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## **Summative Evaluation of the Canadian Biotechnology Strategy Program**

**Final Report**

**Audit and Evaluation Branch**

**June 2005**

**Tabled and approved by DAEC  
on April 13, 2006**

**Canada**





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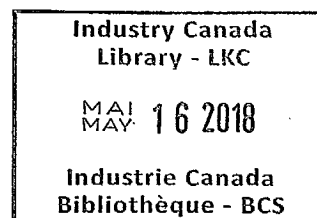
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*NOTE:*

*Minor editorial changes were made to this report in order to prepare the document for posting Internet (including removal of standard Appendices such as list of interviewees and questionnaires). Readers wishing to receive a copy of the original version of this report should contact the Audit and Evaluation Branch at Industry Canada.*



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**List of Acronyms**

AAFC	Agriculture and Agri-Food Canada
ADM	Assistant Deputy Minister
BACC	Biotechnology Assistant Deputy Minister Co-ordinating Committee
BDGCC	Biotechnology Directors General Co-ordinating Committee
BDMCC	Biotechnology Deputy Minister Co-ordinating Committee
BMCC	Biotechnology Ministerial Co-ordinating Committee
CBAC	Canadian Biotechnology Advisory Committee
CBS	Canadian Biotechnology Strategy
CBSec	Canadian Biotechnology Secretariat
CFI	Canadian Foundation for Innovation
CIHR	Canadian Institutes of Health Research
CRSB	Canadian Regulatory System for Biotechnology
CSTA	Council of Science and Technology Advisors
DM	Deputy Minister
EC	Environment Canada
EMR report	Report of the Expenditure and Management Review (EMR) of the Federal Government's Investments in Biotechnology
ENGO	Environmental Non Governmental Organization
GM	Genetically Modified
GMO	Genetically Modified Organisms
HC	Health Canada
IC	Industry Canada
IOG	Institute on Governance
IP	Intellectual Property
IT	Information Technology
JC	Justice Canada
NBAC	National Biotechnology Advisory Committee
NGO	Non Governmental Organizations
NRC	National Research Council
PCO	Privy Council Office
RMAF	Results-based Management and Accountability Framework
SAGE	Scientific Advice for Government Effectiveness
S&T	Science and Technology
SBDA	Science based Departments and Agencies
TBS	Treasury Board Secretariat
TOR	Terms of Reference



## **Executive Summary**

### **Introduction**

This evaluation of three horizontal elements of the Canadian Biotechnology Strategy (CBS), namely the Canadian Biotechnology Strategy Fund (CBS Fund), the Canadian Biotechnology Advisory Committee (CBAC) and the Canadian Biotechnology Secretariat (CBSec) – the three elements hereinafter referred to as the Canadian Biotechnology Strategy program – was conducted as recommended in the Results-based Management and Accountability Framework developed in 2002. This evaluation was originally scheduled for 2003-2004, but was delayed to take advantage of the results of other relevant studies going on at that time.

This evaluation study covered formative issues associated with design, implementation and performance measurement, as well as, to the extent possible, issues associated with program success (progress). The issues include:

- ▶ ***Program relevance*** – How relevant is the program to the needs of the stakeholders?
- ▶ ***Program design and implementation*** – Has the program been well designed and implemented?
- ▶ ***Continuous improvement*** – How can the CBS program be improved?
- ▶ ***Performance measurement system*** – Does the CBS program have a useful, appropriate performance measurement system?
- ▶ ***Success*** – What have been the results of the CBS program?

This evaluation intended to examine the operation of the CBS program for the three-year period 2002-2003 to 2004-2005 covered by the funding renewal in 2002. The study made use of three methodological approaches to examine the issues. These included:

- ▶ ***Document and File Review*** of CBS program internal reports and files, as well as a large number of related reports. There were a number of reports that were closely related to the issues being examined.
- ▶ ***Analysis of CBS Program Tracking System Data*** was originally intended to provide useful information on program success, but proved to be less useful than expected.
- ▶ ***In-depth Interviews*** with 36 stakeholders with a range of roles in the three components of the program (departments – from senior management to operational levels, CBAC,

CBSec).

While these approaches generally provided the basis to conclude on issues using multiple lines of evidence, there were some imbedded limitations to the overall evaluation methodology, including:

- ▶ the documents review were limited to those provided by stakeholders;
- ▶ the Report of the Expenditure and Management Review (EMR) of the Federal Government's Investments in Biotechnology was used extensively even though the report has not yet received final approval by all stakeholders;
- ▶ internal databases were not used as extensively as anticipated because of limitations with the information in the databases; and,
- ▶ there is a large number of stakeholders who could have been consulted; the interviews therefore did not include a representative sample of any one group of stakeholders; additionally, external groups of stakeholders such as provincial representatives, industry representatives, etc. were not consulted.

## **Conclusions and Recommendations**

Based on the findings presented throughout this report, the following conclusions and recommendations can be made.

### **1. *Relevance***

There are several conclusions that can be made regarding the relevance of the Canadian Biotechnology Strategy program. From a more general perspective, the objectives of the CBS program are broad enough to be reflective of the needs of the federal biotechnology community. Additionally, the program has been able to adapt to the changing or evolving needs of the community and thus be more relevant. This is evident through such reports as "Building the 21<sup>st</sup> Century Economy – A Government of Canada Blueprint for Biotechnology – *Realizing Canada's Potential*" and the "Statement on Renewal of the Canadian Biotechnology Strategy and the Evolving Role of CBAC".

The CBSec plays a unique and useful horizontal role. It brings together departments and agencies to address common interests. It does not duplicate the roles of other agencies and is therefore needed. However, in order to be successful in contributing to some of the CBS program's objectives, the CBSec needs to be able to more directly influence some of the linked federal biotechnology programs, such as the Canadian Regulatory

System for Biotechnology (CRSB) and the Genomics R&D initiative. Currently, the CBSec can, at best, indirectly influence these initiatives.

The CBS Fund provides useful financial assistance to undertake projects that deal with emerging issues, horizontal issues, issues that do not fall under the direct purview of any single department, and / or to undertake projects outside departments' A-base funding.

Finally, CBAC's role is to provide independent advice to the federal government. Notwithstanding other conclusions regarding design, implementation and success, CBAC's independent advice is particularly relevant in contributing to public reassurance and international credibility for Canadian federal biotechnology policies and initiatives. Additionally, CBAC's broad membership gives it most of the expertise it requires to cover a broad range of issues related to biotechnology. While other S&T advisory groups (such as the Royal Society of Canada) may have some capacity to provide biotechnology advice, no other group can deal with the breadth of biotechnology issues that can be addressed by CBAC given its uniquely broad membership. This unique value is, unfortunately, reduced by the lack of a platform to attract the attention of senior officials.

While the CBS program, its objectives and its components are relevant to the needs of the federal biotechnology community, the resources are insufficient to undertake the full range of activities to achieve the broad objectives laid out in 1998 in the creation of the CBS with influence over the entirety of Government of Canada investments in biotechnology (approximately \$750 million per year). In other words, given its level of resources and activities, the CBS program cannot be reasonably expected to influence the full extent of federal objectives and investments.

**RECOMMENDATION 1:** It is recommended that the CBS program objectives be redefined to focus on horizontal priorities within the context of the broader federal framework and investments strategy for biotechnology. In doing so, the specific focus for the three program components would be refined.

## **2. *Design and Implementation***

For the design and implementation issue, there are conclusions related to the individual components as well as the CBS program as a whole.

Regarding the CBS Fund design and implementation, the following are the key conclusions:

- ▶ The basis for allocating funds to horizontal priorities in the different pillars and



particular projects is not clear. Additionally, the pre-allocation of funds is not conducive to the selection of the most important projects. Similarly there is no indication that the project approval process is effective for selecting the projects that will address the most critical federal government priorities.

- ▶ There is no mechanism in place to ensure that the CBS Fund does not provide funding for regulatory or other initiatives that are best suited for funding by the CRSB or departmental A-base.
- ▶ While there is flexibility for multi-year projects (usually through a multi-phased approach), the allocation of funds is in general on a yearly basis. This is not necessarily the most cost-effective approach from all perspectives. The process is somewhat bureaucratic, particularly considering the limited dollars involved.
- ▶ In successive CBS Fund allocation processes, there has been a noted shift in the horizontal priority emphasis towards investments in stewardship and regulation over investments in the other two pillars of innovation and citizen engagement.

**RECOMMENDATION 2:** It is recommended that the CBS Fund be targeted at the most critical horizontal federal priorities. It is also recommended that the process be streamlined and adapted to respond to these priorities and be more flexible for multi-year projects.

Regarding various aspects of the CBAC design and implementation, the study led to the following key conclusions:

- ▶ CBAC is comprised of a wide range of biotechnology experts with a dual role. First, the members manage studies and produce reports on biotechnology issues of importance to Canada. Second, CBAC is responsible for engaging Canadians in a public way in an impartial dialogue about biotechnology. The committee is comprised of volunteers; CBAC receives only \$2.25 million annually to fund studies and engage Canadians; and the committee has produced numerous reports within this limited budget. As such, the federal government is getting good value. However, the reports produced by CBAC are not effective in reaching and being used by Ministers and senior bureaucrats for policy setting and decision-making. The committee is therefore not as cost-effective as it could be.
- ▶ The lack of engagement of federal officials has been a major barrier to the effectiveness of CBAC. Ministers and senior bureaucrats have not effectively been engaged in identifying priority issues for the committee to examine nor have they been effective receptors of CBAC's reports.

- ▶ Within its existing budget, CBAC cannot truly be effective in engaging Canadians. Rather within its budget, CBAC can only consult with Canadians through limited public consultation events, communication of information to and with Canadians through its website and public documents / reports, and limited public opinion polling.
- ▶ Depending on the priority role for CBAC, its current composition may not be appropriate. There is some indication that the committee does not have sufficient representation of the ethical and societal aspects of biotechnology. Nevertheless, the committee has implemented an effective approach to fill some of its knowledge / expertise gaps through Expert Working Parties on studies.

**RECOMMENDATION 3: It is recommended that, if Ministers and senior bureaucrats want and need to have access to an independent advisory committee on biotechnology, a more formal process be put in place for: 1) refocusing the priorities of this advisory committee; 2) ensuring that the composition of this committee is appropriate to address these priorities and continues to have access to other expertise as needed; 3) ensuring that the committee is adequately financially resources to address these priorities; 4) providing a process for the committee to directly report back to Ministers and senior bureaucrats on these priorities; and 5) having Ministers respond in a systemic way to advice and reports from CBAC.**

In terms of the CBSec, the key design and implementation issue was related to its independence. It is not possible to conclude in this regard since, while there are some perceptions that the Secretariat would be more independent if it was not located in a department, there is no concrete evidence that its location within Industry Canada has affected its independence.

From a more general perspective, the roles and relationships of some of the program delivery elements are not clearly defined or agreed to. Furthermore, there is clear evidence that, in some cases, those that are defined have not been adhered to. In particular, the lack of engagement of senior officials, in particular those from Industry Canada, who chair the main coordination and governance committees, has been an impediment to success. This has been despite active ADM involvement to engage.

As also concluded under relevance, it is unrealistic to expect the CBS program to achieve, or be able to demonstrate a major contribution to the Government of Canada CBS objectives given the resources, structure and accountability regime. The CBS program also has little operational connection with the other two linked horizontal elements (the CRSB and the Genomics Initiative), limiting its ability to coordinate work

with those initiatives or to influence them.

**RECOMMENDATION 4:** It is recommended that the roles and accountabilities of the Secretariat be clearly defined in the context of addressing the unique horizontal challenges and priorities within the broad Government of Canada framework for biotechnology. This should include clarification of key elements of the governance structure to ensure these horizontal priorities are addressed. In particular, this should include clarification of the roles and relationships of the broad management functions of the Biotechnology ADM Coordinating Committee (BACC), and the nature of the specific oversight function by BACC of the horizontal CRSB and Genomic initiatives.

**3. *Continuous Improvement***

The conclusions and recommendations provided under the other issues have already addressed the changes that are required to make the CBS Fund, CBAC and the CBSec more successful. No new conclusions and recommendations are required.

**4. *Performance Measurement System***

It is important to set the context for the conclusions and recommendations associated with the CBS program's performance measurement systems. The key component of the CBS performance measurement system is the CBS tracking system. The system was established based on the broad Government of Canada objectives for biotechnology approved in 1998 and performance indicators developed for the CBS program RMAF. It should be noted that this was the first horizontal RMAF developed in the federal government. Given that little expertise was therefore available for the development of this difficult RMAF, it is not surprising that there were many lessons learned along the way. Nevertheless, the program can benefit from the following conclusions and recommendations:

- ▶ The present performance measurement system is not focused on capturing information about the outcomes and results of the program. Rather, the project tracking system captures data on resources, activities and project deliverables, with little attention to outcomes. The system relies on departments inputting the information, which is highly variable in terms of accuracy, completeness and quality.
- ▶ The tracking system has been improved significantly over time. As such, it is easier to input and manipulate information in the system. Nevertheless, the system is designed to capture information on the CBS Fund projects and partners,

on other initiatives (non-CBS program related) and on overall departmental performance progress. The information in each of these sections is highly variable in terms of accuracy, completeness and quality; therefore, reliance on the information it contains is questionable.

- ▶ The information in the tracking system is useful to the CBSec in tracking and reporting on resource utilization and outputs.
- ▶ Outcomes information is currently available through ad hoc feedback on specific project successes provided by Accountability Working Group members in the development of the CBS yearly performance report.
- ▶ There is no formal mechanism to track the performance of CBAC and of the CBSec.

**RECOMMENDATION 5:** It is recommended that a renewed RMAF be developed for the CBS program based on feasible horizontal objectives. The RMAF should capture the essential elements of the expected results, and the outputs and outcomes needed to achieve these expected results in a revised program logic model. An important component of the RMAF should be the identification of the performance measures needed to monitor program implementation and outcomes for all elements of the program. This will provide important input for a determination of the appropriate tracking system elements needed to track all aspects of program performance.

## **5. Success**

Notwithstanding some of the previously noted conclusions and recommendation dealing with needed improvements to the CBS program and its elements, the program has made a difference in the federal biotechnology community. The following conclusions are reflective of the success of the program:

- ▶ The projects and working groups associated with the CBS Fund have contributed to bringing departments together, and helping them anticipate and prevent, rather than react. The Fund has also contributed to addressing emerging issues and providing seed money outside areas departments would fund from their A-base. The reports that have been produced and distributed throughout the departments have been useful. However, this success is not systematically tracked and captured but rather is available through ad hoc feedback. As such, the program cannot effectively track and report on the success of the Fund.



- ▶ CBAC has produced a number of credible reports that addressed major issues related to stewardship and regulation of biotechnology. Unfortunately, the intended audience of these reports have not effectively used the valuable information provided by CBAC.
- ▶ The CBSec had led the development of the Blueprint, a policy document outlining the way forward for federal biotechnology, that had been well received by the federal biotechnology community.

While no new recommendation is required, these conclusions strongly support the need for a renewed CBS program RMAF that more appropriately defines how success should be defined and measured.

#### **6. *CBS Program versus the Canadian Biotechnology Strategy***

Within the overall Government of Canada investments on biotechnology of over \$750 million per year, the Canadian Biotechnology Strategy has three specifically linked elements. In addition to the CBS program with its \$9.52 million in annual funding, there are two other elements, namely the Canadian Regulatory Strategy for Biotechnology (CRSB) that provides \$34.6 million per year to individual government departments to support regulatory initiatives, and the Genomics R&D initiative, that provides \$19.9 million annually to individual departments and agencies to support genomics R&D. In addition to these three elements, the Government funds biotechnology related programs within departments and agencies, as well as through separate initiatives. Chief among those recently introduced is Genome Canada, which funds major R&D projects involving universities and other partners.

