stakeholders for different purposes (e.g., in material transfer agreements, in patent applications, or in the process of product approval for commercialization). Any system should be designed to avoid unnecessary impacts on trade to circumvent any conflicts with World Trade Organization agreements.

The participants of the roundtable concluded that a certificate of origin scheme will need to consider and balance the heterogeneity of users and providers of genetic resources by addressing the interests of the research community, the business community, local and indigenous communities, and provider countries. Any regime has to be developed with full participation of all stakeholders; only then can it protect the interests of resource providers, in particular with regard to traditional knowledge, without being restrictive and preventing desired exchanges of genetic resources. The participants also suggested that the design of any regime should be guided by "the four Ts": transparency, traceability, tractability, and trust.[6]

While further research is necessary, the Paris Roundtable highlighted that the need for implementation of a functional ABS regime at the global level requires action in the near future. Development of a certificate system to support the enhanced effectiveness of international ABS governance requires prompt attention, and could be adopted with a view to progressive implementation, regular review, and modification as part of a process towards the consolidation of an international ABS regime.

Future directions for certificates of origin

The best way to test a system will be through pilot studies. Case studies could be conducted with partners in a range of genetic resource provider countries to see how (and if) countries could implement a certificate system. The feasibility of implementing a certificate of origin system for traditional knowledge could also be investigated. One interesting proposal would be to incorporate pilot studies into capacity development projects relating to ABS that are being developed with the support of the Global Environmental Facility.

Many complex questions will need to be addressed. What authority can legitimately provide access and issue a certificate? What happens when a resource may be obtained from a range of countries, and knowledge from a range of local communities in one or more countries? How far could a resource be traced in practice, and what measures could be put in place for penalties, liability, and redress? These questions also apply to the related issue of traditional knowledge, innovations, and practices associated with biodiversity.

Further research is required to investigate how these challenges could be met when it comes to implementing a model in practice. An analysis of the economic impacts and implications of any certificate of origin system would help to identify the true potential of the model to effectively support the objectives of the CBD and advance its implementation.

1 See also the article about the international regime for ABS on page 6.
2 Brendan Tobin, "Alternative Mechanisms for Protection of Indigenous Rights", paper presented at the "Symposium of Indigenous Peoples of Latin America: Indigenous Peoples, Biodiversity and Intellectual Property", Santa Cruz, Bolivia, 27–30 September 1994. See also Brendan Tobin, "Certificates of Origin: A Role for IPR Regimes in Securing Prior Informed Consent", in Mugabe et al. (editors), *Access to Genetic Resources*, ACTS Press, Nairobi 1997, http://www.ias.unu.edu/binaries2/Tobin_Certificates_of_Origin.doc
3 Brendan Tobin, David Cunningham, and Kazuo Watanabe, "The Feasibility, Practicality and Cost of a Certificate of Origin System for Genetic Resources – Preliminary Results of a Comparative Analysis of Tracking Material in Biological Resource Centres", UNU-IAS, December 2004.
4 C.F. Barber, S. Johnston, and B. Tobin, "User Measures: Options for Developing Measures in User Countries to Implement the Access and Benefit-Sharing Provisions of the Convention on Biological Diversity," 2nd edition, UNU-IAS, 2003.
5 UNEP, "Analysis of Measures to Ensure Compliance with Prior Informed Consent of the Contracting Party Providing Genetic Resources and Mutually Agreed Terms on which Access was Granted, and of Other Approaches, Including an International Certificate of Origin/Source/Legal Provenance", UNEP/CBD/WG-ABS/3/5, 10 December 2004.
6 The first three "Ts" formed the basis of a keynote presentation to the roundtable by Leonard Hirsch of the Smithsonian Institution.

Prior Informed Consent and Access to Genetic Resources and Benefit-Sharing: Paralysis or Prudence?*

By Sofia R. Hirakuri and Brendan Tobin

Prior informed consent is at the very heart of the Convention on Biological Diversity's compact on access and benefit-sharing. Results of UNU-IAS's comparative research on national implementation of prior informed consent highlights the need for a balanced approach to avoid paralysis of desirable scientific and commercial research.

Adoption of effective prior informed consent (PIC) procedures in both provider and user countries has a crucial role to play in achieving realization of the Convention on Biological Diversity's (CBD's) objective of ensuring equity and fairness in benefit-sharing, and in consolidating international access and benefit-sharing (ABS) governance. However, excessive bureaucracy can lead to a virtual paralysis in access to genetic resources.

