

ABS Policies in Canada

Scoping the Questions and Issues

*Prepared by the Federal/Provincial/Territorial Working Group on
Access and Benefit Sharing of Genetic Resources*

*Approved by Federal/Provincial/Territorial Ministers Responsible for
Forests, Wildlife, Endangered Species and Fisheries and Aquaculture*

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EXECUTIVE SUMMARY

Access and benefit-sharing (ABS) is an emerging policy area, promoting the fair and equitable access to genetic resources, and the sharing of the benefits derived from their utilization. This policy paper is a part of a broader task related to genetic resources given to the Federal/Provincial/Territorial Working group on ABS (FPTWGABS) by Federal/Provincial/Territorial (F/P/T) Ministers of Forests, Wildlife, Endangered Species and Fisheries and Aquaculture, in September 2004.

The paper identifies the parameters of ABS as a policy issue by identifying its key policy components. It translates some of the key principles contained in the Convention on Biological Diversity (CBD), such as “the transfer of accountability for genetic resources to the Sovereign State”, into concrete issues that need to be considered from a Federal/Provincial/Territorial approach. It explores the connections with other relevant and key Federal/Provincial/Territorial policy issues and sectors, such as the contribution ABS can make to economic development through the bio-based economy, its role in fostering sustainable development strategies, and its relationship with the patent system. It also proposes a set of principles that will guide the ABS policy development process at all levels.

Building on the draft *Scoping Paper on ABS* presented to Deputy Ministers in June 2005, this paper takes a more focussed approach as a concrete way to move the ABS policy exercise to a second stage. The policy analysis contained in the present paper, read in conjunction with the key elements of the *ABS Policies in Canada: Engagement Strategy*, will contribute to developing a targeted approach to ABS policy development. Together, they provide direction for fully engaging relevant stakeholders and for shaping the many questions to be answered by jurisdictions in this emerging policy area.

Future discussion and analysis on ABS, and the further elaboration of ABS policies in Canada, could be usefully framed through consideration of the following:

What relevant policy goals does ABS touch on?

- Improving Canada’s economic competitiveness through sustainable development opportunities
- Promoting the conservation and sustainable use of Canada’s biodiversity
- Supporting research and innovation in science and technology
- Improving the health and social welfare of Canadians

How can ABS contribute to these policy goals?

- By creating a policy and legal framework that provides certainty to investors and biotechnology firms
- By creating market conditions that support both R&D in genetic resources, and the public bodies (communities, governments, institutions) that steward them
- By developing common practices that promote compliance with community Codes of Ethics and legal certainty within the research community
- By providing mechanisms for the public sector to benefit from biotechnological developments

- By protecting Canadian genetic resources and associated traditional knowledge from foreign misappropriation

What are the key policy challenges that arise from the implementation of ABS?

- Defining the scope of ABS policy
- Facilitating access: granting prior informed consent (PIC) and identification of granting authorities
- Sharing the Benefits: negotiating mutually-agreed terms (MAT)
- Devising compliance measures: Documentation, tracking and compliance
- Protecting traditional knowledge

How can those challenges be addressed?

- By an improved coordination and consistency between policies and legislation that facilitates access and benefit sharing of genetic resources in a number of jurisdictions, including with a possible international legally-binding ABS regime
- By increasing the level of knowledge of ABS principles and objectives among all stakeholders and levels of governments

The further elaboration of ABS policies in Canada should consider and take into account the following core principles:

- Environment-focused — contributing to the conservation and sustainable use of biodiversity,
- Practical and Economically Supportive — generating and sharing economic benefits of the utilization of genetic resources among both providers and users as a means of contributing to sustainable development,
- Simple, Efficient and Adaptable — taking into account different sectors and allowing for different approaches in different jurisdictions,
- Supportive of current governmental policies, and building on and respecting Canada's existing international commitments,
- Balanced, equitable and transparent — balancing responsibilities between users and providers of genetic resources in a manner that is clear and whose rationale makes sense to all concerned,
- Inclusive, developed and implemented with the appropriate involvement of Aboriginal groups and communities.

Creative policy work in the area of ABS, based on sound and agreed-upon principles and clear key objectives, will lay the basis of a renewed Canadian commitment to conserve and sustainably use biodiversity and demonstrate the positive impacts of jointly developing innovative policies.