Based on the evidence in this evaluation, the CBS program needs to rethink its design and structuring. The first step in the restructuring should be to examine the role of horizontal programming with the specifically identified Canadian Biotechnology Strategy elements, as well as how they relate to the Government of Canada investments as a whole. Through this exercise, the horizontal contributions of the various government programs and initiatives to the Strategy could be identified. This should include the other two elements linked to the CBS, namely the CRSB and the Genomics R&D initiative. It may also be appropriate to include Genome Canada in this review. Following clarification of the roles and objectives of the other elements of the CBS, a needs and gaps analysis should be undertaken to identify the appropriate horizontal objectives for the CBS program that would complement the other elements and provide the basis for a design and delivery approach that would be realistic and achievable.

**RECOMMENDATION 6:** The Treasury Board Secretariat should require that a horizontal RMAF be developed for the key elements of the Canadian Biotechnology Strategy. These include the CRSB and the Genomics initiative. The horizontal RMAF should identify the contribution of each element to the overall objectives and describe the linkages between the elements as well as with other federal biotechnology initiatives in departments and agencies, such as Genome Canada, that contribute to the Strategy. As such, this should provide the basis for identifying the gaps in the horizontal elements of the Strategy, and thus set the basis for the CBS program objectives and related structure.

## **1.0 Introduction**

On August 6, 1998, the Federal Government announced a renewed Canadian Biotechnology Strategy (CBS). A major part of the Strategy was the funding and elements contained in the Canadian Biotechnology Strategy (CBS) program. These elements included the Canadian Biotechnology Secretariat (CBSec), the Canadian Biotechnology Advisory Committee (CBAC) and the Canadian Biotechnology Strategy Fund (CBS Fund). A Results-based Management and Accountability Framework (RMAF) for the CBS program was approved in 2002. This document recommended conducting a formative evaluation for the Strategy in 2003-04 in order to evaluate the success of the renewed CBS program. A decision was taken to delay this evaluation due to another study / evaluation happening at the same time. The Report of the Expenditure and Management Review (EMR) of the Federal Government's Investments in Biotechnology, conducted by Treasury Board Secretariat (TBS), hereinafter referred to as the EMR report, was carried out over the period March to December 2003.

Since the EMR report was not available in early 2004-05, the Canadian Biotechnology Secretariat further postponed the formative evaluation to late 2004-05 to ensure that the results of the EMR report could be fully used for the evaluation, as well as to minimize the need to consult once again with already burdened departmental biotechnology representatives.

However, since a summative evaluation was also planned for 2004-05, this evaluation of the CBS program conducted in late 2004-05 included both formative evaluation issues and, to the extent possible, issues associated with program success (progress).

This evaluation report is the result of an evaluation of the CBS program which was conducted in late February to April 2005. The report is organized as follows:

- ▶ **Section 2** outlines the evaluation methodology, identifies how each source helped address the approved evaluation issues, and discusses the study limitations.
- ▶ **Sections 3 to 7** presents the findings for each issue category, that is relevance (section 3), program design and implementation (section 4), continuous improvement (section 5), performance measurement system (section 6) and success (section 7) with ensuing conclusions and actionable recommendations.
- ▶ **Section 8** introduces additional conclusions and recommendations that do not belong to any of the specific issues.

A profile of the CBS, which helps understand the scope of this evaluation, is provided in

**Annex A** of this report. It is important to note that the Canadian Biotechnology Strategy is much broader in scope than the CBS program which is being examined in this evaluation. Therefore, unless specified otherwise, whenever we make reference to the CBS program in this report, we are referring to the CBS Fund, the Canadian Biotechnology Secretariat (CBSec), the Canadian Biotechnology Advisory Committee (CBAC) and the governance structure described in Annex A. In other words, the scope of this evaluation is limited to the elements and activities funded through the \$9.52 million per year for the CBS Fund, CBSec and CBAC.



## **2.0 Evaluation Methodology**

### **2.1 Detailed Evaluation Methodologies**

#### **2.1.1 Document and File Review**

There is a wealth of documents, files and literature available on the CBS and its environment. A large number of documents were reviewed during this evaluation in order to better understand the environment in which the CBS program operates as well as to help address the evaluation issues.

A list of the documents reviewed is provided in Annex B.

#### **2.1.2 Data Analysis**

The project information from the CBS tracking system was reviewed and a statistical analysis database was prepared to help in the analysis of the information contained in the tracking system. This was useful in helping address some of the issues related to relevance, the performance measurement system and, to some extent, success.

#### **2.1.3 In-Depth Interviews**

Many of the evaluation issues could only be fully addressed through consultations with specific groups or individuals. Initially, 20 in-depth interviews were planned in order to cover a broad range of stakeholder groups (departments, CBAC, CBSec, others) as well as to include individuals with different roles in the context of the CBS. It was recognized that additional interviews were needed, and, in the end, a total of 30 interviews were completed involving 36 individuals.

The interview guide used is provided in Annex C. Annex D provides an overview of the groups covered in the interviews.

### **2.2 Evaluation Issues and Sources Matrix**

The table which follows identifies the evaluation issues and how each evaluation methodology contributed to the issues.

Evaluation Issues and Sources Matrix			
Issues	Document / File Review	Data Analysis	In-Depth Interviews
<b>Relevance</b>			
1. What are the needs of the biotechnology community which are pertinent to the CBS mandate?			
a. Is there still a need for the CBS to address those needs or can the needs be more effectively addressed some other way?	Medium	Low	High
b. Is the CBS meeting these needs through the CBS Fund, CBAC, and the CBSec?	High	Low	High
c. Is the Strategy able to respond to a changing environment?	Medium	Low	High
2. Does the CBS duplicate or overlap with other initiatives of the federal or provincial governments?			
a. In what way does the CBSec play a unique role? In what way does its activities and initiatives complement or overlap with those of others?	Low	Low	High
b. In what way does the CBS Fund add unique value?	Low	Medium	High
c. In what way does CBAC add unique value?	Medium	Low	High
3. Given its level of resources and activities, are CBS objectives (and its component objectives) plausible?	High	Low	High
<b>Program Design and Implementation</b>			
4. Is the design of the CBS appropriate? Does it work?			
a. Does the design of the CBS Fund make sense?	High	Low	High
b. How cost-effective is CBAC?	High	Low	High
c. Is there a better model to engage high level government officials in understanding and using the advice from external committees such as CBAC and the results of the CBS Fund projects?	High	Low	High
d. Is the CBSec designed appropriately to ensure its independence?	Low	Low	High

Evaluation Issues and Sources Matrix			
Issues	Document / File Review	Data Analysis	In-Depth Interviews
5. Are the roles and relationships clearly defined and appropriate?			
a. Are the roles and relationships (including reporting relationships) in determining and setting priorities (for all components of the Strategy) effective?	Medium	Low	High
b. How effective is the governance structure?	High	Low	High
6. Are the communications effective?	Medium	Low	High
<b>Continuous Improvement</b>			
7. How could the CBS be improved?			
a. What changes are required to make the CBS Fund more successful?	Medium	Low	High
b. What changes are required to make CBAC more successful?	Medium	Low	High
c. What changes are required to make the CBSec more successful?	Medium	Low	High
<b>Performance Measurement System</b>			
8. How appropriate is the performance measurement system of the CBS?			
a. How effective is the CBS tracking system from the perspective of those who have to input the information? Is the value of the information worth the effort required to provide it? What are the strengths and weaknesses of the tracking system / progress reporting?	Low	High	High
b. How is the information used? By whom? What information is not useful? What additional information would be more useful for decision-making purposes?	Medium	Low	High
<b>Success</b>			
9. What difference are we making, and can we make, with the CBS Fund?			
a. What is the profile of those funded through the CBS Fund?	Low	Medium	Low

Evaluation Issues and Sources Matrix			
Issues	Document / File Review	Data Analysis	In-Depth Interviews
b. To what extent have policy-related horizontal initiatives been undertaken as a result of the CBS?	Medium	Medium	Medium
c. How successful are the projects that have been funded to date in terms of achievement of project objectives and as they relate to the intended outcomes of the CBS and the CBS Fund?	Low	Low	Medium
10. What have been the actual versus intended outcomes of CBAC?			
a. How have the reports produced by CBAC been used? By whom? How could the reports be more effectively used by the target groups?	Low	Low	High
b. What have been the facilitating and impeding factors for CBAC success?	Medium	Low	High
11. What have been the actual versus intended outcomes of the CBSec?			
a. What type of support is the Secretariat providing, to whom? What else should it do?	Medium	Low	High
b. What have been the facilitating and impeding factors to the success of the CBSec?	Medium	Low	High

### 2.3 Study Limitations

While the overall methodologies used in this evaluation were intended to provide the basis for an evaluation report that addresses the issues in sufficient depth as well as with sufficient levels of reliability, there are some imbedded weaknesses in the evaluation methodology that are important to recognize. These include:

- ▶ The documents are limited to those that were identified through various sources during the course of the evaluation. However, there is no assurance that all relevant documents were reviewed. It was not possible within the scope of this evaluation to undertake a thorough literature search. As such, the evaluation documents were limited to those provided by stakeholders during the evaluation or to those specifically requested by the evaluators.
- ▶ As mentioned previously, the EMR report examined many of the same issues as



this evaluation, and has been used extensively. However, this report has not yet received final approval by all stakeholders.

- ▶ While the CBS program tracking system contains a wealth of information on the projects in terms of inputs (resources), activities, outputs and direct reach, the information on project partners was incomplete, with the result that the system could not be used to examine the extent to which the projects brought departments together. The project information in the system also did not yield information related to the impacts of the projects on target groups. As such, the tracking system did not provide information on several success issues. No other evaluation methodology was included to truly complement the tracking system from a quantitative perspective (e.g., a survey of project recipients to obtain quantitative information on project results and outcomes).
- ▶ The CBS involves a large number of stakeholders at different organizational levels and with different types of involvement in the Strategy. A large number of consultations have been done with these stakeholders over the past few years. Not long before this evaluation, the EMR had involved consultations with many of the stakeholders. In addition, at the time of this evaluation, the Office of the Auditor General of Canada was undertaking an audit of the CBS; this audit involved consultations with many of the same stakeholders. The relatively small number of interviews undertaken in this evaluation was therefore aimed at minimizing the burden on an already heavily consulted community, and relying on existing studies to a greater extent than usual. Nevertheless, this did result in the fact that many individuals who could / should have been interviewed were not directly consulted. However, those interviewees who were selected were chosen to cover as broad a sample of stakeholders as possible.
- ▶ The evaluation was limited to what is being done in the Canadian Federal Government, to the most part directly through the \$9.52 million funding. The two other elements directly linked to the Strategy, namely the Canadian Regulatory System for Biotechnology (CRSB) and the Genomics R&D initiative are referred to, but the study did not include an examination of the many other Federal Government biotechnology expenditure by departments of other agencies, such as Genome Canada. Provincial or international biotechnology initiatives were also not reviewed.

### **3.0 Evaluation Findings – Relevance**

#### **3.1 Issue 1 – What are the needs of the biotechnology community which are pertinent to the CBS mandate?**

As described in the EMR report, the initiatives under the Canadian Biotechnology Strategy are only a small fraction of the federal government expenditures on biotechnology. Average annual federal spending on biotechnology related science and technology (S&T) is estimated to be approximately \$700 million, which represents about 10 to 15 percent of total federal S&T expenditures. In addition to the CBS program and regular department initiatives, the federal government has also put in place a number of other initiatives that involve biotechnology. These include:

- ▶ the Canadian Foundation for Innovation (CFI) (1997);
- ▶ the Canadian Institutes of Health Research (CIHR) (1998-99);
- ▶ the Genomics R&D initiative (1999);
- ▶ Genome Canada (2000);
- ▶ Canadian Regulatory System for Biotechnology (CRSB) (2000);
- ▶ Smart Regulations (2003); and,
- ▶ Biotechnology Regulatory Framework (1993).

Many of these initiatives have a lot more resources than the CBS program, and the large majority of federal funds are linked to the creation of knowledge through research and development (R&D) rather than its regulation or utilization. In addition to the \$9.52 million CBS program, there are two other major initiatives linked to horizontal activities that are considered to be part of the Canadian Biotechnology Strategy. These are the CRSB (\$35 million per year) and the Genomics R&D initiative (\$20 million per year). On the other hand, the CBS program was allotted \$9.52 million per year. Some feel that this sent a signal about the relative importance of the CBS program and its position in the government's overall strategy.

The mandate of the overall Canadian Biotechnology Strategy can be found within three statements for the vision, objectives and themes of the Strategy. The vision and objectives set the direction and the themes describe the approach that is to be followed to achieve those objectives.

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

The objectives of the CBS program are to:

- ▶ ensure that Canadians have access to, confidence in, and benefit from safe and effective biotechnology-based products and services;
- ▶ ensure an effective scientific base and make strategic investments in R&D to support biotechnology innovation, the regulatory framework and economic development;
- ▶ position Canada as an ethically and socially responsible world leader in the development, commercialization, sale and use of biotechnology products and services;
- ▶ be sensitive to the need for developing countries to build indigenous capacity to assess and manage the risks of biotechnology;
- ▶ improve public awareness and understanding of biotechnology through open, transparent communications and dialogue;
- ▶ solicit broadly based advice to the government on biotechnology;
- ▶ support the development of Canadian biotechnology human resources strategy to ensure an adequate supply of highly qualified personnel; and,
- ▶ promote awareness of, and maintain excellence in Canada's regulatory systems, based on the Federal Regulatory Framework for Biotechnology (1993), to ensure the country's high standards for protecting health, safety and the environment.

The ten themes were intended to provide direction for the implementation of the Strategy. They are found in Annex A, as part of the CBS Profile.

**3.1.1 *Is there still a need for the CBS program to address those needs or can the needs be more effectively addressed some other way?***

Several reports supported the continuing need for the Strategy. One report, produced in February 2004, entitled "Building the 21<sup>st</sup> Century Economy – A Government of Canada Blueprint for Biotechnology – *Realizing Canada's Potential*", provided a renewed focus on the need for a horizontal systems approach to biotechnology. This policy document sets out a map for the Government of Canada, with the objective of "accelerating the commercialization of Canadian biotechnology research for social, environmental and economic benefit to Canadians". The report discusses the current environment, role of

government, and objectives for biotechnology in the priority areas of health, sustainable economic development and international opportunities.

The CBAC Statement of Renewal of the Canadian Biotechnology Strategy and the Role of CBAC from December, 2004, also makes the case for the continuation of CBS. As stated: "There is a continuing need for a strategy that focuses on biotechnology per se, that embraces the economic, scientific, ethical, legal, social, regulatory, environmental and health aspects of this transformative technology, and that is linked to the programs and responsibilities of several federal ministries. The need is greater now than ever before." The statement goes on to give a number of reasons linked to the increasing economic and social importance of biotechnology.

Interviewees were shown the CBS vision and objectives and asked whether they are relevant to the needs of the biotechnology community.

All interviewees felt that, in general, they were relevant. However, a number of interviewees commented on the broad, high level nature of the objectives. As one person commented, the Strategy, as promulgated in 1998, was very lofty and ambitious, and was intended to be reflective of what the federal government biotechnology community needed to achieve as a whole. Others commented that mandate of CBS and the federal government was to provide to industry and other sectors the proper technical, regulatory and commercial infrastructure and foundation that reflected the public interest and societal values. Several interviewees noted that the CBS and CBAC were created by the government at a time when the public was concerned about the social and ethical dimensions of applications of biotechnology. Some interviewees focussed on what they felt was the specific purpose of the Strategy, namely to help build bridges between government departments involved in various aspects of biotechnology. In general, interviewees commented that the mandate focussed on the government role in biotechnology on behalf of Canadians.

