



Institute On  
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Institut sur  
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Final Report – Institute On Governance  
Executive Workshop on Biotechnology –  
May 25-26, 2004

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# Report on the Executive Workshop on Biotechnology Institute On Governance

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## **Executive Summary**

On May 25-26, 2004, the Institute On Governance held an Executive Workshop on biotechnology in Ottawa for approximately 50 persons. Half were senior representatives of federal departments & agencies, the other half, representatives of industry, civil society organizations, provinces and academia. The workshop was held under the patronage of Dr. Arthur Carty, National Science Advisor to the Prime Minister, and was executed in collaboration with the Canadian Biotechnology Secretariat.

The purpose was to examine, from a national perspective, both the potential and the concerns associated with biotechnology, to consider how different parts of society could work together to deal with its possibilities, to identify priorities and develop an action program. The following results were achieved through the extensive dialogue among participants at the event.

Participants noted that not every aspect of biotechnology could be addressed within the time available – for example, security and defence concerns were not discussed. However, the conversation was broad ranging and it identified five major priorities or themes.

With respect to the first priority, *national leadership and governance mechanisms*, participants commented that the federal government has a leadership responsibility that it should be discharging. Key legislation such as the Patent Act is outdated. While a lot of money is being spent by the federal government on biotech, we do not know how well those funds are being allocated to priority needs. Stronger ‘horizontal governance’ is required. Participants called for a clear statement from the federal government: recognizing the value of biotechnology in meeting Canadian social and economic objectives, and identified six other action steps that could improve leadership at the national level (see pages 9-10).

Strong concerns were expressed with respect to the lack of *regulatory responsiveness and coherence* (priority no. 2). Canada’s regulatory approach was described as traditional, reactive, resource-intensive, responding after demand, often guided by outdated acts and regulations and lacking a strong international focus. Participants cited the need to build incentives into the system to promote innovation and proposed that the government set a timetable for systematic review of relevant legislation, as well as other measures (see page 11).

The third priority was *effective commercialization of Canadian innovation*. Here, participants identified problems with respect to capital investment, the lack of forums to bring people together to discuss commercialization opportunities, and the need for better measures to address the requirements of SMEs. Canada needs to think in terms of an overall system or ‘railroad’ for biotech development, from R&D through to the commercialization process, from small start-up to larger receptor companies that can compete internationally. We need to conceptualize what this biotech railroad looks like and make sure that critical segments are not weak or missing. Eleven action steps were proposed addressing issues such as financing, the legislative framework, human resource needs and other dimensions of commercialization (see pages 15-16).

*Social, ethical & quality of life issues* were seen as closely linked to the need for better strategies for *public engagement* on biotech issues. Mechanisms for dealing with the ethical and related aspects of biotech were called into question. These considerations were brought up too late in the decision-making process, and processes for securing public input were not sufficiently effective. Various ideas on improving this situation were discussed, including improvements in public education, earlier involvement of citizens in consultation, better collaboration with the media, and more rigorous methods of monitoring and evaluating progress. Four action steps were proposed (see page 18-19).

The fifth theme or priority area identified was *meeting the needs of developing countries*. We have a responsibility to developing countries but do not know how to connect to them, and they lack the ability to innovate or to import Canadian goods. Participants called for a strategic investment framework that could help define targets for investment in developing countries and facilitate the flow of ideas and capital. It was suggested that Canada might, possibly following some leads provided by the Swiss, become a leader in facilitating the responsible use and application of biotech in these countries (pages 20-21).

Complementing these ideas, Dr. Carty concluded the workshop by making a number of important commitments. These included:

- Bringing workshop results to the attention of the relevant federal committee of Assistant Deputy Ministers and also to that of Deputy Ministers
- Assembling a small, influential group of ‘wise persons’ who could help make the case re the importance of biotech to the federal government, and who could counsel on strategies to improve collaborative arrangements among stakeholders inside and outside government
- Elaborating the concept of the Canadian ‘biotech railway’ as a way of taking a more systemic view of needs and potential at a national level, and as a framework for considering how to promote innovation (see page 6, also Appendix C).

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## **Acknowledgments**

On behalf of Institute On Governance, I wish to express our appreciation to the following individuals and organizations who contributed to the success of this event:

- The participants: the program required a high degree of interaction among participants. There were few speeches or presentations. Without participants' cooperation, the event would never have succeeded. Our thanks to all who took time out of their own agendas to join in the program, and who provided so many thoughtful and at times vigorous contributions to the proceedings.
- Dr. Arthur Carty, National Science Advisor to the Prime Minister, for agreeing to act as patron for the Workshop, for his counsel on program content and objectives, for his active participation throughout the event, and for his commitment to action expressed in his closing remarks.
- Kim Elmslie, Executive Director, Canadian Biotechnology Secretariat, for her foresight in seeing the importance of this event, for her own collaboration and that of her colleague at the CS Secretariat, Glen Kendall, in shaping the program and in providing the bulk of the funding that made the workshop possible.
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André La Prairie  
Marc Saner
- For their assistance in shaping the program design: those many representatives of federal departments and agencies who took part in “working group” meetings hosted by the Institute prior to the workshop.
- The members of the IOG “Biotech Team” for this event, for their many, many hours of work before, during and after the workshop to ensure that the program ran flawlessly both substantively and logistically:  
Jennifer Chandler  
Andrew Davidge  
Marc Saner.

*Tim Plumptre, President, Institute On Governance*



## **1. Objectives of the Workshop**

On May 25-26, 2004, the Institute On Governance held an Executive Workshop on Biotechnology, under the patronage of the newly appointed National Science Advisor to the Prime Minister, Dr. Arthur Carty, and with the sponsorship of the Canadian Biotechnology Secretariat.

The goals were:

- (a) to consider the elements of the ‘system’ involved in developing biotechnology-based applications and products, regulating them, and making them available to citizens;
- (b) to take account of biotechnology’s social, ethical, cultural, economic and environmental implications;
- (c) to consider the different organizations and jurisdictions involved with biotechnology (both public and private sectors), the relationships between them, and the question of how to make connections between organizations work better, for the public good.
- (d) to identify major priorities that should be pursued so that Canada could reap the benefits of biotechnology while dealing responsibly with concerns to which it gives rise.