I

Foreword – Investing in Natural Capital: Sustaining Biodiversity in the “Bio-based Economy”

1) International Context and Mandate

The United Nations Convention on Biological Diversity (CBD) has three objectives: the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources. The Convention supports the greater valuation of biological/genetic resources by recognizing States’ sovereign rights over them¹. Previously, genetic resources were generally viewed as the common heritage of humankind and research scientists freely accessed plants and animals throughout the world. The Convention sets out the parameters for accessing genetic resources that require the users of the genetic resources to obtain prior informed consent from the providers and to develop mutually agreed terms before sampling of genetic resources proceeds².

In 2002, the voluntary *Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits Arising from their Utilization* were adopted by CBD Parties. The guidelines were intended to assist Parties, Governments and other stakeholders in developing strategies and in establishing legislative, administrative or policy measures on access and benefit-sharing. They include prior informed consent procedures, benefit-sharing provisions for genetic resources and associated traditional knowledge, and user country measures. The Guidelines are considered as a useful first step in an evolutionary process in the implementation of access to genetic resources and benefit-sharing related provisions of the Convention.

At the World Summit on Sustainable Development (WSSD), held in Johannesburg in 2002, Heads of State agreed to negotiate an International Regime on ABS under the Convention on Biological Diversity. The WSSD Plan of Action also called on countries to implement the voluntary CBD Bonn Guidelines at the national level.

¹ Article 15 of the CBD States that, “(r)ecognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments, and is subject to national legislation” (Article 15.1).

² Article 15 of the Convention States that access is to be facilitated and that “(a)ccess to genetic resources shall be subject to the prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party” (Article 15.5) and that “(a)ccess where granted, shall be on mutually agreed terms and subject to the provisions of this Article” (Article 15.4).



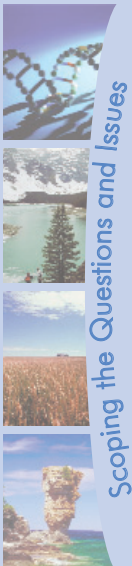
At their Seventh Meeting (2004), Parties the CBD mandated the Ad Hoc Open-ended Working group on Access and Benefit-sharing (WGABS) to elaborate and negotiate an international regime on access to genetic resources and benefit-sharing with the aim of adopting an instrument/ instruments to effectively implement the provisions in Article 15 and Article 8(j) of the Convention and the three objectives of the Convention.

Negotiations are on-going and it is impossible to predict when talks will conclude or to anticipate the shape of the International Regime. It is certain, however, that the call for a legally binding Regime (i.e., an ABS treaty) will continue and that measures related to user countries will be a principal focus of the Regime.

If not well-designed, this international regime has the potential to negatively affect the development of Canada's economy by restricting access by Canadian researchers to genetic resources and by increasing transaction costs when accessing or transferring genetic resources. Canada's participation, as a user country with investments in a growing biotechnology industry, is crucial to the creation of an agreement that facilitates access, provides legal certainty and promotes the conservation of resources. At the same time, it will be crucial for the regime to ensure that Canada can derive benefits as a small but important provider of genetic resources.

2) Domestic Context

In September 2004, the Federal/Provincial/Territorial (F/P/T) Ministers of Forests, Wildlife, Endangered Species and Fisheries and Aquaculture considered the emerging issue of ABS. Ministers recognized the importance of the current international negotiations and the need for the stewardship of Canadian genetic resources. They appreciated that ABS could contribute to a number of emerging policy areas, including the conservation and sustainable use of Canada's biological diversity (the "raw material" of the bio based economy), the enhancement of economic productivity through research and innovation, and addressing rural and aboriginal community health and well-being. The FPT WG was tasked with the preparation of a draft scoping paper and a companion national strategy for domestic ABS engagement.



II

The Key Challenge of ABS: Fostering a Common Approach

For ABS policies to contribute to the policy goals set out in Section II and to address the policy questions noted in Section IV a common or complementary approach is required. This means integration with other ABS-related policy areas and the elaboration of consistent measures across jurisdictions:

1) Coherence and Integration with ABS-related Policies

Establishing a common approach to ABS should be done through improved policy coherence and deeper integration of ABS policies with other life sciences strategies funded by governments and universities. ABS can also benefit from, and contribute to, the harmonization of natural resources management policies among jurisdictions by bringing together resource managers to elaborate management methods for genetic resources. Finally, finding the best approach to meeting ABS objective may mean developing policy coherence between key policies including sustainable development, intellectual property, and foreign policies.

