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Certificates of Clarity or Confusion:

The search for a practical, feasible and cost effective system for certifying compliance with PIC and MAT

This report was written by
Brendan Tobin, Geoff Burton and Jose Carlos Fernandez-Ugalde.

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The ideas and opinions expressed in this paper remain the responsibility of the authors alone.

Front cover background document provided by Australia's National Competent Authority on Genetic Resources showing a mock-up of the revised Access Permit and Certificate of Compliance to be released shortly.

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Copy Editor: Michael Tobin

For further information, contact:
United Nations University Institute of Advanced Studies (UNU-IAS)
6F, International Organizations Center
Pacifico-Yokohama 1-1-1 Minato Mirai
Nishi-ku, Yokohama, 220-8502 Japan
Tel: +81-45-221-2300, Fax: +81-45-221-2302
Email: unuias@ias.unu.edu
URL http://www.ias.unu.edu

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Brendan Tobin

Geoff Burton

Jose Carlos Fernandez-Ugalde

Contents

List of Boxes

Foreword

Ever since the adoption of the Convention on Biological Diversity (CBD), in Rio de Janeiro in 1992, the international community has been grappling with the problem of how to secure its third objective, the fair and equitable sharing of benefits derived from access to and use of genetic resources. The subject of more than a third of all Convention decisions, regulating access to genetic resources and benefit sharing (ABS), is amongst the most complex and challenging issues currently facing CBD negotiators. Previous efforts to develop international law and policy in this area culminated with the adoption of the voluntary Bonn guidelines on ABS, at the 6th meeting of the Conference of the Parties (COP) to CBD in The Hague in 2002. A few months later, the World Summit on Sustainable Development called for negotiation of an international regime on benefit sharing relating to genetic resources, within the framework of the CBD.

The CBD has given a mandate to the Working Group on ABS to negotiate an international ABS regime, covering both genetic resources and associated traditional knowledge. It has requested that the Working Group conclude its work by 2010. The 6th meeting of the Working Group, held in Geneva in January 2008, established a framework for future negotiations by agreeing upon a list of components to be further elaborated with the aim of incorporating them in an international regime. These have been grouped under five headings: fair and equitable benefit sharing; access to genetic resources; compliance; traditional knowledge associated with genetic resources; and, capacity. Compliance measures will be central to the success of any international regime in securing the CBD's objectives. One potential measure, in particular, has been singled out by the Working Group for further elaboration. This is an internationally recognized certificate issued by a domestic competent authority. The group has also identified a certificate system as deserving further consideration in the development of measures relating to traditional knowledge.

The UNU-IAS Biodiplomacy Initiative has, since the early part of the decade, been responsible for promoting research into certification proposals and their potential role in an international ABS regime. In 2003 a UNU-IAS report - *User measures: Options for Developing Measures in User Countries to Implement the Access and Benefit-Sharing Provisions of the Convention on Biological Diversity* - suggested that the parties to the CBD consider development of a certification system as a means to implementation of the Bonn Guidelines and a response to the WWSD call for negotiation of an international regime on benefit-sharing. In 2004, UNU-IAS in collaboration with the Royal Botanical Gardens, Kew, the Smithsonian Institution and INBio prepared a series of case studies on the documentation practices of ex-situ collections and biodiscovery research institutions. The results of this research were included in a report - F*easibility, practicality and cost of a certificate of origin system for genetic resources*: *Preliminary results of comparative analysis of tracking material in biological resource centres and of proposals for a certification scheme* - which was provided as an information document for the third meeting of the Working Group on ABS.

In 2004, UNU-IAS, together with the Institut du Dèveloppement Durable et des Relations Internationales (IDDRI) and the Centre for the Philosophy of Law (CPDR) at the University of Louvain, organised the 2nd Paris ABS Roundtable on the "Practicality, Feasibility and Cost of Certificates of Origin." The results of the Paris roundtable were made available to delegates at the 3rd Working Group on ABS. In January 2007, UNU-IAS in collaboration with the Peruvian National Council for the Environment (CONAM), Environment Canada and the Asociación para la Defensa de los Derechos Naturales (ADN), organized the Lima ABS Dialogue on "The Role of Documentation in ABS and TK Governance." This meeting was held back to back with the meeting in Lima of the meeting of The Group of Technical Experts on an Internationally Recognized Certificate of Origin/Source/ Legal Provenance (GTE).

The current report builds upon this earlier work examining four proposals for documentation schemes based around the notion of certification, including certificates of origin, source, legal provenance and compliance. Comparative analysis of the proposals highlight similarities and differences in their overall makeup, and their potential utility as a means to ensure realization of the CBD's benefit sharing objectives. Based on this analysis, the report identifies the main elements for development of an international certification system and makes specific proposal for future work in this area. The report proposes that the Conference of the Parties to the CBD call upon the Working Group on ABS to develop a set of minimum standards and procedures for the implementation of an international certificate system. The report also suggests that COP reconvene the GTE to provide the Working Group on ABS with technical support in the preparation of such standards and procedures.

To prepare this report, UNU-IAS has turned to three people whose work has helped to frame the debate on certificate systems and the development of law and policy on certificate schemes as well as technical modalities for their implementation. Brendan Tobin, who coined the term "certificates of origin" in a proposal for a certificate of origin/disclosure of origin system in 1994, and has been instrumental in promoting research into certification systems ever since. Geoff Burton, who played a leading role in the development of a system of virtual certificates of origin and provenance, which formed the basis for the Australian Genetic Resources Information Database (GRID); and Jose Carlos Fernandez, author of numerous studies on the economic rationale for certificates and instigator of the proposal for certificates of legal provenance.