## **2. Participants, Program and Process**

Participants, approximately 50 in all, included senior federal public servants and a broad group of stakeholders from industry, academia and the non-profit sector.<sup>1</sup> Participants were roughly equally balanced between representatives from outside the federal government and officials from within federal departments and agencies.

The workshop opened with remarks by Dr. Carty<sup>2</sup> on the purpose of the event. A panel discussion profiled the views of three well-known Canadians, Maureen McTeer, author, Dr. Peter Morand, scientist, entrepreneur, and former President of the Natural Science and Engineering Research Council, and Dr. Robert Slater, scientist and until recently, Senior Assistant Deputy Minister, Environment Canada. The panel was chaired by Kathryn O’Hara, a prominent journalist and faculty member of Carleton University’s School of Journalism.<sup>3</sup>

The main portion of the program was devoted to small group discussion and feedback. The diversity of participants helped broaden the dialogue and led to results that reflect a national (rather than an exclusively federal) view of biotechnology, its promise and challenges.

The workshop moved participants through the following steps:

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<sup>1</sup> See Appendix A for a full participant list.

<sup>2</sup> See Appendix B.

<sup>3</sup> Comments from the panel members and the subsequent discussion have, where appropriate, been integrated into the overall ‘action plan’ developed through discussions at the workshop. See section 3 of this report

1. Identifying critical gaps and barriers to realizing biotechnology's potential for the benefit of Canadians and handling technology responsibly for the long-term good
2. Prioritizing issues and brainstorming on solutions
3. Developing action steps to address them.<sup>4</sup>

### **3. Workshop Results**

#### **3.1 Dr. Carty's Comments and Commitments**

At the conclusion of the workshop, Dr. Carty provided his comments on the results of the workshop and outlined list of actions that he would take, as National Science Advisor, to further its goals. Highlights of Dr. Carty's address:

- The discourse at the workshop was excellent, with great participation and openness
- Canada has made important progress in biotechnology, but to move forward now, there is a need for a national – not just a federal – Vision of how to deal responsibly with the promise of biotechnology in future
- He undertook to bring the outputs of the workshop to the attention of the Committee of ADMs and the Committee of Deputy Ministers charged with responsibilities related to biotechnology at the federal level.
- Dealing effectively with biotechnology will require federal collaboration or partnerships with the provinces and the private sector, both of which have important roles to play. To advance this collaboration, he stated his intention to assemble “a small group of credible, wise people with high profiles who can help us to make the case for clusters and commercialization in biotech and convince government to be a partner in actions.”
- Finally, he endorsed an idea proposed at the workshop, namely, the establishing “The Canadian Biotech Railway” as a national initiative – “building a national backbone which will link clusters and communities (nations) across the land, within the framework of putting all of the elements of an innovation system in place across the country”.<sup>5</sup>

#### **3.2 Barriers, Solutions and Actions, by Theme**

Discussions among participants generated a rich array of ideas. In the following section of this report, rather than provide a detailed record of all proceedings, we have chosen to collate the results of all sessions into five priority areas or themes identified by participants.<sup>6</sup>

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<sup>4</sup> The detailed agenda for the Workshop is in Appendix D.

<sup>5</sup> For the full text of Dr.Carty's address, see Appendix C.

<sup>6</sup> In some cases, notably at the last workshop session, due to limitations of time, facilitators were not able to report fully on the results of their discussions. However, IOG staff secured written copies of reports from each discussion and also took detailed notes throughout the workshop at all plenary sessions. While not every idea or viewpoint expressed at the workshop found its way into this report, we believe that all key suggestions have been captured; and we felt that a shorter, more focused report was more likely to be useful to participants than a very lengthy, less focused document that sought to capture every nuance of the discussion.



Each thematic section first outlines *gaps and barriers* that were thought to stand in the way of progress. The subsequent sub-section, entitled *Perspectives and Solutions*, reviews participants' comments on measures that could be taken and problems and possibilities associated with such measures. Each thematic section concludes with a list of *action steps* identified during discussions.

This report concludes with notes on several 'overarching issues' that participants considered important.

## **Theme One: National leadership and governance mechanisms**

### Gaps and barriers identified:

- Lack of priorities and goals for biotech at national level
- Unwillingness of politicians to engage in file
- Getting the Federal house in order
- Federal-provincial relationships
- Lack of coordination between provinces
- No metrics to manage investments
- Need for better performance measurement tools at the national level

### Perspectives and solutions

**National leadership:** National not federal leadership is required to establish the "winning conditions" for the application of a new technology. It is a fundamental obligation of government to assist a society to learn how to adjust or adapt to a new technology. If the federal government is not going to lead this exercise, who will? The end result could mean adopting, adapting, profiting from new technologies, or rejecting them. Society will ultimately make these decisions. The challenge for the federal government is to display national leadership without being paralyzed into inactivity due to fear of owning the issue. Federal government needs to recruit the players who will play a national role from the private sector, civil society the public at large.

**Convincing leadership of value of biotech:** Leadership has to emerge in biotech by altering the perceived cost-benefit analysis weighing action or inaction. The goal is not biotech for biotech's sake. The question is how can biotech help us meet national goals. Both leaders and the public would be more greatly interested in biotech's contribution in dealing with these priority issues. We need to energize biotech in pursuit of the issues leaders want to lead on, and encourage entrepreneurial activity in these areas. This would change the cost-benefit perception they have that effects their willingness to lead on biotech issues.

**Parliament:** The Schmeiser decision by the Supreme Court was a narrow application and extension of patenting to plants. Parliament should legislate on this matter in a broader sense.



This would open up real public debate on the Patent Act and what forms of life can be patented. It is paternalistic to not open these matters up to the public because they are believed not understand the issues. This is a debate about values. Having that debate should not be considered to be anti-business.

**Patent Act:** The Patent Act did not anticipate genetic engineering. Law on patenting of life and genes must be explicit (especially concerning human life). What we have now are narrow interpretations of outdated legislation. A new system is needed that gives the flexibility to make the best of new technology (possibly by limiting the scope and breadth of patents) while preserving commercial rights with the patent holder.

**Protecting the public health care system:** Far reaching patents on human genes can have a devastating impact on our publicly funded health system. Allowing the current business model, means a monopoly system. Even the most affluent countries will not be able to pay.

**Dual role of government:** Government is a leader and agenda-setter but also a corporation of sorts – its role as an operator of departments, organizations, facilities, with research capacity and human resources at its disposal to mobilize and direct towards objectives.