2) Consistent and Complementary Legislative Measures across Relevant Jurisdictions, and with a Possible International ABS Regime

Relevant jurisdictions in Canada need to ensure the consistency and complementarity of measures in order for ABS to be effective yet not administratively burdensome. This does not mean that the same measures or policies need to apply across different jurisdictions. Rather, a common approach seeks to ensure consistency in the application of ABS policy principles in meeting the often unique circumstances of different jurisdictions across Canada.

In pursuing this common approach, the following questions will serve as a guide in implementing ABS measures as required:

- Whose jurisdiction would a particular measure fall within?
- Is there a regime in place that provides the basis for new measure?
- If not, what is required to close any gaps?
- How is duplication minimized?

II



ABS

Policies in Canada

At the same time, because negotiations on an international ABS regime under the Convention on Biological Diversity will likely include some legally-binding elements, some additions to existing laws in various jurisdictions may be needed to support compliance with the ABS policies/laws of other Parties to the Convention. Canada should seek to ensure that this international framework is consistent with Canadian values, Canada's strategic economic and trade interests, and Canadian leadership on global environmental challenges.

II



III

Public Policy Objectives

The overarching policy goals of ABS should be to support sustainable economic development and sound environmental stewardship. Thus, the development of ABS policies in Canada will necessarily intersect with a number of existing policies and programmes with similar and complementary objectives. This section describes those intersections.

1) Promoting the Conservation and Sustainable Use of Canada's Biodiversity

In Canada, sustainable development is increasing in prominence and good ABS policies can make an important contribution. ABS will contribute to meeting sustainable development objectives by supporting the conservation and sustainable use of biodiversity. Canadian industries based on biological resources will continue to be able to access the genetic resources they need to be competitive, whether this is the enzymes needed to improve the pulping process or the genetic material needed to produce new pharmaceutical applications. Access measures will protect ecosystems through ensuring conservation of species prior to "biodiscovery"³ activities (especially where sensitive ecosystems or endangered species may be affected).

Benefit-sharing arrangements of these developments will ensure that public sector capacity to steward biodiversity is supported, either in monetary and non-monetary ways. Non-monetary benefits, which are likely to be much more common, include training of personnel, *pro bono* research, development of local infrastructure, and sharing of knowledge that feeds into or supports conservation management and education efforts. Monetary arrangements with commercial "bioprospectors"⁴ can generate needed funding for conservation activities, such as park research and management, specimen collections in universities and museums, efforts to protect the traditional knowledge of Aboriginal communities or improved management measures in production landscapes like forests.

One of the most promising benefits of ABS is the potential generation and sharing of taxonomic information about the biodiversity in areas (or

³ "biodiscovery" means the collection of biological specimens for further analysis in the laboratory.

⁴ "bioprospecting" means the collection of biological specimens for further analysis in the hope of developing a commercial product.





collections) that are researched by bioprospectors. This is an easily shared benefit, and will provide the foundation for better conservation by integrating genetic resource conservation considerations into biological resource management strategies. From a bio based economy perspective, the conservation of genetic diversity within species is important because different sub species often have unique traits, each of which could have different applications. For example, one variety of Echinacea may be the best for the nursery trade while another variety may produce higher yields of chemicals for herbal products.

2) Improve Canada's Economic Competitiveness in the Bio-based Economy

Biodiversity [is a fundamental component of] markets that last year moved more than 90 billion dollars, including sales of medicines (including vaccines) for humans and livestock, for around 41 billion dollars, but also of cosmetics and personal care products, especially for the skin. On top of this are the burgeoning markets for herbal medicines and functional foods (for specific ends), which mobilized around 20 billion dollars in 2004; agricultural biotech (from seeds to biopesticides), with four billion dollars; and at lesser volumes, industrial enzymes, biogenetics (databases and software on genetics), and electronic bioconductors, a sector that is growing by 40 percent annually.⁵

Biological resources are the basis of many major economic sectors. The "bio-based economy" is as a key strategy for achieving sustainable development and the use of biological processes instead of traditional oil- or chemical-based ones has been shown to reduce energy use, pollution and contribute to other sustainability criteria.⁶ Pharmaceuticals, agriculture, forestry, aquaculture, and "natural products" are key sectors that stand to gain from the "bio based economy" because they all rely on genetic resources and are all changing with the application of biotechnology.

