



## **The Horizontal Coordination of Biotechnology: An International Comparison**

A paper produced for the Canadian Biotechnology Secretariat

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## **I. Introduction outlining purpose and approach**

### **1) Purpose**

The Government of Canada's current approach to biotechnology, outlined in the 1998 Canadian Biotechnology Strategy, is now five years old. The Canadian Biotechnology Secretariat is examining the governance structures in place to deliver the Strategy, and considering areas for possible improvement. The purpose of this paper is to examine the approaches taken in the governance of biotechnology in other jurisdictions, both in Canada and abroad. The paper specifically focuses on cross-governmental coordination and strategy development. It does not address broader dimensions of governance, such as a coordinated regulatory structure or government relationships with industry and civil society. This information will allow the Secretariat to consider the experience of other jurisdictions when mapping out future paths for Canada.

The jurisdictions selected for study were Australia, the European Union (EU), Japan, the United Kingdom (UK) and the United States (US). Two provinces, Ontario and Quebec, were also chosen. All these jurisdictions are world leaders in biotechnology and at the forefront of developing policy or program approaches which reflect the complexity of the area. In an intense international race to attract capital for the research, development and commercialization of biotechnology, the countries studied are also Canada's competition.

### **2) Approach**

The initial stage of research was a literature and document review, carried out mainly over the Internet, to compile key policy documents and information available on government web sites. Since much of the most applicable activity around biotechnology is very recent, information is not always available in written form. Interviews with officials from the selected jurisdictions were an essential part of filling the information gaps and the most valuable source of perceptions on how governance structures worked in practice. Government web sites and DFAIT science advisors in missions abroad were consulted to find suitable interviewees.

## **II. Policy Objectives, Frameworks and Strategies**

Not surprisingly, all jurisdictions examined recognized biotechnology as an area with important implications for their societies and economies. However, jurisdictions varied in their perceptions of the policy issues and the approaches required.

Clearly these policy approaches are very much a reflection of the public and commercial environment in each jurisdiction. Government's approach is influenced by the different forces at play in the public domain, including, for example, pressure from industry, vibrancy of



academic/research sector and public attitudes. As well, they reflect different traditional roles for government and the pre-existing institutional base within each jurisdiction.

The cases studied generally fell into two categories:

- 1) Jurisdictions that approach biotechnology as a technology that is best addressed within policies designed for science and technology in general.
- 2) Jurisdictions that identify biotechnology as a special case which requires a different or separate approach from science and technology policy as a whole. Specific policies and structures have been created to meet biotechnology's demands on society and government.

### **1) *Biotechnology within Science and Technology Frameworks***

Quebec and the US fall within the first category. Quebec has no policy framework or strategy devoted solely to biotechnology. Furthermore in their current policy document on science and technology, "Politique québécoise de la science et de l'innovation – Savoir changer le monde", biotechnology is not specifically mentioned. Rather, aspects of biotechnology are treated in a section on dynamic sectors (genomics, pharmaceuticals, agri-foods). The capitalization of biotechnology does have a focussed program, but not vastly different than approaches to other technologies.

In the US, biotechnology is considered one technology sector among many, and dealt with through policies and structures already in place. In some instances, very specific aspects of biotechnology are identified as requiring attention, such as the bioethical dimensions of stem-cell research. In these cases special policy responses are developed.

The American approach would seem to emerge from two realities. One is government's perception of its own role in science and technology. According to one official interviewed, the government's main role is to promote research by using government resources to leverage funding from other sources and to provide a regulatory system which is beyond reproach, science-based and which sends clear signals to industry. In general, government leaves the technology to sink or swim on its own merits. The second reality is that the US is a world leader in biotechnology. There are no glaring gaps in the research-development-commercialization chain. Therefore the attitude seems to be if the system works, why fix it. According to another senior official, treating biotechnology as one technology among many has avoided its demonization, as has happened in other jurisdictions.

In the US, biotechnology became a priority issue in the early 1990s. At this time, there was a focused review of the portfolio and how it was funded (addressing a broader range of issues, ie. research funding, IP). It was at this point that biotechnology was absorbed into the larger framework for science and technology.

## **2) Biotechnology-specific policies – Strategies**

The second category includes the EU, Japan, Australia and Ontario. All four have specific strategies which outline their approach to biotechnology. While the focus of these documents is different, in each biotechnology has been featured as an area of science and technology that requires special attention.

In the EU, Japan and, to a lesser degree, Australia, the strategies not only deal with research and industrial issues, but recognize the importance of biotechnology for societies and economies. They express a desire to maximize the benefits of biotechnology, but tie accomplishing this task closely to the ability to deal with biotechnology's broader implications, including potential risks.

The strategies are an acknowledgement that government has an important role in seeing that all parts of the system, however defined, are functioning well. In some cases the driving force behind the creation of a strategy was the perception that the system was not working as well as it should. In other cases, it was the realization that government was uniquely positioned to take advantage of opportunities to improve the functioning of the system. Closely tied to these driving forces was an acute awareness of the importance of international competitiveness. A key aim of all the strategies is to improve performance relative to other jurisdictions.

The strategies weight the government role differently. In some, government is a partner with industry, in others government is the catalyst for making the most of strategic opportunities, in others government is the keeper of a system in balance.

Japan has identified the 21<sup>st</sup> century as the “life sciences century”, during which life sciences will provide the engine of growth, improve living standards and play a role as important to Japan as electronics did in the 20<sup>th</sup> century. But Japan perceives itself as having fallen behind the competition in this field. Their strategy focuses on industrial growth, but also acknowledges the broader socio-eco-ethical implications of biotechnology. The Japanese strategy clearly expresses priorities and connects general policy to specific action plans, with designated responsibilities.

The EU life sciences strategy is similarly action-focussed. Despite its strong science base, the EU also sees itself falling behind its competitors. Biotechnology's applications, especially on the GMO issue, have generated more controversy in Europe than elsewhere. These controversies have coloured attitudes towards biotechnology as a whole. The European Commission decided that the only way to move forward and regain a position among world technology leaders was to address all issues relating to biotechnology in one policy document, and find a balance between the two impulses present within the EU: the desire to promote biotechnology by stimulating innovation and its applications, and the need to secure control over biotechnology for society. The EU strategy covers a wide spectrum of issues including the promotion of the research, development and commercialization of biotechnology, but also human resource issues, intellectual property, public education, public dialogue, ethics, traceability and labelling of GM foods, Europe's responsibilities to the developing world, and foresight mechanisms.

Australia created the National Biotechnology Strategy to build on its strengths and remedy some weak links in the research-development-commercialization chain, as well as develop a new

structure for regulation. Other areas addressed in the strategy are bioprospecting, public awareness, technology transfer, new enterprise development, research coordination, user uptake and overall coordination of biotechnology policies. In contrast to the documents produced by other jurisdictions, the Australian strategy does not, for the most part, venture past generalities. This makes it difficult to determine where the real priorities lie.

Ontario has a biotechnology strategy, but has taken a very focussed, program-centred approach rather than producing a broader, more inclusive policy statement. The aim of the Ontario Biotechnology Strategy is to strengthen the research-development-commercialization chain at its weakest parts by providing an environment attractive to start-ups and taking steps that would facilitate the entry of more mature parts of the industry into the production phase. According to one official, this is a great departure from normal practice which, especially over the past several years, has done little sector-specific promotion but instead concentrated on creating the macro-economic climate right for growth and development which would benefit all sectors. In this case, Ontario identified an opportunity for government to play a catalyst role in a dynamic new sector.

### **3) *Somewhere in Between: the UK case***

The UK is a special case which seems to straddle the two approaches. The UK approach to biotechnology has been very thorough and incorporated the broader dimensions of biotechnology: ethics, public consultation, and other societal and economic impacts. There is no one single policy document which expresses this domestic approach (although they subscribe to and contributed to the development of the EU strategy). The UK has a strong science base and a well-developed approach to science by government in general. Structures and policies are already in place that facilitate horizontal approaches to issues, horizon-scanning activities, and mechanisms for incorporating scientific advice into policy-making. For this reason, the UK has decided to tailor its current system to deal with biotechnology and its many aspects rather than developing a separate approach.

