

ABS ACCESS AND BENEFIT-SHARING OF GENETIC RESOURCES

The "S&T AGENDA" Experts' Workshop



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ACCESS AND BENEFIT-SHARING OF GENETIC RESOURCES

The “S&T Agenda” Experts’ Workshop

Workshop design

A one-and-a-half-day “S&T Agenda”¹ workshop was held on December 1 and 2 in Ottawa. Given that access and benefit sharing of genetic resources (ABS)² is a multifaceted policy issue, some 40 participants from a wide variety of backgrounds were invited to help support the development of an integrated science policy perspective on this emerging issue.

The workshop’s goals were to:

- inform the participants about the goals and concepts surrounding ABS;
- seek information on how genetic resources (GR) are currently managed in Canada;
- receive preliminary advice on aspects of domestic ABS policy; and
- foster relationships that could evolve into a formal/informal external advisory committee on the S&T issues regarding ABS.

Report outline

This report offers a brief synopsis of the information presented to participants during the workshop, followed by a summary of participant feedback. These sections are followed by a brief indication of “next steps” for this initial phase of the ABS policy development process.

Presentations

ABS in the context of federal policy — Robert McLean

In the opening address to the workshop, Robert McLean, the Director General responsible for ABS policy development, noted that although ABS was originally conceived to ensure equity between developing nations as providers of GR and developed nations as users of GR, it is now acknowledged by many that all nations are potentially *both* providers and users of GR.

He argued that Canada lags behind its biotechnology competitors in developing national ABS policies, noting that the United States, the European Union, and other countries, such as Switzerland, are working bilaterally with biodiversity-rich developing nations to ensure that their researchers have continued access to GR. Canada cannot afford to wait any longer, as the rest of the world is moving forward with ABS policy development.

McLean outlined the growing momentum in the federal government to more fundamentally integrate environmental considerations into economic decisions. The objective of the new Ad Hoc Cabinet Committee on Sustainability and the Environment is to ensure that the federal government “build[s] sustainable development systematically into decision making.” Biotechnology has long been regarded as a potential major contributor to a new, innovative Canadian economy. McLean argued that a successful ABS policy is an essential stewardship component of such an economy, a social contract that outlines how “the fruits of innovation based on genetic resources will go to all those who should benefit.”

He emphasized the **enabling** potential of a Canadian ABS policy through:

- enhancing the social acceptability of biotechnological innovation;
- building capacity in those institutions and regions responsible for maintaining Canada’s biodiversity; and
- encouraging research, knowledge sharing, and development of GR.

In short, a well-conceived ABS policy can support the environment, the economy, and human well-being.

Both positive and negative cases from other national contexts served to highlight issues that Canada must consider in developing its domestic ABS policy:

1) Positive:

- In **Australia**, ABS policy seeks to achieve national biotechnology *and* biodiversity objectives.

¹ The term “S&T Agenda” is used to reflect the wide variety of issues associated with science and technology (S&T) activity in the access and benefit sharing of genetic resources (ABS) policy, such as research, research administration, S&T policy, etc.

² ABS policy derives from a commitment in the United Nations’ Convention on Biological Diversity (CBD), signed and notified by Canada, to work toward “fair and equitable sharing of the benefits arising out of the utilization of genetic resource” (see <http://www.biotech-monitor.nl/4902.htm> for a brief overview).

- Under the rubric of its ABS policy, Yellowstone National Park in the **United States** has signed more than 100 ABS research contracts. These contracts provide immediate benefits in the form of scientific information relevant to the conservation of ecosystems and species in the Park and allow for potential future financial benefits in the event that findings from research conducted in the Park are used in commercial applications. The Yellowstone National Park ABS policy is now being extended to all U.S. National Parks.