The large majority of interviewees said that there was still a need for a federal biotechnology strategy, due to the widespread influence of biotechnology in many sectors, the moral, ethical and public health issues associated with biotechnology applications and overall public interest and concern. Most felt that the elements of the CBS program, namely CBSec, CBAC and the CBS Fund, as well as the Biotechnology Assistant Deputy Minister Co-ordinating Committee (BACC) and the working groups are still needed and can still play an important role in contributing to the CBS objectives. This perspective was captured by one person who said "There is tremendous good work being done, but we have not been good at providing evidence and reporting on the outcomes of our work". However, everyone who wanted CBS to continue felt that a number of changes needed to be made. Potential changes will be discussed in more detail

in later sections.

A few government officials felt that more extensive changes were needed, but specific suggestions varied. A couple felt that the small amount of additional resources the CBS Fund can provide makes little difference in the innovation area, given the high percentage of total federal biotechnology spending already in this area. Several people felt that the CBS Fund should focus on stewardship and regulatory issues, where support was needed; another said that stewardship and innovation should be left to the lead departments who were already working together, and that CBS should focus on citizen engagement and communication, the area most in need and under-resourced.

Many interviewees commented that, in spite of the many deficiencies in the processes associated with the Strategy, at a substantive level, there has been some significant success, and that the CBS Fund and working groups have contributed to bringing departments together in a way that they would not have done without the structures and funding provided through the CBS program. It was noted that the CBS program has helped departments improve their ability to anticipate and prevent, rather than just react. Several interviewees said that the CBS program continues to be an important mechanism that the government needs to help manage the risks associated with biotechnology. There are times (as has been seen) when the mechanism is not being used, however, it is and will continue to be needed to deal with issues that arise and that the government directs to CBS.

### ***3.1.2 Is the CBS meeting these needs through the CBS Fund, CBAC, and the CBSec?***

There is some confusion over what is considered to be part of the Canadian Biotechnology Strategy. A review of documents shows that the Canadian Regulatory System for Biotechnology and the Genomics R&D are both considered to be part of the overall Canadian Biotechnology Strategy, and report to the Biotechnology Assistant Deputy Ministers Advisory Committee that is supported by CBSec and is part of the CBS program management structure. It is interesting to note that both of these programs have significantly more resources than the \$9.52 million in the CBS program.

Genome Canada is considered as a horizontal initiative within an overall Canadian Biotechnology Strategy. However, this initiative was later removed from the CBS umbrella and introduced as a separate initiative under Industry Canada.

A number of documents and reports addressed this issue directly in terms of the contributions of the three major elements of the CBS program. For example, the EMR report indicated that the overall needs of the government are not being met through the CBS program at the level expected. The report found that all three elements within the

CBS program have problems, and in particular that a number of objectives of the CBS Fund are not being met. The report found that there is little evidence that the Fund has been able to lever significant levels of departmental resources, one of the objectives. (However this analysis did not include departmental in-kind contributions to funded projects or the amount of resources expended in managing projects and participating in working groups.) The study also found that there has been inadequate guidance to CBAC on what policy issues are most in need of examination, and that CBSec has had limited ability to influence departments to participate in horizontal management of biotechnology.

Some of the needs of the biotechnology community for independent advice and information on high level technical and societal issues are met via CBAC. The Advisory Committee has produced a number of formal reports on a wide range of biotechnology related subjects involving regulation, health, and other topics.<sup>1</sup> It is important to note that, in addition to utilizing the expertise of its members, CBAC is mandated to utilize a formal consultation process to engage a wide range of stakeholders and members of the public in examining the various topics covered by their studies. In addressing a major issue, CBAC produces a consultation document which provides a number of specific questions intended to focus input and discussion. The views obtained through this consultation process are considered by CBAC in developing its reports and formulating conclusions and recommendations. More recently, CBAC has also broadened its sources of expert input by using an "Expert Working Party" strategy to engage additional individuals with the specific expertise required for the study. These processes contribute to the achievement of a number of CBS objectives, including solicitation of broadly based advice to the government on biotechnology.

Some reports noted the difficulties in meeting needs caused by a lack of response from government. For example, the Executive Workshop on Biotechnology held in May 2004 noted that, in many areas linked to CBS objectives, there was a clear need for immediate action. It was also noted that stronger federal leadership and horizontal governance are needed. More particularly, "strong concerns were expressed with respect to the lack of regulatory responsiveness and coherence".

Several interviewees commented that there is a major disconnect between the stated mandate and high level objectives of the Strategy and the level of influence of the three areas funded under the CBS program (CBSec, CBAC and CBS Fund) on those objectives. However, many commented that these three elements each have made a contribution to achieving the CBS objectives. Some noted that the working groups under the BACC also

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<sup>1</sup> A list of CBAC reports is found in Annex B.

provided an important contribution by co-ordinating the work of different departments. However, as stated previously, many interviewees commented that the missing element in the system's ability to achieve the impacts that were intended is the engagement of DMs and Ministers. Several interviewees noted that the federal community has difficulty dealing with horizontal strategies and the loss of departmental independence.

### ***3.1.3 Is the Strategy able to respond to a changing environment?***

Several reports addressed how the Strategy can be responsive to changing needs. For instance, the previously discussed report entitled "Building the 21<sup>st</sup> Century Economy – A Government of Canada Blueprint for Biotechnology – *Realizing Canada's Potential*" describes how the capabilities of the horizontally focussed Canadian Biotechnology Strategy can be directed to address current priorities and needs.

A review of the minutes of the BACC and BDMCC over the period 1998 to 2005 shows that the committees that guide the work conducted under the CBS have responded to a changing political environment. For example, the Stewardship and Regulatory Pillar responded to the federal Smart Regulations initiative by reviewing the CBS program, as outlined in the Biotechnology Blueprint, to develop ways to respond and contribute to Smart Regulations agenda.

The general limitations caused by lack of senior manager involvement are also seen by some interviewees to affect the Strategy's ability to be truly responsive to changing environment and changing need. It was also noted that the consensus-driven, process heavy approach used to select CBS Fund projects does not encourage responsiveness. Several commented that the confusion within the community about the roles of the various players, such as CBSec, hinders the ability of the Strategy to be responsive. On the other hand, the general nature of the objectives and themes were seen by some as allowing the CBS program to adjust its approach to meet the circumstances.

Some pointed out that CBSec can flag new issues through environmental scanning. It was also observed that the environment has not changed dramatically over the past few years, as shown by the continued interest by the public on the same general topics and recent work by CBAC on extending earlier work. As discussed in Section 3.2, a number of interviewees commented that the fact that CBS involves only some of the federal biotechnology performers and stakeholders (with other agencies and elements, such as Genome Canada also in play) limits the ability to appropriately respond. The increasing role played over the past few years by universities and provinces, compared to 1998 when CBS began, was also identified as a factor. Although the original CBS description included a mandate to partner with provinces / territories and academia, the CBS program does not have effective means to link to stakeholders outside the federal government



other than through CBAC and its stakeholder consultations.

**3.2 Issue 2 – Does the CBS duplicate or overlap with other initiatives of the federal or provincial governments?**

**3.2.1 *In what way does the CBSec play a unique role? In what way does its activities and initiatives complement or overlap with those of others?***

Several of the documents examined addressed the role of CBSec. The EMR report indicates that the CBSec plays an important co-ordinating role for a wide range of federal biotechnology related initiatives. However, the study found that the Secretariat does not have strong linkages to work on strategic horizontal policy issues.

Many interviewees commented that the role of CBSec was relatively unique and that it did not overlap with other agencies. Interviewees noted that CBSec in conjunction with the CBS Fund plays a unique role when it is able to bring departments and agencies together to address common interests, something that is unlikely to happen in the absence of CBSec. Many said that it is needed, as it plays both strategic and operational roles. Strategically, the Secretariat tries to identify emerging issues and complementary interests among departments. Operationally, the Secretariat supports CBAC through environmental scanning. CBSec manages some of the CBS Fund projects, such as regular polling of Canadians on biotechnology related issues. CBSec also provides the process and administrative support in some cases for the interdepartmental CBS management committees and working groups. It also provides an interface with TBS on reporting requirements associated with the CBS Fund. It was noted that CBSec has no authority, only suasion, which is ineffective when there is limited receptivity. There is no overlap with other groups as no other group is linked to horizontal co-ordinating in biotechnology. Some commented that the CBSec co-ordination role should complement pre-existing networks and departmental initiatives, however contacts into the departments are very limited, based mostly on those participating in the working groups.

Another important role that the CBSec has performed is taking a leadership role on a number of interdepartmental and horizontal issues, such as the development of the Blueprint and renewal of the CBS Fund.

Some interviewees said that the CBS and the CBS program may be seen to complement other initiatives such as Genome Canada and NSERC's biotechnology funding at universities, but has no influence over them, nor formal connections with them.

### **3.2.2 *In what way does the CBS Fund add unique value?***

The views of the interviewees regarding the unique value added of the CBS Fund varied. Many felt that the Fund provided unique value by having resources available to investigate emerging issues and provide seed money outside areas the departments would fund from their A-base. In general, interviewees believed that the redirection of the Fund in 2003 towards policy related, horizontal projects was a positive step that supported CBS objectives. Several felt that the projects in the innovation area were largely R&D projects linked to departmental interests, not horizontal ones<sup>2</sup>. Some also felt that the innovation area was least in need of additional resources, due to the heavy emphasis on S&T in A-base departmental funding.

In general, interviewees felt that the projects in the stewardship / regulatory area dealing with genetically modified food, biosafety and ecosystem effects of novel life forms were more important as they were linked to social issues that had often received limited attention previously. It was noted that, in government priorities "safety trumps all". The bio-statistics and public opinion research provided through the Fund were also identified as unique products that no one department would fund, but that were very useful as background to setting priorities and decision making. The role played by the Fund in bringing departments together under the three pillars (Stewardship / Regulation, Innovation and Citizen Engagement) was also considered by most to add unique value, although some felt the processes associated with the working groups were too bureaucratic and inefficient. A few interviewees were of the opposite opinion, and felt that the Fund was a distraction, focussing participants' interest on dividing up the pie rather than working together.

### **3.2.3 *In what way does CBAC add unique value?***

A number of documents provided information that addressed the issue of CBAC's role. As noted in the government report entitled *Biotechnology Transforming Society – Report on Biotechnology 1998-2003*, during "the 1998 CBS Task Force consultations, Canadians called for an independent advisory body that would operate at arm's length from government, to provide independent and comprehensive advice on crucial policy surrounding biotechnology". The formation of the CBS also supported the creation of an independent advisory group to provide independent expert advice and an ongoing forum for Canadians to voice their views and participate on relevant social and ethical issues related to biotechnology. The Canadian Biotechnology Advisory Committee (CBAC) was created to meet this need.

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<sup>2</sup> In reality, as demonstrated in the summary from the tracking system in a further section, this is not unique to the Innovation Pillar, but to all pillars.

However, the EMR report gave a negative view of the committee, as it reported that “the focus of the expert advisory role of CBAC is not aligned with federal priorities”. This was found to be the result of lack of direction and engagement by the federal government rather than any fault of the committee.

As noted in the CBAC Annual Report, CBAC provides the government with a mechanism to obtain credible, independent input from experts and interested stakeholders outside the government on a wide range of issues related to biotechnology, at a level beyond that available from any one department’s stakeholders. Through its members, the committee provides the government with expertise and perspective from individuals from diverse fields linked to biotechnology. An examination of the biographical notes of the 14 CBAC members in March 2004 listed backgrounds in medicine / health, genetics, food / nutrition, plant agriculture, agri-food, animal husbandry and diseases, communication, law, bio-ethics, environment / sustainable development, and citizen’s interests. Also, as mentioned previously, through the recently introduced Expert Working Party and consultation process used as input for all major studies, CBAC provides mechanisms for subject matter experts, interested stakeholders and the public to provide input to deliberations on major public policy issues involving biotechnology. At the time of this evaluation (March 2005), the committee membership had shrunk to 12 as compared to 20 in 1999. It included six of the original members and six new members which were added between 2002 and 2003.

As mentioned, one of the objectives of CBAC is to provide a mechanism for public and stakeholder engagement. However, discussion at the Executive Workshop on Biotechnology, held in May 2004, implied that this was not happening early enough or well enough, as the contribution of CBAC in this area has gone largely unnoticed by government officials.

A number of interviewees noted that CBAC’s role is to provide independent advice to government on biotechnology related interests that go beyond any one department. Through this means, CBAC contributes to public reassurance and international credibility for Canadian Federal Government biotechnology policies and initiatives. It was also noted that a departmental advisory committee would not be able to address broadly-based issues. Several interviewees noted that the membership of CBAC provides a broader range of social, legal and ethical perspective on issues than available from a typical scientific advisory group. It was noted that biotechnology is relatively unique as a technology, as it involves the use of genetic material which has a higher perceived risk, a higher social dimension and greater public interest and concern than, for example, information technology (IT). For these reasons, some interviewees observed that the government needs to use “a broader lens” when making decisions, and to include social as well as economic and technical perspectives. Some feel that the unique value of CBAC is reduced by the lack of a platform to attract the attention of senior officials to what advice is provided. In

terms of overlap or duplication, the Royal Society and the new National Academy of Science were identified as being perceived as able to provide technical advice on biotechnology as well as other areas of S&T. However, it was noted that these groups do not have the range of expertise found in CBAC to address broad social and ethical issues.

The CBAC approach to addressing an issue includes a consultative process of identifying the issue being examined and requesting input from stakeholders and the public during the investigation and analysis phase of the project. This approach is relatively unique among the standing advisory groups, but most interviewees who addressed this aspect, felt that most government officials do not really distinguish the CBAC process from those organizations that focus only on expert input.

Other interviewees noted that, in order for citizens to have confidence, the government needs to know what they are concerned about and engage them in dialogue about alternative policy options. Some interviewees believe that, at the moment, CBAC does not have a credible citizen engagement process and does not really address issues that capture the public interest or address public concerns in a way to which they relate.

### **3.3 Issue 3 – Given its level of resources and activities, are CBS objectives (and its component objectives) plausible?**

The question of how plausible it is to expect the resources and program elements under the CBS program to achieve the stated CBS vision and objectives (see Annex A) has been addressed in both the original program development discussions and in the 2002 RMAF. Interdepartmental co-ordination is crucial for biotechnology” and identified the co-ordination mechanism as the high level Ministerial, DM and ADM committees of the seven key departments that would oversee the CBS and address issues cutting across the mandates of various departments and agencies. The interdepartmental co-ordination and co-operation to be achieved through the management structure (BMCC, BDMC BACC and working groups) are outside the control of the CBS program elements, but are crucial for the achievement of the objectives. In other words, the contributions of the three elements of the CBS program are necessary, but not sufficient for the achievement of CBS objectives.

The RMAF for the CBS program, developed in 2002, also discussed the difficulties in assigning attribution and accountability for the CBS to the CBS program. The report noted that the overall purpose of the CBS was to provide “an enabling mechanism which allows the federal government to act with coherence on biotechnology” and acknowledges the difficulties in attributing expected results to the CBS program. The report noted that the purpose of the RMAF was to “identify and evaluate the impact of the program beyond its

limited funding and authority and to determine its influence to affect policy and programming on a horizontal basis". The RMAF went on to report that "A major challenge for the Strategy is its mandate to bring together federal government organizations with potentially competing mandates and interests". It is interesting to note that in the section under Area of Direct Control, the RMAF states "The CBS is an enabling mechanisms which allows the federal government to act with coherence on horizontal biotechnology issues". The RMAF notes that accountability for the CBS is shared among the members of the Biotechnology Ministerial Co-ordinating Committee. Many would feel, especially in hindsight with the lack of engagement by senior officials, that this is an area of direct influence at best, rather than control.