## **III. Political and Executive Structures and Horizontal Coordination**

The two policy approaches to biotechnology described above (one biotechnology specific, the other with biotechnology incorporated into pre-existing policies designed for science and technology) are also reflected in the political and bureaucratic structures for the coordination of biotechnology in government. All jurisdictions examined had structures in place to coordinate biotechnology issues across departments, some were contained within pre-existing structures for science and technology and others created specifically for biotechnology, often expressly for the purpose of developing a strategy.

## **1) Examples of the coordination of biotechnology within the science and technology framework**

The US and UK have established mechanisms for the coordination of science and technology policy across government. Both have organizations which coordinate the research budget for science and technology, the Office of Science and Technology Policy (OSTP) in the United States and Office of Science and Technology (OST) (housed in the Department of Trade and Industry) in the United Kingdom. These organizations also have the responsibility of providing science and technology advice directly to the executive. They support cabinet-level committees on science and technology and subcommittees on biotechnology. In both cases these committees rarely meet, leaving the coordination to committees at the bureaucratic level. Much of the coordination is done on an informal basis. In the US, areas of coordination of biotechnology are limited in scope, focusing on research funding and regulatory overlap. The coordination of biotechnology in the UK is more generally defined, addressing topics as they arise.

In the UK, the head of the OST, the Chief Scientific Adviser, has the larger responsibility for coordinating government policy on science and technology both nationally and internationally. The Chief Scientific Adviser and the OST play a much larger and more active role in addressing biotechnology issues than their US counterparts. Biotechnology has been a much hotter issue in the UK than in the US and the OST has taken a high profile role in defining the UK's approach to biotechnology. In the US, biotechnology as a new issue was addressed in the early 1990s. These efforts focussed on dividing regulatory responsibilities and adjusting research money and IP protection to promote innovation. In particular instances, biotechnology has been singled out for special attention, such as with the President's Council on Bioethics, which advises the President on the ethical considerations arising from advances in biomedical science and technology. In the UK, biotechnology did not become hot until 1999. The issue remains very political to this day. For this reason the Cabinet Office has often taken the lead in addressing the issue in cooperation with the OST. They have performed extensive and transparent reviews of some of biotechnology's most controversial topics and adjusted government structures accordingly. In 1999, the Cabinet Office and OST carried out a government review which led to the creation of an independent, multi-disciplinary advisory structure to help set a strategic framework for the development of biotechnology in the UK. Currently, they are coordinating a comprehensive review of GM crops, including science and economic reviews and a process for managing public dialogue.

## **2) Examples of the coordination of biotech-specific frameworks**

In the jurisdictions where a policy framework was created specifically for biotechnology, much of the horizontal coordination focussed around strategy development and implementation. In a number of jurisdictions special structures were developed to create and maintain a strategy as a horizontal approach.

## A) The balancing point - the political-bureaucratic approach of the EU

The European Union is a special case, due to 1) its particular responsibilities as a supra-national body, 2) the interface between the political level and the bureaucratic level within the European Commission and 3) the controversy surrounding biotechnology in Europe in general. (See appendix for a note on the EU institutional framework)

The European Commission has had formal structures for the horizontal coordination of biotechnology at the service level (the bureaucratic level) for the past twenty years. These efforts were an effective mechanism for information sharing but not for decision-making. The issues being dealt with required decisions that had to be made at the political and broad policy level, not the technical.

In 2000, emerging out of a push from the highest political level to improve Europe's approach to science and technology, the President of European Commission formed a Biotechnology Steering Committee (BSC) with the purpose of creating a strategy for life sciences. In a departure from previous groups, the BSC included members from the service level (including high-level officials and technical staff), but also cabinet officials representing key Commissioners (political staff from the office of the responsible Commissioner – a political position in the executive branch, see appendix). The BSC added a political dimension to the coordination which had previously been carried out solely by the bureaucracy. This gave the coordinating body the authority, as well as the technical capacity, to make what in the end were political compromises. The resulting strategy (of two parts: policy document and plan of action) reflects the political balance that had been struck. The BSC is coordinated by the Secretariat General of the European Commission.

## B) Other jurisdictions

### *a) Incorporating Expert Advice*

The approaches of the remaining three jurisdictions, Australia, Japan and Ontario, looked very similar in the initial stages of strategy development, but subsequently went in different directions.

In these jurisdictions stakeholder feed-in was an important part of the initial coordination around strategy development. The BIOCouncil in Ontario, the BIOCOCG in Australia and the Biotechnology Strategy Council in Japan were mechanisms for incorporating the advice of high profile experts into the process. The make-up of these advisory groups demonstrate the pro-industrial development orientation of the processes.

In Ontario, the BIOCouncil was made up of industry leaders, several people representing the research community and government representatives at the Deputy Minister level from key ministries. The task assigned to the BIOCouncil was to give advice on how to most effectively build a biotechnology corridor in Ontario. Their report was, in effect, directly converted into the Ontario Biotechnology Strategy.



In Japan, the Biotechnology Strategy Council was a high profile exercise, including industry and research leaders as well as appropriate Cabinet Ministers and the Prime Minister. The Council's task was to directly develop a set of Biotechnology Strategy Guidelines to act as an action plan for government. The process demonstrates the close partnership between industry and government in Japan. This exercise was carried out by the Cabinet Office and the work of the Council provided the focal point for the coordination of all ministries involved as they supported the process.

The expert panel in Australia, the Biotechnology Consultative Group, BIOCOG, included for the most part industry and research leaders but also ethicists and nutritionists. Their work was a starting point, from which the five departments involved moved forward their own agendas to develop the National Biotechnology Strategy.

*b) Mechanisms for coordination during and after strategy development*

In Ontario the process of strategy development was dominated by the lead agency, the Ministry of Enterprise, Opportunity and Innovation (MEOI), although four other departments were involved. The main conduit for the coordination surrounding the development and delivery of the programs included in the strategy is the Ontario Biotechnology Secretariat (a part of MEOI). Life sciences working groups were created on pharmaceuticals, bioproducts, agriculture and food and biotechnology clusters with participation at the ADM, Director and Manager level. They feed into a formal ADM Science and Technology Council which meets quarterly. MEOI controls the funds associated with the strategy.

Of all the jurisdictions examined, Australia's approach probably most closely reflects the Canadian example. At the same time as BIOCOG was set up in 1999, two other mechanisms were created to develop a biotechnology strategy: the Commonwealth Biotechnology Ministerial Council consisting of the five Cabinet Ministers responsible for biotechnology-related issues, and Biotechnology Australia, a multi-departmental agency responsible for supporting the Ministerial Council and coordinating non-regulatory biotechnology issues for the Australian government (coordination of regulatory issues are dealt with through a separate mechanism, see appendix). Unlike the Canadian case, half way through the life of the strategy, the political level Ministerial Council still meets (if only twice a year). A great deal of the horizontal coordination that takes place is centred around preparing the issues to be addressed at the political level. Although it claims to be a multi-departmental agency, BA is housed in the Department of Industry, Resources and Tourism. Both the strategy and the coordination of biotechnology issues have a distinct leaning in the direction of Industry's agenda.

## IV. Themes

### **1) *Political-level participation***

The big decisions surrounding biotechnology are ultimately political ones. In all jurisdictions (with the exception of Quebec) at some point biotechnology has been a priority issue on the political agenda. Focussed attention from the political level was the catalyst for developing policy frameworks and mechanisms for horizontal coordination.

In Ontario, a commitment on a strategy for biotechnology was made in the Speech from the Throne. This facilitated the process of horizontal coordination by making what had been a departmental issue a government-wide commitment. Individual commitment at the political level, from the Minister of the lead department, MEOI, as well as high-ranking bureaucrats, sped up the process of strategy development dramatically.

