'hypoallergenic' soybean for the food industry

Genomics and proteomics of protein stabilization and production during seed development in oilseed crucifers

Structural genomics of soybean seed quality: protein content in standard soybeans and water uptake in natto soybeans

Proteome and transcriptome characterization of the biochemical basis for *Fusarium* head blight (FHB) resistance and susceptibility in winter wheat

C.2 Environment Canada

C.2.1 Phase 1 Projects

Environmental Ethics of Biotechnology

Environmental Non-Governmental Organization Perspectives on Genomics

Summary of Global Assessment for Potential Environmental Applications of Genomics

Application of DNA Arrays for Environmental Effects Monitoring

Microbial Ecology of Flocculated Sediments

Enhancement of Rhizosphere Phytoremediation of Hydrocarbon Contaminated Sites Using Plant and Microbial Genomics

Cold Adaptation Functional Genomics of Arctic Rhizobial Strain N33 and its Application for Improving Soil Bioremediation in Temperate and Arctic Climates

Technological Advancement of Genomics for Improving the Bioremediation of PCBs and Energetic Materials

DNA Chip Applications for the Detection and Monitoring of Microorganisms in the Environment: Demonstration of Low-Cost DNA Chips for Wastewater Analysis

Environmental Plasmid Genomics and Technology

DNA Microarray Technology – Applications to Avian Wildlife Toxicology

Development of Rapid Species-Specific DNA Detection System for Forensic Investigations Involving CITES Listed Species

Using Hypervariable Minisatellite DNA to Determine the Relative Role of PAHs, PCBs and Heavy Metals in the Induction of Heritable Mutations in Herring Gulls Nesting Near Steel Industries

Use of DNA Microarray Technology to Evaluate Ecosystem Integrity at an Ecological Monitoring and Assessment Network Site

Development of Genomic Markers for the Identification of Populations and the Genetic Variability in Thrush Species

Genetic Variation Among Eastern Breeding Populations of Harlequin Ducks

Genetic Perspectives in Conservation of a Declining Songbird: Diversity, Demography and Hybrid Zone Dynamics

Microgeographic Genetic Variation in Ipswich Sparrow and Mainland Savannah Sparrow

Delineation of Neotropical Migrant Bird Populations Using DNA Markers: Conservation Through Linkage of Breeding and Wintering Locations

Genetic Structure of Lesser Snow Goose and Ross's Goose Populations: Linking Breeding Origins to Harvest, Population Management and Conservation

Genetic Structure of Canada Goose Populations in Ontario: Linking Breeding Origins to Harvest, Population Management and Conservation

Identification of Conservation Units, Genetic Diversity and Population-Specific Markers for North American Shorebird Species of Concern

Delineation of King Eider Populations in the Canadian Arctic Using Genetic Techniques

Genotyping Workplan – HR Capacity

Test Methodology Development – HR Capacity

Test Methodology Development – Lab Infrastructure

Microarrays – HR Capacity

Microarrays – Lab Infrastructure

Microarrays – Advancement of Research

ETAD HQ

C.2.2 Phase 2 Projects

Genotyping Workplan (8 projects funded)

Genetic Structuring Within and Among Global Populations of Brant

Polar Bear Male and Female Reproductive Success

Linking Wintering and Breeding Ground Populations of Loggerhead Shrikes

Development of a genetic approach to determine population structure and breeding-wintering ground affinities of Razorbills

Bicknell's Thrush: Determining species distributional limits and population structure using genomics tools

Genetic Status of Horned Grebes nesting on Iles-de-la-Madeleine

Genetic Structuring Within and Between Populations of Barrow's Goldeneyes and Common Eiders

DNA Barcodes for Canadian Birds

Test Methodology Development

Microarrays – WTC

Microarrays – NWRI

Microarrays – NWRC

Microarrays – PESC

ETAD HQ

C.2.3 Phase 3 Projects

Genotyping Workplan (6 projects funded)

DNA Barcodes for Canadian Birds

Genetic Structuring Within and Among Global Populations of Brant

Quantitative Genetics and Candidate Genes for Trait Variation in Polar Bears in W. Hudson Bay

Distinguishing Between Canada Geese and Cackling Geese Species

Genetic Structuring Within Populations of the St. Lawrence Common Eider

Conservation Genetics of the Ivory Gull

Test Methodology: Development of Genomics Capacity and Environmental Genomics Techniques to Support EC's Regulations

Microarrays: Genomics Methods for Pathogen Detection in Municipal Wastewater

Microarrays: Toxicogenomics Applications

Microarrays: Application and Optimization of DNA Microarrays for Environmental Effects Monitoring

Microarrays: Gene Expression Technologies – Applications to Wildlife Toxicology

Validation of toxicogenomics for use in regulatory toxicology

Biomarkers of Exposure and Effects of Inhaled Contaminants in Atherosclerosis and Asthma

Environmental Health Applications of Toxico-Genomics and Proteomics. Identification of Exposure and Effects Biomarkers for Mutagenic Carcinogens in Complex Environmental Matrices

Biological Validations of Instability in Tandemly Repeated Genomic Sequences in Rodent and Human Cells for Purposes of Regulatory Genotoxicity Evaluations

Office of Biotechnology and Science, Administration and Management of Genomics R&D Fund

Study of Interferon-induced Hepatic Injury Using Genomic and Proteomic Approach

Application of the p53+/- transgenic mouse for alternative cancer bioassays: Genomic characterization of tissues from mice exposed to genotoxic and non-genotoxic carcinogens

Immuno-informatics for epitope discovery in infectious pathogens: applications in identification of potential diagnostic markers and vaccine candidates

Genomic approaches to provide molecular makers for *Salmonella* typing

Biomarker Discovery for Diagnosis of Prion Disease

A Genetic "Knock-Down" Approach to Identify Host Cellular Factors Essential for Infectious Agent Replication and Pathogenesis