**Evaluating contribution to priority areas:** In its role as an operational manager, the Government of Canada has major assets to deploy. Currently we spend a lot on biotech. What we do not know is how well those resources are being allocated towards priority issues. This includes granting councils and foundations. The use of these resources is completely supply-driven, focussed on objectives rather than performance and market demand.

**Get own house in order:** The government has many responsibilities relating to the application of new technology. It finances science through universities and the private sector for the public good. It regulates the introduction of goods and services into the Canadian economy. It negotiates international agreements and promotes technological opportunities. It should also monitor and report on the results of these activities and distribute this information. To do this, you need to be able to work across the system in the federal government. There are three different types of horizontal management within the federal government: collaboration (working together when moving in the same direction), coherence (make efforts not to be overtly antagonistic – lining things up for neutral reinforcement) and coordination (moving toward common goals while working together on timing, resource allocation, level of effort). All three levels of horizontal management are required within the federal government. As well, it is important to have the right authority to work on the issue if you are going to work together to mobilize science toward national goals.

**Horizontality:** Recognition that this is a horizontal issue, requiring stronger horizontal governance (industry, public, academic, civil society) that addresses the contributions biotech can make from sector/issue perspective. These will be diverse, the impact and significance of biotechnology in natural resources management is very different than how it plays into leaders' interests in the health care system.



**Private and public sector cycles:** The problem is that biotech is not just a transformative technology, but a highly regulated transformative technology. The regulatory framework means a process of between 9-12 years (in the case of biotech’s application in the health area). This cycle is not in phase with government and investment cycles. How can government policy, whether it’s tax or technology transfer, be adapted to a different life cycle (which is higher risk)? As well, different applications of biotech bring with them different issues and unique and appropriate approaches need to be developed to encompass the entire range of these issues.

**Goal-specific systems:** To move toward solutions we need to develop systemic systems that supply leadership and structural and operational support akin to the efforts made to reduce the deficit. This also demands systems in place to develop and evaluate objectives, data collection to analyze supply and demand, performance metrics, systems to collectively manage and track performance and to ensure accountability.

Action items

<b>WHAT</b> <b>Goal to be Accomplished?</b>	<b>HOW</b> <b>Action steps required?</b>	<b>WHO</b> <b>Who should be Involved (initiate)?</b>
1. National leadership and governance	Communication, outreach and training along the lines of the Biotechnology Human Resource Council. Target wider political area: ministers and senior bureaucratic staff. Can be expanded to parliamentary arena as well by communicating to MPs the value of strategy/commitment in this area.	Ministers Senior bureaucrats
2. Leadership and horizontal management	Clear statement needed from federal government: recognizing the value of biotechnology in meeting Canadian social and economic objectives	Leadership of federal government: performance assessment built into Federal Government (tie Deputy Ministers’ performance objectives to moving biotech strategy forward)
3. Leadership and horizontal management	Embrace, energize and articulate already established national goals: two pillars of Environmental Technology and Health Innovation (rather than “biotech” as a whole)	Prime Minister as champion National Science Advisor Existing Science Advisory Bodies Senior public servants
4. Better federal government leadership and horizontal management	Alignment through a champion (such as the National Science Advisor) of objectives, horizontal policies and activities. One lead would be able to ensure a common focus.	Federal government

<b>WHAT</b>	<b>HOW</b>	<b>WHO</b>
<b>Goal to be Accomplished?</b>	<b>Action steps required?</b>	<b>Who should be Involved (initiate)?</b>
5. Communication between levels of government	Develop a new and ongoing mechanism that allows the three levels of government to talk to each other on biotech issues and sector development; to facilitate fed/prov/municipal communication and collaboration.	Federal Provincial Territorial Municipal (Central agencies, biotech coordinating units, relevant ministries)
6. To create/establish ongoing for a and points of contact within and across government to facilitate dialogue between private sector, government and other institutions in civil society to address biotech-related policy issues and sector development	Establish and hold a National Biotech Leaders Summit, held every 3 years and run by a third party – to involve all leaders from key organizations (private, government, non-government) to improve collective understanding and build collective support for biotech-related policy issues and sector development.	3 <sup>rd</sup> party, such as the IOG; National Science Advisor; Private sector organizations
7. Setting targets based on commitments	Measure performance of biotech activities in terms of meeting national priorities	

## **Theme two: Regulatory responsiveness and coherence**

### Gaps and barriers identified:

- Insufficient regulatory coherence – across departments of government, across jurisdictions – and lack of regulatory responsiveness to pace of technology
- Lack of international standardization across legislative frameworks
- Need an appropriate pace for our policy and regulatory framework
- Regulatory lag and gaps in dealing with new types of products

Perspectives and solutions

**Starting point:** Our regulatory approach is traditional, reactive, resource-intensive, responds after demand, is often guided by outdated acts and regulations and does not have a strong international focus.

**Needs:** Government should invest in regulatory research to explore new systems and approaches. Our regulatory approach should be in step with national goals and priorities. There should be more robust forms for discussion of the regulatory system. There should be clear international strategies for Canada.

**Approaches:** Canada’s regulatory system should have the capacity to recognize new challenges and build capacities ahead of the curve and carry out research to meet needs of regulators. In doing so, it should be recognized that there are different communities in regulation (basic scientists – risk assessors – science-policy interface). Regulatory agencies should continue to build relationships with the private sector and industry – improve trust and develop pre-market tools (e.g. tax software for industry).