For instance, only two genetic resources projects (out of 37 applications) have been approved by the competent national authority in the Philippines since its enactment of national ABS regulations in 1996. That regulation has been seen as impeding scientific research, including that carried out by national researchers, bringing it to a virtual halt and leaving research programmes bereft of foreign

funding. In Brazil, while legislation adopted in the wake of the adoption of the Bonn Guidelines on ABS has proved less onerous, only 11 projects out of 31 applications were approved during the period 2001–2003. And more than eight years since the development of the Andean Community's regional regime on ABS, some countries in the region still have not adopted national implementing legislation; many commentators have suggested the regime needs to be reviewed, in part because of difficulties associated with establishing a clear mechanism for PIC.

Prior informed consent is not a new concept, but derives from the medical practice whereby patients are considered to have a right to be provided with sufficient information to make informed decisions regarding important personal health matters.[1] PIC emerged most prominently in international environmental law in the context of the transboundary movement of hazardous and dangerous substances, with the first legally binding instrument on PIC being the 1998 Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade. In contrast to the conventional application of PIC, which focuses on risk, prior informed consent within the context of the CBD is also intended to act as a guarantee of equitable benefit-sharing and, therefore, plays a contractual as well as a regulatory role.

CBD provisions on prior informed consent

The CBD did not set down specific steps for PIC; that came later, with the Bonn Guidelines (adopted in 2002) that outline practical procedures for the implementation of ABS, including PIC. The Bonn Guidelines recognize that both countries and stakeholders face responsibilities to ensure that the CBD's ABS objectives relating to the acquisition of genetic resources and benefit-sharing are realized. The Guidelines set out the basic principles and elements for a PIC system that cover such issues as establishment of a competent authority, timing and deadlines, specification of use, mechanisms for consultation with relevant stakeholders, procedures for obtaining PIC, and the process of issuing a permit or license. The Guidelines also set out basic requirements for mutually agreed terms, which are the contractual provisions reflecting PIC.

Among the basic principles for a system of PIC laid out in the Guidelines are the following:

- There should be legal certainty and clarity;
- Access to genetic resources should be facilitated at minimum cost;
- Restrictions on access to genetic resources should be transparent, and not run counter to the objectives of the CBD; and
- PIC from the government of the provider country and any relevant stakeholders (such as indigenous and local communities) should be obtained according to the circumstances and applicable domestic laws.

The CBD recognizes the need for equitable sharing of benefits arising from the use of traditional knowledge, innovations, and practices relevant to the conservation of biodiversity and the sustainable use of its components. The Fifth Conference of the Parties to the CBD decided that "Access to traditional knowledge, innovations and practices of indigenous and local communities should be subject to prior informed consent or prior informed approval from the holders of such knowledge, innovations and practices."[2]

Comparative analysis of PIC implementation

The history of PIC procedures in ABS is extremely short. However, two distinct policy contexts can be discerned, depending upon whether the regimes were developed before or after the adoption of the Bonn Guidelines. The Philippines and Andean Pact regimes were both established prior to the Bonn Guidelines. On the other hand, Australia and Brazil are federal countries whose ABS regimes were implemented following the adoption of the Bonn Guidelines. The PIC procedures in these countries are particularly interesting, given their federal complexity and influence of the Bonn Guidelines.

PIC procedures in the countries examined demonstrate many similarities. The first step for an individual or organization requiring access to genetic resources is to apply to a competent national authority within the country. If access is granted, it is through a bilateral agreement that is based on mutually agreed terms. Prior informed consent from the provider, for either *in-situ* or *ex-situ* sources, is a precondition for mutually agreed ABS terms.

In Brazil, the Council on Management of Genetic Resources (Conselho de Gestão do Patrimônio Genético), which is part of the Ministry of Environment, is the competent authority. A new draft law, however, establishes two competent authorities for issuing authorization of access to genetic resources, depending on the purpose. In the Philippines, more autonomy is granted to the local community, with the competent authority being the Inter-Agency Committee on Biological and Genetic Resources, which is responsible for enforcement and implementation of the bioprospecting regulations. In Australia, the Commonwealth Environment Ministry assesses biological resource permit applications in Commonwealth areas, whereas in non-federal areas the competent authority in each state or territory is responsible for granting permission to access genetic resources. In contrast, the Andean Decision 391 gives total power to the government, thereby emphasizing the role of the government as the main negotiator of access.

In each of the case studies, the national government has sovereign rights over genetic resources; nevertheless, all regulations establish a basis for recognition of indigenous peoples and local community rights. The extent of this recognition varies among the countries. The Andean community, Philippines and Australia give recognition of local peoples, communities, and landowners' rights over genetic resources, and the Andean Pact Decision 391 further encourages the strengthening and development of their capacities.