In the EU, the issue was already very visible, but needed political action to overcome an impasse, a clash of conflicting interests, and to find a way forward. Strategy development was a top-down priority, a task given by the President of the European Commission, reflecting the proceedings of the Lisbon and Stockholm summits of the Heads of Member States. The Biotechnology Steering Committee was a fusion of the political with the bureaucratic. The evidence of the political resilience of the document they produced was its approval by the European Parliament and the European Council. The continuing high profile of biotechnology makes the BSC a relevant mechanism for maintaining the political balance as new issues arise and the strategy is implemented.

As the US example shows, priority issues come and go. After the science and technology framework was adjusted to meet the new demands of biotechnology, it dropped off the political agenda. New priority issues emerge. Today nanotechnology and the security implications of science and technology are the priority issues.

### **2) *What to include in policy approaches***

The scope of horizontal coordination and strategy development has been defined very differently among the jurisdictions examined, spanning the spectrum from focusing on limited strategic goals to a expressing a comprehensive way forward.

Ontario has coordination throughout government on different aspects of biotechnology. However its largest initiative, the Ontario Biotechnology Strategy, is in no way comprehensive and selects very specific research and industrial development aspects of biotechnology as its focus.

The UK government has a system in place for looking at biotechnology as a whole, but selects particular issues for special attention, such as the GM food review.

In Australia, the regulatory aspects of biotechnology are mentioned in the National Biotechnology Strategy, but separate structures have been developed to manage horizontal coordination on these issues at both the political and bureaucratic level. Biotechnology Australia deals only with coordination of non-regulatory issues and these issues are defined quite broadly.

In the EU, all aspects of biotechnology are covered by one committee and one strategy so that they might be part of a balanced approach to the issue.

### **3) Finding balance – agreement on a common agenda**

Finding the right balance between the interests of different players at the table is a challenge. Very rarely do these players come to the table completely as equals. In the EU example, a good balance seemed to have been struck, although some promoters of biotechnology might say that so many controls have been put on biotechnology that it renders some of the goals around the promotion of biotechnology impossible to fulfil. However, according to one official, no one could accuse the document of being one-sided.

The Australian example is a case of unequal weight being placed on competing priorities. According to one official interviewed, due to the manner in which the strategy was financed and the location of the coordinating agency within the Department of Industry, that department has dominated the process. Although the strategy document includes the interests of all, its implementation and new funding attached to it have been weighted to the priorities of Industry. In interviews with officials from other departments, they indicated that they have to work very hard to get their issues onto an agenda basically controlled by Industry.

In Ontario as well, the process was dominated by the lead department, MEOL. However, the strategy was program-focused rather than a comprehensive statement of policy, and the interests of the other participating departments did not run at cross purposes with MEOL. For these reasons all interests could be represented in the end product without a great deal of conflict.

### **4) Challenges for the lead**

The challenge of any coordinating agency is to have a clearly defined role, and enough resources and authority to carry that role out. As laid out earlier, the coordinating body can be many things: a convenor supporting the work of committees and working groups, a keeper of a policy document tracking progress, or a leader pushing the agenda forward and consulting with other stakeholders as they go. Horizontal initiatives can rarely please all participants. Thus coordinating bodies might be accused of not demonstrating enough leadership at the same time as being accused of leading in the wrong direction.

Of the jurisdictions reviewed, the EU had clearest coordinating structure. The structure was coordinated from the Secretariat General which had a clear convenor role. From the research done for this study, Australia had the murkiest. Biotechnology Australia, the multi-agency

coordinating body is actually housed in and reports to the most dominant department, Industry. This has negatively impacted how the other partners view the process.

### **5) Importance of having the structure in place**

Many of the interviewees identified having developed effective mechanisms for horizontal coordination as one of the keys to success. As one European official expressed, working horizontally requires a great deal of up-front effort, another layer of bureaucracy and consultation. However, it allows for dissenting views to be dealt with at the beginning of the process rather than at the end. Almost all officials interviewed, regardless of their comments on the effectiveness of coordinating mechanisms, said that the system worked much better with them and all their faults, than without them. Even where informal coordination is the primary level of coordination, these informal routes are shaped by the formal mechanisms.

### **6) Getting the right people at the table**

The European Union and Ontario demonstrate two contrary approaches, both successful, in determining what players should be present during strategy development. The European Commission's process focussed on getting all the necessary people involved regardless of level. Directorate-Generals (departments) sent the people with the necessary level of knowledge and the practical authority for making decisions. Despite this combination of political staff with technical and policy service staff, in this rare instance hierarchy did not dominate the process. The EU approach is the only one where there is only one level of formal coordination.

In Ontario, previous committees that had tried to be all-inclusive and include representatives from as many as eleven different departments had not led to effective decision-making. In creating the Ontario Biotechnology Strategy the group was narrowed down to the five lead departments. The small size of this group increased the speed at which the policy was developed.

### **7) Establishing an end date**

Most of the policy approaches to biotechnology that have occurred in the jurisdictions examined are between one and four years old. In the jurisdictions where a strategy was developed, the strategy has included hard goals and specific programs or an action agenda to meet it. These are not open-ended strategies. Sunset dates are incorporated into the document (2004 for the Australians, 2010 for the EU and Japan and four years for Ontario). After the development of a strategy, the focus of horizontal coordination is the evaluation of the strategy and adjustment to reflect progress and changing priorities, in other words, maintaining the relevancy of the policy framework.

## **8) Working among different levels of government**

A key challenge in many jurisdictions is working with other levels of government, which adds a new dimension to the struggle to reach consensus. The European Commission was able to reach a compromise on a strategy, but making progress on that strategy often depends on action by the Member States, which implement Europe-wide policy items at their own pace.

In Australia, a national strategy was implemented with a pro-development approach. At the same time four state governments issued moratoriums on the planting of GM crops. Creating a “national” strategy becomes much more complicated when other levels of government must buy-in to a common approach. Australia has developed a liaison committee to improve the flow of communication between state and commonwealth levels of government.

# Appendix A: Australia - Country Study

## 1) Policy Objectives – Desired Outcomes

Vision as stated in the *National Biotechnology Strategy 2000*:

“Consistent with safeguarding human health and ensuring environmental protection, that Australia capture the benefits of biotechnology for the Australian community, industry and the environment.”

## 2) Policy Specifics

From the *National Biotechnology Strategy 2000*:

Biotechnology was singled out for special attention because:

- Biotechnology was identified as an enabling technology key to future economic performance, one that promises to bring about radical and pervasive change
- Australia’s industrial competitiveness and standard of living will depend on how Australia handles biotechnology
- The pace of change in biotechnology is extremely fast, other countries that have invested in biotechnology have seen impressive ongoing growth
- A desire to build on strengths – Australia has a strong institutional base and is already a leader in certain biotechnology niches
- Biotechnology is not well suited to the traditional sectoral approach the government takes for other industries. Biotechnology does not fit neatly into one portfolio.

Government’s goals:

- Safeguard human health and the environment through a rigorous, efficient and transparent system of regulation for gene technology and genetically modified organisms and products
- In the research and application of biotechnology, ensure that high ethical standards are observed
- Improve public awareness of the risks and benefits of biotechnology and the ethical questions they raise
- Enhance the economic and community benefits of biotechnology by creating an internationally competitive environment for investment and enterprise development, strengthen links between the research sector and industry, improve management of intellectual property
- Maintain and develop infrastructure for generating biotechnology applications by investing in research and development, offering world class education in biotechnology, securing access to and conserving genetic and biological resources



### 3) Policy Development Process

In 1999, the Prime Minister created the Commonwealth Biotechnology Ministerial Council and Biotechnology Australia (BA), a multi-departmental agency, to coordinate non-regulatory aspects of biotechnology for the Australian Commonwealth Government and to develop a national strategy.

The Biotechnology Consultative Group (BIOCOG) was formed to give independent advice on the development of a strategy. The group consisted of 22 members from the research and business sectors, including ethicists and nutritionists.