Action items

<b>WHAT</b> <b>Goal to be Accomplished?</b>	<b>HOW</b> <b>Action steps required?</b>	<b>WHO</b> <b>Who should be Involved (initiate)?</b>
8. Turn regulatory system into an asset stimulating Canadian innovation	Build incentives into the regulatory system that promotes invention and innovation in Canada and sees Canadians benefit from their application	Health Canada Industry Canada
9. Clarify and solidify legislative frameworks to support appropriate adoption of biotech	Set a timetable for systemic reviews of legislative frameworks – to consider necessary changes due to biotechnology and other emerging technologies (privacy, patent, security, human rights, Health Protection Act, Canadian Environmental Protection Act); Legislation could also be updated to ensure that the benefits of IP derived from publicly funded research remain in Canada (potential model: Canadian Environmental Protection Act is reviewed every 5 years)	Federal Provincial Industry NGO

### Theme three: Effective commercialization of Canadian innovation

#### Gaps and barriers identified:

- Capital investment is poorly targeted, badly timed
  - Lack of early capital investment with sufficient depth to sustain growth
  - Focus of investment has been supply-side rather than demand side oriented
  - Lack of focus on needs of marketplace
  - Inability to achieve critical mass and compete internationally
- Lack of focus and forums to bring people together (clusters) to foster commercial progress.
  - Lack of a critical mass of people and focus on public private partnerships
  - Need focus and forums to bring people together for synergies re: (a) products (b) marketplace and (c) clear benefits
- Inadequate strategy aimed at small and medium enterprises (SMEs) to support commercialization

#### Perspectives and solutions

**Getting the basics right:** If we do not get commercialization right there will be little to govern. Government should work to create the right conditions for commercial activity (framework law, tax law). Get these basics right first before government starts playing venture capitalist.

**Biotech railroad:** We need to build railroads for biotech development, from R&D through to the commercialization process, from small start-up to larger receptor companies that can compete internationally. We need to conceptualize what this biotech railroad looks like and make sure that critical segments are not missing.

**Frogs or tadpoles:** Having too many small companies in Canada is not really the problem. It is a challenge to get IP into an entity that can make hard-nosed decisions and focussed investment. You can not do this in an university/institutional setting. That is the difference between funding research and funding products. Why do frogs lay 1,000 eggs – because not many survive? The important question is are we getting big frogs?

**Strong companies:** Only when strong products are produced will Canadians benefit from biotechnology. Companies produce products. Companies are central to value capture. We need to consider what are the right ingredients necessary to have strong companies in Canada.

**Networks of Centres of Excellence:** Networks of Centres of Excellence are a vehicle for looking at existing technology and pulling together areas of Canadian expertise so they can be world leaders. Biochips initiative is an example currently being pursued through µSIC Net



application. It also brings together scientists and social scientists to consider the full societal impact of the technology.

**Clusters:** The traditional cluster approach around geographic locations (example MARS Discovery District in Toronto) should be replicated in other areas where clusters make sense. As well as geographic clusters, thematic clusters can be created around specific fields of science and technology (Networks of Centres of Excellence are virtual clusters of this variety). Clusters can be used to pool intellectual property and capital (Stem Cell Network model sees agreement among scientists, universities and hospitals to pool IP and manage it collectively). The key here is to exploit IP pools by matching them with necessary capital. We can build on existing models and experience.

**Business models:** The description of functional clusters (IP, human resources, capital) is an interesting one. The traditional roles of corporations are maybe not appropriate for some of these challenges. Who is looking at different kinds of business models, different structures to deal with these technologies? Should Canadian business schools do this?

**Patent pooling:** We need to be innovative in creating the right conditions for commercialization. Some ideas: reactivate patent pooling which involves fitting together many pieces to make a greater whole, with a system of attribution in place to share benefits among contributors.

**Challenge:** In competing internationally, how can benefits be realized in Canada and how can value from publicly-funded research be preserved for Canadians. We need to develop conditions in Canada that allows companies to stay at home.

**Domestic commercialization:** We will not get a good return on our investments if we allow our investments to be commercialized by outside multinationals. The U.S. has a strategy for late stage commercialization, they have built a tax system which encourages companies to stay.

**Receptors:** We are good at creating small companies but less good at growing them. How do we take the wealth of small companies and create bigger receptor companies that retain value in Canada? We need pools of capital that can slam together the smaller companies.

**Getting incentives right:** Government structures/incentives should be put in place to support company growth beyond early stage. Risk capital is needed in sufficient quantity to support this (large institutional investment). Create structures to diversify risk for investors. Tax structures and government role in matching (pool resources around specific sectors) and free up private sector to do what they need to do. Currently are we creating disincentives through taxation to achieve critical mass?

**Pre-commercial activity:** We need to consolidate precommercial early stage science and technology with fewer bigger investors. Take national approaches to IP management in early stage science. An explicit strategy to build a sector or a company (like Bombardier in the transportation sector) could be helpful. There are not that many companies in Canada at the



commercialization stage. Many Canadian companies are spun off too early – need to support research “past the bench” in universities.

**Human resources:** When a company is at the commercialization stage a key challenge is to build the necessary skill set to take them through this process. Regulatory expertise is especially needed and there are generally not enough of these people active. Building networks and sharing expertise is one way to address this problem. Physical clustering and co-location should be encouraged.

**Diversity of biotech:** There is no one program for all biotech. Many of the issues facing the health biotech area are not the same as those faced by other subsets of biotech, like the bioindustrial area or agricultural biotech. They have different requirements and concerns – each sector has own set of rules and distinct most pressing needs at any particular time.

Action items

<b>WHAT</b> <b>Goal to be Accomplished?</b>	<b>HOW</b> <b>Action steps required?</b>	<b>WHO</b> <b>Who should be Involved (initiate)?</b>
10. Better results from federal R&D investments	Create a National S&T Applied Research Plan – to provide direction on priorities, focus on areas of high return and comparative advantage, and provide the critical mass to achieve results (potential model: NASA)	Federal government
11. Clarify and solidify legislative frameworks to support appropriate adoption of biotech	Set a timetable for systemic reviews of legislative frameworks – to consider necessary changes due to biotechnology and other emerging technologies (privacy, patent, security, human rights, Health Protection Act, Canadian Environmental Protection Act); Legislation could also updated to ensure that the benefits of IP derived from publicly funded research remain in Canada (potential model: Canadian Environmental Protection Act is reviewed every 5 years)	Federal Provincial Industry NGO
12. Improve value capture from Canadian Biotech industry	Develop the tools (e.g. communication tools) that would facilitate a Canadian-wide integration of clusters – linking up to share resources, expertise,	Federal government working as “midwife”