The skilful use and development of genetic resources through biotechnology is the central technological enabler of the bio-based economy. Canada is well-positioned world-wide in biotechnology, and the bio-based economy is an opportunity for enhancing its global competitiveness. Currently, Canada is third in the world in the export of genetically modified products, and its

⁵ Márquez, Humberto. (2005, Friday, July 11). *Colombia, Peru and Venezuela are the Andean vanguard in exploiting biodiversity for biotechnology, a global market that moves more than 90 billion dollars annually*. Originally published on July 2nd by a Latin American newspaper that is part of the Tierramérica network. Tierramérica is a specialised news service produced by IPS with the backing of the United Nations Development Programme and the United Nations Environment Programme <http://tierramerica.net/english/2005/0716/index.shtml>.

⁶ *Biotechnology for Sustainable growth and Development*, found at: www.oecd.org/dataoecd/43/2/33784888.PDF, accessed July 2005.





biotechnology revenues, though a small contributor to the overall domestic economy, rival those of all of South East Asia⁷. There is also public support behind the development of the sector, although this support is dependent on the government enacting proper regulatory oversight⁸.

As a global initiative, however, the bio-based economy is going through growing pains. There are a number of issues, most related to either the question of ownership of real or intellectual property in areas that had previously been considered global commons, or challenges related to the conservation and sustainable use of genetic resources, such as a lack of clear ownership or the loss of genetic resources and traditional knowledge.

a) A role for patent policy in advancing ABS

Patent practices have reduced access to genetic resources, and are thought by some to present barriers to widespread market entry because of the “IP thicket” of multiple patents on technology platforms and routine processes. Current practices around the granting of patents for genetic resources have generated concerns, particularly on the part of developing countries.

Developing countries, which have sovereignty over most of the world’s *in-situ* genetic resources, have reacted to the patent-based control of genetic resources by developed countries by restricting access to their *in situ* genetic resources. As mentioned earlier, the Convention on Biological Diversity (CBD) has enshrined nation States’ control over their genetic resources, and it has become more difficult for firms to gain access to many nations’ genetic resources.

The patent system is a key tool for encouraging economic growth by promoting innovation and the advancement of scientific and technical knowledge. Policy initiatives in this area aim to create a business climate that encourages research and development, the commercialization of new technologies, and the promotion of trade and investment⁹.

The current discussions under ABS that relate to patent policy arise from the fact that patents have become a preferred method for protecting biotechnological inventions, and thus control access to valuable genetic

⁷ 3rd largest producer: see http://w01.international.gc.ca/minpub/Publication.asp?FileSpec=/Min_Pub_Docs/106146.htm&Language=E, accessed September 27, 2005; Canada’s global revenue, Ernst & Young, (2003) “Beyond Borders”.

⁸ From: *Summary of Public Opinion Research into Biotechnology Issues in Canada* www.biostrategy.gc.ca/english/view.asp?x=543&all=true, accessed July 18, 2005.

⁹ Complete information available at: <http://cbac-cccb.ic.gc.ca/epic/internet/incbac-cccb.nsf/en/ah00405e.html>.



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resources. These inventions are often based on the use and modification of genetic material (by definition, derived from genetic resources). Modification of the IP system should be explored to determine the extent to which it can contribute to ABS objectives.

The main change under discussion is the inclusion of “disclosure of origin/source of genetic resources and associated traditional knowledge” in patent applications. This concept, proposed by developing countries and supported by some developed countries, would use the patent system to track the origin of a genetic resource used in a patented innovation so that benefits arising out of the commercialization of the invention would flow back to the countries from where the resources have originated.

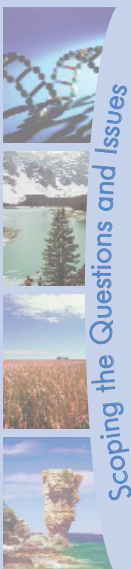
The Canadian *Patent Act* does not require the disclosure of the origin of genetic resources in patent applications. Technical and administrative solutions arising from the concept of disclosure of origin/source will have to be fully explored before any determination can be made as to the feasibility, costs, and real impact of a disclosure requirement included in the Canadian *Patent Act*.