C.3 Fisheries and Oceans Canada

C.3.1 Phase 1 Projects

Northern abalone conservation using DNA fingerprinting

Population structure of candidate species for marine protected areas

Characterization of salmonid Y chromosome

Carotenoid pigment metabolism and transport in fish

DNA promoters for expression of proteins in fish somatic cells

Sequencing aquatic pathogens "Like-to-like": Phylogenetic evaluation of *Kudoa thyrsites* isolated from different hosts and geographic locations; and in strain variation in BC isolates of *Aeromonas salomnicida* and VHS

Development and validation of molecular biotests to monitor bioremediation success

C.3.2 Phase 2 Projects

A scientifically-based approach to the development of aquaculture broodstock and fisheries management: Identify genetic markers and their patterns to develop genetically soundbreeding and brood stock programs that will ensure intraspecies biodiversity

Development of triploid and tetraploid scallops for aquaculture

Physiological effects of changing environmental condition on sockeye salmon: Stress, immunosuppression and predisposition to disease

Genomic characterization of growth in fish

Genetic characterization of the salmon Y chromosome and sex determination

Comparison of viral pathogens in aquatic animals to ascertain similarities and differences between geographical zones in support of the new Canadian aquatic animals health program (Phase II of Like-2-Like)

Comparison of viral pathogens in aquatic animals to ascertain similarities and differences between geographical zones in support of the new Canadian aquatic animals health program (Phase II of Like-2-Like) (Different Regions)

C.3.3 Phase 3 Projects

Genetic profiles of Mytilus edulis and Mytilus trossulus: Species identification, intravariation among populations, and the heritability of important traits

The Phylogeography and pathogenomics of viral hemorrhagic septicemia virus (VHSV) in Canada

Application and validation of metagenomics for monitoring aquatic ecosysts health

Development and use of comparative molecular markers to assess levels and patterns of genetic diversity in water skate (leucoraja ocellatea)

Sequence-level comparison of Atlantic and Pacific Salmon growth hormone gene genomic regions

Expression profiling of Fraser River late run sockeye salmon: migration physiology uncovered using cDNA microarray technology

The Phylogeography and pathogenomics of infectious salmon anemia virus (ISAV) in Canada

C.4 Health Canada

C.4.1 Phase 1 Projects

Novel Vaccines

Genetic testing surveillance

Knowledge and attitudes of genetic testing, educational strategies

Detection of pathogens using biosensors

rDNA / protein reagents for viral diagnostics

Surveillance of human pathogens using DNA chips

Identification of genetic loci affecting drug metabolism

Validation of a framework for genetic testing

Oral / edible vaccines

Genetic testing: laboratory to community

Cloning Tyrosine kinase

Gene abnormalities in child leukemia

Toxicogenomics

Biomarkers for food contaminants

Studies on safety of GM foods

Fund management

C.4.2 Phase 2 Projects

A Network Approach to Quality Management and Policy Research of Genetic Testing and Services in Canada

Evaluation of Environment Toxicogenomics for Use in Regulatory Toxicology & Risk Assessment

Integrated Genomic and Proteomic Approaches to Research Addressing the Safety and Efficacy of Biotherapeutics

Genomics approaches to reducing the public health risks associated with foodborne and waterborne enteric pathogens

A Food Directorate Research Program in Support of the Evaluation of Safety, Nutritional Quality, and Short- and Long-term Health Effects of Foods Developed Through the Application of Genomics

Genomics of Infection and Immunity

Genomics-proteomics based evaluation of toxicity and pathogenicity of microorganisms used in environmental biotechnology applications

Determining Changes in Human Bacterial Populations as a Function of Diet and Disease

Microarray methodology for examining gene expression changes in a rodent reproductive model: assessment of endocrine disruptors

Comparative genomics of Verocytotoxin-producing *Escherichia coli* (VTEC) serotypes that differ in their propensity to cause sever and epidemic disease

Genomics Research and Benefit Sharing: Towards Building a Common Understanding

Characterization of Gene and Protein Expression Profiles During Diet Induced Mammary Gland Cancer: A Rodent Model Biomarker Development System to Evaluate Chronic Effects of Food Borne Carcinogens and Anti-carcinogens

Genomic approach to detect and differentiate verotoxigenic *Escherichia coli*

Developmental and Age-Specific Neurotoxocology of Foods and Environmental Contaminants: A Mechanistic-Based Assessment

Comparative sequencing and identification of human virulence markers of primate herpes simplex viruses

Applications of Genomics Technology to Assumptions and Problems in Toxicological Risk Assessment

C.4.3 Phase 3 Projects

Validation of toxicogenomics for use in regulatory toxicology

Biomarkers of Exposure and Effects of Inhaled Contaminants in Atherosclerosis and Asthma

Environmental Health Applications of Toxico-Genomics and Proteomics. Identification of Exposure and Effects Biomarkers for Mutagenic Carcinogens in Complex Environmental Matrices

Biological Validations of Instability in Tandemly Repeated Genomic Sequences in Rodent and Human Cells for Purposes of Regulatory Genotoxicity Evaluations

Office of Biotechnology and Science, Administration and Management of Genomics R&D Fund

Study of Interferon-induced Hepatic Injury Using Genomic and Proteomic Approach

Application of the p53+/- transgenic mouse for alternative cancer bioassays: Genomic characterization of tissues from mice exposed to genotoxic and non-genotoxic carcinogens

Immuno-informatics for epitope discovery in infectious pathogens: applications in identification of potential diagnostic markers and vaccine candidates