<b>WHAT</b>	<b>HOW</b>	<b>WHO</b>
<b>Goal to be Accomplished?</b>	<b>Action steps required?</b>	<b>Who should be Involved (initiate)?</b>
	experience	
13. Improve value capture from Canadian Biotech industry	Improve cluster formation with a view to improving geographic distribution (potential model: Labor Force Development Initiative)	Leadership of federal government – working with universities, provinces, municipalities and granting councils
14. Improve financing for early and late stages of commercialization	Mentorship programs to pass experience on from established companies to start-ups  Create incentives and tax credits Look at a different structure for how commercialization funding is supported by government (with grants for earlier stages and loans for late stages commercialization)	Partnerships between Canadian companies  BDC
15. Keeping benefits of biotech for Canadians by improving commercialization mid-stage	Create larger Canadian receptor companies which would allow the consolidation of smaller companies by domestic organizations rather than by foreign ones	Industry and industry networks
16. Improving commercialization	Develop mentorship program using mature developed companies to serve as a resource tool for developing companies	Industry
17. Greater private sector leadership and involvement	Encourage private sector companies and associations to unite efforts in support of goals related to national leadership and their participation in biotech-related governance	Private sector companies – CEOs Associations such as BIOTECanada and BIOQuebec
18. Keep benefits from Canadian biotech for Canadians by improving mid to late stage commercialization in Canada	<ul style="list-style-type: none"> <li>▪ Industry matchmaker/net</li> <li>▪ Offset/subsidize risk on commercialization of pharma</li> <li>▪ Link institutions/clusters/research hospitals</li> <li>▪ Access to capital pool</li> <li>▪ BDC needs new model(s) that are guided by private sector knowledge</li> </ul>	Industry Associations Federal (legislative change) Provinces Municipalities NGO

<b>WHAT</b>	<b>HOW</b>	<b>WHO</b>
<b>Goal to be Accomplished?</b>	<b>Action steps required?</b>	<b>Who should be Involved (initiate)?</b>
	and advice	
19. Improve commercialization	<ul style="list-style-type: none"> <li>▪ Develop mentorship program (expert panel, clinic) – skill set development</li> <li>▪ Resource pool, not run by academics or granting agencies</li> <li>▪ Road maps for early stage company</li> </ul>	Partnerships between Canadian companies NRC as a dispatcher BDC
20. Develop industry champions for Canadian Biotech Sector (small number of bigger companies that provide critical mass in global context)	<ul style="list-style-type: none"> <li>▪ Private sector venture capital fund (including public money) – financial tools to accelerate consolidation and growth</li> </ul>	Private sector Government Financial community

#### **Theme four: Social, ethical & quality of life issues and public engagement**

##### Gaps and barriers identified:

- Lack of adequate mechanisms to address the social, ethical and quality of life issues raised by biotechnology
  - Disconnect between governance systems and uptake (public or marketplace), especially in the health area.
  - Failure to address social and ethical issues sufficiently early and selectively (inadequate mechanisms)
  - Imbalance between who shares the benefits of biotechnology and who shares the risks
- Inadequate and insufficiently effective engagement of the public on biotech issues
  - Lack of ‘real’ public engagement
  - Lack of public understanding of science
  - Erosion of post secondary educational infrastructure (and funding problems for students) creates problems for the ‘knowledge economy’

## Perspectives and solutions

**Engaging Canadians:** Public attitudes determine the fate of technology – whether it will be accepted or rejected. Government has an extensive history of public opinion research in the area. If the government is to engage Canadians on the issue, they must be prepared to inform/educate on the topic and be prepared to use 3<sup>rd</sup> parties to do so.

**Preserving Trust:** Public opinion research shows that the Canadian public has a high level of trust in the federal government's performance as a regulator. This is a huge value to the federal government and it is very important to preserve because once lost it is very hard to regain. To do this the federal government must follow three approaches: 1) Be inclusive, make sure all parties are engaged, 2) Be transparent (be prepared to open up the books), 3) Be prepared to be held accountable for results (monitor and report on performance measurement).

**Starting point:** In a democracy, people are in charge, therefore what do Canadians want out of biotech if they want anything out of biotech at all? How do you find out what they want? Once you know what they want, how to implement that knowledge?

**Understand level of scientific literacy:** Currently there is no hard data on the level of science literacy in the general population. Some level of science literacy is important for an informed dialogue around these issues. Citizens understand values but not propositions brought forward by scientists. Mainstream education system is an important spot to begin public education and improve understanding of science. Scientists and academics also need to be educated about their responsibilities regarding broader social and ethical issues.

**Start engagement upstream:** Public engagement must start early. Genuine public deliberation can only happen if there is still a choice to make. Deliberating after the fact will not help. Issues should be broken down (health, environment, etc. rather than biotech as a whole). There should be dedicated bodies responsible for seeing that engagement and debate take place (example: Senate hearings on reproductive technology have brought in many different perspectives).

**Public information:** Government must deal with its mixed roles of promotion and regulation. When starting process, do it with care. Government has a role in providing information to the public, although this may be judged as propaganda. These efforts should not be focused on trying to convince public of benefits, but rather as an act encouraging transparency, to let them know what is going on.

**Tying in social/ethical issues to grants:** Government is a large funder of research. This leverage should be used to include components on social and ethical issues in grant giving (public engagement and reporting might be tied in as conditions for the grant).

**Evaluate performance:** Performance indicators must be developed that consider social and ethical issues. This is a constantly underfunded area that will come back to haunt us.



**Independent foundation:** A foundation for public engagement is needed – ex. Nuffield Council in the UK – gives out fellowships to journalists – lead to credible independent assessment of what is going on in technology. It could do early engagement, even at the research stage, on new technologies.

A foundation would be able to assist society in having a long-term social discourse of understanding tech so its benefits can be received. Serving media interests should not be the focus. The notion is broader than that.

**Media:** One way to deal with public is through the media. Initiatives are needed to deepen the media's understanding of complex issues (ex. Pew Foundation supporting civic journalism) and improve science literacy. Government must do this at arms length, can not be seen as propagandizing (paid advertisements 'trust us'). Media engagement with issues could happen with seminars and other civic journalism approaches. The President of the Canadian Science Writers' Association is now the President of the World Federation of Science Journalists. This existing infrastructure and focus on Canadian science writing should be capitalized on.

The people shaping the stories are people doing S&T (industry, university, government) – they have a lot of control. Reporters do not work on specific beats anymore. Out of vast array of what could be covered, media does not know which biotech would be of public interest and where it is in the pipeline, how significant, how long until it comes to market. We need a clearinghouse of information available to the media.

**Does the public know what they need?:** The public needs to tell us ahead of time what they want and need from biotech and they need to be informed about the possibilities and the role in their lives. We need to jettison something society does not want otherwise this technology will act as a barrier to progress. The general view is that need is the mother of invention. In fact invention is the grandmother of need (cell phone example – wait for the right time – people did not know they needed it for a long time after the technology was first available).