The development of the strategy involved a consultation process. A discussion paper, *Developing Australia's Biotechnology Future*, served as a focus of this process. Submissions were received from organizations and individuals, and a series of open forums were held in all capital cities. BIOCOG provided advice and all State and Territory Governments were consulted. Biotechnology Australia consulted widely with industry experts and carried out a number of background studies.

The National Biotechnology Strategy (NBS) was released in July 2000 and accompanied by another document, *Australian Biotechnology: Progress and Achievements*, which outlined progress already made in biotechnology.

The NBS outlines the government's vision and support of biotechnology for 2000-2004. It lists objectives, as well as strategies that will be pursued to meet them. Some of these objectives and strategies are quite specific – setting up a Biotechnology Advisory Council to provide expert advice on non-regulatory issues, for example. Others are much more general and the strategies outlined give little or no detail about how the objective will be reached.

Although not specifically detailed in the NBS, many programs have been developed to meet its objectives. The most significant include the A\$40 million Biotechnology Innovation Fund, which supports the commercialisation of biotechnology research through the proof-of-concept phase, and the A\$46.5 million Biotechnology Centre of Excellence to establish Australia as a regional and world centre for biotechnology innovation and application.

The purpose of the NBS is to promote biotechnology and create the conditions in Australia for the development of a strong, internationally competitive biotechnology sector. As a document, it does make an effort to balance this promotion role with the need to advance in a manner both ethically sound and safe to human health and the environment.

The Ministerial Council and BA continue to manage the horizontal coordination of biotechnology at the political and bureaucratic levels during the implementation of the strategy. They have made annual and mid-term reports on the progress of the strategy. A central agency type review is being carried out on the NBS and BA to evaluate the Government's approach to biotechnology. The steering group managing this review includes representatives from different departments, central agencies, research organizations, and a representative from the Australian Biotechnology Advisory Council.

## Regulation

Although the NBS mentions regulation, the Australian government has created separate political and bureaucratic structures to handle its horizontal dimension. The regulatory role for biotechnology falls on many different government agencies, including the Therapeutic Goods Administration, Food Standards Australia New Zealand and the Australian Pesticides and Veterinary Medicines Authority. In the Gene Technology Act 2000, the responsibility for regulating GMOs was made to ultimately rest with the Department of Health and Ageing. The position of the Gene Technology Regulator was created as an independent statutory office holder with responsibility for administering and enforcing the national regulatory system for the development and use of gene technology. The Gene Technology Ministerial Council, which includes representatives from both Commonwealth and State governments was created to govern the work of the Regulator and issue policy principles which establish parameters for the national regulatory system. A number of gene technology advisory committees feed into this structure. (Note: this country study focuses on the coordination around the National Biotechnology Strategy, not the regulatory system)

### **4) Machinery of Coordination**

#### Biotechnology Australia

Biotechnology Australia (BA) is a multi-departmental Government agency responsible for coordinating non-regulatory biotechnology issues for the Australian Government, as well as providing balanced and factual information on biotechnology to the Australian community. BA is housed within the Department of Industry, Tourism and Resources but is funded separately.

Its two main tasks are:

- the development and implementation of the National Biotechnology Strategy
- public awareness

Other responsibilities include:

- coordinating the Department of Industry, Tourism and Resources' input into the Gene Technology Regulatory System
- coordinating the Department of Industry, Tourism and Resources input, regarding biotechnology issues, into international biotechnology forums
- secretariat support of the Biotechnology Ministerial Council, expert panels, and meetings of Secretaries and Officials from Biotechnology Australia (Commonwealth) departments
- Ministerial briefings and support on biotechnology issues
- coordinating Australian Biotechnology Advisory Council

## Commonwealth Biotechnology Ministerial Council

BA reports to the Commonwealth Biotechnology Ministerial Council which comprises:

- Department of Industry, Tourism and Resources (Chair)
- Department of Health and Ageing
- Department of Agriculture, Fishing and Forestry
- Department of Education, Science and Training
- Department of Environment and Heritage

The Ministerial Council meets about two times a year.

The meeting of the Ministerial Council helps to focus political attention and structure horizontal coordination. Meetings at the Secretary-level (equivalent to DM) are held about 3-4 times a year. There are more frequent meetings at the branch-head and division-head level (director equivalent).

Biotechnology Australia constantly liaises with departments.

Biotechnology Australia has also increased the priority of communication and coordination between the States and Commonwealth through a Biotechnology Liaison Committee.

The Australian Biotechnology Advisory Council was formed in 2002 to advise the Government on priority issues in biotechnology, including research and development, international links, commercialization, public interest and ethics.

### **5) *Opinions of Selected Interviewees***

#### The Horizontal Approach

- Overall the horizontal mechanisms in place have functioned well. As issues have become more political (ex. GMOs), it has become increasingly important to have the political level engaged to address these issues. The Ministerial Council is a useful vehicle for getting attention for the file. Especially on controversial topics, the Council allows the different departments to strongly put their positions, back them by hard facts and let the political level decide. This allows for an informed and balanced debate where the best policy outcome emerges out of diverse interests. At all levels a key challenge of the horizontal approach is to reach agreement without diluting the initiative to the lowest possible denominator.
- The Ministerial Council delivers mixed results. The Ministerial Council meets infrequently (twice a year) and meetings are generally more informational than focussed on decision-making. It is a struggle for some departments to get their issues on the agenda, which



requires building alliances and getting the support of other departments on issues. The process is dominated by the Department of Industry.

### Balance

- There is a general acknowledgement that the strategy is a well-balanced document which takes into account both the benefits and risks associated with biotechnology. Although the strategy itself is well-balanced, its interpretation has been very pro-biotech and focussed on commercial benefits through the private sector.
- BA's location within the Department of Industry, Resources and Tourism means that its orientation leans strongly toward the interests of that department. Other departments see the value in the role that BA plays, but do not feel that BA represents the interests of their departments well.
- Although BA itself feels that its public awareness program is well balanced and not necessarily pro-biotechnology, others say it has taken a very promotional approach, with a marked absence of acknowledging risks.

### Commonwealth-State Liaison

- In order for a national strategy to be effective, coordination must incorporate the States as key stakeholders. Their buy-in is important for the success of a strategy. Over the past couple of years, several states have issued moratoriums on the planting of GMOs, effectively catching the Commonwealth-level off guard. A Liaison Committee was set up in 2001 to better facilitate coordination between levels of government on biotechnology.

## Appendix B: European Union – Jurisdiction Study

### Note on the European Union

As a supranational body, the EU is a special case. For this reason, this note has been added to explain its basic institutional framework. The EU is a union of Member-states established by treaties, and under constant evolution both in terms of what the union means and who should be included. The EU's initiatives are guided by the "subsidiarity principle". Initiatives relate only to those areas where EU-level action would be more effective than action taken at national, regional or local levels. The basic responsibilities at EU-level relevant to biotechnology are product approval, trade and agriculture policies, and safeguarding the internal market.

The three main institutions of the EU are:

#### Council of the European Union

- The Council is the EU's main decision-making legislative body.
- The Council is composed of one representative at ministerial level from each Member State, who is empowered to commit his Government. Council members are politically accountable to their national parliaments.
- There are different councils for different topics. Most pertinent to biotechnology is the Competitiveness Council (Internal Market, Industry and Research).
- The European Council is made up of the Heads of State of all Member-States.

#### European Parliament

- The European Parliament is a legislative body elected by direct universal suffrage. It shares legislative powers with the Council and exercises democratic supervision over the Commission.

#### European Commission

- The European Commission is the executive branch of the EU and the home of the bureaucracy. Only the European Commission can initiate legislation. Its other main tasks are to administer and implement EU policies, enforce EU law and carry international relations on behalf of the EU.
- The Commission has 20 politically-appointed members each with a specific portfolio. Each Commissioner has a political cabinet office (political staff working in the Commissioners' offices are referred to as cabinet staff). At the bureaucratic level, the Commission is organized into Directorates-General, each of which reports to a specific Commissioner (people working at the bureaucratic level are referred to as service staff).