2) Negative:

- In **South Africa**, attempts to commercialize a compound found in the *Hoodia* cactus of the Kalahari floundered in the absence of domestic ABS regulations. *Hoodia's* appetite-suppressing properties were well known by San (Bushmen) of the Kalahari and constituted traditional knowledge. The South African national laboratory, which had identified the active ingredient in *Hoodia*, filed for a patent and licensed its patented discovery to a UK biotech firm without first obtaining prior informed consent from the San people. The resulting negative international publicity led to significant delays in the development of what promised to be a financially lucrative drug, as both industry and government had to “backpedal” to establish fair terms for benefit sharing before proceeding with development.
- ABS regulations in the **Philippines**, one of the first countries to adopt access laws, were so onerous that scientific and commercial research virtually ceased. The Philippines has since rewritten its ABS law to address these negative implications.

McLean closed his talk by challenging participants to provide substantive input into the Canadian ABS policy development process.

International considerations in ABS policy: the GR “life cycle” approach to understanding ABS — Timothy Hodges

Timothy Hodges, Executive-in-charge with the Genetic Resources Unit of Environment Canada, spoke on the international developments that are spurring the development of Canada’s policy. He described how ABS evolved within the “Grand Bargain” of the Convention on Biological Diversity (CBD), where developing nations, which are biodiversity-rich, and developed nations, which tend to be poorer in biodiversity, reached mutual agreement on the Convention’s objectives. According to many, the first two “pillars” of the CBD — those of conservation and sustainable use of biodiversity — were only agreed to contingent on the Convention’s acceptance of the third pillar, which ensured fair and equitable

sharing of benefits derived from the utilization of GR. The developed nations insisted that fair and equitable access to GR also be included in the third pillar. Achieving the third objective of the CBD was seen as contributing to redressing the imbalance that has evolved between developed and developing nations in terms of biotechnology and wealth generation. Hodges described how the debate and activities related to ABS goals have matured over time, through the development of the voluntary Bonn Guidelines, to the commitment of the World Summit on Sustainable Development to develop an international regime on ABS, to where we are today — facing the development of an international regime that is very likely to have legally binding components if developing country desires are met.

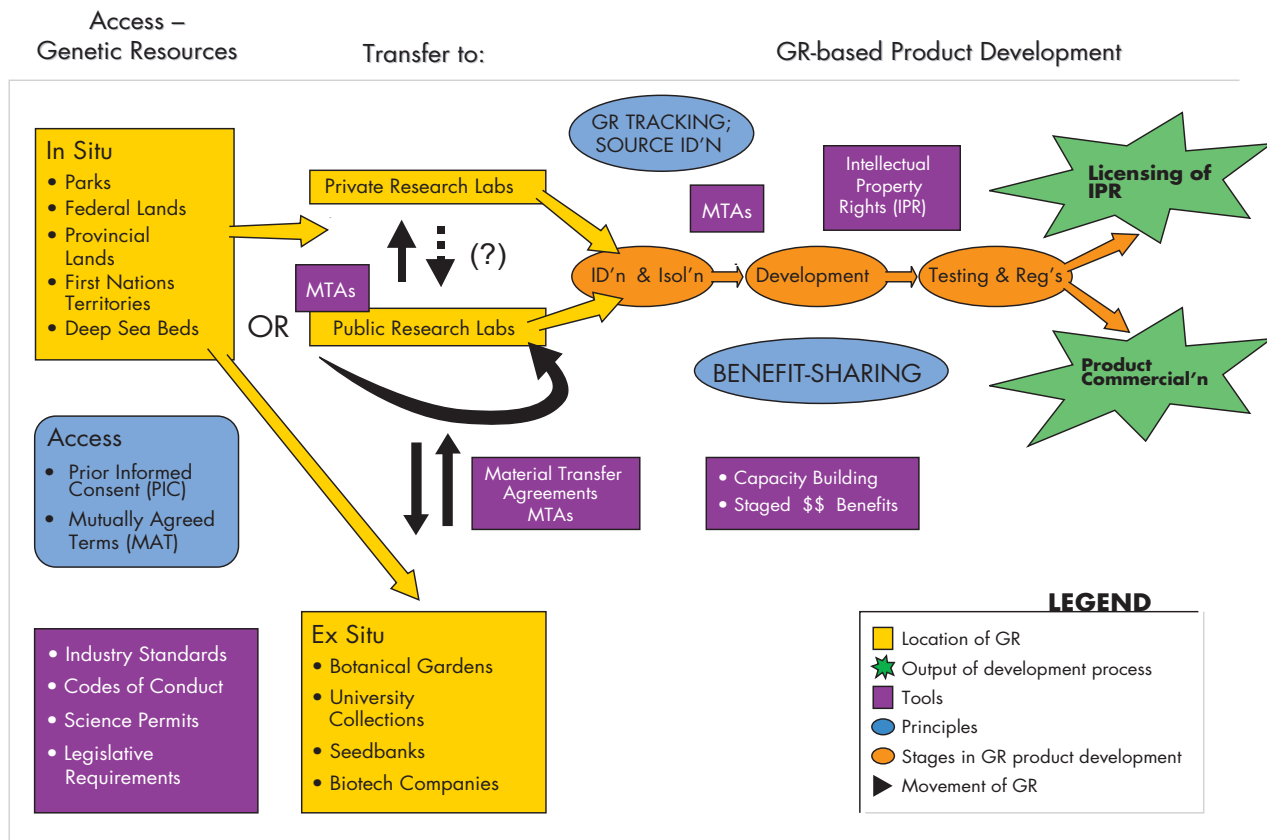
Central to the development of an international regime are the concepts of:

- *prior informed consent* — the host nation has been notified of researchers’ intent to use its GR;
- *mutually agreed terms* — the researchers and host state come to agreement regarding the terms under which utilization of GR will occur; and
- *benefits* — a benefit-sharing agreement is reached. Benefit-sharing agreements can be very flexible. They can be monetary, but it is much more likely that they are related to building research capacity, whether human or infrastructure, in the host state. They can be staged or be made contingent upon other factors, such as success of product development.

Whether it is supplying germplasm to forestry plantations worldwide or cultivating crops domestically whose origins lie elsewhere, Canada is both a provider and a user of GR. As such, we have much to gain from an effective international regime. Internationally and domestically, Canada lags behind many of the world’s nations in developing ABS policy. Developing countries, such as Brazil, the Philippines, and Indonesia, as well as developed countries, such as Australia, have national ABS laws in place. Canada is only beginning the policy dialogue.

In the next few years, Canada plans to be a constructive presence on the world stage, working with other countries to ensure that the international regime is based on sound research and practical experience with the implementation of the voluntary Bonn Guidelines. Workshops (including this one) on topics ranging from marine biodiversity, agricultural GR, Northern GR, and indigenous issues underline the Canadian government’s seriousness in dealing with this issue. Dialogue has started among federal, provincial, and territorial governments in order to ensure that all levels of government and all relevant

FIGURE 1. GENETIC RESOURCES “LIFE CYCLE”



expertise in natural resource management are brought to bear on the development of a Canadian position.

Efforts in the near term include:

- leading a pilot project with Colombia to build the capacity of indigenous communities on ABS at the community level;
- working with Parks Canada to develop an ABS policy for Canada’s National Parks system; and
- working with the scientific community to elaborate a code of conduct for researchers working with non-human genetic material.

A heuristic diagram of a GR “life cycle” was used to outline the different issues and locations for policy development in order to successfully implement a domestic ABS policy. The GR life cycle made clear the need for a flexible design that is sensitive to different conceptions in different sectors of what constitutes “fair and equitable” sharing and that accounts for the different stages in the development of a GR (see Figure 1).

ABS and biodiversity conservation in the United States: The Yellowstone model — Preston Scott

Preston Scott, of the World Foundation for Environment and Development in Washington, DC, provided a comprehensive overview of the history and development of ABS policy and regulation in Yellowstone National Park. The presentation highlighted key issues for policymakers to consider as they develop an ABS regime that encourages research and supports conservation.