**Defining progress:** Public engagement processes need to be selective and evaluating key changes in science. An example is the cloning of humans. For example, China may have no rules on the cloning of humans and advance quickly in this field. Meanwhile North America may have decided that human cloning cannot be ethically pursued and fall behind technologically. If China is way ahead in this field, is the inference that North America is behind or are we actually ahead?

**Continuing process:** Public engagement is an iterative process. There must be a clear recognition that science advances will take place and public engagement on many issues will have to continue to be revisited.



## Action items

<b>WHAT</b> <b>Goal to be Accomplished?</b>	<b>HOW</b> <b>Action steps required?</b>	<b>WHO</b> <b>Who should be Involved (initiate)?</b>
21. Meaningful public engagement	Ensure a visible, credible place for public engagement. Could be an already existing organization, such as CBAC or NRTEE (provided with appropriate resources). Or could involve the creation of a new foundation to act as a visible, credible place for public engagement (include media opportunities, fellowships).	
22. Address public education and input	Create an independent research body that would evaluate and comment on the direction of S&T policy broadly, and also play a role in public education and citizen engagement and participation. The body would be independent of government and not simply an expansion of existing science advisory bodies. (potential model: Nuffield Council in UK)	Not National Science Advisor Not existing science advisory bodies
23. Assessing social and ethical implications and enhancing public engagement	Undertake retrospective study of introducing Roundup Ready canola in Canada (social, ethical, economic, environmental and other implications). Look backward to identify gaps, learn from mistakes in order to make sure appropriate systems are in place for the future.	CBAC NRTEE New foundation on public engagement
24. Public confidence	Report card to public from start to finish	Canadian companies

## **Theme five: Meeting the needs of developing countries**

### Gaps and barriers identified

- We have a responsibility to developing countries but do not know how to connect to them
- Inability of developing countries to innovate and import Canadian goods

## Perspectives and Solutions

Need for a strategic framework for investment and action, including:

- Setting targets and priorities for investment in developing country context characterized by: an ends focus – disease and problem focus (not all things to all people, identify niches and target areas), specific partnerships with foundations (like Gates) active in the area, institutional foci, not one size fits all (poorest of the poor nations and economies in transition have different needs and requirements)
- Parallel suite of policy and capacity building and programming (build receptor capacity in country to deal with issues arising from technology)
- Technological solutions must be put in context – only one among a number of strategies to meet goals
- Increase availability of information on Canadian technological capacity targeted at developing country needs
- Increase availability of information on developing country needs for technology (matched with our needs). Create broader program of S&T advisors in DFAIT that connects to developing countries
- Encourage foreign direct investment from private sector to buttress investment related to S&T and do so in a manner that avoids fragmentation and disconnection with other investment
- Canada should take a leadership role in international fora. Currently we are not visible (the Swiss are, bilaterally and in developing countries). We need to show more leadership in the UN system. The Canadian leadership position could be enhanced by joining the UN Commission on Science and Technology for Development (UNCSTD).

**Private sector:** Canadian private sector can become involved by providing inducements that facilitate the establishment of SMEs in developing countries (communicate information on opportunities where Canadians can benefit). The Swiss are doing these things. They actually finance technology transfer and facilitate investment, which builds stronger linkages and partnering with developing countries. The challenge will be for Canadian companies to see the potential in working in the developing world when many companies fight to survive domestically and in the rest of the developed world.

Encouraging private sector involvement is very different under the conditions of different nations in the developing world: poorest of the poor where the impetus for action is social and moral vs. economies in transition where the business opportunities are more traditional. This issue is definitely visible in other countries – in the U.S., the Gates Foundation has played a role in mobilizing the private sector.



Action items

<b>WHAT</b> <b>Goal to be Accomplished?</b>	<b>HOW</b> <b>Action steps required?</b>	<b>WHO</b> <b>Who should be Involved (initiate)?</b>
25. Develop an international monitoring capacity for new technologies	Establish a mechanism to undertake international foresight activities on new technologies coming down the pipeline and provide the public, governments and others with information on their potential implications (possibly an international commission).	Canada in concert with other countries, possibly working through the UN
26. Make Canada a world leader on responsible use and development of biotech for developing countries (leadership role)	<ul style="list-style-type: none"> <li>▪ Capacity-building</li> <li>▪ Industry FDI</li> <li>▪ S&amp;T partnership network involvement</li> <li>▪ Challenges for investment</li> </ul>	CIDA IDRC Genome Canada Industry NGOs

### 3.3 Overarching issues & other ideas

**Government’s role:** The assumption is if we get governance right, biotech will happen. This is faulty. In fact it is a creative act done by individuals. If there is a creative thought, let’s not “governance it to death”. Most of biotech will be pushed forward by a private sector with a high tolerance for risk. We are dealing with two very different worlds. One is government, which is by nature bureaucratic, interdepartmental, risk-averse, managerial in culture, and works through regulation and collaboration. People in business and science exist in another world and think and communicate differently. It is therefore difficult to establish effective lines of communication. Government and the private sector are good at different things and have different responsibilities. Government should not be involved in resolving all these problems.

**Interconnectedness:** Central in considering any of these gaps and barriers is interconnectedness. We need to look at individual problems but see how they fit into the system. What are the linkages? Many of these issues will be resolved by developing and using linkages between sectors – government, academia, industry and civil society.

**Human resources:** An important part of the equation is human resources. Universities are a key to this pipeline, but we should also track performance of middle and high schools in math and science as well. We need better information on how the pipeline is working. This is true also in the management area – there is a serious gap of experienced managers.

**Security and privacy:** There are many security and privacy issues that are raised by biotechnology, particularly the privacy of genetic information. These issues are of growing concern to Canadians and the issues will be treated differently than in other countries because of the Charter. All plans to collect information should be accompanied by a privacy assessment.

**Federal-provincial investments:** A review might be undertaken of federal-provincial investments in R&D. It could evaluate the benefits of closer collaboration rather than the almost entirely separate approaches that are now undertaken. The degree to which the provinces and the federal government work together to get the biggest bang for the buck is important.

**Stocktaking:** A stocktaking study should be undertaken to take a look at biotechnology in Canada and evaluate unique Canadian strengths that we should be focussing on.