Genomic approaches to provide molecular makers for *Salmonella* typing

Biomarker Discovery for Diagnosis of Prion Disease

A Genetic "Knock-Down" Approach to Identify Host Cellular Factors Essential for Infectious Agent Replication and Pathogenesis

C.5 National Research Council

C.5.1 Phase 1 Projects

Genome Sciences in Agriculture

Genome Sciences in Aquaculture

Prototyping of Biodiagnostics Devices

Genome Sciences in Age Related Diseases

Genome Sciences in Infectious Diseases

Research Platform – DNA Sequencing

Research Platform – Proteomics

Research Platform – DNA Array

Program Administration / Networking

C.5.2 Phase 2 Projects

Enhancing Crop Performance and Value Through Genomics

Genomics of Aquaculture

A Genomic-based Approach to Enhancing Bioremediation through Microbial Identification and Community Profiling

Cancer Genomics

Genomics of Human Pathogens and their Host Interactions

Multimodeal Characterization of Disease

Structural Biology of Cellular Protein Assemblies

Systems Biology of Brain Cell Interactions

Research Platform Support

Program Administration / Networking

C.5.3 Phase 3 Projects

Brassica Seed Development

Aquatic Animal Disease Management

Personalized Medicine for Cancer

Kinase Signalling Networks

Chronic Cardiovascular Disease

Technologies for Pathogen Detection

Research Platform Support

Program Administration / Networking

C.6 Natural Resources Canada

C.6.1 Phase 1 Projects

Bioinformatics for CBS genomics R&D programs

Molecular markers to differentiate between native species of lps and exotic lps species, forest insects of quarantine significance

Somatic embryogenesis of conifer species and its application in commercial plantation forestry

Sawfly Nucleopolyhedrovirus functional genomics

Laboratory and field studies on the persistence of free DNA and bacterial transformation in forest litter and aquatic substrates
Genomic sequencing of spruce budworm and its viruses: Marketing spin-off technologies by establishing proof of concept of fusolin and defensin

Development and pilot scale production of a recombinant virus for spruce budworm control: Phase II – Establishment of control potential

Improving toxicity of Bt to spruce budworm by enhancing proteolytic stability of delta-endotoxins in the larval midgut

Hydrolytic enzymes: Potential agents to improve tree resistance to pests

Juvenile hormone-based pest management tools for forest insects

Gene stability and expression in transgenic trees and their potential impact on forest ecosystems

Isolation and characterization of gene and regulatory components (GREs) and anti-microbial peptides (AMPs) for use with crop plants and forest trees

Microarrays for the diagnosis of forest pathogens

Creation of a national tree functional genomics platform for collaborators in tree biotechnology

Molecular approaches to understanding conifer somatic embryogenesis

Genome architecture of economically important conifers

Juvenile hormone-based pest management tools for forest insects

Development of molecular tools to screen for resistance factors in spruce trees conferring reduced reproduction in Pissodes strobi

Molecular analysis and genetic engineering of resistance of white pine to blister rust fungus

Investigation of the cold protein gene

Gaining understanding and support in forest biotechnology

C.6.2 Phase 2 Projects

Sawfly Nucleopolyhedrovirus functional genomics

Genomic sequencing of spruce budworm and its viruses: total sequencing, analyses and an expression vector of an entomopoxvirus; development of fusolin delivery and marketing of spin-off technologies by establishing proof of concept of fusolin defensin

Development and pilot scale production of a recombinant virus for spruce budworm control: product development and optimization. Renamed in 04: Genetic engineering of viruses and insects for pest management and protein expression

Improving toxicity of Bt to spruce budworm by enhancing proteolytic stability of delta-endotoxins in the larval midgut

Expressed Sequence Tags (ESTs) of spruce budworm epidermis and midgut for analysis of global gene expression and identification of novel genes

Competition and gene flow among co-infecting transgenic and wild-type microorganisms: can engineered genes move into other organisms?

Microbial chitinases: potential agents to improve tree resistance to pests

Genomics of transcriptional factors involved in tree defense response

A national tree functional genomics platform for collaborators in tree biotechnology

Molecular approaches to understanding conifer somatic embryogenesis

Structural genomics of conifer species through functional genomics approaches

Novel platform for molecular diagnosis of forest pests

Juvenile hormone-based pest management tools for forest insects; search for new bio-rational target sites

Molecular analysis, elicitor activity, isolation of functional R gene and genetic engineering of resistance of white pine to blister rust fungus

Molecular and genetic characterization of conifer host-laminated root rot (Phellinus weirii) pathosystems

Coordination of the genomics program and communication to the general public on forest genomics research

C.6.3 Phase 3 Projects

Nucleopolyhedrovirus functional and comparative genomics

Functional genomics of CfMNPV: role of all the open reading frames in the infection process

Transcriptomics analysis of insect molting

Effects of the larval host on genomic variation and evolution of insect viruses: implications for pest control

Molecular tools for studies on the ecology and phylogeny of microsporidia in forest defoliators

Interacting genomes

A tree functional genomic platform for gene function discovery

Fungal genomics for protection and conservation
Genome-wide scan to reveal genes underlying growth productivity traits in white spruce (Picea glauca)

Association mapping of wood characters in white spruce

Molecular analysis, elicitor activity, isolation of functional R gene and genetic engineering of resistance of white pine to blister rust fungus

Molecular and genetic characterization of conifer host-laminated root rot (Phellinus spp.) pathosystems