Possible reforms to patent policy would be one of the most significant policy and legal challenges in Canada and elsewhere. At the genetic level, questions remain about the patentability of genetic material and ownership of intellectual property rights over genetically-based inventions. The matter is under discussion in a number of international fora, including the Convention on Biological Diversity, several committees of the World Intellectual Property Organization, and at meetings of the Council on Trade-Related Aspects of Intellectual Property Rights at the World Trade Organization. Canada continues to participate in these fora mindful of ways that ABS may necessitate changes to international and national patent policy to ensure that the system continues to operate to the public’s benefit.

b) Loss of genetic resources and traditional knowledge

Another pressure is that the “source material” for biotechnological innovations, biodiversity, is being lost rapidly to habitat destruction. Loss of genetic resources is also happening through insufficient maintenance the specimens of public collections like those found in universities or museums.

As well, the role of traditional knowledge holders in the context of ABS is not established. Though they have specialized knowledge of local biodiversity, especially the medicinal properties of plants, many are hesitant to share, for fear of exploitation by companies. Many traditional cultures are at threat of extinction, which means that the traditional knowledge of biodiversity and its sustainable use in supporting human health and well-being is also at risk.



c) Lack of clear ownership over genetic resources or regulations to govern access

The ownership of genetic resource located in “global commons,” such as the deep sea bed where many robust enzymes are likely to be found, is not clear. A legal lacuna exists...

In absence of legal certainty over ownership or appropriate processes for consultation, biotechnology firms are at risk of generating negative publicity for “pirating” genetic resources that they subsequently develop. They are therefore hesitant to use and develop genetic resources derived from biodiversity.

What is clear in this situation is that for developers, there is a problem of access to genetic resource, and for providers, there is a problem of the fair sharing of the benefits derived from the use of genetic resource. A well designed and balanced ABS policy would address these problems by providing clear, transparent and simple procedures to access genetic resources, while encouraging flexible benefit-sharing agreements between users of genetic resources and the countries, communities and/or institutions that provide them.

3) Support Ethical Scientific Research and Development

Science and technology (S&T) is at the core of ABS policy. ABS is predicated on developments in biotechnology that facilitate the development of genetic resources.

Well designed ABS policies can encourage scientific research through private-public partnerships that feed some benefits of commercial research back to organizations and institutions involved in conservation research and management. This has already been shown to be the case in a number of instances internationally, where *ad hoc* arrangements have been made. By establishing a formal and uniform ABS approach, the benefits can become systemic. Early results in countries like Australia suggest that this approach works. However, most of the benefits will be non-monetary such as increased knowledge, training opportunities and support for conservation of biodiversity, either *in situ* or in *ex situ* collections and museums.

The work of scientists in both the public and private sectors is likely to be impacted in two significant ways. The first and most obvious is that they will likely be required to go through more formal processes before collecting genetic resources regardless of whether they are working for commercial benefit or not and may face civil or criminal sanctions for not complying with ABS regulations in some jurisdictions with national ABS measures.



Scoping the Questions and Issues



In Canada, traditional knowledge of the medical uses of biodiversity is a potential resource for innovation. Canadian Aboriginal groups are well aware of the risks that unprotected sharing of knowledge poses, and are likely to want to have agreements in place before they participate in the bio based economy. It will also be important that scientists working with Aboriginal groups understand that ABS rules may also apply in situations where traditional knowledge is involved and may have to revisit their relationship with aboriginal partners.

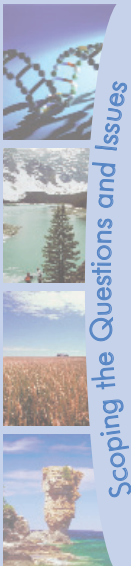
The second issue is one that will need to be managed thoughtfully. Since ABS policy hinges on the identity of the origin of genetic resource, a system will need to be implemented to track genetic resources so that, as benefits arise, they flow back to the provider. However, devising a system to track all genetic resources used by researchers may be very burdensome and could be a hindrance to innovation. A well thought-out strategy must be implemented in order to allow research to proceed while ensuring the fair sharing of benefits.