UNU-IAS welcomes comments on this paper and hopes it will serve to stimulate more informed debate on the issues covered.

A. H. Zakri
Director , UNU-IAS
April 2008

Executive Summary

1. Introduction

One of the major challenges facing the Convention on Biological Diversity (CBD) is how to secure the realization of its third objective - the fair and equitable sharing of benefits derived from use of genetic resources. The Convention has given a mandate to the Working Group on Access to Genetic Resources and Benefit Sharing (WGABS) to negotiate an international ABS regime by 2010. At the 6th meeting of the working group a number of central thematic areas were agreed upon as requiring further development as part of an international regime. One of these areas is compliance, including tools for monitoring compliance. One tool in particular is identified, an internationally recognised certificate issued by domestic authorities. This paper examines the debate on certificates through examination of: a series of certificate proposals; practical experiences with resource documentation; innovative models for resource management; and potential modalities for an international certificate system. The paper concludes that a certificate system is viable and will be beneficial for both providers and users of genetic resources. The paper also concludes that it is too early to determine the utility of a certificate system for traditional knowledge (TK) and calls for more work in this area.

2. Comparative analysis of certification proposals

Four proposals exist for certification systems to document genetic resources and TK. These are certificates of origin, source, legal provenance, and compliance under these proposals:

1. A certificate of origin would identify the country of origin of a resource and provide evidence of PIC for its use. Certificates could be issued for resources provided by any country which has them in-situ, or which obtained the resources in accordance with the CBD (Pre-CBD collections would not be covered). Where TK is involved, certificates would be issued subject to PIC of indigenous peoples or local communities. Certificates would be monitored through a system of checkpoints, including intellectual property (IP) applications and product approvals procedures. This would place the burden for demonstrating a right to use genetic resources and TK upon users.

2. Certificates of source would cover genetic resources provided by primary sources - such as the Contracting Party providing resources, and the Multilateral System established by the FAO-ITPGRFA - and secondary sources - such as ex situ collections, databases on genetic resources and traditional knowledge, and scientific literature. Certificates would be linked to obligations for disclosure of the source of genetic resources and TK in patent applications. Patent authorities would be obliged to inform competent authorities of countries identified as the source of genetic resources and/or TK of relevant IP applications where the source is declared.

3. Certificates of legal provenance would provide evidence of the geographical origin of resources and of compliance with the access laws of the providing country. Users would be legally obliged to maintain the link between the certificate and genetic resources. Certificates would be recorded in an international clearing house. Certificates could be requested at specific check points related to grant of intellectual property rights, product approvals, grant making, and journal publications. Certification of legal provenance of TK may potentially provide a means to extend protection to TK which has fallen into the public domain as a result of breach of a contractual or fiduciary duty, or due to misappropriation.

4. Certificates of compliance would demonstrate compliance with domestic ABS regimes. The certificate would not replace the need for contracts. This proposal favours a system of internationally recognised certificates. Its proponents have argued against the establishment of checkpoints to monitor certificates and resource use. The proposal draws a distinction between PIC requirements under the CBD as they apply to genetic resources, and the lesser obligations relating to TK under Article 8(j) of the CBD. It makes no explicit provision for certification of TK.

5. COP 8 established a Group of Technical Experts on Certificates of origin/source/legal provenance (GTE). The Group identified a number of points common to all four proposals, including: (i) a certificate would be a public document issued by a competent national authority; (ii) it would serve to provide evidence of compliance with national ABS legislation; (iii) it could be required for presentation at specific checkpoints in user countries. Review of all models showed that they could cover all genetic resources. A mandatory system would be restricted to the scope of the CBD; however, a voluntary system might extend beyond the Convention, including pre-CBD collections. The potential benefits of a certificate system to achieve the CBD's ABS objectives were considered likely to increase with greater participation of parties at both the user's and provider's end. A paperless system is favoured by the GTE. However, due to differences in the capacities of the countries involved, any system should be flexible enough to allow for a mixture of paper and electronic formats. The GTE found that the intangible nature of TK poses practical difficulties requiring special consideration before development of a TK certification scheme.

3. Practicality, feasibility and costs of certification

The true test of practicality, feasibility and costs lies in the willingness and capacity of national authorities, ex-situ collections, research institutions, indigenous peoples

and other stakeholders to establish and/or submit to any certification or other harmonized documentation system.

6. Research on existing documentation practices demonstrates that almost all collections, accessions and transfers of biological and/or genetic material are subject to documentation. The experience of ex-situ networks such as IPEN and MOSAICC demonstrate the practical benefits of harmonised documentation. At the national level, the Australian Genetic Resources Information Database (GRID) has established a virtual certificate of origin and provenance system built on open source software. The lack of ABS legislation in many countries may hinder implementation of a certification system. This might be partially addressed by developing global standard MTAs. Use of and a two-tier system for commercial and non-commercial research would facilitate access to resources for scientific research.

7. Simplified procedures for maintaining a chain of custody and demonstration of clear benefits for doing so will be crucial to gaining the support necessary for any certification system to succeed. One potential model is for a "one up, one down" system, where each party in a chain keeps information on where they obtained resources and to whom they have transferred resources. Experiences such as that of INBio and the Science Commons demonstrate the role documentation can play in the development of contractual mechanisms that facilitate access to genetic resources while ensuring fair and equitable benefit sharing.