Yellowstone is an excellent site for bioprospecting activity because it has the greatest concentration and diversity of terrestrial thermal habitats in the world. Consequently, there are many ecological niches for microorganisms that can withstand high temperatures and harsh chemicals. Enzymes and other useful biological molecules found in these organisms are of potential commercial interest because they can be active in the harsh conditions of industrial processes and thus can replace more expensive or toxic chemicals. It was the value of these microbes and their enzymes that provided the context for the development of Yellowstone’s benefit-sharing agreement.

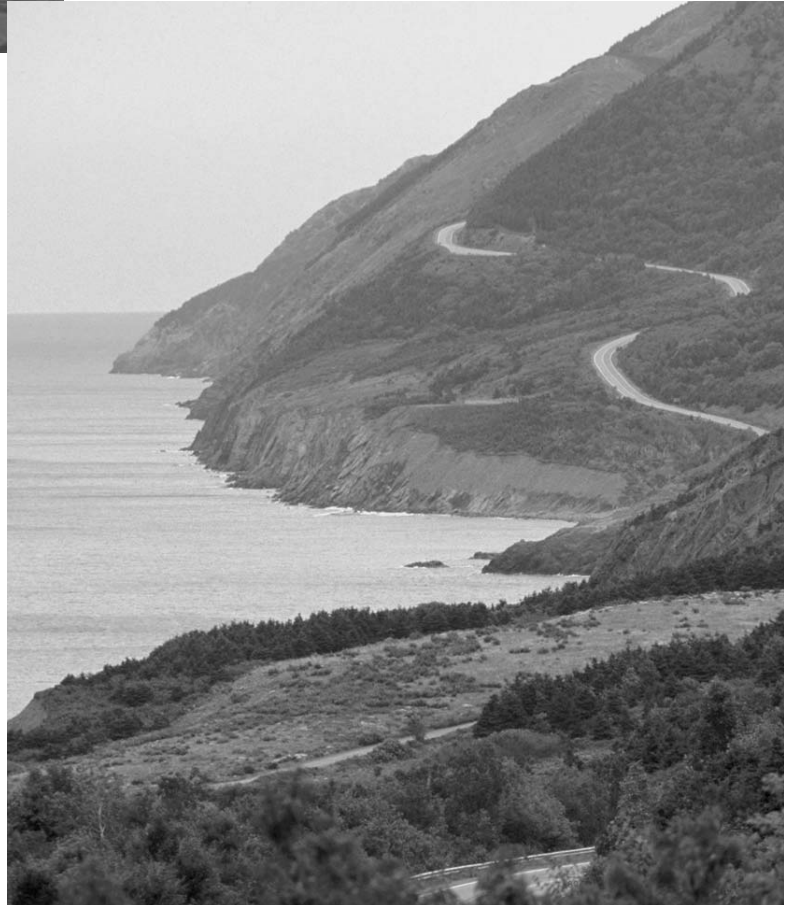


- performed “in-kind” scientific work, including using DNA methods to identify wolf populations in the Park, which has helped with the management of their reintroduction into the Park.

The agreement protects the company’s intellectual property while stipulating that Yellowstone National Park must use its royalties to support research and conservation in the Park.³ Thus far, Diversa has derived one commercial product from its bioprospecting activities in Yellowstone. For its part, Yellowstone National Park has retained ownership over all samples removed from the Park, thus ensuring that if the samples are placed in *ex situ* collections, this is done under terms specified by Yellowstone.