One of the most complex issues with regard to PIC relates to the measures involved in obtaining permission from indigenous and local communities in order to collect resources. In Brazil, for instance there is a requirement that PIC be obtained from each concerned indigenous group or local community. This has caused confusion and delays in the process, as often there is sharing of the same resources and knowledge across communities, peoples, and regions. There are cases in Brazil where PIC has been obtained from three indigenous groups, but subsequently a fourth group challenges the validity of the PIC. A new Brazilian Draft Bill outlines an innovative mechanism called the "Benefit Sharing Fund", which intends to secure a percentage of the benefits to mitigate oversight in participation.

In Australia, PIC is obtained through a University Ethics Committee. First, the applicant submits a research proposal to the

committee, and if approved the proponent must then get PIC from the provider of the genetic material. However, it is the committee that gives final consent. This procedure has been criticized, as it is considered that this formula does not allow the local provider an opportunity to make free and informed consent regarding PIC and to fully engage in the process of negotiating benefit-sharing arrangements, leaving both the provider and the potential users fate in the hands of the committee.

The Bonn Guidelines provide that the decisions on applications for access should be taken within a reasonable period of time, but it does not actually set a timeframe. However, Australian, Andean, and Philippine legislation all specify 30 days for an evaluation decision.

Common challenges

Countries concerned about preventing loss of control over genetic resources have tended to establish highly restrictive regimes. This reflects a number of concerns, including a lack of confidence that national rights will be respected when resources leave the jurisdiction, lack of national capacity to negotiate and enforce ABS agreements, and the difficulties of regulating PIC for local and indigenous communities due to a lack of traditional knowledge-related laws and policies.

The earliest ABS laws tended to establish complex access procedures for both commercial and scientific research purposes. Subjecting all scientific research activities to lengthy and costly access procedures, even when carried out by national scientists without commercial intent, has impeded much potentially beneficial research. Following much criticism in this regard, the Philippines recently modified its procedures to distinguish access to genetic resources for research and commercial purposes. Similarly, the Australian NCA distinguishes between uses for commercial research and non-commercial public interest research, while the Malaysian ABS Bill does not apply to pure scientific research. The Andean Pact and the Brazilian ABS laws, however, do not distinguish access to genetic resources for research from that for commercial purposes, in terms of the bureaucratic paperwork needed to obtain a permit for access.

Countries also face institutional hurdles for the implementation of ABS law and policy – including, for instance, the difficulty of identifying one focal point to approach for consent because of sectoral interests of different ministries or divisions of the government dealing with genetic resources issues. Another difficulty is the lack of institutional and technical capacity to implement ABS law at the legal, administrative, and technical levels. Generally, in the cases examined, an overly bureaucratic and complex process to procure PIC, rather than the lack of PIC procedures, may be seen as the key barrier to accessing genetic resources.

Conclusion

Development of functional PIC systems must be seen as a multifaceted process rather than merely a technical or legal challenge. Implementation of the Bonn Guidelines provisions on PIC by countries, as both providers and users of genetic resources, may play an important part in the development of an effective international ABS regime. The major challenge is to translate the international regulation into legislation and practical policy at the national level.

The effectiveness of the PIC procedures of a country will be determined by the country's technical and institutional capability to implement them, and the assurance that prior informed consent has been obtained properly through consultation with the stakeholders. Meeting these challenges implies a commitment to capacity development and development of international mechanisms to support national implementation.

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* This article discusses preliminary results of a paper in progress.

1 Discussion paper on "Facilitating Prior Informed Consent", CIEL, 19 May 2004.

2 UNEP/CBD/COP/5/23, Decision V/16/5.

Bioprospecting in Antarctica

By Sam Johnston and Dagmar Lohan

Though research institutes and multinational corporations have feigned a lack of interest in the Antarctic region, UNU-IAS has uncovered significant bioprospecting activities in the region, and associated patenting of products and processes.

What does the ice-cream in your freezer have in common with an extremely salty Antarctic lake? Not much at the moment, perhaps, but in the future that could change. Uniliver, the food giant, has patented an anti-freeze protein found in the bacterium *Marinomonas protea,* which lives in Antarctic lakes. This protein might someday be added to ice-cream to keep it creamy even when thawed.

This is just one example of the potential value that genetic resources of the world's last frontiers, such as Antarctica, represent for researchers and corporations. Bioprospectors' interest in Antarctica stems from two factors. First, the lack of knowledge surrounding Antarctic plant and animal life provides an opportunity to discover novel organisms of potential use in biotechnology. Second, Antarctica's environmental extremes (cold temperatures and extreme aridity and salinity) present conditions in which life forms have evolved unique characteristics for survival. Bioprospecting opportunities thus include, inter alia, the discovery of novel active principles in species found in cold and dry terrestrial habitats, new pigments found in hyper-saline lakes, and anti-freeze metabolisms in sea-lakes.