8. Certificates would not, of themselves, serve as a means of enforcing compliance with ABS laws. However, when linked to a system of checkpoints for monitoring and control of the use of genetic resources they may provide significant incentives for compliance. Persistent global unique identifiers may enhance the ability to document resources and maintain a link with the terms and conditions for their use.

9. To avoid unnecessary costs, any certification system should focus on defining minimum criteria for documentation of collections rather than requiring harmonisation of internal record keeping practices. A study of ABS under the ITPGRFA estimated that the bulk of management costs are related to handling of MTAs. While costs of contract negotiations cannot be avoided, they may be reduced through the use of standard MTAs. Online contracting could further reduce transaction costs. The GTE anticipated high costs in the start-up phase of a certification system, while transaction costs may prove relatively low. Further analysis is required of the potential costs related with establishment and maintenance of checkpoints in user countries, and of implementation costs in provider countries.

10. The effectiveness of any system of internationally recognized certificates would be significantly enhanced if the authenticity and content of certificates can be verified quickly and at minimal cost. Recent advances in information technology have reduced the cost and complexity of establishing searchable certificate databases. These could be introduced through a Clearing House Mechanism or by integrating them into national certificate systems.

11. The existence of pre-CBD collections may undermine effective implementation of a certificate system. A number of potential solutions to this problem exist. These include the provision of incentives to promote voluntary inclusion of pre-CBD collections in any system; their specific exclusion; deeming pre-CBD collections to be held under trust for countries of origin; establishment of procedures to sanitise pre-CBD collections (e.g. by international agreement creating a multilateral benefit sharing mechanism); and limiting their commercial use.

12. To date, there has been insufficient research into the potential and limitations of a certification system to protect rights over TK. Requiring disclosure of evidence of PIC - as a condition for processing IPR grants and product approvals - would reduce the commercial value of collections of TK obtained without PIC. Certification of compliance with PIC would provide legal certainty for users. A certification system may serve as an interim measure in the process for development of international and national TK law and policy.

4. User Measures, access to justice and disclosure of origin

Amongst the most challenging issues facing negotiators will be those of access to justice and the question of disclosure requirements in IP regimes.

13. Providing access to justice will require the adoption of measures by both provider and user countries. National enforcement measures will need to be supplemented by international alternative dispute resolution mechanisms. Establishment of an international ombudsman's office to support developing countries, indigenous peoples and local communities is considered desirable. Clear and harmonised documentation procedure will facilitate administrative, regulatory and enforcement agencies in the execution of their duties.

14. A majority of certificate proposals envisage a system of checkpoints at which disclosure of the origin and/or source and/or legal provenance of genetic resources and/or TK would be required for the purposes of processing IP applications, among other things. An increasing number of developing and developed countries have adopted, or are in the process of developing, disclosure requirements within their IP regimes. These range from voluntary

provisions, with remedies lying outside the patent system, to mandatory obligations with substantive effect within IP law. A majority of WTO member states now support a proposed amendment to TRIPS for the inclusion of mandatory disclosure requirements on origin, PIC, and fair and equitable benefit sharing.

15. Compliance with disclosure requirements would be facilitated where an internationally recognised certificate could act as evidence of conformance with national and international law. For any system to work effectively, it will need to avoid creating uncertainties regarding the status of patents and the introduction of requirements which would be beyond the capacity of patent examiners to process. The administrative burden of checkpoint authorities will be lessened where certificates act as prima facie evidence of compliance with obligations relating to PIC and MAT. Certificates may also provide a rebuttable presumption of fair and equitable benefit sharing. This would provide greater legal certainty for users, and create incentives for use of a certificate system.

16. Advances in areas such as genomics and bioinformatics are redefining the nature of natural products research. These, and other technological advances have significant implications for the design and implementation of disclosure requirements and any certification system. Care will need to be taken to ensure that the scope of disclosure requirements is sufficiently inclusive to encompass both direct and indirect uses of genetic resources, which are of significance to the development of (or form part of) the subject matter of IP applications. This highlights the need for increased efforts to define derivatives and the extent (if any) that they are to be covered by any international ABS regime.

5. Elements of a certificate system

Existing proposals provide a rich variety of options for consideration in relation to certification of genetic resources and TK. While hands-on experiences in resource management offer practical examples of how a certification system could work in practice, taken as a whole they provide the basis for identification of the key elements of a certification system.

17. Development of any certification system will need to start with a clear idea of its objective(s), which may include:

    - Identifying the origin and/or source of resources and/or TK
    - Establishing a standardized international system for traceability
    - Tracking flows of genetic resources and TK
    - Consolidating national permitting procedures, and reducing bureaucratic delay
    - Providing evidence of legal provenance
    - Evidencing PIC, MAT and/or fair and equitable benefit sharing
    - Demonstrating compliance with domestic ABS and/or TK legislation
    - Facilitating implementation of user measures and checkpoints
    - Assisting customs control of transboundary movement of resources
    - Providing legal certainty regarding rights to use resources
    - Establishing a market tool to control market use of resources and TK

18. All certification proposals envision the establishment of some form of standardised or internationally recognisable system of documentation, to provide information on resources and/or TK covered by the certificate. The subject matter covered by a certificate may range from a single sample to all material collected under a bioprospecting agreement. Certificates will need to be flexible, and capable of following resources as they go through multiple transformations. The adoption of a unique identifier for each certificate issued would greatly assist in that process. The relative utility of any certificate system will depend upon its capacity to promote compliance with ABS and TK laws.