Coordination of the genomics program

Annex D – List of Potential Interviewees

List of Potential Interviewees

Name	Department / Organization	Type
Agriculture and Agri-Food Canada (AAFC) – A total of 24 interviews were completed with 4 management, 15 project leads and 5 stakeholders. They were sampled from the following individuals.		
Dr. Gordon Neish	Agriculture and Agri-food Canada	Management
Dr. Lianne Dwyer	Agriculture and Agri-food Canada	Management
Dr. Dalia Kudirka	Agriculture and Agri-food Canada	Management
Dr. Mark Jordan	Agriculture and Agri-food Canada	Management
Dr. Derek Lydiate	Agriculture and Agri-food Canada	Project Lead
Dr. Roger Rimmer	Agriculture and Agri-food Canada	Project Lead
Dr. Isobel Parkin	Agriculture and Agri-food Canada	Project Lead
Dr. Dwayne Hegedus	Agriculture and Agri-food Canada	Agriculture and Agri-food Canada
Dr. Daryl Somers	Agriculture and Agri-food Canada	Project Lead
Dr. Sylvie Cloutier	Agriculture and Agri-food Canada	Project Lead
Chris Rampitsch	Agriculture and Agri-food Canada	Project Lead
Travis Banks	Agriculture and Agri-food Canada	Project Lead
Dr. Jas Singh	Agriculture and Agri-food Canada	Project Lead
Linda Harris	Agriculture and Agri-food Canada	Project Lead
Dr. Stephen Molnar	Agriculture and Agri-food Canada	Project Lead
Dr. Gopal Subramanian	Agriculture and Agri-food Canada	Project Lead
Dr. Jim Brandle	Agriculture and Agri-food Canada	Project Lead
Dr. Mark Gijzen	Agriculture and Agri-food Canada	Project Lead
Dr. David Theilman	Agriculture and Agri-food Canada	Project Lead
Dr. Krystof Szczyglowski	Agriculture and Agri-food Canada	Project Lead
Ben Landry	DNA Landmarks	Stakeholder
John Thompson	Department of Biology, University of Waterloo	Stakeholder
Steve Barnes	SES Europe NV / SA	Stakeholder
Ashley O'Sullivan	Ag-West Bio	Stakeholder
Lanette Kuchenski	Western Grains Research Foundation	Stakeholder
Henry Olechowski	Hyland Seeds	Stakeholder

Name	Department / Organization	Type
Environment Canada (EC) – A total of 18 interviews were completed with 4 management, 11 project leads and 3 stakeholders. They were sampled from the following individuals.		
Terry McIntyre	Environment Canada	Management
Matthew Schacker	Environment Canada	Management
Miguel Providenti	Environment Canada	Management
Shirley-Ann Scharf	Environment Canada	Management
Sean Kennedy	Environment Canada	Project Lead
Graham van Aggelan	Environment Canada	Project Lead
John Lawrence	Environment Canada	Project Lead
Lee Beaudette	Environment Canada	Project Lead
Rick Scroggins	Environment Canada	Project Lead
Tom Edge	Environment Canada	Project Lead
Ian Sterling	Environment Canada	Project Lead
Sean Boyd	Environment Canada	Project Lead
Andrew Diduk	Environment Canada	Project Lead
Francois Schaffer	Environment Canada	Project Lead
Charles Francis	Environment Canada	Project Lead
Robert Wenting	Environment Canada	Project Lead
Greg Robertson	Environment Canada	Project Lead
Jim Leafloor	Environment Canada	Project Lead
Jean-Pierre Savard	Environment Canada	Project Lead
Manon Bombardier	Environment Canada	Stakeholder
Jim Louter	Environment Canada	Stakeholder
Anoop Poovadan	Environment Canada	Stakeholder
Kim Hibbeln	Environment Canada	Stakeholder
Lindsay Copeland	Environment Canada	Stakeholder
Department of Fisheries and Oceans (DFO) – A total of 15 interviews were completed with 4 management, 8 project leads and 3 stakeholders. They were sampled from the following individuals.		
Sarah Cosgrove	Fisheries and Oceans Canada	Management
Sylvain Paradie	Fisheries and Oceans Canada	Management
Dan McPhee	Fisheries and Oceans Canada	Management
Ingrid Burgetz	Fisheries and Oceans Canada	Management
Kristi Miller-Saunders	Fisheries and Oceans Canada	Project Lead

Name	Department / Organization	Type
Dr. Robert Devlin	Fisheries and Oceans Canada	Project Lead
Dr. Gilles Olivier	Fisheries and Oceans Canada	Project Lead
Dr. Simon Jones	Fisheries and Oceans Canada	Project Lead
Ken Lee	Fisheries and Oceans Canada	Project Lead
Nellie Gagné	Fisheries and Oceans Canada	Project Lead
Lorraine C. Hamilton	Fisheries and Oceans Canada	Project Lead
Ruth Withler	Fisheries and Oceans Canada	Project Lead
Charles Greer	Fisheries and Oceans Canada	Stakeholder
Dr. Ben Koop	University of Victoria	Stakeholder
Anthony P. Farrell	University of British Columbia	Stakeholder
Health Canada (HC) – A total of 21 interviews were completed with 6 management, 11 project leads and 4 stakeholders. They were sampled from the following individuals.		
Nigel Skipper	Health Canada	Management
Pierre Charest	Health Canada	Management
Hans Yu	Health Canada	Management
Brian Colton	Health Canada	Management
Bahman Assadi	Health Canada	Management
Shannon Lewis	Health Canada	Management
Anton Andonov	Public Health Agency of Canada	Project Lead
Stéphane Belisle	Health Canada	Project Lead
Raymond Tsang	Public Health Agency of Canada	Project Lead
Mike Debrot	Public Health Agency of Canada	Project Lead
Dr. Eileen Tackaberry	Health Canada	Project Lead
Dr. Remy Aubin	Health Canada	Project Lead
Maya Kozlowski	Health Canada	Project Lead
Dr. Ivan Curran	Health Canada	Project Lead
Dr. Rekha Mehta	Health Canada	Project Lead
Dr. Sithian Pandian	Health Canada	Project Lead
Carole Yauk	Health Canada	Project Lead
Renaud Vincent	Health Canada	Project Lead
Paul White	Health Canada	Project Lead
Craig Parfett	Health Canada	Project Lead
George Douglas	Health Canada	Project Lead