The Executive Workshop on Biotechnology held in May 2004, addressed the issue of the resourcing of the CBS program and CBAC. In discussing the need to engage in meaningful public engagement on biotechnology issues, the workshop found that there was a clear sense that this was not happening in Canada early enough in the decision making process. The workshop report identified CBAC as one option (among others) for a visible, credible option for meaningful public engagement, if appropriate (i.e. sufficient) resources were provided.

The EMR report addressed this question indirectly. The report recommended giving the CBSec much wider responsibilities linked to management of horizontal biotechnology issues, including:

- ▶ high level management of the three CBS Fund Pillars to focus on higher priorities associated with horizontal issues;
- ▶ policy research on government wide issues such as social and ethical impacts of biotechnology;
- ▶ horizontal environmental scanning and trends analysis;
- ▶ contingency planning for national crises; and,
- ▶ sharing best practices to facilitate wider adoption.

Even if the CBS Fund and CBAC funding levels were to remain constant, these additional duties would require significantly higher resourcing for CBSec.

As discussed previously, the CRSB and Genomics R&D are considered to be included as elements of the Canadian Biotechnology Strategy and report to BACC.

As mentioned previously in Section 3.1.1, some felt that communications and citizen engagement aspects of the program carried out through CBAC and the CBS Fund are under resourced and would require significant additional funding to be effective.

Several interviewees commented that the \$9.52 million and the elements under the CBS program were never intended to be solely responsible for achieving the stated CBS objectives, and cannot. As mentioned previously, some interviewees felt that there remains considerable confusion about what is included in the Strategy and the purpose of the CBS program. This confusion contributes to implementation problems. In fact, several noted that the vast majority of federal government expenditures in biotechnology are outside the control and direct influence of the CBS program. Some felt that the three elements of the CBS program (CBAC, CBSec and the CBS Fund) were to be the means of getting the attention of BMCC and the government on horizontal biotechnology issues, and to leverage departmental resources to address identified issues requiring greater resources. Some felt that the low level of funding was seen as an indicator of the importance of the Strategy compared to other government initiatives.

Several interviewees commented that the failure to engage Ministers and DMs has meant that the CBS and CBS program cannot succeed as intended.

Other interviewees commented on the relative priorities among the objectives and said that those involving the public interests are most important, beginning with safety, followed by stewardship and regulation. Commercialization and intellectual property (IP) were considered less important.

### **3.4 Relevance – Conclusions and Recommendations**

There are several conclusions that can be made regarding the relevance of the Canadian Biotechnology Strategy program. From a more general perspective, the objectives of the CBS program are broad enough to be reflective of the needs of the federal biotechnology community. Additionally, the program has been able to adapt to the changing or evolving needs of the community and thus be more relevant. This is evident through such reports as “Building the 21<sup>st</sup> Century Economy – A Government of Canada Blueprint for Biotechnology – *Realizing Canada's Potential*” and the “Statement on Renewal of the Canadian Biotechnology Strategy and the Evolving Role of CBAC”.

The CBSec plays a unique and useful horizontal role. It brings together departments and agencies to address common interests. It does not duplicate the roles of other agencies and is therefore needed. However, in order to be successful in contributing to some of the CBS program's objectives, the CBSec needs to be able to more directly influence some of the linked federal biotechnology programs, such as the Canadian Regulatory System for Biotechnology (CRSB) and the Genomics R&D initiative. Currently, the CBSec can, at best, indirectly influence these initiatives.

The CBS Fund provides useful financial assistance to undertake projects that deal with emerging issues, horizontal issues, issues that do not fall under the direct purview of any single department, and / or to undertake projects outside departments' A-base funding.

Finally, CBAC's role is to provide independent advice to the federal government. Notwithstanding other conclusions regarding design, implementation and success, CBAC's independent advice is particularly relevant in contributing to public reassurance and international credibility for Canadian federal biotechnology policies and initiatives. Additionally, CBAC's broad membership gives it most of the expertise it requires to cover a broad range of issues related to biotechnology. While other S&T advisory groups (such as the Royal Society of Canada) may have some capacity to provide biotechnology advice, no other group can deal with the breadth of biotechnology issues that can be addressed by CBAC given its uniquely broad membership. This unique value is, unfortunately, reduced by the lack of a platform to attract the attention of senior officials.

While the CBS program, its objectives and its components are relevant to the needs of the federal biotechnology community, the resources are insufficient to undertake the full range of activities to achieve the broad objectives laid out in 1998 in the creation of the CBS with influence over the entirety of Government of Canada investments in biotechnology (approximately \$750 million per year). In other words, given its level of resources and activities, the CBS program cannot be reasonably expected to influence the full extent of federal objectives and investments.

**RECOMMENDATION 1:** It is recommended that the CBS program objectives be redefined to focus on horizontal priorities within the context of the broader federal framework and investments strategy for biotechnology. In doing so, the specific focus for the three program components would be refined.



## **4.0 Evaluation Findings – Program Design and Implementation**

### **4.1 Issue 4 – Is the design of the CBS program appropriate? Does it work?**

Some of the discussion under Issue 3 concerning the weak linkages between the work carried out under the three elements of the CBS program, co-ordination with CRSB and the Genomics R&D initiative, and the achievement of the broad objectives of the CBS is equally relevant to this issue.

One of the main purposes of the logic model and governance discussion in an RMAF is to examine how well a program or initiative is designed, and whether there are logical linkages between the activities, outputs and intended results. In the case of the CBS, several assumptions were made that have not proven to be correct in practice. For example, the CBS Accountability Structure shown in the RMAF and included in Annex A of this report portrays the seven Ministers at the top of the pyramid and having the ultimate responsibility for the Strategy. The assumption was that they would meet and exercise some control and direction, although there was no requirement built into the Strategy design for that to happen.

The RMAF also acknowledges the difficulties with accountability and attribution in the design of the Strategy. For example, challenges identified include the following: “How does the CBS RMAF describe and attribute the CBS (program) for its key results when the CBS’s (program) only involvement was in a seminal co-ordinating, enabling or leveraging activity?”.

#### **4.1.1 Does the design of the CBS Fund make sense?**

In using document review as a source of information on this issue, it is important to remember that the funding criteria changed for the 2002-2003 fiscal year, and that a number of observations made in documents written before 2004 would be largely based on the mechanisms and choices made in the earlier years. This would to some extent include the EMR report cited below, which took place in 2003.

All aspects of this issue were addressed in the EMR report, which reported that the funds were not being used to support strategically important horizontal issues. This TBS report clearly found that the present system is not selecting the most appropriate projects, and by implication, that the present process is not working. However, the report implies that the problem is associated with lack of clear guidelines for project selection that are linked to ensuring that projects support high priority horizontally focussed initiatives, as well as with the conflict of interest associated with having those receiving the funds also selecting the projects.

However, somewhat contradictory evidence is found in an internal CBSec report dated January, 2003. The report describes the requirement for departments to link project proposals to the key policy objectives in the Blueprint under the three pillars (Stewardship and Regulations, Innovation and Citizen Engagement).

The focus in the original criteria was on R&D, its application and potential economic impact, not on horizontally or stewardship. The 2002 renewal of the funding did not mention funding criteria at all, the criteria were revised for the 2002-2003 fiscal year based on a BAAC decision to focus on the proposed project's contribution to strategic policy priorities.

It is interesting to note that in April, 2003, BACC requested that a clear decision-making process be applied for allocation of the CBS Fund in future years.

A review of documents shows that the original allocation of the CBS Fund in 1999 was to be roughly equally divided between the three pillars of Stewardship, Economic Development and Citizen Engagement. For 2001-2002, at the time of the CBS renewal, the allocation had changed to about 55% for Stewardship, 28% for Innovation (Economic Development) and 17% for Citizen Engagement. The basis for these changes was not clear from the information in documents reviewed.

Several interviewees noted that the project selection process has traditionally been delegated to the working groups, with BACC agreeing in most part to the decisions. Some felt that this has led to allocation of funds based mostly on departmental priorities rather than horizontal crosscutting priorities. Many projects have been seen to be operationally focussed rather than strategic. Some felt that the quality of projects was variable. Some interviewees also suggested that the makeup of the ADM Committee was an issue in setting priorities and project selection, and that there should be more ADMs with policy responsibilities on the committee.

The question of adding external input to the project selection process also came up. The possibility of having CBAC or some other peer review committee with a broader perspective review the proposals was raised. However, some felt that if the projects were primarily to support government horizontal issues, external groups may not have the right perspective, and that government officials need to make the final decisions.

A number of interviewees said that the existing decision making process was very bureaucratic and inefficient, considering that a total of \$6 million was involved. (This did not apply for the 2005-2006 funding decisions, when most funding was based on the

previous year's allocation given the need to complete existing projects in the final year of the current funding.)

One of the weaknesses noted by several interviewees was the lack of consistency in the project selection criteria and funding process from year to year. Interviewees commented favourably on the shift in 2002-2003 towards policy and away from S&T as a product. Another weakness identified was the failure to start the decision making process early enough to allow for consensus building. Some felt that holding workshops in the early fall to discuss strategic issues would also lead to better proposals.

#### **4.1.2 *How cost-effective is CBAC?***

In 1998 the decision to form the CBS noted the binary nature of the CBAC mandate to provide both advice and a mechanism for Canadians to voice their perspectives. As stated the "Advisory Committee will serve as a source of independent expert advice on biotechnology issues. An important part of its mandate is to provide an ongoing forum for Canadians to voice their views and participate on relevant issues, including social and ethical issues". CBAC receives \$2.25 million annually to fund studies and conduct citizen engagement.

CBAC reports also emphasize the role of CBAC in consulting with stakeholders and also in terms of deliverable reports with advice and recommendations. This has been discussed under previous issues.

The report on the Use of External Advice in Federal Biotechnology Policy Making concluded that there is a conflict between the two roles given to CBAC, namely to provide expert and perhaps confidential advice to government and "to engage Canadians in a public way in an impartial dialogue about biotechnology". The report suggests that there is a very real difference in these two roles, primarily one of perceived neutrality.

A review of the consultation documents provided by CBAC as part of the collection of information for every major study shows that the documents are intended to add value by shaping the consultations with Canadians on biotechnology issues in several ways. That is: they provide valuable context to the issue being discussed, placing it within the Canadian regulatory, economic and societal system; they also provide references for further reading by stakeholders in shaping their responses; and, they focus stakeholders' input by providing a number of questions to be answered that are directly linked to the issue being debated.

A review of CBAC annual reports shows that, in addition to the consultation process for specific projects, CBAC has several other mechanisms to communicate with the public and stakeholders. These are:

- ▶ a CBAC website, enhanced in 2003;
- ▶ posting of reports and background papers on the web and distribution in hard copy to key stakeholders, such as parliamentarians and senior government officials;
- ▶ a kiosk and exhibit for use at public fairs, and media news releases;
- ▶ providing briefing documents to Members of Parliament and senior government officials; and,
- ▶ hosting and participating in various biotechnology related conferences and workshops.

CBAC also analyses public opinion reports as input to policy deliberations.

In 2001, CBAC initiated an ambitious citizen engagement plan that included building a partnership network through vehicles such as the SchoolNet Partnership Initiative and the Community Access Plan. This plan was not implemented due to lack of resources.

The EMR report found that CBAC is not very effective at this time as it is not clear how the committee's work is informing biotechnology related policy development, priority setting and decision making. However, the problem is at least partially associated with getting federal officials to identify high priority issues for the committee to examine and to be informed by the responses.

In examining this issue, several interviewees felt that the role of CBAC was primarily to frame the question, consult with stakeholders and then provide an informed report that took account of all perspectives in a balanced manner. The role is not to act as an expert committee like the Royal Society of Canada, but to provide a pathway for others to provide input, and include their perspectives as well as those of CBAC members.

Some interviewees commented that there were not enough resources available to CBAC to conduct an appropriate citizen consultation. For example, in the case of the review of genetically modified food, the Committee could only afford to visit five cities across Canada, when there was a general consensus that considerably broader consultation was needed.

It was generally felt that CBAC is doing all it can within the present resource level. In fact, to move more quickly on projects, CBAC would need more resources. A full project involving significant citizen engagement costs at least one million dollars overall. The committee has a strategy of overlapping projects, with one at the preliminary phase as one is moving to completion. This allows the committee to complete about one project per year involving stakeholder consultation. However, as previously noted, it is not clear to what extent the government is aware of, and values, the consultation aspect of CBAC. There appears to be a tendency to think of advisory groups as bodies that provide advice based on

the expertise of members.

Some interviewees felt that the committee was biased towards those who are pro-progress, and did not have sufficient representation of the ethical and societal aspects of biotechnology. Some felt that the few CBAC members representing social issues were not really listened to seriously. Others provided similar views, saying that CBAC was seen from the beginning to be focussed on promoting biotechnology for use in the economy. There was a suggestion to change the makeup of the committee to include more representatives with expertise in social, ethical and sustainable development areas (possibly including ENGO representation). It was believed that this would support the government's need for input on stewardship, regulation and citizen engagement.

With respect to the selection process for members, it was noted that the process can take over two years.

When asked about the pros and cons of having an independent advisory group such as CBAC, some noted the advantage to the government of having access to external advice on horizontal issues from a broader perspective. Several interviewees commented that there is value to the government in having a committee such as CBAC to whom they can give a contentious complex public policy issue for reflection and considered judgement. This can serve both a political and bureaucratic purpose of giving enough time for an informed, considered response.

Another advantage is the ability of individual departments to give the advisory committee specific issues on which to provide advice. Although many are unaware of it, in addition to its larger multi-year studies, CBAC also provides advice on specific issues focussed to departments on a much shorter time frame, typically six to eight weeks. This allows the committee to be more directly relevant to government officials.

One significant disadvantage noted was that members of the committee came to the task with varying expectations. In some cases, those expectations were not met and people became discouraged and began to disengage and, in at least one case, even resigned from the committee. It is not easy to manage and direct an independent advisory group made up of high level, well respected expert volunteers from a wide variety of disciplines and stakeholder groups.

Another disadvantage of external advice noted is the "not invented here syndrome", with government officials reacting defensively to what is perceived as a challenge to their approach by CBAC.

In summary, many see CBAC as a valuable resource that is under utilized.

**4.1.3 Is there a better model to engage high level government officials in understanding and using the advice from external committees such as CBAC and the results of the CBS Fund projects?**

The issue of getting government to respond to advice is not unique to CBAC. In fact, one of the first studies conducted by the Council of Science and Technology Advisors (CSTA) several years ago was entitled *Science Advice for Government Effectiveness (SAGE)* and involved how to get government to better make use of S&T input in decision making.

A number of the reports examined described the difficulties CBAC has had influencing government decisions. One problem is getting government to identify areas where it wants input. For example, a review of minutes of the BACC and BDGCC meetings shows that, on several occasions, CBAC invited requests from government for advice as part of its annual work planning process<sup>3</sup>. However, this should not be surprising. While documents associated with the development of the CBS refer to the relationship between Ministers and CBAC<sup>4</sup>, the actual design of the CBS as shown in official documents pays little attention to the role of CBAC and its linkages to the other groups in the management structure. For example, the Terms of Reference (TOR) of the major CBS committees (BMCC, BDMCC, BACC) have almost no references to CBAC. The one reference is contained in the BMCC TOR, which says that as a group or as individual Ministers they may refer issues to CBAC for examination. There is no reference to CBAC having access to BMCC or having CBAC reports considered by BMCC. There is no reference to CBAC in the TOR for the BDMCC or BACC.