4) Foster Regional and Aboriginal Development

By providing a link between the discovery and development of genetic resources and public institutions, ABS policies could support regional economic development strategies. For example, there may be good potential for genetic resources to contribute to Northern economic development if ABS measures were in place. Many of the region's diverse and endemic plants, fungi, and micro-organisms hold great promise as possible sources of new products such as medicines or low temperature resistant enzymes. These bio products are of interest to both scientists and biotechnology companies seeking to develop new innovations. ABS policies, through encouraging investment in research facilities, capacity-building in land management, partnerships with research institutions and companies, and by providing a framework for sharing benefits locally, could be a tool that facilitates this development. It has been shown to work this way in other parts of the world.

Existing Northern research legislation and permitting systems (such as the *Northwest Territories Scientist Act*) contain elements of ABS. Northern institutions, such as the Nunavut Research Institute, have already integrated measures into their operating procedures that facilitate access to their territory for scientific purposes while ensuring the information generated is shared with Nunavut. The adoption of a regional ABS approach can contribute to the capacity of the North to become an economic and scientific player while ensuring the protection of resources and social values.

Scientific research undertaken in the North involving the gathering of biological material often relies on information provided by Aboriginal and





local communities about how to use the biological/genetic resources. Traditional knowledge provided by Aboriginal healers may help scientists understand what resources are useful for the development of new medicines. By making access to these resources and this knowledge contingent on the granting of prior-informed consent, Aboriginal and local communities can ensure that traditional knowledge is accessed by scientists in a manner that respects communities' traditional values. A respectful interaction of scientific researchers with Aboriginal communities may spur the development of innovative products – such as new medicines based on traditional knowledge – that can benefit society as a whole.

From a social justice perspective, the recognition of social concerns and cultural perspectives (e.g. the protection and respectful use of traditional and local knowledge) in ABS policies should help engender respect for the rights and concerns of aboriginal people. In short, a good way to conserve and sustainably use these resources is by accommodating the unique social, political and environmental complexities of Northern Canada in the management of the region's genetic resources. ABS, properly implemented, can offer just such an approach.

5) Support Canada's Foreign Policy Objectives

ABS as an international policy issue represents an opportunity for promoting Canada's new *International Policy Statement: A Role of Pride and Influence in the World*. The government identified science and technology as an important component of Canadian foreign policy. It also announced its intention to strengthen relationships with emerging powers such as China, India and Brazil.¹⁰ India and Brazil are main proponents of an international regime on ABS. They are also seen as future strategic economic partners for Canada and potentially key players in the area of biotechnology development. By participating constructively in the design of an international ABS regime, Canada may enhance its relationships with these countries while more generally contributing to a better North-South dialogue. The good will and positive relationships built through developing a fair international ABS regime should contribute to the success of Canadian foreign policy objectives.

6) Contribute to the Improvement of the Health of Canadians

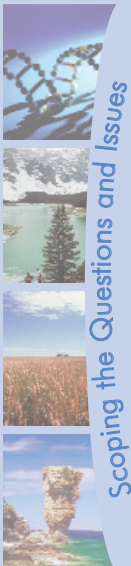
By providing the conditions for efficient access to genetic resources, ABS policy offers the opportunity to promote the discovery of new bio-active compounds that contribute to the health of Canadians. For example, a drug

¹⁰ Canadian International Policy Statement available at: www.dfait-maeci.gc.ca/cip-pic/ips/ips-diplomacy8-en.asp.





developed by ABS pioneer Shaman Pharmaceuticals, is now being brought to final round of clinical trials. This drug may have a large impact on infant mortality in the developing world as it prevents diarrhoea through a new biological mechanism that avoids the side effects of current medicines¹¹. In a broader sense, the potential use of biological processes instead of petroleum products or high energy chemical ones will reduce our industry's environmental footprint, leading to a healthier environment for Canadians.



¹¹ Philipkoski, Kristen. (July 11, 2005). *A Drug to Eradicate Diarrhea*. See: http://wired-vig.wired.com/news/medtech/0,1286,68145,00.html?tw=wn_13techhead, accessed July 18, 2005.

IV

Policy Questions in Implementing ABS

ABS is a broad ranging, innovative and complex policy area. It raises some very important policy questions that will have a large bearing on its impact in Canada. Some of the major issues that must be discussed as ABS policy moves forward are presented below.