This case study will focus on the work of the European Commission.

## **1) Policy Objectives – Desired Outcomes**

From *Life sciences and biotechnology – A Strategy for Europe*:

To capture the benefits that technologies will generate for societies and economies while making sure that the necessary safeguards and channels are in place so that the development and application of life sciences are consistent with common fundamental values and ethical principles.

## **2) Policy Specifics**

The driving force behind the creation of a life sciences strategy was the recognition that Europe has reacted slowly to addressing the challenges and opportunities of new technologies and therefore fallen behind its international competitors. The strategy lays the framework to move from a passive and reactive role towards biotechnology to more proactive policies to exploit these technologies in a responsible manner, consistent with European values and standards. The strategy was created to ensure coherence across Community legislation and policies and to encourage an integrated approach towards all applications of life sciences and biotechnology.

The strategy addresses three key points:

- Attracting the human, industrial and financial resources to develop and apply new technologies to meet society's needs and increase its competitiveness
- Ensuring broad public support by addressing the societal and ethical implications of new technologies
- Responding to global challenges presented by new technologies and meeting Europe's global responsibilities

## **3) Policy Development Process**

At the Lisbon 2000 summit, the European Council advanced the goal of making Europe the most competitive and dynamic knowledge-based economy in the world by 2010.

Focussing specifically on life sciences during the Stockholm 2001 summit, the European Council invited the Commission to examine measures required to meet certain policy objectives (outlined above in section 1).

In response, the President of the European Commission assigned the task of setting out a strategic vision for life sciences to six Commissioners over 2001. The President also formed the Biotechnology Steering Committee (BSC) to act as the point of coordination in the creation of the strategy. The BSC combined technical and policy staff from the necessary services with cabinet staff from the offices of the Commissioners.

In preparing the strategy, the Commission launched a broad public consultation based on a working document entitled *Life Sciences and Biotechnology - Towards a Strategic Vision*. Around 320 contributions were received from Member State governments and public authorities, the European Group on Ethics, industry and professional associations, academics and individuals. A stakeholder consultation conference was organised in September 2001 to consult with invited stakeholders.

The Communication, *Life Sciences and Biotechnology - A Strategy for Europe*, was presented by the European Commission in January 2002. The strategy consists of two parts: a policy paper and a 30-point plan of action. The strategy provides a vision for life sciences in Europe to 2010. The Communication was approved by both the European Parliament and the European Council.

The BSC continues to provide horizontal coordination on biotechnology. The European Commission produces an annual progress report on the implementation of the strategy, tracking progress made on the 30-point plan of action and incorporating emerging issues into the strategy.

#### **4) Machinery of Coordination**

The horizontal coordination of biotechnology has slowly evolved over time. In 1991, the Biotechnology Coordinating Committee (BCC) was formed. It included 13 Directorates-General and focussed on the technical aspects of biotechnology. It served as a communicating mechanism rather than as a decision-making one, allowing the different DGs to update each other and exchange ideas and views. Since it did not have a political dimension, its decisions were often overruled by the political level.

Acknowledging the weaknesses of the BCC, a political dimension was incorporated into the Biotechnology Steering Committee, in order that the key political issues to be included in the strategy could be discussed and decisions made. The BSC is made up of a mix of technical and policy people from the services and political staff of Commissioners.

Represented on the BSC are:

Cabinets for Commissioners:

- Internal Market
- Health and Consumer Protection
- Research
- Agriculture, Rural Development and Fisheries
- Trade
- Enterprise and Information Society
- Environment

Services (equivalent to departments):

- Agriculture
- Enterprise
- Market

- Research
- Trade
- Sanco – Health and Consumer Protection
- Environment

Technical Correspondents were also invited to attend meetings from:

- Legal Service
- Joint Research Centre
- Group of Policy Advisors
- Development
- Regional Policy
- Employment and Social Affairs
- Fisheries
- EuropeAid Cooperation Office
- External Relations

The BSC is chaired by the Deputy Secretary-General and coordinated by the Secretariat General. Communications (strategy and progress reports) are issued by the Secretariat General. Director-Generals or delegates sit on the BSC.

The BSC is now renewing and enlarging its membership.

## **5) *Opinions of Selected Interviewees***

### Political consensus

- The creation of the strategy is viewed by many involved in the process as a great accomplishment, representing the agreement of 13 Directorates-General on common goals and a commitment to a plan of action. While this agreement is impressive, it is difficult to predict what results will be achieved. There are so many contradictions, even within the individual governments of Member States, that finding a compromise on controversial issues at the EU-level is very challenging. Despite this reality, some issues are being resolved, ie. the Commission’s legislation on coexistence and the traceability and labelling of GMOs is moving through the political system.

### Schizophrenic Mess or Fine Balance

- The strategy is a “schizophrenic” document, full of internal contradictions. There is a strong pull in two directions, with the promoters of biotech pulling one way and the regulators pulling in the other. Different parts of the strategy were written by different Directorates-General, therefore making progress in one area of the strategy might reduce the likelihood of success in another.

- The challenge and value of the exercise was the production of a comprehensive and coherent policy. The two pillars of the policy are:
  - Promotion – stimulating innovation and its application
  - Control – securing societal and political control over new technologies

The document is not contradictory, rather it represents the balance point between these two diverging impulses.

### The Biotechnology Steering Group

- The BSC was a unique effort. The large numbers of services involved and the sensitivity of the subject required an unusually formal approach, one that incorporated representatives of political decisionmakers directly into the process. A key to success was the uncharacteristically non-hierarchical nature of the committee. The BSC directly involved the people with the practical knowledge and authority to make decisions, regardless of level.
- The Commissioners involved shared a common basic orientation: biotechnology is an important new technology and should be promoted, but appropriate control needs to be in place. This common orientation facilitated the process and was the cornerstone of collaboration.

# Appendix C: Japan – Country Study

## 1) Policy Objectives – Desired Outcomes

Paraphrased from *Biotechnology Strategy Guidelines*:

Developments in biotechnology will be the most significant scientific results of the 21<sup>st</sup> Century. Biotechnology will give rise to great changes, both in industry and in human life on this planet. While we must face biotech-related issues of ethics and safety head-on, it is absolutely necessary for our would-be techno-superpower to link the fruit of the outstanding developments in biotechnology to both improvements in the lives of our citizenry, and to industry and manufacturing.

## 2) Policy Specifics

A driving force behind the creation of a national strategy was the realization that despite biotechnology's importance for the national economy and the quality of life of citizens, Japan was lagging behind Western countries, especially the United States.

The strategy guidelines aim to promote biotechnology in Japan through public- and private-sector efforts to achieve:

- 1) overwhelming enhancement of R&D
- 2) fundamental strengthening of the industrialization process
- 3) thorough understanding of the people

## 3) Policy Development Process

Since the late 1990s, industry has put pressure on government to develop a national strategy on biotechnology.

In the late 1990s, an IT Council, a standing advisory committee chaired by the Prime Minister, served to direct funding for a comprehensive approach to IT. The Biotechnology Strategy Council (BTSC) was convened in June 2002, based on this model, with the aim of establishing and promoting a national strategy for biotechnology.

The BTSC is made up of Cabinet Ministers, the Prime Minister and leaders from academia and industry. After several months of deliberations, in November 2002, the BTSC produced the Biotechnology Strategy Guidelines to act as government's biotechnology plan to 2010.

Previous attention paid by the Japanese government to biotechnology was focussed on R&D. The Biotechnology Strategy Guidelines broadens the approach to include the industrial, commercial and public environment aspects of biotechnology. The Biotechnology Strategy



Guidelines include 50 guiding principles, 88 basic action plans and 200 detailed action plans. Responsibility for its different components has been given to different parts of government.