Scott’s account of the development of Yellowstone’s ABS policy was grounded in two real-world examples:

- 1) *Access with no benefits* — A biotechnology tool (*Taq* polymerase, an enzyme that copies DNA), developed from research on an organism (*Thermus aquaticus*) found in the Park’s hotsprings, has reportedly generated hundreds of millions of dollars in revenue for Hoffman-LaRoche, the company that owns the patent for the tool. Yet without an ABS policy, Yellowstone has received no benefits from this commercial success.
- 2) *Access with benefit-sharing* — Learning from this experience, Yellowstone developed an ABS policy. Based on the policy, it has signed a benefit-sharing agreement with Diversa, a biotechnology company. In the agreement, Diversa has:
 - paid \$100 000 as a “creditable minimum annual royalty”;
 - agreed to pay other royalties based on revenues generated by successful commercial development; and



³ For more details on this case study, please see Scott’s chapter in the book “Accessing Biodiversity and Sharing the Benefits: Lessons from Implementing the Convention on Biological Diversity,” available on-line at the World Conservation Union (IUCN) web site: <http://iucn.org/dbtw-wpd/edocs/EPLP-054.pdf>.

The Yellowstone case highlights the many types of benefits a good ABS policy might provide:

- scientific;
- environmental;
- educational;
- economic; and
- institutional.

Taking advantage of the opportunity provided by these benefits requires building both individual and institutional capacity. Enhanced market and scientific research can clarify issues and raise the awareness of key stakeholders. Natural resource managers in public institutions must have training in negotiation to ensure that appropriate value is captured from the resources they steward in the public interest. Institutionally, measures to build capacity should include ensuring that appropriate legislative and/or regulatory measures are in place to support ABS agreements, integrating ABS into biodiversity strategies, and developing and sharing model commercial ABS agreements. Ultimately, the development of these agreements with National Parks can support the Parks' mandate to protect and conserve nature.

Participant feedback

SESSION DESIGN

The one-and-a-half-day workshop was divided into two principal components. The first part of the meeting was devoted to providing information to participants on the state of the issue, both domestically and internationally. As many of the participants were directly or indirectly involved in the management and development of GR, the second part of the workshop focused on collecting information on current practices and receiving policy development advice.

The following sections of this report summarize the information provided to us by the participants.

GENERAL IMPRESSIONS/MESSAGES

Three key messages emerged from the workshop:

- 1) Participants were substantially involved in research activities with GR. There is significant activity in this field across Canada.
- 2) There was general support for the broad goals of ABS and strong interest in learning more about ABS principles and requirements. The group supported the development of effective, efficient ABS policy.
- 3) Participants indicated that definitions — from GR to property to ownership — *do* matter and require careful consideration and fuller discussion. It is important in making ABS policy to be clear about the topic of discussion, or guidelines/policies may miss the mark.

CURRENT ACCESS, TRANSFER, AND BENEFIT-SHARING ACTIVITIES

A morning roundtable session was devoted to collecting information on the current “landscape” of GR-related activity in Canada. It was acknowledged that this workshop was not meant to provide an exhaustive picture, but rather an indicative one.

1) Canadians accessing GR

- *Broad-ranging collection* — GR are being accessed by a wide range of Canadian researchers and businesses from a large variety of sources — i.e., *in situ* sources across Canada, including in many provinces and in the territories; *ex situ* collections in Canada, the United States, and other countries; and *in situ* collections from the field in most regions of the world.
- *Extensive transfers* — There are significant flows of GR within Canada; one researcher estimated that his university alone engaged in approximately 1000 transfers per month.
- *Documented transfers* — At some Canadian universities, GR are considered the intellectual property of the university, and transfers proceed with attendant “material transfer agreements” stipulating the uses to which the GR can subsequently be put.
- *Free sharing* — Canadian collections are also quite freely sharing agricultural (and botanical) GR with colleagues and research institutions in other countries.
- *Not commercial* — Based on the experience of the experts at the workshop, most transfers of GR are not for activities that yield commercial benefit, but rather for non-commercial research purposes.



Many of these practices are deeply held in the cultures in which they are embedded and have co-evolved with the industry or discipline with which they are associated. When suggesting ABS policy in these contexts, it is important to recognize and respect existing cultural practices to the greatest extent possible, if for no other reason than to obtain greater compliance.