1) Defining the Scope of the ABS Policy Area

The CBD defines “genetic resources” as the units of functional heredity (e.g. seeds, cuttings, etc.) of biological resources (e.g. micro organisms, plants and animals), which may have real or potential value.¹² The scope accorded to the term “genetic resources” will be the key to understanding the scope of ABS policy in Canada. In some countries, the term “genetic resources” has been limited to refer to *in situ* “unmanaged” biodiversity, and excludes biodiversity found in commercial settings like forestry and agriculture. In some cases, genetic resources are defined as all biodiversity, including agricultural and other commercial organisms. In yet other cases, the scope of ABS is enlarged beyond the functional units of heredity to include biochemical products such as extracts and specific compounds. Defining this term will determine the scope of the ABS policies and the subject matter of implementation measures.

Canadian ABS policies will need to address some key questions:

1. What are “genetic resources” in the context of Canadian policy?
2. Should the scope of ABS policy include commercial species?
3. Should genetic resources be defined to include products derived from genetic material?
4. What impact will the different definitions have on:
 - scientific research(ers)?
 - commercial breeders?
 - traditional knowledge holders?
 - bio based industries?
 - existing IP protection?
 - innovation in the bio based economy?

¹² The CBD currently defines the term “genetic resources” as: “genetic material of actual or potential value”; “genetic material” is: “any material of plant, animal, microbial or other origin containing functional units of heredity” (Convention on Biological Diversity, article 2: *Use of terms*).



2) Facilitating Access: Granting of Prior Informed Consent (PIC) and Identification of Competent Authorities

According to the CBD, States have jurisdiction over their genetic resources. Therefore, to access genetic resources, one must have the prior informed consent (PIC) of the providers of the resources. The main function of PIC is to ensure transparency in the ABS system and facilitate appropriate access to genetic resource. It is not intended to hinder or restrict access.

The implementation of PIC raises technical and legal questions. The following scenario illustrates these: a genetic resource is located on provincial Crown land within territory claimed by an Aboriginal community in the context of land claims negotiations. With respect to PIC, some of the questions that would arise include:

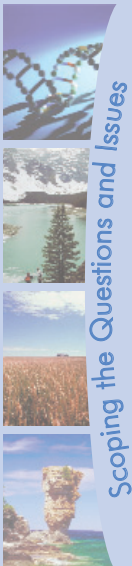
- Would the approval for access be given at the government level? At the community level? At both levels?
- At the community level, who has authority to grant PIC? Does their particular community claim sole ownership over the resource/traditional knowledge?
- Who can verify that PIC was appropriately granted? Who keeps the records? Who decides what information to collect?
- Should there be a coordinating authority at the national level that would help all jurisdictions liaise with one another and with foreign entities?
- How will the process involved in developing an approach to PIC (and subsequent identification of the appropriate authority) affect the type of measure taken (i.e. law, regulation, code of conduct, guidelines, etc.) by various jurisdictions?

3) Sharing the Benefits: Mutually-agreed Terms (MAT)

As envisioned, mutually-agreed terms (MAT) in ABS systems are to be negotiated between the user and the provider of a genetic resource. They serve as a contract, stating how the resources are to be used, by whom, and for what purpose. They would also include the terms and conditions for benefit sharing. While there is no common model for MAT, some nations have specified in their national ABS laws as requirements in MAT contracts elements such as joint research partnerships, deposit of samples in a national gene bank, and involvement of local people in research projects. Codes of conduct may also provide a means for ensuring that negotiations take place in good faith and according to best practices.

Key Questions for Canada:

- Should MAT be case-by-case or would a national or provincial template be more effective?



- Should a trigger for negotiations be included as a standard term, at what point should this take place? Following interesting research findings? At the patent application stage? Prior to commercialization?
- Should possible benefits be spelled out (such as those contained in the Bonn Guidelines)? Should there be a focus on either monetary or non-monetary benefits?
- What complementary measures can be taken to ensure a smooth negotiation process? What role should voluntary codes of conduct or ethical guidelines play?

4) Ensuring Compliance

Genetic resources, by their very nature, present a challenge to a property system that is grounded in spatial terms and has historically operated at the scale of visible commodities of immutable form. Genetic resources can be magnified far away from their origin, they can be split up, they are easily transferable, and as DNA sequences, they can be freely available for all to see on the internet. A number of approaches to solving this tracking problem have been proposed.