Name	Department / Organization	Type
Vern Seligy	Health Canada	Project Lead
Sean Li	Health Canada	Project Lead
Michel Girard	Health Canada	Project Lead
Genevieve Bondy	Health Canada	Project Lead
Stephen P.J. Brooks	Health Canada	Project Lead
Olga Pulidio	Health Canada	Project Lead
Lynn Mainland	Health Canada	Project Lead
Frank Plummer	Public Health Agency of Canada	Project Lead
Cornelius Pope	Public Health Agency of Canada	Project Lead
Stephanie Booth	Public Health Agency of Canada	Project Lead
Markus Czub	Public Health Agency of Canada	Project Lead
Debra Lynkowski	Public Health Agency of Canada	Project Lead
Mike Coulthart	Public Health Agency of Canada	Project Lead
Roger Johnson	Public Health Agency of Canada	Project Lead
Mohammed Karmali	Public Health Agency of Canada	Project Lead
Lai King Ng	Public Health Agency of Canada	Project Lead
Alberto Severino	Public Health Agency of Canada	Project Lead
Irene Hay	Natural Resources Canada	Stakeholder
Dr. Bill Casley	Health Canada	Stakeholder
Peter Monette	Health Canada	Stakeholder
Grant McClarty	Public Health Agency of Canada	Stakeholder
Marc Ekker	University of Ottawa	Stakeholder
National Research Council (NRC) – A total of 11 interviews were completed with 3 management, 6 project leads and 2 stakeholders. They were sampled from the following individuals.		
Gary Fudge	National Research Council	Management
Dr. Richard Isnor	International Research Development Centre (formerly National Research Council)	Management
Dr. Gabrielle Adams	National Research Council	Management
Dr. Michel Desrochers	National Research Council	Management
Dr. Kutty Kartha	National Research Council	Management
Ms. Denise LeBlanc-MacDonald	National Research Council	Management
Dr. Ian Smith	National Research Council	Management
Dr. Laura Brown	National Research Council	Project Lead

Name	Department / Organization	Type
Dr. Wilf Keller	National Research Council	Project Lead
Dr. Martin Young	National Research Council	Project Lead
Dr. Mike Jackson	National Research Council	Project Lead
Dr. Stewart Johnson	National Research Council	Project Lead
Dr. Myrek Cygler	National Research Council	Project Lead
Dr. Charles Greer	National Research Council	Project Lead
Dr. Maureen O'Connor-McCourt	National Research Council	Project Lead
Dr. Andrew Storer	National Research Council	Project Lead
Dr. Roy Walker	National Research Council	Project Lead
Dr. Martin Young	National Research Council	Project Lead
Dr. Mark Bisby	Canadian Institutes of Health Research	Stakeholder
Dr. Christian Burks	Ontario Genomics Institute	Stakeholder
Dr. Kevin Keough	Alberta Heritage Foundation for Medical Research	Stakeholder
Dr. Alex MacKenzie	Children's Hospital of Eastern Ontario	Stakeholder
Dr. Kevin O'Brien-Fehr	GlaxoSmithKline Inc.	Stakeholder
Brian Harling	MDS Inc.	Stakeholder
Dr. John Thomspon	University of Waterloo	Stakeholder
Dr. Brian Wilson	Ontario Cancer Institute	Stakeholder
Dr. Steve Pelech	Kinexus Bioinformatics Corp.	Stakeholder
Dr. Thomas Chen	University of Connecticut	Stakeholder
Dr. Marvin Bayne	Schering-Plough Research Institute	Stakeholder
Dr. William Thomlinson	Canadian Light Source	Stakeholder
Natural Resources Canada (NRCan) – A total of 17 interviews were completed with 5 management, 10 project leads and 2 stakeholders. They were sampled from the following individuals.		
Anne-Christine Bonfils	Natural Resources Canada	Management
Geoff Munroe	Natural Resources Canada	Management
Tony Hopkins	Natural Resources Canada	Management
Ariane Plourde	Natural Resources Canada	Management
Gary Hogan	Natural Resources Canada	Management
Bruce Pendrel	Natural Resources Canada	Management
Dr. Armand Séguin	Natural Resources Canada	Project Lead
Dr. Nathalie Isabel	Natural Resources Canada	Project Lead

Name	Department / Organization	Type
Dr. Richard Hamelin	Natural Resources Canada	Project Lead
Dr. Michel Cusson	Natural Resources Canada	Project Lead
Dr. Chris Lucarotti	Natural Resources Canada	Project Lead
Dr. Basil Arif	Natural Resources Canada	Project Lead
Dr. Abdul Ekramoddoullah	Natural Resources Canada	Project Lead
Dr. Rona Sturrock	Natural Resources Canada	Project Lead
Dr. Van Frankenhuyzen	Natural Resources Canada	Project Lead
Dr. Jean Beaulieu	Natural Resources Canada	Project Lead
Dr. John MacKay	Université Laval	Stakeholder
Dr. Peter Krell	University of Guelph	Stakeholder
Dr. Jean Bousquet	Université Laval	Stakeholder
Horizontal – A total of 9 interviews were completed from a horizontal perspective. They were sampled from the following individuals.		
Tom Wright	Industry Canada (IC)	Stakeholder
Barry Stemshorn	Environment Canada	Stakeholder
Brian Emmett	Natural Resources Canada	Stakeholder
Simon Kennedy	Privy Council Office (PCO)	Stakeholder
Jane Huntley	Privy Council Office	Stakeholder
Dr. Judith Bossé	Canadian Food Inspection Agency	Stakeholder
Bart Bilmer	Canadian Food Inspection Agency	Stakeholder
Myles Kirvan	Justice Canada	Stakeholder
Robert Walker	Defence Research and Development Canada	Stakeholder
Dr. Roman Szumski	National Research Council	Stakeholder
Wendy Watson-Wright	Fisheries and Oceans Canada	Stakeholder
Neil Yeates	Health Canada	Stakeholder
Mario Ste-Marie	International Trade Canada	Stakeholder
Dr. Marc Fortin	Agriculture and Agri-food Canada	Stakeholder
Kim Elmslie	Canadian Biotechnology Secretariat	Stakeholder
Anahita Ariya-Far	Justice Canada	Stakeholder
David Brener	Canadian Institutes of Health Research	Stakeholder
Marcel Chiasson	Treasury Board Secretariat	Stakeholder
Peter Armstrong	Treasury Board Secretariat	Stakeholder
Dr. Denis Faubert	Defence Research and Development Canada	Stakeholder