SUGGESTED GOOD ABS PRACTICES

The afternoon session followed from Preston Scott's informative lunch-hour presentation on Yellowstone National Park's ABS experience. In this session, participants were asked for their perspectives and preliminary advice to help inform the development of Canadian ABS practices and policy. The workshop articulated four key principles to guide "good ABS practices":

- 1) *Codification of ethical guidelines* — Ethical guidelines or codes of conduct for the research community must be developed and implemented, based on the basic principle of "don't rip off the original sources."

The message from the workshop participants was that Canadian performers of S&T in many fields were actively researching, developing, and transferring GR.

2) Models for regulating GR transfer

There are a number of practices currently "regulating" GR transfer, each with its own ABS mechanisms. These include:

- *free transfer* between public institutions, including those outside of Canada;
- *informal "in-the-pocket" movement* of GR into Canada (with a likely parallel flow out of Canada) by field researchers;
- *informal, reciprocal transfer* of GR among researchers;
- *transfer with strict conditions* by provider institutions, such as botanical gardens and some universities;
- transfer of GR within a system that *tracks and taxes commercial benefits* in order to support further research (e.g., ornamental plants); and
- *transfer on a private contractual basis*, usually with specific intellectual property rights.



- 2) *Support implementation of CBD principles* — Benefits must flow back to support the CBD principles — fair and equitable benefit sharing and conservation of biodiversity.

- 3) *Flexible measures* — Benefit-sharing measures need to be flexible and different for different sources of GR, for different sectors, and for different uses of GR. Benefit sharing needs to focus substantially on capacity building, not just on a project-by-project basis, but on the beneficiary's research enterprise / technological capacity as a whole.
- 4) *Culturally appropriate approaches* — It was noted that researchers need to recognize the very different understandings and customs of Aboriginal peoples with respect to their GR and that Aboriginal and local community rights to their traditional knowledge need to be respected.

SUGGESTED ELEMENTS OF A SOUND POLICY APPROACH

The afternoon session also sought to collect advice on key “pressure points,” from the perspective of those who perform, administer, or study S&T, for the development of a domestic ABS policy. Many individual points were made, but they can be distilled to the following key suggestions:

- 1) Domestic ABS policy should be an enabling policy, driven by Canadian interests and including Aboriginal contexts.
- 2) Domestic ABS policy should encourage high standards through clear guidelines and triggers, building on existing regulations, guidelines, and practices, and placing a low information/compliance burden on researchers. Codes of conduct and voluntary guidelines are preferable to legal regulation.
- 3) Domestic ABS policy should rely on solid communication and educational strategies to raise awareness as the main method to achieve compliance. Key groups to engage include:
 - the Canadian research community;
 - owners of GR, Aboriginal communities and others; and
 - an ABS “working group” that could aid in the establishment and implementation of an ABS system, which could include all possible and potential stakeholders or could drive a wide-ranging consultation process.
- 4) Domestic ABS policy should be clear on the terms and conditions that shape the ABS process, such as:
 - the definitions of ownership and property;
 - non-commercial and commercial GR research; and

- multi-tiered jurisdiction over and ownership of GR (e.g., by the public, the private sector, and First Nations people) and the cultural context in which the resources are found.

Next steps

The Biodiversity Convention Office / Genetic Resources Unit has noted support for the concept of a code of practice/ethics among the S&T community. The longer-term goal, therefore, is to work towards the development of a possible code of conduct.

On the basis of advice from the workshop on building on existing mechanisms, the first steps in the development of the elements of a possible code(s) are:

- to find out in clearer detail what mechanisms already exist within academia, the non-governmental organization community, and industry. The Biodiversity Convention Office / Genetic Resources Unit has initiated a research project to this end; and
- to convene a multistakeholder steering committee to guide the development of the code and its best practices. We anticipate that this will begin in the spring of 2005.

Conclusions

Participants deemed the workshop a success. Many remarked on the benefit of having people from so many disciplines in the same room in advancing their understanding of aspects of the issue that had previously been opaque to them.

Acknowledgements

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