As mentioned in the previous section, some argue for changing the patent system to make the disclosure of the country of origin a requirement to be included in patent applications. Another proposed approach is for the issuance, by those who provide genetic resources, of a “certificate of origin” that would indicate that the genetic resource was obtained under ABS compliant conditions. Material transfer agreements, which means in this instance contracts that govern the transfer of genetic material between two organizations, have also been proposed as mechanisms to ensure that the genetic resources are in fact being used for the purposes specified in the MAT. The inclusion of these or other requirements in ABS policies will affect the ability and willingness of both users and providers of genetic resources and traditional knowledge to comply with the policies.

In Canada, the elaboration of appropriate compliance measures may vary between jurisdictions and will greatly depend on the nature of the adopted ABS frameworks. One challenge for Canada in this area will be to ensure a consistent “compliance approach” by which all users would potentially face similar non compliance consequences in all jurisdictions.

Key Questions for Canada:

- Foreign ABS legislations include compliance measures from criminal sanctions to civil monetary penalties. What types of compliance measures could be considered in a Canadian context?
- Would there be one authority in each provincial and territorial government responsible for compliance with ABS policies?

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- Should non compliance lead to criminal or civil sanctions?
- Could non-compliance lead to a withdrawal of financial support for research?
- Could the patent system, through a disclosure of origin/source requirement, be used as a means verify compliance with ABS by allowing the tracking of scientific activities involving genetic resources and traditional knowledge?
- What other measures should be put in place to both monitor and enforce compliance with ABS?
- How can the ease and transparency of compliance measures be assured?

5) Administration: Documentation and Tracking

Tracking and documentation of genetic resources will be a challenging task and can have a great impact on whether ABS is taken up as a viable policy tool. There is a risk that any administrative measures necessary to support the functioning of an ABS system will be too burdensome, and undermine the objectives of fair and equitable sharing of the benefits arising from the use of genetic resources. Administrative measures must be efficient and effective, avoiding the creation of extra and unwarranted burden on both the users and providers of genetic resources in Canada.

Key Questions for Canada:

- How should administrative measures inform the scope of ABS policies in Canada? What is the best way to achieve a balance between rigorous measures that ensure equitable sharing and requirements that are overly burdensome on those wishing access to genetic resources?
- Who will be responsible for producing documentation? What safeguards will be necessary to ensure the integrity of the documentation?
- What is the best way to support the capacity of communities/providers of genetic resources so that they will be in a position to produce any documentation required?
- Should genetic resources be tracked in any formalized way? If so, what is the easiest and most cost-effective way to do so?

6) Protecting Traditional Knowledge

In many cases, Aboriginal and local knowledge holders share their knowledge with researchers and help them identify the interesting and potentially valuable properties of biological resources. In many places, there is a close relationship between genetic resources and traditional knowledge. Access and benefit



measures contained in ABS policies should address this close relationship. Finding the right balance between the respect for cultural practices and spiritual beliefs inherent in traditional knowledge and knowledge sharing is crucial for advancing scientific research that can support the health and well-being of Canadians.

The challenge for Canada in this area is to ensure that modalities for accessing traditional knowledge are respectful of the rights of the knowledge holders.

Key Questions for Canada:

- Who is/are the traditional knowledge holder (s)? Is it the community, individuals within the community, families within a group?
- Should the protection of traditional knowledge also apply to other knowledge holders, including fishermen, farmers, and local communities?
- Should a board of Aboriginal representatives be created as a mechanism to enforce compliance with PIC and ABS principles when there is traditional knowledge involved?
- How can the relationship between customary and statutory law contribute to ABS?

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Principles and Features of Canadian ABS Policies

The following are proposed principles that can be used to form the basis of ABS policy development. These principles are derived from an emerging consensus stemming from the practical experience of other nations as they have implemented ABS policies.

- Environment-focused — contributing to the conservation and sustainable use of biodiversity,
- Practical and Economically Supportive — generating and sharing economic benefits of the utilization of genetic resources among both providers and users as a means of contributing to sustainable development,
- Simple, Efficient and Adaptable — taking into account different sectors and allowing for different approaches in different jurisdictions,
- Supportive of current governmental policies, and building on and respecting Canada's existing international commitments,
- Balanced, equitable and transparent — balancing responsibilities between users and providers of genetic resources in a manner that is clear and whose rationale makes sense to all concerned, and
- Inclusive, developed and implemented with the appropriate involvement of Aboriginal groups and communities.