#### **4) Machinery of Coordination**

Horizontal coordination across departments is managed by the Cabinet Secretariat and Cabinet Office.

##### The Biotechnology Strategy Council (BTSC)

The Biotechnology Strategy Council was created in 2002 to create a national strategy on biotechnology. It is an advisory council attached to the Prime Minister's Office. Included on the Council are the Prime Minister, relevant Cabinet Ministers and 12 members from industry and academia.

The BTSC will continue to oversee the implementation of the guidelines and associated action plans.

##### The Council for Science and Technology Policy (CSTP)

The BTSC is closely linked to CSTP, which provides administrative support.

The CSTP is one of the national supreme councils attached to Cabinet Office. It formulates policy and ensures the general coordination of science and technology in Japan. The Prime Minister chairs the Council and 14 members are appointed, including the Chief Cabinet Secretary and the Minister of State for Science and Technology Policy.

Under the leadership of the Prime Minister, the Director General for Science and Technology Policy supports policy formation and general coordination on science and technology issues throughout the government and plays the role of a secretariat for the Council by information gathering and situation analysis regarding trends and prospects of science and technology both in Japan and abroad.

#### **5) Opinions of Selected Interviewees**

- Reforming institutions to better facilitate biotechnology has proven difficult. According to one of the industry members of the BTSC, Katsuhiko Utada, in an interview with *Science and Technology Japan*, "When we negotiated with the various ministries and agencies, we had to face intense opposition from working-level officials even though we had approval at ministerial level... We had to deal with strong resistance in such regards as budget, deregulation, institutional reform, and so on"

- During the development of the Strategy Guidelines there was a lack of the strong leadership for horizontal cooperation. The Cabinet Office was a coordinator between the Ministries, but did not have very strong power. The Ministries already had their own plans for biotechnology. It was difficult to create new general and cross-departmental plans. The Guidelines include many of the Ministries' existing plans.

## Appendix D: United Kingdom – Country Study

### 1) Policy Objectives – Desired Outcomes

As taken from *ibio*, the UK cross-government biotechnology web portal:

The UK Government promotes scientific innovation as a driver of human progress, and supports the balanced and regulated use of biotechnology as a new frontier in science. The UK's world-class science base is continually generating important new products, and is therefore successfully investing in a future productive base. The Government believes it is critical to allow scientists to find the facts, and let society judge and govern the next stages to which those facts are taken. This process must encompass a balanced and careful examination of all the implications, including key risks and benefits, which means it is important to raise the standard of debate on the complex issues surrounding biotechnology.

### 2) Policy Specifics

The UK government does not have one policy document that encompasses all aspects of biotechnology. Instead issues are addressed as they arise (see the advisory framework example below).

Individual departments do have specific biotechnology policy documents. Most recently, in June 2003, the Department of Health released a White Paper, *Our Inheritance, Our Future – Realising the potential of genetics in the NHS*. The document sets out the Government's commitment to realise the benefits of genetics within the National Health System by investing more than £50 million over three years.

### 3) Policy Development Process

In the UK, biotechnology did not become a hot political issue until the late 1990's. In 1998, the Minister of Environment and Minister of Agriculture, appearing before a parliamentary committee, made a joint announcement on a pause in the commercialization of GM crops. A Cabinet Sub-Committee on Biotechnology was created in 1999 to address biotechnology issues.

The UK has a highly developed approach to integrating scientific advice into policy-making. A wide variety of committees feed in at various levels of government to provide advice on science and technology-related issues. In 1998, the Cabinet Office and Office of Science and Technology carried out a government review examining the regulatory and advisory framework in place to deal with biotechnology and made recommendations on how it could be better tailored to meet biotechnology's growing demands. Out of this review the government created an advisory structure to set a strategic framework for the development of biotechnology in the

UK. Independent, multidisciplinary and transparent advisory bodies were set up to provide the government with the necessary expert advice (see machinery of coordination section below).

More recently, in 2002, in the wake of public reaction toward GM foods, the UK Government began a national dialogue on genetic modification led by the Cabinet Office and the Office of Science and Technology. The dialogue involves three strands: a science review, an economic study and a public debate. The exercise is an effort to inform public debate, demonstrate that government is responsive to all concerns and proceed cautiously on the issue.

#### **4) Machinery of Coordination**

##### The Political Level

The Secretary of State for Trade and Industry has overall responsibility for the Government's science policy and support for science and technology in her cross-Departmental role as the Cabinet Minister for Science and Technology. She is supported in this role by the Department of Trade and Industry, the Minister of Science and the Office of Science and Technology.

##### The Cabinet Sub-Committee on Biotechnology

The Cabinet Sub-Committee on Biotechnology rarely meets and does so only when an issue arises that requires a high-level political response. Much of the horizontal coordination of biotechnology happens at the bureaucratic level. An Officials Committee meets on an ad hoc basis and is issues-based (recently they have been meeting frequently on issues surrounding the GM review and response to new EU legislation on the traceability and labelling of GMOs). Much of the coordination is done on an informal basis.

##### The Cabinet Office

The Cabinet Office is often the lead in the UK government's responses to politically sensitive issues. Its Strategy Unit recently finished the economic review portion of the GM dialogue.

##### The Chief Scientific Adviser and the Office of Science and Technology

The Chief Scientific Adviser is responsible for coordinating government policy on science and technology both nationally and internationally. The Chief Scientific Adviser heads up the Office of Science and Technology (OST), housed in the Department of Trade and Industry, and reports directly to both the Cabinet Office and the Minister responsible for the Department of Trade and Industry. The OST's largest role is allocating the government's R&D funding through the Research Councils. It also assists the Chief Scientific Adviser by carrying out transdepartmental coordination for science and technology.

## The Advisory Framework

As discussed above, there are many advisory bodies that feed into government decision-making around biotechnology. In 1999, the Government's review of the advisory and regulatory framework for biotechnology led to the creation of three new bodies:

- The already existing Food Standards Agency was given a new responsibility for all aspects of safety of GM foods
- The Human Genetics Commission, to advise on genetic technologies and their impact on humans (reporting directly to Health and Science Ministers)
- The Agriculture and Environment Biotechnology Commission, to advise on all other aspects of biotechnology (reporting to the Chair of the Cabinet Sub-Committee on Biotechnology)

These advisory bodies are made up of outside experts, representing the broad range of stakeholders involved with biotechnology. They are funded by government, but independent.

### **5) *Opinions of Selected Interviewees***

- There is an extremely strong science base in the UK. However, being part of the European Union is an incredibly time-consuming process which adds another level of debate to the resolution of every issue. Even after the UK has made a decision on an issue, issues are usually held up at the EU-level. The length of the process is damaging for innovation opportunities.
- The UK has made special effort to address biotechnology's most controversial elements in as thorough and transparent a manner possible. Maintaining public confidence in the system is extremely important.
- Informal horizontal coordination is the predominant mode of operation of the Officials Committee that operates under the Sub-Committee on Biotechnology. Usually, the lead department writes a letter outlining a proposal and other departments respond.

## Appendix E: United States – Country Study

### 1) *Policy Objectives – Desired Outcomes*

In the US, science and technology policy focuses on promoting research and development. Current policy reflects overall government priorities: winning the war on terrorism, protecting the homeland and reviving the economy.

### 2) *Policy Development Process*

In the US, biotechnology was the target of focussed attention in the 1980s and early 1990s. This attention concentrated on issues involving the regulation of biotechnology and the funding of research. In 1991, the President's Council on Competitiveness issued a *Report on National Biotechnology Policy*, which offered a detailed look at the portfolio and how it was funded. Potential bottlenecks were an important issue at this time.

At present there is no one within government pressing for this level of attention to be put on biotechnology. A Biotechnology Sub-Committee of the National Science and Technology Council still exists but never meets. Biotechnology is now being handled like any other technology. There is no concerted effort to promote biotechnology over other kinds of technology.

In the opinion of officials interviewed for this paper, the government's priority has been a regulatory system that is entirely science-based and beyond reproach. This is important in obtaining public acceptance of new technologies and in encouraging industry by sending them clear signals.