There is also confusion among government officials over the role of CBAC. For example, the EMR report found that “the expert advisory role of CBAC is not aligned with federal priorities”. However, the same report notes that “Canadians want their concerns factored into the government’s priorities, policies and investment choices, and expect government to demonstrate that they are taking these concerns seriously”. There is a dichotomy between these two statements if government expects CBAC to do both. In fact, the CBAC mandate is more closely aligned with the latter, in providing to government an informed, well reasoned view of what really concerns Canadians. Some interviewees noted that, in reality, some CBAC projects have been chosen on the basis of committee member’s interests and concerns.

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<sup>3</sup> BACC March 11, 2002, BDGCC July 14, 2003, April 22, 2004

<sup>4</sup> For example, “A new Biotechnology Ministerial Co-ordinating Committee will oversee the implementation of the Strategy, address issues that cut across the mandates of various departments and agencies and give direction to and receive advice from the CBAC and the government’s internal co-ordinating structures”.

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CBAC itself recently produced a report (December 2004) that included recommendations on how to make better use of external advice. In this report entitled "Statement on Renewal of the Canadian Biotechnology Strategy and the Evolving Role of CBAC", CBAC identifies the need to "facilitate the over-arching policy integration necessary for a complex horizontal file" and recommends "the introduction of a revised reporting mechanism that would have CBAC report formally and regularly to a cabinet committee". CBAC suggests that a Cabinet Committee could provide an appropriate forum.

The September 2003 report on the Use of External Advice in Federal Biotechnology Policy Making provided recommendations on how to improve the engagement of high level government officials in understanding and using the advice from CBAC. The report recommended that CBAC members meet with ADMs to present and explain their reports, including findings, conclusions and recommendations. At the present time, it seems that CBSec presents or provides written summaries of the reports to BMCC and other government officials on behalf of CBAC.

In terms of seeking evidence of the connection between any CBS work and senior policy makers, a search of minutes of BACC meetings shows that representatives from Privy Council Office (PCO) often attend and occasionally speak at these meetings. However, the names of the PCO representatives often change. This is an indication that there is at least some level of engagement at the senior government policy level, however, some interviewees noted that the PCO representatives are not senior people and that there is no continuity.

Many interviewees made some suggestions to improve the engagement of Ministers, DMs and other officials, particularly of the seven lead departments. In most cases, suggestions were linked to the governance structure and accountability. At the moment, many felt that there is no willingness among senior officials to become engaged. Some felt that the Blueprint policy document (2003) was a good effort to provide a rationale for horizontally developed public policy on biotechnology, however, some also noted that the report, produced in 2003, does not seem to have provoked much response. Others commented that the departmental focus supported by the Canadian parliamentary system, with Ministerial responsibility and focus on departmental issues, does not support horizontal initiatives in general.

Several people noted that, in the original design, there was no requirement for Ministers or DMs to meet. This was perceived as a design flaw. Similarly, it was noted that there is no built in connection to PCO or Cabinet that would require or encourage senior government officials to become involved. According to some interviewees, there were numerous attempts, in some cases almost successful, to engage senior officials and find a champion, but they all failed. Some interviewees suggested that having responsibility for advancing



the horizontal biotechnology files in the letters of engagement of the seven Ministers and the accountability accords of the seven DMs would send a signal of the importance of this file to the government.

There was some input about CBAC specifically. Several interviewees noted that, in the early days, CBAC had missed an important opportunity to be seen as useful to the government. The government wanted external advice on genetically modified (GM) food and came to CBAC. However, CBAC was just getting set up and was unable to respond effectively in a timely manner, and the government turned to the Royal Society to provide input. CBAC then developed a major project on the regulatory structures and processes required for GM food that took account of the input from the Royal Society study. However, government officials were apparently disappointed that CBAC did not respond as they had hoped. The extent to which this early problem has affected the relationship afterwards is not known.

#### *4.1.4 Is the CBSec designed appropriately to ensure its independence?*

Interviewees from CBSec and the government were the main source of input to this question, as CBAC members are largely unaware of the detailed operations of CBSec. A number of interviewees discussed this issue from several perspectives.

First, several commented that CBSec is not supposed to be independent, at least not in the way that CBAC is. CBSec is an instrument of government and is to co-ordinate and enable the activities of the seven government departments working together to implement the Canadian Biotechnology Strategy. CBSec also has a role in providing administrative support to CBAC.

However, in order to co-ordinate a horizontal initiative such as the CBS, the agency must be seen to be neutral and not under the influence of any one department or agency. There is some concern that CBSec is part of Industry Canada (IC), an economic development agency and is therefore seen to be focussed on the objectives of that department. Some also felt that the Strategy is pro business and there has been too much focus on R&D and innovation and not enough on stewardship, regulation and social issues. Some link this focus to the fact that the Secretariat is housed in IC. It was noted that the Secretariat even reports to the Industry Sector of IC rather than the Policy Sector, adding to the perception of being pro business and focussed on innovation rather than having a broader focus inclusive of stewardship policy issues.

When the Strategy was set up in 1998, there was considerable discussion about an appropriate location, but the secretariat had to be put somewhere. It was housed in IC, but

placed in a separate “storefront” with minimal linkage to Industry Canada<sup>5</sup>. Interviewees commented that IC has not taken the leadership position on the Strategy that was expected based on the IC role at the Ministerial and DM levels, and that, therefore, CBSec is quite independent of IC influence in reality.

Several interviewees observed that there have been several attempts since 1998 to obtain greater input from PCO, as a means of both linking to policy makers and ensuring that CBS and CBSec were focussed on truly horizontal issues, beyond the self interest of any one department (i.e., independent). These all failed. A number of interviewees said that there have been a number of suggestions as to where the CBSec could be situated to be more effective. PCO has been mentioned most frequently, due to its perceived central place in government policy. Some people have suggested the Office of the National Science Advisor, but this location is not seen as having much influence. The suggestion by CBAC that it should report to a Cabinet Committee could also apply to CBSec.

#### **4.2 Issue 5 – Are the roles and relationships clearly defined and appropriate?**

##### **4.2.1 *Are the roles and relationships (including reporting relationships) in determining and setting priorities (for all components of the Strategy) effective?***

There is considerable evidence in various documents that the roles and relationships involving Ministers and DMs envisaged in the original design have not worked out in practice. For example, the August 2003 Canadian Biotechnology Governance Review reported that the original intention of having the BMCC and BDMCC involved in setting priorities for CBSec, the three pillars and CBAC and to engage and receive the results of their work has not occurred in practice, and that the relationships have therefore proven ineffective through inactivity<sup>6</sup>.

The EMR report also addressed this issue and found “that Ministers and DMs have not participated as planned”, and “a pattern of inadequate engagement of senior management and policy officials in ... setting horizontal priorities to guide CBS investments”. The report also found that CBAC is not being used to help set priorities by informing decision makers about the concerns of Canadians.

The Executive Workshop on Biotechnology held in May 2004, identified a number of improvements in roles and relationships, that would improve the effectiveness of decision

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<sup>5</sup> For example, the secretariat has a separate email address that does not refer to IC.

<sup>6</sup> Minutes show that BMCC has met once in 2000 and BDMCC has not met since 2002.

making. For example, a need was identified for improved federal leadership and horizontal management of biotechnology issues. Successfully communicating to Ministers and senior bureaucrats the importance of a federal strategy and commitment was identified as one objective. As well, it was recommended that, for those departments and agencies involved in important biotechnology related areas, the accountability agreements / performance objectives of Deputy Ministers should include their contribution to advancing the federal biotechnology strategy.

Several individuals spoke to this issue, some saying that the roles and relationships among the various actors are identified but not understood, and that accountability is a real problem. Others said that the roles and relationships are not clearly identified, understood or followed. Some said that both the original very broad scope of the CBS program and the role of CBSec need to be clarified. Several interviewees commented that, at the DG and working level, the roles and relationships in setting priorities are as effective as they can be under the difficult circumstances of little leadership from senior management and the problems associated with horizontal management.

The same interviewees felt that, to some extent, there is successful co-ordination at the working level in spite of failure at the higher levels. However, it was noted that the reporting relationship for CBAC is very poor, and that there is little or no linkage between CBAC and the departmental work under the three pillars. Several interviewees spoke of the fact that the CBS was formed as a result of a letter from the Prime Minister which is considered to be a very unusual high level approach. Another interviewee commented that adding to the confusion is the fact that the BACC Chair is from the IC Industry Sector whereas one might expect it to be under the IC Policy Sector.

Many interviewees spoke of the ineffectiveness of the process for determining and setting priorities. Almost all considered the primary failure as the lack of engagement of the seven Ministers and Deputy Ministers in the Strategy in general and in setting priorities in particular. Some felt that due to the lack of leadership, there is too much bottom up in developing proposals and too much attention to making sure that every department received some funding for its proposals. The difficulties under our political system of Ministerial responsibility for a single department in getting departments to work together on horizontal issues was noted by many. Some interviewees noted that the role of IC in particular was unclear in practice, if not in theory. IC is supposed to be the lead department and to set the tone for co-operation, but has not done so in practice. In fact, the Minister, Deputy Minister and Assistant Deputy Minister of Industry Canada are responsible for convening the BMCC, BDMCC and BACC, and their lack of leadership is an effective roadblock to an effective CBS program.

Some observed that the roles and responsibilities of the working groups are developed on a

group by group basis. In general, it appears that there are no minutes or accountability in most cases for what goes on in working groups.

#### **4.2.2 *How effective is the governance structure?***

A number of documents provide information about the intended governance structure and roles and relationships. They are discussed below.

A review of documents indicates that the proposed committee of CBS Ministers provides the means to address a need for a political biotechnology champion in the federal Cabinet and to promote Canadians' wish for a stronger stewardship role for government.

The August 2003 Canadian Biotechnology Governance Review examined the governance structure and found that it is complex and cumbersome. Also, as discussed in Section 3.1, large elements of the federal government biotechnology funded programs, such as Genome Canada and CIHR fall outside the influence of CBS. This puts severe limitations on the ability of the Strategy to influence federal biotechnology. The report also provided evidence on the problems with the present approach to setting priorities. The report also states that there "has been a perceived lack of leadership on biotech at the level of both Minister and Deputies" and "in the absence of clear direction from Ministers and Deputies, it has been difficult to address significant policy issues through the governance structure".

The most recent version of the CBS management structure (see Annex A) does show that CRSB and the federal intramural Genomics R&D initiative are associated with CBS program working groups and report to BACC, so the CBS program does have some, perhaps limited, influence beyond the immediate groups and projects funded from the \$9.52 million.

The EMR report found that "the horizontal funding and management structure for CBS represents appropriate attributes for horizontal mechanisms. However, the report also determined that the implementation of this model has been ineffective at many levels. The report found that there has been inadequate engagement of Ministers and Deputy Ministers. In order to improve governance and accountability, the report recommended that the Minister of Industry, as Chair of the CBS Minister's committee, table an annual report to Parliament including financial and performance information on federal biotechnology investments and outcomes. The report also recommended that TBS should clarify its role in advancing biotechnology objectives and providing leadership and guidance to ensure advancement of horizontal goals.

A comparison of the CBS management structure in 2002 (Figure A-1 in Annex A) and the

present structure (Figure A-2 in Annex A) shows that there has been some change in the specific working groups under the Stewardship and Innovation Pillars. Under the Stewardship Pillar, the Genetic Privacy and Information working group has closed down, as has the Ethics working group. Also, the Ecosystem Science working group has transformed into the EENovel Living Organisms working group. Under Innovation, the Analysis working group has been inactive since 2003 and a new Health Biotechnology working group was formed. The CBSec was not included in the original diagram, but has been added to the new structure.

Interviewees spoke extensively about the ineffectiveness of the governance structure. The primary reason identified, as stated many times previously, is the lack of participation by Ministers and senior officials that was expected in the formal governance structure. Even though high level engagement was expected, it was not required and there were no consequences to Ministers or DMs of not being involved. Interviewees confirmed that the BMCC met only once in 2000, and the BDMCC has not met since 2002. It was observed that the leadership for the CBS has moved steadily downwards, beginning with Deputy Ministers in the early years, to ADMs, and most recently in many cases to DGs representing ADMs on BACC.

A couple of interviewees complained about the role being played by BACC Executive Committee in assuming a leadership role that was, from their perspective, never intended, and setting directions for the working groups to pursue. The BACC Executive Committee structure was added in the 2002 CBS funding renewal to help improve co-ordination and provide leadership. The negative comments may be an indicator of the difficulties in getting individuals to put aside departmental interests and coming to a consensus to work together on horizontal issues.

A number of interviewees addressed the political dimension of the question and noted that, in recent years, the government in power has focussed on managing issues and reducing political risk, an approach that was not compatible with addressing high level social and ethical issues associated with the exploitation of biotechnology. Some felt that for government officials have simply responded to political priorities, and biotechnology has not been a top priority. As noted previously, some felt that departmental ADMs on BACC should have policy related responsibilities.

Interviewees discussed the governance question at several levels. If the issue is the governance of the \$9.52 million in the CBS program budget, then the level of expected governance was very onerous. If the expectation was that, through the programs, committees and activities resourced through the \$9.52 million, the CBS program would contribute to the governance of horizontal issues affecting biotechnology, particularly in federal government departments, then the governance structure as designed would be

appropriate. Some interviewees observed that, at the time the CBS was designed, there was every reason to believe that the importance of biotechnology to the government would continue and perhaps increase, and that there would be good reasons for Ministers and DMs to meet to deal with biotechnology related issues. It was noted that, in practice, biotechnology has declined as a “hot button issue”, with the resulting reduction in interest in the file. However, there may very well be opportunities in the near future of improved utilization of the capabilities of the CBS program, particularly if biotechnology related issues become more highly visible.

As already discussed to some extent under Issue 4, some consider the design of the governance to be a problem. Several interviewees commented on the poor design of the initiative, and one noted that one of the original design problems was that the Ministers formed an Ad Hoc Advisory Committee with no requirement to meet rather than a decision making committee. Some suggested that, rather than being a co-ordinating committee, BACC should be a management committee and that ADMs should have accountability requirements to represent their departmental interests.

It was observed that the lack of success in managing the horizontal dimensions of biotechnology should not be surprising as the same has been true of R&D in general.

CBAC interviewees also reported that there was no requirement or opportunity for CBAC to present its reports to BMCC, BDMCC, or BACC or in fact any government representatives, in spite of the reporting relationship shown in the management structure.

It was noted that for another horizontal file, Climate Change, the government had designed a very different approach. In this case, PCO is actively involved, and a reference group of Ministers meets weekly. This provides a completely different visibility and credibility to the initiative compared to CBS.

#### **4.3 Issue 6 – Are the communications effective?**

The EMR reported that there are inadequate and ineffective linkages and communications between CBS and key stakeholder at several levels. For example, the study found that senior government officials have not communicated to CBAC the topics for which they wish expert advice, and, according to the EMR report, there is little evidence that government officials have utilized much of the advice in CBAC reports.

The EMR report also found that the Canadian public is less aware of the risks and benefits of biotechnology than Americans, and “that there is a need for further investments in communications activities to increase Canadians’ engagement and ability to project their

views into the policy and decision making processes of government”.

One view of the present state of communication and engagement can be found in one of the 2005-2006 proposals for funding under citizen engagement which states: “it is premature at this time to develop extensive corporate outreach and engagement with the general public, when government itself, including key Ministers, senior management and individuals who deal with or influence policy, need to increase their engagement and involvement”.