Name	Department / Organization	Type
Dr. Ann Fraser	Canadian Food Inspection Agency	Stakeholder
Fred Gault	Statistics Canada	Stakeholder
Nick Heseltine	Industry Canada	Stakeholder
Sara Hradecky	International Trade Canada	Stakeholder
Ailish Johnson	Privy Council Office	Stakeholder
Dr. Janet King	Industry Canada	Stakeholder
Robert Maine	Industry Canada	Stakeholder
Thomas Shenstone	Agriculture and Agri-food Canada	Stakeholder
Martin Godbout	Genome Canada	Stakeholder

Annex E – Interview Guides

Evaluation of the Genomics R&D Initiative
Management Interview Guide

Introduction

Thank you for taking the time to participate in this interview for the horizontal evaluation of the Genomics R&D Initiative which, in your department / organization is delivered through:

- AAFC – Bioproducts and Bioprocesses Coordinator, National Science Program
- DFO – Office of Aquatic Biotechnology, Aquaculture Science Branch
- EC – Environmental Biotechnology Applications
- HC – Departmental Biotechnology Office
- NRCan – Biotechnology Coordinator, Forest Science Division
- NRC – Genomics and Health Initiative (GHI)

The primary reasons for conducting a horizontal evaluation of the Genomics R&D Initiative at this time are to measure the genomics R&D capacity that has been established by Phase 1 in federal labs, and to evaluate the progress towards longer outcomes made to date. The evaluation aims to examine the Initiative from its inception in 1999 (Phase 1) through Phase 2 and the transition to Phase 3 (FY 2005-2006). It is intended to assess the horizontal aspects of the Initiative as well as success within departments / organizations.

We are gathering information on the ongoing need for a horizontal initiative such as the Genomics R&D Initiative, the impact of the Initiative as a whole as well as its impacts in the departments / organizations, the design and delivery of the Initiative, and obstacles, barriers or unexpected opportunities that have arisen.

The interview will be treated confidentially. Only summary results will be provided in our report and we will ensure that responses cannot be attributed to any one individual.

The interview guide is targeted at different individuals within the departments. Therefore, some questions may not apply to you. Please just let me know if you cannot answer a particular question and we can just skip it.

Do you have any questions for me before we begin?

First, I would like to ask you about your involvement in the Genomics R&D Initiative? Have you been involved in all three phases? How?

Rationale

To the best of your knowledge, what was the rationale behind the creation of the Genomics R&D Initiative? Does that rationale still make sense today? To what extent is the Genomics R&D Initiative, as currently designed, addressing those needs?

What was the rationale behind your department's / organization's participation in this initiative? Does it still make sense for your department / organization to be involved?

Is the Genomics R&D Initiative well linked to your department's / organization's priorities? Please elaborate. Could any of these priorities be addressed elsewhere, such as by the provinces, the private sector or the voluntary sector? If yes, which priorities and why? If no, why not?

Success

What are the specific objectives / goals of your department / organization related to the Genomics R&D Initiative? To what extent have these objectives been achieved? How have each phase contributed to these objectives?

What have been the specific results of Phase 1 projects? To what extent would those results have occurred without the Genomics R&D Initiative? Consider the incremental impacts of the horizontal initiative; the ability to undertake the projects without the funding; impact on quality, scope, timing, etc. of the project completion.

What factors facilitated success in Phase 1? What factors impeded success? Consider all factors directly or indirectly related to the Initiative which facilitated or impeded success.

To what extent and in what way did the projects funded under Phase 1 build capacity in your department / organization to carry out genomics research? Please elaborate through specific examples.

How did this increased capacity strengthen the research carried out in your department? What has changed in the research carried out in your department as a result of the Phase 1 projects that is, how has the profile of your departmental research changed?

How has the increased capacity translated into benefits for Phase 2 projects? Consider Phase 2 projects that could not have been undertaken without the Phase 1 project results; the multi-phased projects undertaken and the resulting benefits; the attribution of Phase 2 results to Phase 1; etc.

What have been the specific results of Phase 2 projects? To what extent would those results have occurred without the Genomics R&D Initiative? What factors facilitated success in Phase 2? What factors impeded success?

To what extent has the Genomics R&D Initiative strengthened coordination, cooperation and linkages between your department and other research institutions? Consider the impacts of the horizontal nature of the Initiative on your department's ability to partner with other departments involved in the initiative; the impacts of Phase 1 capacity building on your ability to partner with other research institutions; etc.

Were there any other intended or unintended impacts resulting from Phase 1 projects? From Phase 2 projects? From the Genomics R&D Initiative overall?

Cost-Effectiveness / Alternatives

Does the Genomics R&D Initiative complement, overlap or duplicate other federal or provincial initiatives related to genomics or biotechnology? In what way is the Initiative different from others such as Genome Canada, genomics research in provincial laboratories, the Canadian Biotechnology Strategy Fund, and others? In what way is the Initiative unique?