19. Checkpoints will play an important role in any international certificate system. For any system of checkpoints to function, whether through disclosure of origin/source or otherwise, it will need to have the capacity to review the existence of rights to access and use resources and TK, and to identify whether or not there has been compliance with such obligations. It is in the interest of all parties that information, which must be provided in order to demonstrate compliance with PIC and MAT, and that provides evidence of a legal right to use resources, be kept to a minimum. Establishment of an internationally recognised certificate would help facilitate that process.

20. Certificates will need to include information on the origin and/or source of genetic resources. They may also require inclusion of information on the legal right to use resources (legal provenance). This legal right, in so far as it relates to genetic resources covered by the CBD, will require compliance with national ABS laws of provider countries. Any certification system should therefore be compliance-

based, and cover the issues of origin, source and legal provenance.

21. Whatever system is developed, there are likely to be incentives for ex-situ collections with pre-CBD genetic resources to bring them within the system and increased pressure to deal with them on the same basis as post-CBD genetic resources.

22. Considering the complex nature of TK systems, it is considered desirable that a special meeting of TK experts be convened to consider the merits and drawbacks associated with developing any certification system to apply to TK.

23. The GTE has shown that, despite various differences in perspective, the four certificate proposals contain many common elements. Building upon these common elements, it should now be possible to begin development of a set of minimum standards and procedures for the development and implementation of an internationally recognized certificate. Existing certificate proposals provide a comprehensive variety of options from which such standards and procedures may be developed.

6. Future Work and General Conclusions

The 6th meeting of the WGABS has identified an international certificate as being one of a number of issues requiring further work in the elaboration of an international ABS regime. In order to build upon the existing work in this area, it is proposed that COP consider calling upon the WGABS to develop a set of minimum standards and procedures for an internationally recognized certificate system for consideration by COP 10 in Japan, 2010. In order to inform such work, a series of research, capacity building and pilot projects should be promoted.

24. The GTE has provided the WGABS with valuable information on the practicality and feasibility of a certification system, and preliminary views on the issue of costs. COP should consider reconvening the GTE to continue this work. In its role as a technical advisory body GTE could be tasked with advising the WGABS on the development of a set of minimum standards and procedures for an internationally recognized certificate of origin/source/legal provenance and/or compliance, taking into account the outcomes of the first meeting of the GTE and WGABS 6 and to further examine implementation challenges of such a certificate for different types of users.

25. The GTE and WGABS should be guided in its work by the principle that the development of an integrated certificate system must meet the needs of the scientific community, commercial actors, and the interests of provider countries, indigenous peoples, local communities and ex-situ collections if it is to be effective. To this end COP should promote the carrying out of information gathering, research, pilot studies and capacity building activities necessary to inform the development of a practical, feasible and cost effective international certificate system.

26. Research to date has focused primarily on the economic and legal aspects of certificate schemes, as well as the documentation practices of ex-situ collections. Increased attention needs to be given to analysis of the genetic resources and TK management and documentation practices of the private sector and scientific community, as well as those of indigenous peoples and local communities.

27. In order to inform the process for development of an international certificate system a number of specific initiatives are proposed, these include preparation of :

    - A wide ranging survey of documentation practices relating to the collection, use, and transfer of genetic resources and TK - this should encompass the activities of government bodies, ex-situ collections, industry, research institutions, indigenous peoples and local communities.

    - Case studies of genetic resource and TK management, documentation and contractual practices, of industry and research institutions.

    - Studies of tracing/tracking of genetic resources and TK across whole supply chains - from geographic source to end use and marketing – in sectors such as biopharmaceuticals, cosmetics, horticulture, other forms of agriculture, and processed food.

    - Case studies on how certification may be used to support indigenous peoples and local communities' resource and TK management practices.

    - Analysis of modalities and mechanisms for the development of simplified systems for managing ABS agreements based upon use of standard MTAs and online licensing. Special attention should be given to analysis of the potential of such systems to facilitate resource management by small island states and least developed countries.

    - Analysis of the relationship of a certificate system with genetic resources collected beyond national jurisdiction including those from Antarctica, the high seas, and the deep sea-bed.

28. A number of expert meetings on certificates of origin/source/legal provenance have been organized at the national, regional and international level over

the past few years. These meetings have helped to inform the work of the WGABS and the GTE in its analysis of issues of practicality, feasibility and costs of an international certificate system. COP may wish to welcome such initiatives and invite countries, international oganisations, civil society oganisations, industry and indigenous peoples and local communities' representative oganisations to collaborate with a view to convening further meetings of this nature in the future.

29. Concerted efforts will be necessary in order to bolster capacity to implement national and local certification systems. To this end COP should call upon UNEP/GEF to provide support for national and regional ABS capacity building projects which address issues of implementation of certificate systems. Funding could also be made available through GEF for pilot projects to test a variety of national certificate systems, including paper-based and electronic systems.

General Conclusion

The creation of an internationally recognized certificate system can play a significant role in facilitating access to genetic resources while protecting the interests of both provider countries and resource users. Development of such a system coupled with measures to ensure transaction transparency and accountability together with measures to address dispute resolution would represent significant progress in developing functional elements of any future international ABS regime.