It is interesting to note the lack of correspondence between the performance indicators for Citizen’s Engagement in the RMAF with the information in the section on citizen’s engagement in the CBS 2003-2004 Results Report. The RMAF performance indicators include the following:

- ▶ the number of Canadians accessing CBS communications, information and education products;
- ▶ the number and profile of participants in CBS managed citizen engagement activities, by activity;
- ▶ the extent to which public and expert views are sought and considered in areas of current and emerging concern; and,
- ▶ the timeliness and relevance of advice to Ministers.

The section of the 2003-2004 report dealing with citizen engagement did not mention these indicators, but rather discussed the activities under this category, which include public opinion research and media and stakeholder analysis, as well as updating the website and developing a bioweb portal to improve access to biotechnology related information from the Government of Canada.

A number of interviewees, primarily from CBSec and the government addressed this issue. In terms of external communications, the primary mechanisms have been CBAC, through the consultations that have been part of the process of examining major issues such as genetically modified food, and CBSec, which has had booths at trade shows and also manages a website. However, most felt that communications with citizens and stakeholders outside of government have been, in general, poor. Most felt that public visibility of CBAC, the program and the Strategy in general are very low. It was noted however, that a summary of a recent CBAC report was in Biotech Focus, an industry biotechnology journal, and was therefore receiving some visibility and recognition. Several people spoke positively of the Government BioPortal, that was recently developed



under the leadership of CBSec, with departments connecting to the portal with their biotechnology related programs and activities. Interviewees mentioned the public opinion survey on biotechnology that is funded through CBS, as a means of informing government officials about the public perception of biotechnology as input to policy making. Others noted, however, that citizen engagement consists of more than conducting polls.

Several interviewees observed that handing out brochures and having a website may be useful means of telling people what government wants them to know, but do not serve as citizen engagement. Several interviewees said that the CBS has done a poor job of engaging citizens and that the CBS program has few mechanisms to gather citizens' input and share it with departments. The mandate of CBAC was noted by several interviewees to include gathering citizen input, but there has been little recent activity in this area.

Interviewees noted that considerable efforts have been made to inform politicians and senior government officials about the key findings of CBAC reports, but there is no mechanism to present the reports and, in terms of effectiveness, there has been little evidence of their utilization or influence on government policies. A Compendium of Biotechnology Statistics was produced in 1999 to provide interested parties with basic information about the state of biotechnology in Canada, an updated version is being produced at this time and should be ready for release soon. In spite of the formal linkages, there has been no direct meetings between politicians or senior government officials and CBAC, other than participation by the Chairman of CBAC in the one BMCC meeting in 2000. It was also noted that, even at the working level, there is little communication between CBAC and those in the three pillars. The general difficulty in handling horizontal issues, government stove pipes and lack of senior official interest were identified as the major impediments to good internal communications.

#### **4.4 Program Design and Implementation – Conclusions and Recommendations**

For the design and implementation issue, there are conclusions related to the individual components as well as the CBS program as a whole.

Regarding the CBS Fund design and implementation, the following are the key conclusions:

- ▶ The basis for allocating funds to horizontal priorities in the different pillars and particular projects is not clear. Additionally, the pre-allocation of funds is not conducive to the selection of the most important projects. Similarly there is no indication that the project approval process is effective for selecting the projects that will address the most critical federal government priorities.

- ▶ There is no mechanism in place to ensure that the CBS Fund does not provide funding for regulatory or other initiatives that are best suited for funding by the CRSB or departmental A-base.
- ▶ While there is flexibility for multi-year projects (usually through a multi-phased approach), the allocation of funds is in general on a yearly basis. This is not necessarily the most cost-effective approach from all perspectives. The process is somewhat bureaucratic, particularly considering the limited dollars involved.
- ▶ In successive CBS Fund allocation processes, there has been a noted shift in the horizontal priority emphasis towards investments in stewardship and regulation over investments in the other two pillars of innovation and citizen engagement.

**RECOMMENDATION 2: It is recommended that the CBS Fund be targeted at the most critical horizontal federal priorities. It is also recommended that the process be streamlined and adapted to respond to these priorities and be more flexible for multi-year projects.**

Regarding various aspects of the CBAC design and implementation, the study led to the following key conclusions:

- ▶ CBAC is comprised of a wide range of biotechnology experts with a dual role. First, the members manage studies and produce reports on biotechnology issues of importance to Canada. Second, CBAC is responsible for engaging Canadians in a public way in an impartial dialogue about biotechnology. The committee is comprised of volunteers; CBAC receives only \$2.25 million annually to fund studies and engage Canadians; and the committee has produced numerous reports within this limited budget. As such, the federal government is getting good value. However, the reports produced by CBAC are not effective in reaching and being used by Ministers and senior bureaucrats for policy setting and decision-making. The committee is therefore not as cost-effective as it could be.
- ▶ The lack of engagement of federal officials has been a major barrier to the effectiveness of CBAC. Ministers and senior bureaucrats have not effectively been engaged in identifying priority issues for the committee to examine nor have they been effective receptors of CBAC's reports.
- ▶ Within its existing budget, CBAC cannot truly be effective in engaging Canadians. Rather within its budget, CBAC can only consult with Canadians through limited public consultation events, communication of information to and with Canadians

through its website and public documents / reports, and limited public opinion polling.

- ▶ Depending on the priority role for CBAC, its current composition may not be appropriate. There is some indication that the committee does not have sufficient representation of the ethical and societal aspects of biotechnology. Nevertheless, the committee has implemented an effective approach to fill some of its knowledge / expertise gaps through Expert Working Parties on studies.

**RECOMMENDATION 3:** It is recommended that, if Ministers and senior bureaucrats want and need to have access to an independent advisory committee on biotechnology, a more formal process be put in place for: 1) refocusing the priorities of this advisory committee; 2) ensuring that the composition of this committee is appropriate to address these priorities and continues to have access to other expertise as needed; 3) ensuring that the committee is adequately financially resources to address these priorities; 4) providing a process for the committee to directly report back to Ministers and senior bureaucrats on these priorities; and 5) having Ministers respond in a systemic way to advice and reports from CBAC.

In terms of the CBSec, the key design and implementation issue was related to its independence. It is not possible to conclude in this regard since, while there are some perceptions that the Secretariat would be more independent if it was not located in a department, there is no concrete evidence that its location within Industry Canada has affected its independence.

From a more general perspective, the roles and relationships of some of the program delivery elements are not clearly defined or agreed to. Furthermore, there is clear evidence that, in some cases, those that are defined have not been adhered to. In particular, the lack of engagement of senior officials, in particular those from Industry Canada, who chair the main coordination and governance committees, has been an impediment to success. This has been despite active ADM involvement to engage.

As also concluded under relevance, it is unrealistic to expect the CBS program to achieve, or be able to demonstrate a major contribution to the Government of Canada CBS objectives identified in 1998 given the resources, structure and accountability regime. The CBS program also has little operational connection with the other two linked horizontal elements (the CRSB and the Genomics Initiative), limiting its ability to coordinate work with those initiatives or to influence them.

**RECOMMENDATION 4:** It is recommended that the roles and accountabilities of the Secretariat be clearly defined in the context of addressing the unique horizontal

challenges and priorities within the broad Government of Canada framework for biotechnology. This should include clarification of key elements of the governance structure to ensure these horizontal priorities are addressed. In particular, this should include clarification of the roles and relationships of the broad management functions of the Biotechnology ADM Coordinating Committee (BACC), and the nature of the specific oversight function by BACC of the horizontal CRSB and Genomic initiatives.

## **5.0 Evaluation Findings – Continuous Improvement**

### **5.1 Issue 7 – How could the CBS be improved?**

In general, several interviewees noted that the CBS is not a national strategy, but a federal government strategy. They felt that there is a real need to expand the scope of the Strategy to make it national, involving other levels of government, industry and citizens.

#### **5.1.1 What changes are required to make the CBS Fund more successful?**

The EMR report found that most CBS Fund criteria were not linked to the achievement of horizontal benefits. Also, it was reported that projects were chosen in a “bottom up” process with little or no guidance for setting priorities. There was also no peer review of proposals by CBAC or any other expert advisors. Similarly, the report found that project monitoring is activity based, rather than performance or results based. This makes it difficult to assess how funded projects contribute to federal horizontal objectives.

The EMR recommended that expenditures through the funds should be managed in a more top-down fashion and be more clearly linked to high level federal priorities in health, safe foods, sustainable development and economic prosperity.

An examination of the portion of the CBS tracking system which deals with the projects undertaken under the Fund reveals possible areas of improvements, in terms of the following:

- ▶ while there is a wealth of information on the projects, this information does not easily provide the basis to identify which horizontal issues are being addressed;
- ▶ the system does not provide the basis to clearly identify the objectives of the projects and track these against achievements; and,
- ▶ there is no way to easily identify the project outcomes.

Interviewees from CBSec and government departments addressed this issue, however CBAC members did not. Several interviewees noted that there was confusion in who was setting the priorities. With respect to the CBS Fund, many commented on the need for senior officials to set high level priorities and ensure that projects, usually involving more than one department, are designed to address them. Several said that the creation of the Blueprint and the resulting new criteria for project selection implemented for the 2003-2004 fiscal year had helped significantly in moving the Fund to a policy orientation, addressing government objectives such as health innovation and the bio-economy.

Others suggested that the project selection criteria should be clarified and made explicit, and that an external peer review of proposals be made, possibly including input from CBAC or representatives with expertise in the area of federal biotechnology policy, as part of the project selection process.

Some interviewees suggested that for many projects, a one year horizon is too short, allowing barely enough time to begin. An annual project selection process also adds to the workload, whereas multi-year projects would allow for more time to be spent on doing the project. Some interviewees also noted that accountability needs to be improved, with more specific project objectives, milestones, specific deliverables and a clear relationship to horizontal objectives.

#### **5.1.2 *What changes are required to make CBAC more successful?***

The CBAC itself made two major recommendations for change in the December 2004 Statement on Renewal of the Canadian Biotechnology Strategy and the Evolving Role of CBAC. These included:

- ▶ increased level of resourcing to undertake increased citizen engagement and to undertake more and larger scale projects; and,
- ▶ improved reporting relationships, with formal reporting to a Cabinet Committee, possible the new Cabinet Committee on the Environment and Sustainable Development. In addition, CBAC would report to individual Ministers or their staff on specific issues.

The EMR report found that the focus of CBAC is not aligned with federal priorities, and that the linkage between CBAC reports and advice and federal policy development and decision making is unclear. The report went on to recommend that CBAC advice should be more strategically focussed on key issues and, additionally, that opportunities for CBAC to inform biotechnology investment strategies and choices should be aligned with federal priorities. However, this recommendation needs to be considered in light of the mandate of CBAC to provide external advice that includes consultations with stakeholders and citizens on what concerns them.

The major point made by most interviewees is that CBAC is not well linked to government, neither in identifying issues of interest nor in disseminating advice and recommendations in reports. There were a number of suggestions to improve this situation. It was noted that CBAC would likely have better success in influencing government decisions at the working level if Ministers and DMs signalled that they valued CBAC expertise and advice by meeting with them occasionally. Some mentioned that government has no accountability and no requirement to respond in any way to CBAC input. It was suggested

that CBAC should sit down with BMCC and BDMCC members to discuss their needs and the results of CBAC investigations. Some suggested that CBAC should report to a Cabinet Committee. However, the need for more resources was also identified if CBAC was going to be asked to do more and in a more timely fashion.

Several interviewees spoke about the committee and the interests that were represented. Some felt that the public interest was not well represented, and that the committee needed to improve its ability to address social issues from a broad perspective in a way that Canadians and stakeholders accept. It was noted that in some provinces, unlike the experience with CBAC, biotechnology related advisory committees do have the attention of politicians and senior officials.

With respect to the operation of the committee, some felt that the strong leadership of the Chair was a strength, and others that it discouraged diverging views. Committee members are chosen for a three year term, with the option for renewal. It was noted that the Chair had remained the same since CBAC was formed in 1998.

#### **5.1.3 *What changes are required to make the CBSec more successful?***

The EMR report recommended repositioning the CBSec from a role of co-ordination to strategic policy support for advancement of federal priorities through an emphasis on horizontal activities that do not exclusively belong to any one department, agency or federal organization.

More specifically, the EMR report recommended giving the CBS program much wider responsibilities, including:

- ▶ high level management of the three CBS Fund pillars to focus on higher priorities associated with horizontal issues;
- ▶ policy research on government wide issues such as social and ethical impacts of biotechnology;
- ▶ horizontal environmental scanning and trend analysis;
- ▶ contingency planning for national crises; and,
- ▶ sharing best practices to facilitate wider adoption.

The Institute on Governance (IOG) report discussed how to make CBSec more successful, but concluded that the real need is to decide on what the CBS should be and do and then position the CBSec accordingly. At one extreme, if biotechnology was to become a top government priority, CBSec could be situated in or near the PCO, led by an ADM, with a strong role in defining, supporting and driving a government wide biotechnology agenda. A less extreme change would have CBSec with a stronger monitoring and challenge

capacity in support of a strategic biotechnology framework. The third option would be to have CBSec providing much the same services as at present, but with CBS focussing on selected issues of cross-departmental interests and better engagement of CBAC, Ministers and Deputy Ministers.

In the context of the performance measurement and reporting system managed by CBSec, there are several possible suggestions for improvements. However, these will be discussed in Section 6.0.

A number of interviewee suggestions for making CBSec more successful are directly related to earlier discussion, as they focus on engagement, location and perceived authority. Some suggested locating CBSec within PCO, while others suggested having it report directly to Ministers through a reference committee of Cabinet or a subcommittee of Cabinet that would ensure political engagement and the attention of senior officials.

Some interviewees said that the CBSec was on the right track in leading the development of the Blueprint, which was seen as an important policy document that sets the stage for departmental co-operation on broad thematic areas. CBSec could also increase its value added by producing position papers on horizontal issues for discussion by BACC and departments. Some said that CBSec is well positioned to provide a leadership role and facilitate strategic discussion among departments.

Other specific suggestions that were seen to increase the credibility of the Secretariat included:

- ▶ increase the reporting level of the Head of the CBSec, and have the Head report directly to a policy ADM; ideally this ADM would have some authority over other agencies;
- ▶ have policy personnel familiar with biotechnology issues seconded to the Secretariat from departments as a method of improving linkages, the credibility of the Secretariat on policy related issues, and a reduction of the "we versus them" mentality among departments;
- ▶ improve the relationships of the Secretariat to external stakeholders;
- ▶ CBSec could provide a valuable service and contribute to horizontal issues management by collecting expenditure and related project data across federal departments on the major areas involving biotechnology, such as life sciences. (This would be at a more detailed level than presently collected by Statistics Canada.) It appears that this information is not available at the moment, and would



be very helpful in discussing allocation and reallocation of all federal biotechnology related resources; and,

- ▶ lead the effort on improving performance measurement, management and reporting related to biotechnology through the development of guidelines and generic techniques that many departments can agree with and utilize.

## **5.2 Continuous Improvement – Conclusions and Recommendations**

The conclusions and recommendations provided under the other issues have already addressed the changes that are required to make the CBS Fund, CBAC and the CBSec more successful. No new conclusions and recommendations are required.

## **6.0 Evaluation Findings – Performance Measurement System**

### **6.1 Issue 8 – How appropriate is the performance measurement system of the CBS?**

#### **6.1.1 *How effective is the CBS tracking system from the perspective of those who have to input the information? Is the value of the information worth the effort required to provide it? What are the strengths and weaknesses of the tracking system / progress reporting?***

CBS program funding called for the establishment of an ongoing monitoring process for funded projects. This process, in support of accountability, was to include the annual dissemination of project reports to BACC which is responsible for monitoring departmental spending and performance against project milestones and objectives.