How satisfied are you with the funding structure of the Genomics R&D Initiative? Why? How would you improve the current funding structure? What problems have you experienced related to the funding structure?

Are there more cost-effective alternative ways of achieving the Genomics R&D Initiative mandate?

What have been the advantages of the three-year funding cycle? What have been the drawbacks? Has the three-year funding cycle facilitated achievement of the results to date or has it been an impediment?

What have been the costs to your department of being involved with the Genomics R&D Initiative in terms of the added cost associated with a horizontal initiative? Consider the costs associated with interdepartmental communications, decision-making, etc. that you would not incur if you were just managing a departmental genomics R&D program. What have been the added benefits of being involved in this horizontal initiative? In your opinion, do the benefits outweigh the costs? Why / why not?

Design and Delivery

Is the position of the Genomics R&D Initiative appropriate within the larger government biotechnology strategy (Canadian Biotechnology Strategy, other programing such as Genome Canada, Canadian Regulatory System for Biotechnology, etc.)? Why do you say that? Is the level of integration with other federal government biotechnology programs appropriate? Do these program add unique value to your department and to the overall federal strategy? How / why not?

How effective is the governance structure for the Genomics R&D Initiative? What are the strengths and weaknesses of the governance structure?

How does the project approval process work in your department? Is this effective for your department? Do you think it is effective in the context of the overall horizontal nature of the Initiative? How could the process be improved?

From your perspective, are the departmental roles, responsibilities and accountabilities clearly defined and understood? Are they appropriate? Why do you say that? Are the horizontal roles, responsibilities and accountabilities clearly defined and understood? Are they appropriate? Why do you say that?

To what extent has your department been able to leverage the funds provided through the Genomics R&D Initiative? What are the pros and cons associated with the leveraging requirements?

What systems do you have in place to measure the performance of the Initiative overall and the projects? How effective is this? What information do you capture? Do you have the performance information you need for decision-making purposes? Have you used the information you currently have for decision-making purposes? Please elaborate.

In what way do you share your performance information in the context of the broader horizontal initiative? Is this effective?

What could be improved about the current performance measurement system for the Initiative as a whole as well as in your department? Consider the requirements for Phase 3 and ongoing.

How could the Genomics R&D Initiative be improved? What changes are required to make the Initiative more efficient?

Conclusions

Do you have any other comments you would like to make on the Initiative?

Thank you very much for your time.

Evaluation of the Genomics R&D Initiative
Researcher Interview Guide

Introduction

Thank you for taking the time to participate in this interview for the horizontal evaluation of the Genomics R&D Initiative which, in your department / organization is delivered through:

AAFC – Bioproducts and Bioprocesses Coordinator, National Science Program
DFO – Office of Aquatic Biotechnology, Aquaculture Science Branch
EC – Environmental Biotechnology Applications
HC – Departmental Biotechnology Office
NRCan – Biotechnology Coordinator, Forest Science Division
NRC – Genomics and Health Initiative (GHI)

The primary reasons for conducting a horizontal evaluation of the Genomics R&D Initiative at this time are to measure the genomics R&D capacity that has been established by Phase 1 in federal labs, and to evaluate the progress towards longer outcomes made to date. The evaluation aims to examine the Initiative from its inception in 1999 (Phase 1) through Phase 2 and the transition to Phase 3 (FY 2005-2006). It is intended to assess the horizontal aspects of the Initiative as well as success within departments / organizations.

We are gathering information on the ongoing need for a horizontal initiative such as the Genomics R&D Initiative, the impact of the Initiative as a whole as well as its impacts in the departments / organizations, the design and delivery of the Initiative, and obstacles, barriers or unexpected opportunities that have arisen.

We are speaking to you because of your particular involvement in the following project(s). ***List of projects for which the individual was the lead researcher.***

The interview will be treated confidentially. Only summary results will be provided in our report and we will ensure that responses cannot be attributed to any one individual.

The interview guide is targeted at different individuals within the departments. Therefore, some questions may not apply to you. Please just let me know if you cannot answer a particular question and we can just skip it.

Do you have any questions for me before we begin?

First, I would like to ask you about your involvement in the Genomics R&D Initiative? Have you been involved in all three phases? How?

Success

Ask only if involved in Phase 1 project(s)

What have been the specific results of ***Phase 1 projects***? To what extent would those results have occurred without the funding available through the Genomics R&D Initiative? Consider the incremental impacts of the horizontal initiative; the ability to undertake the projects without this special fund; etc.

What factors facilitated success in ***Phase 1 projects***? What factors impeded success?

To what extent and in what way did the projects funded under Phase 1 build capacity in your department / organization to carry out genomics research? Please elaborate through specific examples.

Did this increased capacity strengthen the research carried out in your department? How? What has changed in the research carried out in your department as a result of the ***Phase 1 projects***? Has the profile of your departmental research changed?

Were there any other intended or unintended impacts resulting from Phase 1 projects?

Ask only if involved in Phase 2 project(s)

How has the increased capacity translated into benefits for Phase 2 projects? Consider Phase 2 projects that could not have been undertaken without the Phase 1 project results; the multi-phased projects undertaken and the resulting benefits; the attribution of Phase 2 results to Phase 1; etc.

What have been the specific results of Phase 2 projects? To what extent would those results have occurred without the Genomics R&D Initiative? What factors facilitated success in Phase 2? What factors impeded success?

To what extent has the Genomics R&D Initiative strengthened coordination, cooperation and linkages between your department and other research institutions? Consider the impacts of the horizontal nature of the Initiative on your department's ability to partner with other departments involved in the initiative; the impacts of Phase 1 capacity building on your ability to partner with other research institutions; etc.