The changing nature and economics of the gene trade creates great challenges but also new opportunities for tracking and monitoring use of resources and compliance with ABS law and policy. These changes need to be taken fully into account in the development of any certificate system and of any associated system for monitoring use of genetic resources and TK.

1. Introduction

The Convention on Biological Diversity (CBD) adopted at the Earth Summit in Rio de Janeiro in 1992 has three primary objectives. These comprise the conservation and sustainable use of biological diversity and the fair and equitable sharing of benefits derived from use of genetic resources. A supplementary objective entails securing fair and equitable sharing of benefits derived from use of traditional knowledge (TK).

Implementation of the CBD's provisions on access to genetic resources and benefit sharing (ABS) has been one of the Convention's priorities. Over a third of decisions of the CBD Conference of the Parties (COP) relate, directly or indirectly, to this issue and to the related question of protection of TK.[1] One of the principal decisions of COP in this area has been the adoption of a comprehensive set of voluntary guidelines on ABS at COP 6 (Bonn guidelines), in The Hague in April 2002. COP 7, held in Kuala Lumpur in February 2004, gave a mandate to the CBD Working Group on ABS (WGABS) to negotiate an international ABS regime covering genetic resources and TK under Article 8 (j) of the Convention.[2] COP 8, in Curitiba in March 2006, tasked the WGABS with concluding its work by COP 10 in 2010.[3]

Negotiations on an international ABS regime began at the third WGABS, held in Bangkok in 2005. This meeting prepared a broad list of issues and objectives for consideration in the development of an ABS regime. The 4th working group meeting, in Granada in 2006, developed a more structured document, which developing countries, in particular, considered should form the basis for negotiations. The 5th meeting of the working group highlighted the continuing discrepancies, between developed and developing countries on the nature of the challenge being faced and the desirability of commencing negotiation on text. Adoption of a new working methodology at the 6th WGABS, which met in Geneva in January 2008, has led to potentially significant advances in negotiations.

The 6th working group identified five areas requiring further elaboration in the development of an international ABS regime. These include:

- fair and equitable benefit sharing
- access to genetic resources
- compliance measures
- traditional knowledge associated with genetic resources
- capacity building

With regard to compliance measures the 6th WGABS identified as areas for further elaboration:

1. Development of tools to encourage compliance

   a. Awareness-raising activities

2. Development of tools to monitor compliance

   a. Mechanisms for information exchange

   b. Internationally recognized certificate issued by a domestic competent authority

3. Development of tools to enforce compliance.[4]

This paper examines existing proposals and experiences in the development of certification proposals (and associated measures), which may inform and facilitate the further elaboration of an internationally recognised certificate system.

Clear documentation of the source and/or origin of genetic resources and TK (and of rights relating to them) is important for the work of regulatory, administrative and enforcement agencies, and those who wish to research and develop such resources. Providers need the means to track use of their resources and to ensure that their use is conditional upon obtaining prior informed consent (PIC) and mutually agreed terms (MAT). Users need the legal certainty that any resources they are using have been obtained in compliance with relevant ABS and TK laws, if they are to invest in developing new products. Administrative, regulatory and enforcement agencies need reliable information in an easily recognisable format, to enable them to exercise their functions regarding access to and use of resources and knowledge in accordance with relevant law and policy. Presently that information may be obtained from a wide range of documents including access and collection permits, export and import permits, sanitary and phytosanitary documentation, contracts both written and oral, publications and other sources. Rationalising existing requirements through the adoption of a standardised international system of documentation should facilitate rather than impede access to and use of resources and TK, while ensuring that such access and use is subject to PIC and MAT.

Proposals for mechanisms to document resources and knowledge began to emerge soon after the entry into force of the CBD. One of the first of these suggested the use of CITES-like permits to document genetic resources.[5] [CITES permits are a prerequisite for the export or import of endangered species and products developed using resources from endangered species.] Although conceptually interesting, there are significant differences between the trade in endangered species and the trade in genetic resources and TK. CITES permits, for instance, only apply to single transactions, and permits are required from both the exporting and importing countries. In the biotechnology and other sectors making use of genetic resources, these resources may be subdivided, processed, and their active components extracted, synthesised, and incorporated into products for the market. Or they may be reduced to digital codes and transferred across the internet as bioinformation. TK can be easily transferred by electronic means, which greatly restricts the ability of customs authorities to control the export and import of

bioinformation and TK.

The nature of the genetic resources trade demonstrates the need for a flexible instrument capable of being linked to resources even as they undergo multiple transformations. This necessitates a mechanism which can be used to identify the origin and/or source of genetic resources and associated TK, and the terms and conditions relating to that use. This mechanism may also be called upon to provide evidence of compliance with obligations relating to PIC and MAT. To play an effective role in securing the CBD's ABS objectives, any mechanism must be capable of continuing to identify the origin of resources or knowledge used, even after multiple transformations. And this must continue to the farthest practicable point at which rights to benefit sharing may still exist. Any system must create a cut-off point after which certification is no longer required - as, for instance, when the inclusion of a resource no longer has any significant role in product development or where they may be easily replaced with other freely available resources.