### 3) *Machinery of Coordination*

#### Office of Science and Technology Policy (OSTP)

The Office of Science and Technology Policy has two primary functions: to coordinate federal R&D activities and to provide science and technology advice to the President. The OSTP reports directly to the Executive Office of the President and also supports the National Science and Technology Council and the President's Council of Advisors on Science and Technology.

#### The National Science and Technology Council (NSTC)

The National Science and Technology Council is a Cabinet-level Council chaired by the President. The NSTC coordinates the diverse parts of the federal research and development



enterprise. The NTSC prepares research and development strategies that are coordinated across agencies to form an investment package aimed at accomplishing national goals.

The Council has a Subcommittee on Biotechnology which never meets. A Steering Group (at the Program Manager level) meets on a quarterly basis. The OSTP coordinates this steering group which is charged with the coordination of research funding for life sciences. It also coordinates a Working Group on Agriculture and Biotechnology (involving policy-level people as well as technical people), connected to the National Economic Council, which coordinates discussion amongst regulators on regulatory overlap. This Working Group meets as issues arise.

### President's Council of Advisors on Science and Technology (PCAST)

The President's Council of Advisors on Science and Technology was formed in 1990 to enable the President to receive advice from the private sector and academic community on technology, scientific research priorities, and math and science education.

### President's Council on Bioethics

The Council was created in 2001 to advise the President on bioethical issues that emerge as a consequence of advances in biomedical science and technology. Council members are drawn from industry, education, and research institutions, and nongovernmental organizations. Stem cell research has been one focus of the Council's work.

## **4) *Opinions of Selected Interviewees***

- The strength of the US approach is that by treating biotechnology as a technology like any other technology, it has avoided the demonization of biotechnology that has happened in other jurisdictions.

# Appendix F: Ontario - Province Study

## 1) Policy Objectives – Desired Outcomes

From the *Report of the BIOCouncil*:

The Ontario Government has set the goal of making Ontario the third-largest home of biotechnology in North America.

## 2) Policy Specifics

The Ontario Biotechnology Strategy's key aim is to promote innovation by encouraging R&D and facilitating commercialization. It has committed \$51 million over three years to a number of programs including the development of biotechnology clusters.

## 3) Policy Development Process

From 1995 to 2000 the Ontario Government did not make special efforts to support any one industry. Instead they focussed on creating the macro-economic conditions for economic growth and development which would benefit all industries.

Over 2000-2002, biotechnology was identified as an issue and a government commitment was made in the Throne Speech to hold BIO2002, a large biotechnology conference, in Toronto.

In 2001, the Minister of Enterprise, Opportunity and Innovation formed the BIOCouncil, a combination of business leaders and key Deputy Ministers, to develop a possible strategy that would move Ontario towards its goal of being the third largest home of the biotechnology industry in North America. In March 2002, the *Report of the BIOCouncil: Building Ontario's Biotechnology Corridor*, was issued.

This report served as the base for the Ontario Biotechnology Strategy which was announced in June 2002. The strategy is program-focussed rather than a statement of broader policy. It sees the government as a catalyst for the growth of the biotechnology industry. Its two major goals are to provide an environment attractive to start-ups and to facilitate the process by which mature parts of the biotechnology industry enter into the production phase. The Ontario Government wanted to capitalize on BIO2002 as a high-profile opportunity to promote Ontario as a centre for biotechnology. Due to the political commitments made, the strategy went through the development, legislative and implementation phases very quickly.

#### **4) Machinery of Coordination**

Five departments were involved in the horizontal coordination around the biotechnology strategy:

- Minister of Enterprise, Opportunity and Innovation (MEOI)
- Ministry of Agriculture and Food (OMAF)
- Ministry of Natural Resources
- Ministry of Health
- Ministry of Municipal Affairs and Housing

At the start of 2001 these ministries formed a working group to work on the strategy with MEOI in the lead. The Ontario Biotechnology Secretariat, part of MEOI, was responsible for coordinating this working group as well as the work of the BIOCouncil.

A formalized ADM Science and Technology Council meets four times a year. Several standing working groups exist that deal with biotechnology and feed into the Council, with participation at the ADM, Director and Manager level:

- Pharmaceuticals
- Bioproducts
- Agriculture and Food
- Biotechnology Cluster

These working groups meet on an on-going basis.

#### **Special Coordinating Secretariat on Business Climate**

Horizontal coordination in the Ontario Public Service has been facilitated at a broader level by the work of a Special Coordinating Secretariat on Business Climate run out of MEOI. The purpose of the secretariat is to increase capacity to work horizontally, and build this into the culture of the public service. Its work has focussed on improving the learning capacity of the public service, coordinating information-gathering and results-sharing, and facilitating cross-ministry projects. The secretariat is financed by contributions from participating ministries.

#### **5) Opinions of Selected Interviewees**

- The Ontario Biotechnology Strategy was developed very quickly. Essential to this speed was the political commitment made in the Throne Speech which made what had been a departmental interest, a government priority. The personal commitment of the Minister and senior civil servants was also key to pushing the issue forward quickly. Without these elements the process would have been much slower and subject to the vagaries of competing interests.

- Initially, the life sciences working group involved 11 ministries. This was too big to be effective. The working groups on biotechnology now only involve the key ministries, which facilitates the speed of the process.
- The cluster approach focuses on building on strengths. Results are the focus rather than the equal distribution of benefits. This approach may be easier to take at the provincial level than at the federal.
- The next wave of biotechnology will require different strategies and different approaches. Not all biotechnology areas need the same things; biomedical applications require a focus on encouraging research and commercialization, bioproducts require working with existing industry. The problem with lumping all of biotechnology together is that you can get arrested at the policy-level rather than focussing on targeted programs and activities.

## Appendix G: Quebec - Province Study

### 1) Policy Development

While the province has a vigorous and competitive biotechnology industry and numerous government programs and measures to advance biotechnology, the Government of Quebec has not chosen to develop a policy or strategy devoted exclusively to the field. Instead, reflecting the view that biotechnology is an enabling technology and not (or not yet) an industrial sector in its own right, biotechnology is usually found as an element of a broader discussions about an industry, research theme, or initiative. For example, biotechnology is examined in the recently developed portrait of the pharmaceutical industry, *La filiere du medicaments*.

The *Quebec Policy on Science and Innovation: Knowledge to Change the World* which was released in 1999 remains the dominant science and technology policy in the province. There is no particular focus placed on biotechnology in the document, rather there are brief, scattered reference throughout. For example, the pharmaceutical sector has been identified as a “leading-edge sector served by the world’s 10<sup>th</sup> largest research centre in biotechnology”. The contribution of biotechnology to “established sectors” is briefly noted, and both biotechnology and geomatics are listed as “expanding economic sectors”. Under “Highly promising research sectors”, reference is made to the fact that genomics and proteomics are arousing interest in the health services sector, medicine and in the pharmaceutical and agri-foods industries.

In a follow-up document to the *Quebec Policy on Science and Innovation - First-Year Results*, the Government reported progress in a number of the areas with a biotechnology component. For example they refer to support by the Ministère de la Recherche, de la Science et de la Technologie with the Ministère de l’Industrie and du Commerce for business “incubation projects, especially in biotechnologies”. Looking forward, they noted that GMOs, which had recently been the subject of an opinion document from the Conseil de la science et la technologie (an arms length policy research body created by the Government), will “be the subject of a special concern for upcoming activities”.

There is broad strategic thinking about biotechnology emerging outside government circles. For example, BIOQuebec, the Quebec bio-industries network recently organized a summit of approximately 100 of the key players in biotechnology (from industry, finance, academic and governmental spheres) during which the participants worked on a plan of action. Their deliberations were informed by several papers, including *Biotechnology in Quebec; An analysis based on 8 growth conditions*.