The Canadian Biotechnology Strategy Overall Performance Report for 1999-2002 discusses the reporting and monitoring systems developed for the CBS funded projects. The report states that the system is focussed on measuring resource utilization, Fund management and the progress of projects (not on project outcomes and impacts). As noted “the system acts as a detailed monitoring tool by tracking project progress and fund usage” and also “this information allows the CBS to evaluate project progress and rapidly detect any delays or funding problems, allowing for reallocation of funds if necessary”.

It should be noted that this report predates the 2002 RMAF which identified the performance measures to be used to report on CBS program.

The information in the tracking system is only partially linked to the performance indicators in the 2002 RMAF. It is almost entirely project based, and has project objective, resources, and outputs or deliverables, but little or no information about the horizontal initiative to which the project is linked nor how it is expected to advance that initiative. The tracking system also does not provide information on outcomes or results associated with the completion of that project.

The tracking systems is organized into the following key areas:

- ▶ *Section A: CBS Fund Projects and Partners* – this section provides a description of the projects funded and can be accessed by year, lead department, pillar, project, CBS Fund allocation, partner contribution and outputs. As previously noted, the problem with this section is that it is not specifically designed to show information on the outcomes of the projects. While some of the reported outputs could be considered outcomes in the right context (for example regulations) many others are true outputs (e.g., reports). The project reports also do not include a list of the participating departments, which is a problem when trying to track the degree of

collaboration among departments on projects defined as horizontal. This also contributed to problems with analysis in the EMR report and reduced the usefulness of the information in the tracking system for this study.

- ▶ *Section B: Other Initiatives* – this section is structured to capture information on other federal, provincial, private sector, institutional / NGOs / Associations / others, and international initiatives. The information included in this section is very basic and seems incomplete (e.g., under international, only Australia items are listed).
- ▶ *Section C: Performance Progress* – this section includes responses to a series of questions from each department for each year. There appear to be two key problems with this section. First, the information provided by department is variable in terms of details and of the nature of the information provided. Second, some of the questions are not directly linked to the logic model or indicators outlined in the RMAF.

One of the main objectives of the CBS Accountability Working Group is the management of the CBS performance measurement system, including the tracking system. The minutes of the meetings of this group provide information that addresses this issue. For example, the minutes of the September 29, 2004 meeting report that “most agree that Section C of the tracking system does not provide meaningful information that could contribute to telling a good story about the CBS program major results ...”. In the January 7, 2005 minutes, a member of the group identified a number of suggestions for future work. These included:

- ▶ better definition of the reporting objectives;
- ▶ analysis of the net benefit of the reporting activities;
- ▶ better understanding of the value of the reports in order to receive stronger reporting efforts from the community; and,
- ▶ reporting more focussed on impacts.

These suggestions show that there is recognition of the need to clarify the objectives of the system, as well as concern about the value of the information compared to the cost of collecting it. There is also recognition of the need to move from not only collecting information on resources, activities and outputs to include the outcomes and impacts of projects and other related CBS initiatives.

It was noted in the EMR report that the information in the tracking system is on a small percentage of federal biotechnology spending and on horizontal issues. The review therefore found that, while the information was somewhat useful, it provided a very limited overview of the overall federal biotechnology picture. For example, there is no information

on the extent of departmental complementary initiatives of a horizontal nature that are an intended outcome of the Strategy. The EMR also found that the tracking system was focussed on project activities and spending rather than results associated with the contribution of the projects to horizontal issues.

The people who have to input the data into the tracking system are from the government departments. Only a few interviewees were responsible for inputting data, and of these most did not use the data. Some found the process tedious, others said it was needed to fulfill the reporting requirements and "the letter of the law". The tracking system collects tombstone data on projects, including planned project outputs or deliverables, as well as how and if resources are spent. It was noted that, without the tracking system, there would not be any consistent record of what had been spent and little accountability for the use of the funds. Some felt that the tracking system is too onerous for the value received in monitoring projects. However, the tracking system fails to identify specifically the project's linkages to the broader horizontal strategies. As mentioned previously, results are not tracked, nor how the results contribute to achievement of higher level objectives.

It was noted that the tracking system relies on departmental personnel to input data and some do not do a good job in terms of both content and timeliness.

It was noted that the data collected is related to the needs identified in the RMAF, which was felt to be too complicated. There is a need for a simplified, more useful document that identifies key performance indicators.

**6.1.2 *How is the information used? By whom? What information is not useful? What additional information would be more useful for decision-making purposes?***

The information in the tracking system is used as the basis for the annual CBS Results Report, which is a requirement of the funding agreement. The report provides a summary of the activities and outputs of CBAC, the Secretariat and the projects funded by the CBS. It does not discuss outcomes resulting from these deliverables.

The EMR found that information about federal biotechnology investments was available for S&T related expenditure as presented by Statistics Canada as part of federal S&T expenditures. (It should be noted that this Statistics Canada report is funded by the CBS Fund.) The EMR collected additional information on non S&T expenditures in the regulatory, commercialization, policy and governance, and public awareness areas. These areas are estimated to represent about 20% of total federal direct expenditures on biotechnology. The report found that a more comprehensive financial and performance tracking system for all federal biotechnology investments was needed to support horizontal management of the biotechnology file and provide input to the new Expenditure

Management Information System.

With respect to the usefulness of the information, the EMR also found that, in spite of the detailed tracking system for CBS funded projects, many of them did not meet CBS objectives linked to horizontality and leverage. The report also noted that, as no performance information related to results was being collected, "it is not clear how CBS Regulatory and Genomic R&D funds contribute to the advancement of federal priorities". The review also recommended that, to support the renewal of CBS, CBSec should establish a common financial and performance tracking system for all federal biotechnology investments and that there be a common priority-setting, tracking and reporting mechanism for CBS, the Genomics R&D initiative, CRSB and any other horizontal biotechnology investments.

The report coordinated by CBSec entitled "Biotechnology Transforming Society – Creating an Innovative Economy and a Higher Quality Life" is a report on federal biotechnology for the period 1998 to 2003. While it purports to be a report on the Canadian Biotechnology Strategy over that five year period, the report includes information on a wide range of biotechnology related expenditures in federal departments. It includes:

- ▶ the CBS program (\$9.52 million per year);
- ▶ CRSB (\$35 million per year);
- ▶ the Genomics R&D initiative (\$20 million per year); as well as,
- ▶ related Science Based Departments and Agencies (SBDA) expenditures on biotechnology.

This report is useful as it attempts to provide information on all aspects of the broader federal biotechnology strategy, not just the \$9.52 million per year expenditures within the CBS program.

CBSec interviewees noted that the Secretariat uses the roll-up of information in the project tracking system as input to the annual report to BACC.

As noted earlier, some said that it would be an improvement if the tracking system was linked to outcomes as well as resource utilization and outputs.

It was also suggested that it would be an improvement if the tracking system was not a separate system but was integrated into departmental requirement and linked to the financial management system, so departments would not have to repeat a lot of data entry.

## **6.2 Performance Measurement System – Conclusions and Recommendations**

It is important to set the context for the conclusions and recommendations associated with the CBS program's performance measurement systems. The key component of the CBS performance measurement system is the CBS tracking system. The system was established based on the broad Government of Canada objectives for biotechnology approved by Ministers in 1998 and performance indicators developed for the CBS program RMAF. It should be noted that this was the first horizontal RMAF developed in the federal government. Given that little expertise was therefore available for the development of this difficult RMAF, it is not surprising that there were many lessons learned along the way. Nevertheless, the program can benefit from the following conclusions and recommendations:

- ▶ The present performance measurement system is not focused on capturing information about the outcomes and results of the program. Rather, the project tracking system captures data on resources, activities and project deliverables, with little attention to outcomes. The system relies on departments inputting the information, which is highly variable in terms of accuracy, completeness and quality.
- ▶ The tracking system has been improved significantly over time. As such, it is easier to input and manipulate information in the system. Nevertheless, the system is designed to capture information on the CBS Fund projects and partners, on other initiatives (non-CBS program related) and on overall departmental performance progress. The information in each of these sections is highly variable in terms of accuracy, completeness and quality; therefore, reliance on the information it contains is questionable.
- ▶ The information in the tracking system is useful to the CBSec in tracking and reporting on resource utilization and outputs.
- ▶ Outcomes information is currently available through ad hoc feedback on specific project successes provided by Accountability Working Group members in the development of the CBS yearly performance report.
- ▶ There is no formal mechanism to track the performance of CBAC and of the CBSec.

**RECOMMENDATION 5: It is recommended that a renewed RMAF be developed for the CBS program based on feasible horizontal objectives. The RMAF should**

capture the essential elements of the expected results, and the outputs and outcomes needed to achieve these expected results in a revised program logic model. An important component of the RMAF should be the identification of the performance measures needed to monitor program implementation and outcomes for all elements of the program. This will provide important input for a determination of the appropriate tracking system elements needed to track all aspects of program performance.

## **7.0 Evaluation Findings – Success**

### **7.1 Issue 9 – What difference are we making, and can we make, with the CBS Fund?**

#### **7.1.1 What is the profile of those funded through the CBS Fund?**

The following table describes the allocation of funds among departments for the three year period of the funding 1999 to 2002. The funding was distributed relatively evenly among the 11 departments and agencies involved in biotechnology. The following table provides a summary of the total allocations for the three years by agency as well as for the 2002-2003 period.

<b>Department / Agency</b>	<b>1999-2002</b>	<b>%</b>	<b>2002-2003</b>	<b>%</b>
Agriculture and Agri-Food Canada	\$ 1,971,700.00	7.2	\$ 210,000.00	2.2
Canadian Food Inspection Agency	\$ 3,952,000.00	14.5	\$ 460,000.00	4.9
Environment Canada	\$ 2,124,100.00	7.8	\$ 750,000.00	8.0
Foreign Affairs and International Trade	\$ 141,000.00	0.5	\$ 470,000.00	5.0
Fisheries and Oceans Canada	\$ 1,737,900.00	6.4	\$ 215,000.00	2.3
Health Canada	\$ 1,509,700.00	5.5	\$ 650,000.00	6.9
Human Resources and Development Canada	\$ 0.00	0.0	\$ 75,000.00	0.8
Industry Canada	\$ 606,900.00	2.2	\$ 860,000.00	9.2
Justice Canada	\$ 0.00	0.0	\$ 380,000.00	4.0
Natural Resources Canada	\$ 1,802,500.00	6.6	\$ 300,000.00	3.2
National Research Council	\$ 2,297,000.00	8.4	\$ 640,000.00	6.8
Statistics Canada	\$ 844,200.00	3.1	\$ 300,000.00	3.2
Veteran Affairs	\$ 0.00	0.0	\$ 85,000.00	0.9
Canadian Biotechnology Secretariat	\$ 10,304,000.00	37.8	\$ 4,000,000.00	42.6
<b>Total</b>	<b>\$ 27,291,000.00</b>	<b>100.0</b>	<b>\$ 9,395,000.00</b>	<b>100.0</b>

\* In addition to the funds for operating CBSec and CBAC, the CBS allocation also covers the resources for performance measurement and tracking, as well as for emerging issues, to be available for funding of work on issues that arose during the year and were not evident at the time of resource allocation.



The Canadian Biotechnology Strategy Overall Performance Report 1999 to 2002, reported that for that three year period, over half the funds were allocated towards science-based projects, and the majority of the science-based projects were on genomics. The report also noted that the Fund supported R&D projects that developed new technologies for Canadian industries.

In 2002 the resource allocation process was changed. Funds were allocated to individual departments in the same way as for the first round for the 2002-2003. The previous table also shows the allocation and percentages. The differences from the 1999 to 2002 allocations should be noted, with major reduction to AAFC, CFIA, Fisheries and Oceans and NRCan, and major increases to DFAIT, IC and JC.

For the two subsequent years (2003-04 and 2004-05), the resources for the CBS program were allocated to the three Pillars, and CBSec at the following levels:

- ▶ Stewardship and Regulation – \$3,320,000 (35%);
- ▶ Innovation – \$1,680,000 (18%); ,
- ▶ Citizen Engagement – \$1,000,000 (10%); and,
- ▶ CBSec – \$3,520,000 (37%).

The new process was for funds to be released to individual projects only after BACC reviewed and agreed with the proposals being recommended and the funding required.

The \$3,520,000 received by CBSec was to fund CBAC (\$2.25 million), CBSec (\$770,000), performance measurement and tracking (\$250,000) and for emerging issues (\$250,000) to allow BACC to access funds for emerging priorities not covered under the regular workplan.

**7.1.2 *To what extent have policy-related horizontal initiatives been undertaken as a result of the CBS?***

The CBS RMAF notes that the attribution of success in accomplishing policy related horizontal initiatives to CBS influence is a difficult task, as many initiatives would be the result of government and departmental decisions, and CBS influence would be one factor among others in making the final decision. The RMAF indicates that the CBS played a role in establishing priorities for federal funding in biotechnology related areas. More specifically, the RMAF indicates that CBS played a role in supporting the allocation of \$55 million in 1999 to federal genomics research and \$90 million to the establishment of Genome Canada in 2000.

The minutes of meetings of the BACC and BDGCC show that the BACC acts as an

information sharing and co-ordinating body and to some extent a decision making body. For example, BACC contributed to the development of the original Federal Genomics R&D initiative (\$55 million over three years), for the recent renewal of the initiative, with over \$50 million in funding for the next three years.

CBSec, with input from BACC, also led the development of the Blueprint, which laid out a proposed biotechnology strategic policy for the federal government. This document was cited by the EMR as the basis for future government horizontal biotechnology policy.

In reviewing some of the information in the tracking system for projects funded under the CBS Fund, it is difficult to match the project description with biotechnology related interdepartmental horizontal objectives. Some projects do seem well aligned, such as the analysis of how workers are currently protected against use of personal genetic material by employers and a review of the policies of other countries and international organizations funded under stewardship. Some project funding has been used to support working groups, such as the \$195,000 provided to the Genetic Privacy and Information Working Group to manage co-ordination of the working group under the Stewardship pillar.

Another relevant document is the report produced by CBSec which captures departmental responses to questions concerning the success of CBS funded projects in terms of the performance indicators found in the CBS RMAF. One of the indicators for both the Stewardship and Innovation Pillars is the extent to which horizontal stewardship and benefits priorities are reflected in the CBS Fund allocations and Horizontal Stewardship initiatives. With respect to Stewardship initiatives, for 2003-2004, the report stated that "the CBS Fund invested \$1.26 million for stewardship policy-related projects to address ethics and public confidence, use and protection of private genetic information, legal analysis of Genetic information and Privacy law and Human Rights law, long term effects of GMOs, safety criteria for foods and seeds and strengthened stewardship of human health related biotechnologies". For innovation, \$550,000 was invested in innovation policy related projects in the regulatory approval system, biotechnology expertise in bioproducts, the biobased economy, privacy, and knowledge management. However, it is not clear from the report how many of these projects were horizontal in nature as opposed to more departmentally focussed. This is a real concern as the reporting is by departments rather than from the group.

A number of initiatives funded through the CBS Fund were identified by interviewees as contributing to the development of horizontal policy initiatives. One interviewee stated that the Fund had been successful in funding a number of projects in the Stewardship / Regulatory area, that supported regulation of genetically modified food, development of a biosafety protocol, and work on environmental effects. Other areas funded that were

considered to have proven useful as a foundation for horizontal initiatives are national and international statistics on biotechnology to help position Canadian efforts, and biotechnology regulations.