**International:** Biotechnology is, by definition, an international affair. A worthwhile topic of study is international integration of efforts in the biotechnology area, both from a comparative perspective and examining the harmonization of efforts in regulation, policy-making and environmental monitoring. We do not want to discover that action has been done better by other countries, years earlier.

**Budget 2004:** Budget 2004 allocated money to research and innovation. BDC should not manage this money. We must look at new ways to leverage this money to attract more capital and players. We should be innovative and experimental about how this money is used.



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## Appendix B: Dr. Arthur Carty's Opening Remarks



Office of the  
National Science Advisor

Bureau du  
Conseiller national des sciences

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# Opening Address – Executive Workshop on Biotechnology

Arthur J. Carty

Institute On Governance  
National Press Club

25 May 2004

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Canada



Bonsoir à vous tous et bienvenue à cet atelier exécutive sur la biotechnologie.

I want to begin by thanking the Institute On Governance for organizing this executive workshop on biotechnology – and the Canadian Biotechnology Strategy Secretariat for providing the financial support.

Je suis ravi d'avoir été invité à participer à cette réunion par l'institut de la gouvernance, car non seulement cela cadre bien avec mes nouvelles fonctions de conseiller national des sciences, mais par surcroît, votre activité tombe à point. Permettez-moi donc de vous en dire plus long.

In my new role, one of the key high level goals is ultimately to improve the overall functioning of our Innovation System across the entire spectrum from discovery research to innovation in the market place – to identify and, if possible, fill gaps; to correct dysfunctional elements; to foster horizontal collaborations and to ensure that we have the programs, tools and mechanisms to make optimal use and reap the benefits of our investments. This is a big task of course – and one which does not just involve the performers of R&D – but the linkages and relationships between many types of institutions both nationally and internationally – public and private sectors; funders and performers; investors and financial organizations; government at all levels; NGOs that influence public opinion; regulatory agencies and so on.

In a real sense the challenges of governance within the national biotechnology system are a microcosm of the issues we face in the broader system of innovation in Canada.

Here are some of the perspectives and issues:

- (i) Biotechnology like information technology is enabling and transformative. It is widely expected to become one of the fundamental underpinning elements of our economy in the years ahead. Just think of the social and economic impacts (health care, food, environment, etc.)
- (ii) The biotechnology system involves many institutions and interests – all levels of government are invested (every region of Canada wants to be a biotech cluster, or have major activities in this area). Multiple departments and agencies have roles; many funding agencies are involved. Many non-government organizations have a strong voice concerning biotechnology.
- (iii) Collectively we face the very major challenge of developing a national vision, as well as coordination and integration of efforts in biotechnology. In my view there is currently a lack of national vision, leadership and coordination in biotechnology.
- (iv) However, this is starting to change – especially with the views of the current Prime Minister – who has clearly outlined his interest in biotechnology through the three pillars of the SFT (Building the 21<sup>st</sup> Century Economy; Social Foundations for the Future; Extending Canada's Place in the World – and his identification in his post-SFT speech of how Canadian Biotech can be brought to bear on the challenges of the developing world

and contributions of Canadian biotechnology internationally. (Also creation of NSA Office – new leadership).

- (v) We are not, however, starting from scratch. Much advice and input has already been provided (e.g. through the National Innovation Summit). We also have multiple and ongoing advisory mechanisms in biotech at many levels (individual institutes, all the way to CBAC). So I think that we collectively already have much to work with.
- (vi) However, we are not very good as a community in identifying priorities about where external advice is needed, and government has not been very good at following up on advice that is offered.

Well I said earlier that this workshop is timely. It seems clear to me that the governance challenges for biotechnology (and S&T in general) are going to increase in complexity – not go away. Technology convergence between biology, IT and nanotechnology for example is already happening. The genomics revolution is in full swing – and we have not really even started to see any of the transformative effects that this will eventually bring.

There was also an important Supreme Court decision at the end of last week on the patenting of plant genes which will no doubt stimulate both national and international comment and debate.

Finally our biotech industry is still fragile and many small companies are poised on a knife-edge looking for new, hard to find investment.

In summary – I think there are reasons for being concerned about our future in biotechnology – and I feel that we are poorly prepared from an overall national governance perspective.

So let me highlight the situation I think we collectively face and need to consider:

- We are a geographically large country with a relatively small population and relatively limited resources to spend on biotechnology. How do we maximize the impacts of our investments?
- We have many institutions playing a role or multiple roles in the biotechnology innovation system. It really is a complex system. How do we get this system firing on all cylinders, and orient our efforts in a common direction? How do we overcome divisions and competitive tendencies – and focus instead on collaboration and integration of our efforts – e.g. What can we do to ensure that federal and provincial programs and investments are synergistic not counterproductive or duplicative?
- We cannot divorce ourselves from the trends and efforts underway outside Canada. We are part of an international economy. How and what do we learn from other countries, how do we remain competitive and relevant internationally, and make sure that those countries less fortunate also benefit from (our) biotechnology?



So in closing: the challenge for us here at this workshop is enormous – but we have to start somewhere.

The question is where. What are the governance priorities to address? How do we get started? What can I do in my new role? What can you do? So let's agree to not try and raise or solve every problem all at the same time, but try and highlight some of the very key issues to start with.

I look forward to our discussions over the next day on this subject.

Merci d'avoir consacré le temps de participer à cet événement.



## Appendix C: Dr. Arthur Carty's Closing Address



Office of the  
National Science Advisor

Bureau du  
Conseiller national des sciences

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# Closing Address – Executive Workshop on Biotechnology

Arthur J. Carty  
Institute On Governance  
Willson House, Meech Lake

26 May 2004

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Canada



The intent of the workshop was to bring together a representative group of interested individuals and players from across a broad spectrum of federal and provincial government, industry, academia and NGOs to discuss governance issues in biotechnology and the gaps and barriers to realizing the potential of biotechnology for the benefit of Canadians and society more generally.

The workshop recognized that there were a number of problems, fault lines and disconnects which were limiting Canada's progress in this area. The intent was to surface the key issues and have a dialogue to openly discuss them. The discourse has been excellent, with great participation, openness and touches of humour.

I was encouraged first of all by the willingness of the communities to come together and try to resolve some of the issues – not necessarily all at the same time.