### 2) Machinery of Coordination

Prior to the change of government in 2002, two separate ministries were the main centres of interest in biotechnology: Ministère de la Recherche, de le Science, et de la Technlogie and Ministère de l’Industrie et la Commerce. They both now form a part of the Ministère de Developpement economique et regional. Another ministry which is referred to as concerned with



biotechnology is the Ministère de l'Agriculture, des Pêcheries et de l'Alimentation. Reflecting the policy view that biotechnology is an enabling technology, there is no structure or mechanism for coordination of issues or activities within the Government of Quebec. A manager who was invited to sit on a Government of Canada committee on biotechnology reported that he had never previously needed the horizontal perspective reflected in the questions posed around the table in Ottawa, and to answer them he had to call numerous colleagues in Quebec. Neither is there a group of officials who meet on an on-going basis to coordinate policy and program in science and technology as a whole.

### **3) *Opinions of Selected Interviewees***

- When asked to comment on whether they thought there was a need in Quebec to develop a policy or strategy (and corresponding structures) on biotechnology, only one interviewee thought that such a policy was needed. He argued that it might help focus activities underway and garner political attention.
- The majority view is that the current Quebec approach is the right one, arguing that:
  - It is difficult to define the boundaries of biotechnology. It touches on too many domains.
  - The issues of biotechnology differ from industry to industry.
  - Biotechnology's challenges are not unique but are shared by all of Quebec industry – lack of capitalization, etc.
  - The S&T community in Quebec is relatively cohesive and coordination easily affected by means less formal than committee.

A number of those interviewed also mentioned events and activities convened by industry and others outside government which bring together key players in biotechnology in Quebec.

## Appendix H: Key Documents

### Australia

*Australian Biotechnology: A National Strategy 2000*

[http://www.biotechnology.gov.au/content/controlfiles/display\\_details.cfm?ObjectID=2361564D-1B3F-4B2D-82C5AA330F344CC6](http://www.biotechnology.gov.au/content/controlfiles/display_details.cfm?ObjectID=2361564D-1B3F-4B2D-82C5AA330F344CC6)

*Australian Biotechnology: Progress and Achievements 2000*

[http://www.biotechnology.gov.au/content/controlfiles/display\\_details.cfm?ObjectID=2361564D-1B3F-4B2D-82C5AA330F344CC6](http://www.biotechnology.gov.au/content/controlfiles/display_details.cfm?ObjectID=2361564D-1B3F-4B2D-82C5AA330F344CC6)

Mid-term Review of the National Biotechnology Strategy 2002

[http://www.biotechnology.gov.au/content/controlfiles/display\\_details.cfm?ObjectID=F3EF3A7C-6A51-441A-8A12784243DFC704](http://www.biotechnology.gov.au/content/controlfiles/display_details.cfm?ObjectID=F3EF3A7C-6A51-441A-8A12784243DFC704)

Gene Technology Act 2000

<http://sca.text.law.gov.au/html/pasteact/3/3428/top.htm>

### European Union

*Life sciences and biotechnology – A Strategy for Europe*

Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions, 23.1.2002

[http://europa.eu.int/eur-lex/en/com/cnc/2002/com2002\\_0027en01.pdf](http://europa.eu.int/eur-lex/en/com/cnc/2002/com2002_0027en01.pdf)

*Life sciences and biotechnology – A Strategy for Europe, Progress Report and Future Orientations*

Communication from the Commission to the European Parliament, to the Council and to the European Economic and Social Committee

[http://www.europa.eu.int/comm/biotechnology/pdf/com2003-96\\_en.pdf](http://www.europa.eu.int/comm/biotechnology/pdf/com2003-96_en.pdf)

*Internal co-ordination on life sciences and biotechnology*

Communication from the President to the Commission, Draft

### Japan

*Biotechnology Strategy Guidelines*

<http://www.biojapan.org/industry/reports/Biostrategy.pdf>



## United Kingdom

*The Advisory and Regulatory Framework for Biotechnology: Report from the Government's Review, 1999*, produced by the Cabinet Office and the Office of Science and Technology  
[http://www.ost.gov.uk/policy/issues/biotech\\_report/index.htm](http://www.ost.gov.uk/policy/issues/biotech_report/index.htm)

*A scenario for success in 2005: Biotechnology in the UK*  
<http://www.ost.gov.uk/policy/futures/biotechnology/index.htm>

*Our inheritance, our future: realising the potential of genetics in the NHS*  
<http://www.doh.gov.uk/genetics/whitepaper.htm>

## Ontario

*Report of the BIOCouncil: Building Ontario's Biotechnology Corridor* March 2002  
<http://www.biotechontario.com/pdf/BIOCouncil%20Report.pdf>

News Release from Premier's Office, "Ontario Launches \$51 Million Dollar Strategy to Become Global Leader in Biotech Research", June 7, 2002  
<http://www.premier.gov.on.ca/english/news/2002/Biotech060702.asp>

## Quebec

*Quebec Policy on Science and Innovation: Knowledge to Change the World*  
[http://www.mrst.gouv.qc.ca/\\_an/politique/document.html](http://www.mrst.gouv.qc.ca/_an/politique/document.html)

*Quebec Policy on Science and Innovation – First-Year Results*  
[http://www.mrst.gouv.qc.ca/\\_an/politique/bilan.html](http://www.mrst.gouv.qc.ca/_an/politique/bilan.html)



## Appendix I: Key Web Sites

### Australia

Biotechnology Australia

<http://www.biotechnology.gov.au/>

Office of the Gene Technology Regulator

<http://www.iogtr.gov.au/>

### European Union

European Commission Biotechnology Web page

<http://www.europa.eu.int/comm/biotechnology/index.html>

European Commission Research Directorate-General Biosociety Web page

[http://europa.eu.int/comm/research/biosociety/index\\_en.htm](http://europa.eu.int/comm/research/biosociety/index_en.htm)

### Japan

Prime Minister's Web Site – Concerning the Biotechnology Strategy Council

[http://www.kantei.go.jp/foreign/policy/bt/konkyo\\_e.html](http://www.kantei.go.jp/foreign/policy/bt/konkyo_e.html)

### United Kingdom

Agriculture and Environment Biotechnology Commission (AEBC) Web Site

<http://www.aebc.gov.uk/>

GM Nation? The public debate

<http://www.gmnation.org.uk/index.html>

GM Science Review led by the Chief Scientific Adviser

<http://www.gmsciencedebate.org.uk/>

Human Genetics Commission (HGC) Web Site

<http://www.hgc.gov.uk/>

ibio UK– the UK cross-government biotechnology portal

<http://www.dti.gov.uk/bioguide/>

Ministerial Sub-Committee on Biotechnology

[http://www.cabinet-office.gov.uk/cabsec/2003/cabcom/sci\\_bio.htm](http://www.cabinet-office.gov.uk/cabsec/2003/cabcom/sci_bio.htm)



Office of Science and Technology  
[http://www.ost.gov.uk/index\\_v4.htm](http://www.ost.gov.uk/index_v4.htm)

Prime Minister's Strategy Unit – GM Crops Project  
<http://www.number10.gov.uk/output/Page3673.asp>

## United States

National Science and Technology Council  
[http://www.ostp.gov/NSTC/html/NSTC\\_Home.html](http://www.ostp.gov/NSTC/html/NSTC_Home.html)

Office of Science and Technology Policy  
<http://www.ostp.gov/>

President's Council of Advisors on Science and Technology  
<http://www.ostp.gov/PCAST/pcast.html>

President's Council on Bioethics  
<http://www.bioethics.gov/>

## Quebec

BIOQuébec  
<http://www.bioquebec.com/>

Conseil de la science et de la technologie  
<http://www.cst.gouv.qc.ca/>

Ministère de la Recherche, de la Science et de la Technologie – Québec Policy on Science and Innovation  
[http://www.mrst.gouv.qc.ca/\\_an/politique/index.html](http://www.mrst.gouv.qc.ca/_an/politique/index.html)



## Appendix J: List of Interviewees

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