Were there any other intended or unintended impacts resulting from Phase 2 projects?

Cost-Effectiveness / Alternatives

Does the Genomics R&D Initiative complement, overlap or duplicate other federal or provincial

initiatives related to genomics or biotechnology? In what way is the Initiative different from others such as Genome Canada, genomics research in provincial laboratories, the Canadian Biotechnology Fund, and others? In what way is the Initiative unique?

From your perspective, are there more cost-effective alternative ways of achieving the Genomics R&D Initiative mandate?

In your opinion, what have been the advantages of the three-year funding cycle? What have been the drawbacks? Has the three-year funding cycle facilitated achievement of the results to date or has it been an impediment?

Design and Delivery

Is the position of the Genomics R&D Initiative appropriate within the larger government biotechnology strategy (Canadian Biotechnology Strategy, other programing such as Genome Canada, Canadian Regulatory System for Biotechnology, etc.)? Why do you say that? Is the level of integration with other federal government biotechnology programs appropriate? Do these program add unique value to your department and to the overall federal strategy? How / why not?

1. How does the project approval process work in your department? Is this effective for your department? Do you think it is effective in the context of the overall horizontal nature of the Initiative? How could the process be improved?

2. To what extent has your department been able to leverage the funds provided through the Genomics R&D Initiative? What are the pros and cons associated with the leveraging requirements?

3. What systems or tools do you have in place to measure the performance of your projects? How effective is this?

4. How could the Genomics R&D Initiative be improved? What changes are required to make the Initiative more efficient?

Conclusions

5. Do you have any other comments you would like to make on the Initiative?

Thank you very much for your time.

Evaluation of the Genomics R&D Initiative
Stakeholder Interview Guide

Introduction

Thank you for taking the time to participate in this interview for the horizontal evaluation of the Genomics R&D Initiative. The primary reasons for conducting a horizontal evaluation of the Genomics R&D Initiative at this time are to measure the genomics R&D capacity that has been established by Phase 1 in federal labs, and to evaluate the progress towards longer outcomes made to date. The evaluation aims to examine the Initiative from its inception in 1999 (Phase 1) through Phase 2 and the transition to Phase 3 (FY 2005-2006). It is intended to assess the horizontal aspects of the Initiative as well as success within departments / organizations.

We are gathering information on the ongoing need for a horizontal initiative such as the Genomics R&D Initiative, the impact of the Initiative as a whole as well as its impacts in the departments / organizations, the design and delivery of the Initiative, and obstacles, barriers or unexpected opportunities that have arisen.

We are speaking to you because of your particular involvement in biotechnology / genomics. The interview will be treated confidentially. Only summary results will be provided in our report and we will ensure that responses cannot be attributed to any one individual. The interview guide is targeted at different individuals. Therefore, some questions may not apply to you. Please just let me know if you cannot answer a particular question and we can just skip it. Do you have any questions for me before we begin?

6. What do you know about the Genomics R&D Initiative in the federal government? Have you been directly or indirectly involved in this Initiative? If yes, how?

Rationale

7. The Genomics R&D Initiative is a broad federal initiative to build capacity inside government laboratories to carry out genomics research. In your opinion, does this rationale still make sense today? Does this Initiative realistically address an actual need?

Success

8. Based on what you know about the Initiative, can you comment on its key successes over the last several years? You can comment based on your experience with the Initiative overall or your experience with specific departments that are part of this Initiative.

9. If you're aware of the early projects (1999 to 2002), to what extent do you believe that these projects increase capacity in the departments and helped strengthen the research carried out in later years? How?

10. Have you seen evidence of stronger coordination, cooperation and linkages between research institutions in the context of the Genomics R&D Initiative? Please explain.

11. Based on your involvement, what have been the factors which have contributed to the success of this Initiative? What about factors that have impeded success?

12. What have been some of the other impacts, either positive or negative, resulting from the Initiative?

Cost-Effectiveness / Alternatives

13. Does the Genomics R&D Initiative complement, overlap or duplicate other federal or provincial initiatives related to genomics or biotechnology? In what way is the Initiative different from others such as Genome Canada, genomics research in provincial laboratories, the Canadian Biotechnology Fund, and others? In what way is the Initiative unique?

14. From your perspective, are there more cost-effective alternative ways of achieving the Genomics R&D Initiative mandate? What would be the strengths and weaknesses of this / these alternatives compared to the Initiative?

15. The Genomics R&D Initiative operates under phases which involve three-year funding cycles. Phase 1, from 1999 to 2002, was focused on developing genomics research capacity in federal laboratories. Phase 2, from 2002 to 2005, was focused on developing and using test procedures and tools to support genomics R&D. The current phase, from 2005 to 2008, is focused on making use of the capacity and tools developed to date to make discoveries and develop applications. In your opinion, what are the advantages of three-year funding cycle of this nature? What are the drawbacks? **Ask only to federal government stakeholders or project partners:** Has the three-year funding cycle facilitated achievement of the results to date or has it been an impediment?

Design and Delivery

16. The Genomics R&D Initiative is an example of several other initiatives in the federal government related to genomics or biotechnology, such as:

- departmental A-base funding for genomics and / or biotechnology research;
- the Canadian Biotechnology Strategy Fund;
- Genome Canada;
- the Canadian Regulatory System for Biotechnology;
- the governance structure surrounding the overall Canadian Biotechnology Strategy; and
- others.

From your perspective, is the position of the Genomics R&D Initiative appropriate within the larger government biotechnology strategy? Is the level of integration with other federal government biotechnology programs appropriate? Please explain.

17. How could the Genomics R&D Initiative be improved? What changes are required to make the Initiative more efficient?

Conclusions

18. Do you have any other comments you would like to make on the Initiative?

Thank you very much for your time.