The initial proposal for what was termed a "certificate of origin" system was made in 1994, soon after the entry into force of the CBD.[6] As debate on the potential merits of a certification system expanded, proposals were made for certificates of source, legal provenance, and - most recently - compliance. Decision VI/24, adopted by COP 6, in The Hague in 2002, called for investigation into the practicality, feasibility and cost of certificates of origin/source/legal provenance.[7] The issue was again on the agenda at COP 8, in Curitiba, in 2006, where a decision was taken to establish a Group of Technical Experts (GTE) to advance investigation of the possibilities of a certification system to serve as a tool to aid ABS governance. The GTE met in January 2007 in Peru.

This paper examines the opportunities and challenges associated with the development and implementation of an international certificate system. It analyses, the four major certificate proposals and their review by the GTE; the practicality, feasibility and costs of certificates; the position of pre-CBD collections; the capacity of a certificate system to protect TK rights; the relationship between certificates and disclosure requirements in intellectual property regimes; and the role of certificates as a tool for securing compliance with rights over genetic resources and TK. This serves as the basis for consideration of the main options and elements for a certification system, and future work required for its development. It is hoped that this analysis will help negotiators to analyse the opportunities and challenges associated with any certification system, as well as to define its purpose, nature, scope and elements.

The paper is set out in four sections. Section 2 examines the four certification proposals in turn, and the comparative analysis of proposals carried out by the GTE. Section 3 addresses key issues which will need to be addressed if a certification system is to play a meaningful role in securing compliance with ABS and TK law. Section 4 discusses compliance, access to justice and disclosure of origin. Section 5 provides an overview of the main elements to be considered in the development of a certification scheme. Section 6 sets out proposals for future work and general conclusions.

The paper concludes that certificates have an important role to play in bringing legal certainty, transparency and equity to ABS governance; that existing certificate proposals demonstrate numerous similarities, and collectively provide the basis for development of a comprehensive international system; and that further development of certification will require the commitment of the international community, governments and the private sector, which should include pilot projects and capacity building. The paper also concludes that development of an international certificate system should receive the economic support of the Global Environmental Facility (GEF).

With regard to TK, the analysis to date of the potential and limitations of certification schemes as a means to help document and protect TK is insufficient. The paper proposes further analysis in this area, and the convening of a meeting of international TK experts on certificates.

2. Comparative analysis of certification proposals

This section reviews proposals for certificates of origin, source, legal provenance and compliance, and the consideration they are given by the GTE.

2.1 Certificates of origin

The term "certificates of origin" was coined in 1994 to describe a proposal for a market-based system to control the use of genetic resources and TK.[8] The objective behind the proposal is to support effective enforcement of the CBD's provisions on ABS. This is to be achieved by obligating users to provide evidence of PIC for use of resources at defined checkpoints. Provision of evidence of PIC is to be facilitated by establishment of an international certificate system.

2.1.1 The Proposal

The certificate of origin proposal is based upon five premises:

- National boundaries limit the power of countries of origin to control access to and use of genetic material and of associated TK once it leaves their jurisdiction;
- Scientific, commercial and industrial users will not invest large sums of money in the research, development and marketing of any product unless they can secure intellectual property (IP) protection for their investment;
- IP regimes require a declaration as to inventorship and disclosure of a detailed description on how to replicate the invention as a condition for processing IP applications - at this stage the use of genetic resources and associated TK should be brought to light;
- Policing IP regimes in order to monitor the use of genetic resources and associated knowledge is beyond the capacity of all but the richest of companies and nations;
- Existing IP regimes are inadequate for the recognition and protection of indigenous people's traditional resource rights.[9]

The certificate of origin proposal is designed to take advantage of the potential of IP regimes to act as a checkpoint for monitoring compliance by users with ABS and TK laws, and the terms of access. At the same time, a mechanism is proposed to facilitate compliance by users and monitoring by relevant checkpoint authorities. These ends are to be achieved by:

1. Requiring disclosure in IP applications of:
   a. use of genetic resources and/or TK, in the development of the subject matter of the application
   b. evidence of PIC for their use.
2. Establishing an international standardised system of certification to provide evidence of:
   a. the origin of resources and knowledge
   b. compliance with requirements for PIC and MAT for use of resources and TK under national ABS and TK laws.[10]

Over the years the certificate of origin proposal has incorporated a wider range of possible checkpoints at which a certificate may be requested. These include commercial checkpoints, such as product approvals procedures,[11] and non-commercial checkpoints, such as professional journals and state grant making procedures.[12] In the event that evidence of origin and PIC is required for processing of IP and product approval applications this would create a firm incentive for users to ensure that the resources and TK they use in their research and development activities has been legally obtained.[13] The intended effect of the certificate of origin system is to shift the burden of proof regarding the right to use resources from the provider to the user.[14] The mechanisms it proposes for achieving this end would create greater responsibilities for user countries in monitoring compliance with ABS and TK laws.

2.1.2 Why "certificates of origin"?

The term "certificates of origin" is used to create a clear link between what is being certified and a Contracting Party entitled to provide PIC for its use. Article 15 states that the genetic resources covered by the Convention's ABS provisions are only those obtained from a "country of origin", or from a country which had obtained those resources in accordance with the Convention (i.e. from a country of origin, with PIC and MAT). Country of origin of genetic resources is defined by the Convention as being "the country which possesses those genetic resources in *in-situ* conditions."[15] In-situ genetic resources are defined as those found in ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties. A certificate of origin system would enable certification of all collections obtained in accordance with the Convention.