Let me just make a few observations:

1. First of all I think we should recognize that all is not doom and gloom in our biotech world. We have in Canada a number of successes – a viable biotech industry with several large homegrown companies such as MDS, QLT, Biovail, Angiotech, etc. and a large number of close to 350 SMEs which while perhaps fragile – represents a base for future development. Contrast Germany, which has made a multimillion dollar investment in biotech, but does not have a single large biotech company.  
We also have a very major investment in biotech and health care research base in our public sector institutions – something which we must lever to produce economic benefits for our country. Again few countries in the world have that strong a base.
2. I think we have recognized here that there is a need for a Vision – but it is not a federal vision – it is a national vision and it needs to be inclusive of all partners across Canada. Federal and provincial, private sector, academia, communities, NGO's, the public.
3. Yesterday we started off with 8 topics/issues and boiled them down to 5 (Governance; Less Developed Countries; Social & Ethical Issues in decision making and public consultation; Regulatory coherence and responsiveness; two groups on clusters, commercialization, etc.). I was concerned last night that we might diverge rather than converge but it has come together.

I do not want to summarize your findings on these – that has already been done. But the issues are important and should somehow be carried forward with the actions you have suggested.

So what can I do from my office to help us to gain further momentum, bring new life to our governance mechanisms and move forward in developing a better, more effective innovation system for biotech?

1. First of all I will commit to bringing the outputs of this workshop to the Committee of ADMs and the Committee of Deputy Ministers. The former has been active the latter has not really been engaged and indeed has only met twice since 1999. They both have important roles to play.



2. While there are governance issues in the Federal regime, government itself cannot solve all of the problems you have discussed today. We did not say very much about federal-provincial or really public-private sector partnerships but clearly these are important.

I am personally convinced that the drivers of innovation in biotech are not governments but the private sector – the companies which develop and market the products and processes. Certainly there is a role for government – setting the environment, the tax structure, the regulatory framework for example – but there is a role for the private sector in building the industry, establishing markets and competing globally.

In this regard I think we need a small group of credible, wise people with high profiles who can help us to make the case for clusters and commercialization in biotech and convince government to be a partner in actions.

I will commit to putting together such a group drawn from the people here today and others with appropriate skills and experience.

On commercialization, progress is being made. There is a consensus across the country that we need to do more on commercialization. There is a good chance this will converge and we will get a solution that will be beneficial to everyone.

Finally knowing that we cannot tackle all of the issues I would like to suggest that we take on a pilot project which was suggested earlier by Cal Stiller – the idea of establishing “The Canadian Biotech Railway” as a national initiative – building a national backbone which will link clusters and communities (nations) across the land, within the framework of putting all of the elements of an innovation system in place across the country.

We will have to do some brainstorming on how to make this happen – but it could be a great rallying project for biotech.



## **Appendix D: Workshop Agenda**

### **Executive Workshop on Biotechnology**

#### **A Component of the Institute On Governance's Biotechnology and Governance Program**

Tuesday, May 25<sup>th</sup> 2004,  
17 15 – 21 00  
Main Dining Room, National Press Club, Ottawa

Wednesday, May 26<sup>th</sup> 2004  
8 30 – 14 30  
Willson House, Meech Lake

#### *Day 1: May 25, 2004*

- 17 15            **Meet and Mingle** (refreshments)
- 18 00            **Welcome and Opening Remarks – Dr. Arthur Carty, National Science  
Advisor to the Prime Minister**
- 18 10            **Workshop Program and Objectives** – Tim Plumptre, President, IOG
- 18 20            **Panel**  
Moderator:  
**Kathryn O'Hara**, Professor at Carleton University's School of Journalism,  
CTV Chair in Science Journalism and broadcast journalist  
Speakers/Panellists:  
**Peter Morand**, President and CEO of the Canadian Science and  
Technology Growth Fund Inc.  
Topic: Realizing the benefits of biotech through collaboration among  
Different sectors
- Robert Slater**, recently retired senior ADM at Environment Canada and  
President of Coleman, Brightman and Associates  
*Topic: What biotechnology teaches us about coping with transformative  
technologies*
- Maureen McTeer**, lawyer and author, most recently of *In My Own Name*  
and *Tough Choices: Living and Dying in the 21<sup>st</sup> Century*  
*Topic: Legal and societal implications*



19 30            **Buffet supper** (working)  
**Session 1: From Research to Benefits for Canadians: Where are the Stronger and Weaker Links?**  
*Presentation on a systems approach to biotechnology - Marc Saner, Director, Institute On Governance*  
*Interactive discussion in mixed working groups to discuss gaps or barriers to realizing biotechnology's potential for the benefit of Canadians and handling technology responsibly for the long-term good. The evening will finish with an exercise to establish priority issues*

20 45            **Report back to plenary**

21 15            **Wrap-up – Tim Plumptre**

*Day 2: May 26, 2004*

7 30            **Bus to Willson House leaves from the Courtyard Marriott Hotel** (see note below\*)

8 30            **Introduction to Day 2 – Tim Plumptre**  
*An outline of the day's program, objectives and process*

8 40            **Results of Session 1**  
*The priority issues identified in the first session will be presented and refined in plenary*

9 00            **Session 2: Clarifying the Issues and Brainstorming Solutions**  
*Building on the priority gaps and barriers identified in the evening session, in small groups participants will brainstorm about solutions and develop a rough list of possible actions*

10 15           **Break**

10 45           **Reporting Back Results of Session 2**  
*Small groups report back and plenary discussion*

12 00           **Session 3: Building an Action Plan** (working lunch)  
*Small breakout groups will select several high priority initiatives and develop*



*a specific action agenda to move the issues forward*

- 13 20            **Reporting Back Results of Session 3**  
*Small groups report back and plenary discussion*
- 14 00            **Wrap-up** – Tim Plumptre
- 14 20            **Closing remarks** – Dr. Arthur Carty
- 15 00            **Bus to Courtyard Marriott House leaves from Willson House** (see note below\*)

**Modified Chatham Rule**

The IOG will ask all participants to abide by a modified version of the “Chatham House Rules”, as follows:

- (1) Direct attributions of quotes to specific participants shall not be made without explicit consent.
- (2) Acknowledgement that information was received at the Executive Workshop, however, is allowed. (This second clause allows for written summaries of the event - without attribution - to be produced and circulated to interested parties.)