Innovation related initiatives include environmental applications of biotechnology, such as lowering production costs using enzymes and environmentally friendly bioprocesses.

It was observed by some that most of the projects reflect departmental interests rather than government level ones. This problem is compounded by the bottom up nature of the development of project proposals.

**7.1.3 *How successful are the projects that have been funded to date in terms of achievement of project objectives and as they relate to the intended outcomes of the CBS and the CBS Fund?***

Limited information is available from documents to address this issue. The CBS RMAF has several indicators that link to this question, but no information is provided on those indicators. The 2003-2004 Departmental Performance Report for the CBS horizontal initiatives provides information on the results achieved by each department from the use of CBS Funds as well as those from CRSB and Genomics R&D. In most cases, the results described are applicable to a wider community than the individual department. For example, Environment Canada reported that using CBS Funds, they had developed a "policy document that will provide future direction to the federal government stewardship community in order to develop effective, non-regulatory, and voluntary initiatives that could be used by industry in becoming more socially responsible for their activities ...". Other projects have produced public opinion research data that can be used to inform policy decisions being made by the wider community.

CBS funding of Statistics Canada work has supported a number of reports including federal, provincial and industrial expenditures on biotechnology R&D; biotechnology use and development survey of industrial firms; and the development of international standards for the measurement of biotechnology activities. The data and analysis have been used to inform policy decisions related to innovation and regulatory initiatives. The international work has been widely recognized and used by several countries as the basis for their collection of information on biotechnology activities, and will be used to benchmark Canadian biotechnology against those of other nations.

Due to the limited number of interviews, information on this issue is sparse and limited to what the individuals could recall. According to those who responded to this question, most projects were completed with their intended deliverables. A number of interviewees commented that in the early days, most projects were aligned with filling gaps in individual

department's capabilities. In at least some cases, for departments receiving significant resources through the Fund, the CBS Fund was directly responsible for major components of the departments' regulatory system approach. Some interviewees commented that, although some projects were aligned with departmental needs, overall the Fund contributed to improving the Federal Government's capability in stewardship and innovation linked to biotechnology. Also, as discussed previously, a number of interviewees noted that following the renewal of funding in 2002, there was a renewed focus on linking proposed projects to the achievement of the formal objectives of the Strategy, based on direction from BACC Executive. This direction from BACC Executive became the basis for the policy objectives identified in the Blueprint.

## **7.2 Issue 10 – What have been the actual versus intended outcomes of CBAC?**

### **7.2.1 *How have the reports produced by CBAC been used? By whom? How could the reports be more effectively used by the target groups?***

CBAC has produced a range of reports, from the major in-depth project reports to the more immediate focussed advice on specific issues of interest and concern. Consultation Documents provide summaries of important workshops or are developed as a means to consult with stakeholders and citizens as a part of the process to develop project reports. A summary of CBAC reports is provided in Annex E.

There is little information in documents that were examined about the use of CBAC reports. However, a review of CBAC minutes shows that there is one recent example of government requesting CBAC to provide advice. In mid-2004, the Industry Canada and Health Canada Ministers asked CBAC to examine Human Genetic Materials, Intellectual Property Regime and the Health Sector. The minutes provide a few other examples of interaction with government officials, including several presentations to the Health Standing Committee Executive, a presentation by the Director of the Innovation Strategy Secretariat in 2002, and other presentations by the Justice ADM and the Director of the Cross-Sectoral Policy Development Division of AAFC.

Based on the interviews, there are a few examples of use of CBAC reports, one relates to the use by the Supreme Court of Canada of a CBAC report. Another example is the use by CIHR of CBAC material in developing its Tricouncil policy statement on genetic information. The CBAC report on biosafety was also used by the government as input in its decisions about international biosafety protocols. However, in general, there appears to be limited use of CBAC reports by government departments. In fact, some interviewees said that there is a major response burden placed in government departments as a result of CBAC reports.

As an example of the general disconnect between CBAC reports and government, some interviewees reported that the government has not yet formally responded to the 2002 CBAC report on Regulation of Genetically Modified Foods. However, several interviewees noted that the CBAC report on GM Food was well received and used. For example, the recommendation to rely on voluntary disclosure was received by the government and helped in making the decision to not require the labelling of GM food, but to use the Canadian General Standards Board voluntary labelling system. More recently, the report on Biotechnology and the Health of Canadians (2004) was identified as being well received. The CBAC report on Patenting of Higher Life Forms (2002) and the advisory memo on the Harvard onco-mouse case were cited in a Supreme Court of Canada case and also in an Australian legal case.

Several interviewees noted that there does not seem to be much appreciation of the widespread consultation process used by CBAC in investigating issues and the additional value in sensing the public and special interest perspective on ethical and social issues.

Others commented that the CBAC reports and expertise are potentially very useful, but in general, they have not seized the attention of government bureaucrats and policy people. Some interviewees said that any failure in achieving impact from CBAC reports is the responsibility of the recipient, the government, not CBAC, which is producing relevant high level socially important products.

It was noted that the committee has a couple of new projects, one requested by the Industry Canada and Health Canada Deputy Ministers to examine the question of protection of intellectual property associated with genetic materials and the health sector and another on the role of biotechnology in sustainable development.

As many interviewees have observed, in order to be used effectively, CBAC needs to produce reports and do things of value to the client, which is the Canadian government. It was noted that CBAC also has the capability to also provide input on specific issues to government departments, as well as undertake the larger more in-depth studies. To date, with one or two exceptions, this additional capability has not been taken advantage of by departments. On another topic, according to some interviewees, CBAC does not have much credibility with ENGOs and NGOs, who consider it too closely tied to government and economic development.

#### ***7.2.2 What have been the facilitating and impeding factors for CBAC success?***

One major report identified impediments to success for CBAC. The September 2003 report on The Use of External Advice in Federal Biotechnology Policy Making included a section on barriers to the effective use of CBAC information and advice. As reported, one barrier

is that, in spite of production of some excellent reports and studies, the government has not made extensive use of the advice as there is little present perceived need for the advice. However, the report suggests that the lack of action does not imply that the CBAC reports are not appreciated. Another impediment reported is that with the present process, there is no single recipient of the advice, no "Lead Department" responsible for developing or co-ordinating a response, even though Industry Canada is designated as lead on all major committees. This allows all departments to avoid action unless they desire to do so. A third impediment is the sheer complexity of analysis, conclusions and recommendations in reports, and the mixed political and bureaucratic nature of the issues. Departments can not respond without Ministerial and Government agreement. Part of the problem is the nature of the advice, which is public, and often calls for changes in legislation or regulations. Government acts at this level only infrequently, often linked to a political agenda. Therefore, the type of advice provided by CBAC is not ever likely to be seen as directly responsible for a policy decision or change in regulation, but rather be one of a number of inputs, albeit an important one. Often the influence of CBAC reports will be present, but difficult to single out and give attribution to. The report noted that the same situation applies to other advisory groups, such as the Council of Science and Technology Advisors.

As already discussed, the EMR found that the CBAC reports and advice were not well aligned with federal priorities. The report also found that the lack of guidance from federal officials on selection of topics for CBAC was a serious impediment to success.

As also stated previously, there was a general agreement among those interviewees who addressed this issue that the largest impediment to CBS and CBAC success has been the lack of attention by Ministers and DMs to the work of the committee (with the recent exception of the 2004 referral from IC and HC Ministers). In addition, interviewees commented that there has been little interaction between the government working groups and the work of the committee. While the BACC did provide input to CBAC on areas of interest earlier, recently there has been less input. CBAC members have little or no interaction with any of the CBS government committees, other than the CBAC Chair participation in the first and only Ministers meeting in 2000. It was noted that, unlike the situation in Europe, where social activists such as the Green Party are in Parliament, there is little political interest in the Canadian Parliament or in the government to address social issues related to biotechnology, and that the ability of NGOs and special interest groups to mobilize Canadian public opinion has been limited.

However, some interviewees observed that, in spite of a general lack of guidance, CBAC has chosen useful, important issues to examine.

One impediment previously noted was the level of resourcing. CBAC has a budget of \$2.25 million per year, which allows it to produce about one major report a year. All

CBAC members have full time positions, and that their role is voluntary with no compensation, which limits the ability of the Committee to work on issues and build awareness through personal action. The recent use of the Expert Working Party, with one or two CBAC members and other subject matter experts addressing a specific issue was seen to be proving successful as a means to achieve good results without giving CBAC members a large work load. Various members can work on different subjects depending on their expertise. Reports from the Expert Working Party are then reviewed and discussed by the Committee as a whole. Several interviewees noted that the sector least represented on CBAC is the public interest one, and that this fact reduces the credibility of the committee in the eyes of the NGOs.

One impediment to success identified by several interviewees is that CBAC is seen by many stakeholders as being pro-development. Another issue is that the credibility of CBAC in the eyes of other stakeholders has been compromised by the lack of attention to its work within the government.

### **7.3 Issue 11 – What have been the actual versus intended outcomes of the CBSec?**

#### **7.3.1 *What type of support is the Secretariat providing, to whom? What else should it do?***

The EMR found that CBSec has been “too narrowly focussed on co-ordination activities rather than supporting overall federal goals and that it has a limited ability to facilitate synergies and partnerships ...”. The review recommends that CBSec be refocused to strategic policy support for advancement of federal priorities through an emphasis on horizontal activities that do not exclusively belong to any one department, agency or federal organization. The CBSec does undertake some policy related functions. For example, CBSec was the primary author of the December 2004 report “Building the 21<sup>st</sup> Century Economy – A Government of Canada Blueprint for Biotechnology – *Realizing Canada’s Potential*”, which is an interdepartmentally focussed policy document identifying priority opportunities and needs for applications of biotechnology and a strategic plan for federal biotechnology related initiatives.

The Secretariat also produces a number of reports associated with accountability and reporting requirements, including the CBS Annual Results Report, and the Annual CBAC Report.

Several interviewees agreed that the primary role of CBSec is co-ordination and management of the processes associated with supporting CBAC, BACC, the annual allocation of funds and some of the working groups. Interviewees spoke of the roles of CBSec in identifying emerging issues, including conducting environmental scanning for

CBAC, and identifying synergies and opportunities among departments as being useful. It was noted that the knowledge among CBSec staff about the various players and issues related to biotechnology have been valuable in developing partnerships and identifying contacts. It was suggested that CBSec should have a stronger policy role, such as directing CBAC to specific areas, based on analysis of government needs. At the moment, it appears that the staff supporting CBAC do not interact in any significant way with other CBSec groups.

Several interviewees noted that, while not usual, CBSec has played a lead role on some initiatives. Examples include the file on genetic information and privacy that was transferred to Justice. CBSec also led the successful development of the BioPortal, with departmental support. The role played by CBSec in “being the pen” for the development of the Blueprint was also mentioned by several people as an important contribution to horizontal biotechnology policy development.

In terms of what CBSec should do, some observed that the Secretariat had been preoccupied with the processes under its direct authority, like managing the funding process and providing secretariat services to CBAC, rather than trying to influence the larger issues through proactive initiatives aimed at seriously influencing the seven departments involved in the biotechnology Strategy and the wider federal biotechnology community. It was conceded that there is great difficulty in moving agendas ahead that involve multiple departments.

### ***7.3.2 What have been the facilitating and impeding factors to the success of the CBSec?***

As mentioned several times, the EMR found that the lack of engagement by Ministers and senior federal officials and willingness to participate in horizontal initiatives of the type envisaged by the CBS MC and program design was a serious impediment to success of CBS and all three elements of the CBS program, including CBSec.

Several people interviewed said that the quality of leadership provided to CBSec was a significant factor in the success of the Secretariat. However, another perspective was that the leadership was too strong and did not empower other perspectives.

As mentioned previously, the positioning of CBSec within Industry Canada is considered to be an impediment by a number of people, as there is an impression that CBSec is an instrument of IC and focussed on economic development and downplaying social and public good issues. It is difficult to convince stakeholders that CBSec is playing an interdepartmental co-ordinating role when seen to be in IC.

The relatively low level of the CBSec Executive Director in the bureaucracy was also seen



to affect the ability of CBSec to influence government departments by some. Others found the level of expertise and credibility of CBSec staff within the federal biotechnology community to be an impediment.

The position of CBSec within the overall design of the CBS program, including CBSec's lack of authority is also seen as a major impediment to some people interviewed. It was noted that they can only persuade and encourage, which is not very effective in dealing with vested interests in departments. Another problem noted is that departments do not give good direction to CBSec. Confusion among government officials about what CBS and the CBS program are supposed to achieve and the role of CBSec was also identified as affecting the Secretariat's level of success, and that of the CBS program in general.

#### **7.4 Success – Conclusions and Recommendations**

Notwithstanding some of the previously noted conclusions and recommendation dealing with needed improvements to the CBS program and its elements, the program has made a difference in the federal biotechnology community. The following conclusions are reflective of the success of the program:

- ▶ The projects and working groups associated with the CBS Fund have contributed to bringing departments together, and helping them anticipate and prevent, rather than react. The Fund has also contributed to addressing emerging issues and providing seed money outside areas departments would fund from their A-base. The reports that have been produced and distributed throughout the departments have been useful. However, this success is not systematically tracked and captured but rather is available through ad hoc feedback. As such, the program cannot effectively track and report on the success of the Fund.
- ▶ CBAC has produced a number of credible reports that addressed major issues related to stewardship and regulation of biotechnology. Unfortunately, the intended audience of these reports have not effectively used the valuable information provided by CBAC.
- ▶ The CBSec had led the development of the Blueprint, a policy document outlining the way forward for federal biotechnology, that had been well received by the federal biotechnology community.

While no new recommendation is required, these conclusions strongly support the need for a renewed CBS program RMAF that more appropriately defines how success should be defined and measured.

## **8.0 Other Key Conclusions and Recommendations**

Within the overall Government of Canada investments on biotechnology of over \$750 million per year, the Canadian Biotechnology Strategy has three specifically linked elements. In addition to the CBS program with its \$9.52 million in annual funding, there are two other elements, namely the Canadian Regulatory Strategy for Biotechnology (CRSB) that provides \$34.6 million per year to individual government departments to support regulatory initiatives, and the Genomics R&D initiative, that provides \$19.9 million annually to individual departments and agencies to support genomics R&D. In addition to these three elements, the Government funds biotechnology related programs within departments and agencies, as well as through separate initiatives. Chief among those recently introduced is Genome Canada, which funds major R&D projects involving universities and other partners.

Based on the evidence in this evaluation, the CBS program needs to rethink its design and structuring. The first step in the restructuring should be to examine the role of horizontal programming with the specifically identified Canadian Biotechnology Strategy elements, as well as how they relate to the Government of Canada investments as a whole. Through this exercise, the horizontal contributions of the various government programs and initiatives to the Strategy could be identified. This should include the other two elements linked to the CBS, namely the CRSB and the Genomics R&D initiative. It may also be appropriate to include Genome Canada in this review. Following clarification of the roles and objectives of the other elements of the CBS, a needs and gaps analysis should be undertaken to identify the appropriate horizontal objectives for the CBS program that would complement the other elements and provide the basis for a design and delivery approach that would be realistic and achievable.

**RECOMMENDATION 6:** The Treasury Board Secretariat should require that a horizontal RMAF be developed for the key elements of the Canadian Biotechnology Strategy. These include the CRSB and the Genomics initiative. The horizontal RMAF should identify the contribution of each element to the overall objectives and describe the linkages between the elements as well as with other federal biotechnology initiatives in departments and agencies, such as Genome Canada, that contribute to the Strategy. As such, this should provide the basis for identifying the gaps in the horizontal elements of the Strategy, and thus set the basis for the CBS program objectives and related structure.

**LKC**  
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