Amongst the perceived benefits of a certificate of origin system are that:

- A certificate system common to all nations would help to harmonize procedures and prevent the need to interpret different contract provisions under differing legal regimes.
- It would protect commercial confidentiality of sensitive contract details not required by patent and product approval authorities.
- A uniform and recognizable certificate would help to

prevent the necessity for verification of the nature of the consent given.[16]

2.1.3 Scope and Nature

A certificate of origin would apply to genetic resources which had initially been provided by a country of origin subject to PIC of that country (unless it specifically waived the need for PIC) and MAT. It would also apply to TK, as will be discussed in further detail below. With regards to genetic resources, a certificate of origin would certify:

(i) The country of origin;

(ii) Compliance with national laws governing access and use.

A certificate of origin system could, therefore, cover all transactions of genetic resources obtained in accordance with CBD which comply with the original terms of MAT. A certificate of origin would, in principle, be issued by a country of origin. However, it has been suggested that any country which is entitled to be considered a "provider country" under the CBD would be capable of issuing a certificate of origin.[17] In such a case, a certificate would still need to identify the "country of origin" of resources; and any agreement for their use would need to comply with the conditions under which they were first obtained. Difficulties could arise in the case of resources collected post-CBD without adequate PIC and MAT. It is possible that such collections - particularly in countries without ABS laws - may be deemed not to have been obtained in accordance with the Convention, precluding certification by a country other than the country of origin.

A certificate of origin system would seem to exclude all pre-CBD collections from certification. However, there may be many cases where pre-CBD collections can identify the origin of resources and provide evidence of PIC and MAT for their use. In such cases they may conceivably be brought within any certificate of origin system through some form of retrospective certification. In all events, the certificate of origin proposal would clearly exclude from certification ex-situ collections whose origin cannot be identified and/or for which PIC and MAT do not exist.

A certificate of origin system would need to be drafted so as not to affect collections and distributions under the FAO International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGRFA), in so far as those are excluded from coverage of an international ABS regime.

2.1.4 Certificates of compliance and TK

Interest in the potential of a certificate of origin system as a means to protect TK came as early as September 1994 when indigenous peoples from the Amazonian region called for further investigation of the concept.[18] Indigenous peoples and local communities continue to call for further in-depth analysis of this and other certification proposals, but from an indigenous perspective.

It has been argued that a certificate of origin system, including disclosure of origin requirements in IP law, could serve as an interim measure to protect TK, while national and international law is being developed.[19] A potential difficulty with the use of the term origin with relation to protection of TK is the potential link to "countries of origin" as defined under the CBD. Indigenous peoples have expressed concern that the exercise of sovereign rights over genetic resources may affect traditional property rights over biological and genetic resources, as well as over associated TK. The certificate of origin proposal does not define the "origin of TK", but merely calls for certification of PIC and MAT of the custodians of TK. Likewise, the CBD does not define "origin of TK", but refers instead to the .□.. knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles."

One potential interpretation of origin of TK for certification purposes would be of "originators of TK.□ The "originators of TK" might be defined as the indigenous people or local community that developed the TK themselves or inherited it as part of their cultural patrimony, passed down over generations. Ascertaining the true originators of TK may be difficult where TK has been shared between and amongst indigenous peoples and local communities. Where the originators cannot be identified certification might be of the "cultural origin" of knowledge i.e. the ethnic group most closely associated with the relevant TK.

Even where TK is widely disseminated it may still be possible to identify the relevant indigenous peoples or local community entitled to be considered the originators of such knowledge. Traditional knowledge sharing is largely governed by customary laws and practices that establish clear rights and obligations for its use and further distribution. These laws and practices may allow for access to knowledge while restricting the right to use it or pass it on to a third person. Indigenous peoples have consistently argued that any measures to protect their TK should be based on their own laws. Likewise, it has been argued that any certification system for TK should be based on customary law and practice.[20] Making certification dependent upon compliance with customary law and practice could help to resolve issues of entitlements to grant PIC and MAT for use of TK disseminated under traditional knowledge sharing practices. The issue of recognition and respect for customary law and practice is complicated by the fact that in some cases customary laws and practices of an indigenous people or local communities may be incompatible with those of other groups holding the same knowledge.

Both the CBD and the WIPO intergovernmental Committee on Genetic Resources, Intellectual property, Traditional Knowledge and Folklore (IGC) have recognised the importance of ensuring that any regime for the protection of TK be developed with due respect for such

customary laws and practices.[21]

2.2 Certificates of source

Proposal of a certificate of source arose as the direct result of a Swiss proposal for the establishment of disclosure of source requirements in patent applications procedures. An explanation of what a certification of source could look like was presented at meetings in Paris and Cuernavaca, Mexico in 2004.[22]

2.2.1 The Proposal

Based upon Swiss proposals[23] for a system requiring declaration of source in patent applications, and later writings on certificates of source,[24] it is possible to identify the key elements of a disclosure of source/ certificate of source system. These include:

- Requirements for declaration of source of genetic resources and associated TK in applications for IP rights
- An internationally recognized certificate of source of genetic resources and associated TK
- Establishment of an international list of competent national authorities to receive information regarding declarations of use of genetic resources and TK in patent applications
- A requirement that patent offices notify competent national authorities when a patent application includes a declaration of source relevant to them

Certificates could play a useful role in such a system, assisting patent authorities in the identification of countries to be notified of applications, promoting transparency, and assisting in the monitoring of resource use. Increasing transparency of patent application information through the use of on-line searchable databases may reduce the need for notification, and is likely to reduce the costs of administering any disclosure system.

2.2.2 Why "Certificates of Source"?

The Swiss proposal for a system of disclosure of source and subsequent proposals for certificates of origin share a number of premises. Firstly, that it may prove difficult - or impossible - to determine the "country of origin" and "geographic origin" of many ex-situ collections of genetic resources.[25] Secondly, that these terms are too restrictive to take into account fully the wide range of entities that may be involved in access and benefit sharing, as contemplated in the CBD and the Bonn Guidelines.[26] Thirdly, if certificates are to be linked to a disclosure system, then both measures should employ the same terminology and be based upon the same concepts.[27] For the purposes of the certificate of source proposal, the term 'source':

> "… is intended to be understood in its broadest possible sense. It not only includes other terms used in this context such as 'origin', 'geographical origin', 'country of origin of genetic resources' or 'Contracting Party providing genetic resources', but also any other source such as publications in scientific journals or books, databases on traditional knowledge, or *ex situ* collections of genetic resources."[28]

The perceived benefits of a disclosure of source - and, by inference, of a certificate of source system - have been stated as being as follows:

- For general researchers, it indicates whether or not their own work risks intruding on another's, whether it is a source of new insights, and tells where (and possibly from whom) similar source material can be obtained.
- For resource regulators or managers, it shows what is happening with their resources, and whether contracts are being complied with. For the patent examiners, it may help them to decide whether an inventive step has been taken, or resolve issues of prior art.
- For investors considering obtaining an interest in IP, it enables them to undertake due diligence, addressing commercial and legal uncertainty, and to determine more accurately the market value of the IP.
- For industry capital providers - whether they are 'ethical funds' or simply concerned to protect shareholder value - they can determine issues of provenance, and satisfy themselves that investing in companies owning the IP involves no risk to their own public reputation.
- For patent applicants, it allows them to obtain the full measure of market reward for their compliance with their legal obligations surrounding acquisition of the source material from which their inventions derive.[29]

There has, in general, been more support from developed than developing countries for the disclosure of source/ certificate of source concept. Developing countries have shown concern that adoption of "certificate of source" system could be misinterpreted as their displaying of support for the position that the right to a genetic resource stems from the source, and not the country of origin.[30]

2.2.3 Nature and Scope

A certificate of source system would apply to both genetic resources and TK. Source under this proposal would include "… the entity competent (1) to grant access to genetic resources and traditional knowledge, and/or (2) to participate in the sharing of the benefits arising out

of their utilization. Based upon the genetic resource or traditional knowledge in question, sources may be either "primary" or "secondary.□ Primary sources would be the Contracting Party providing genetic resources, indigenous and local communities, and the Multilateral System established by the FAO-ITPGRFA. Secondary sources would be *ex situ* collections such as gene banks and botanical gardens, databases on genetic resources and traditional knowledge, and scientific literature.[31]

The proposal is unclear in regard to the status of pre-CBD collections. However, it does appear to limit the scope of certification to resources provided by entities which fall within the scope of the CBD and Bonn Guidelines. On the face of it, this would appear to exclude pre-CBD collections which are not covered by the Convention.

2.2.4 Certificates of source and TK

The certificate of source proposal encompasses certification of TK associated with genetic resources. Obligations to disclose the source of TK in patent applications would be mandatory. Disclosure of TK in development of the subject matter of IP applications would, it is argued, "… support the determination of prior art …"[32] by simplifying the search of TK databases.[33] The proposal does not define what the term 'source' means in regard to TK, and whether or not this would include primary and secondary sources. Primary sources might be seen as indigenous peoples and local communities, while secondary sources could include databases (such as the TKDL database in India).

2.3 Certificates of legal provenance

As an alternative to both certificates of origin and source, it has been proposed that a system of certificates of legal provenance be established.

2.3.1 The Proposal

It is argued that the purpose of a certificate of legal provenance system should be to provide a history of custody of the materials obtained.[34] To this end, a 'certificate of legal provenance' would refer, not to the supplier of genetic resources, but to the status of the resources themselves, certifying that they have been legally obtained.[35] It would serve as evidence of compliance with the access provisions of the providing country,[36] and would travel with resources even after their transformation, continuing to provide evidence of legal provenance.[37]

The proposal argues that the most economically efficient system would require provision of certificates only at late stages of research and development (R&D), when it would be required for funding applications, product approval processes, and, in particular, applications for intellectual property rights.[38] Careful design of checkpoints is considered necessary " …to ensure that by the time that *results* have been derived or *benefits from utilization* have been realized, the relevant contracting Party has been identified and terms for the sharing of the benefits have been negotiated."[39]

The certificate would constitute the minimum piece of information that must be maintained by those accessing genetic resources, and which must be passed along to subsequent users to assist in the identification of the Contracting Party providing resources.[40] Users would be legally obliged to maintain the link between resources and the certificate, and to make it known to recipients of material or information derived from genetic resources.[41]

The proposal suggests that certificates be recorded in an international clearing house, in order to enable not only providers but also third parties to play a role in monitoring use of resources.[42] The majority of information on certificates would be stored in the international clearing house, which would be linked to a registry number or a code which would travel with resources.[43]

The components that need to be defined for the clear and effective operation of the certificate of legal provenance have been defined as follows:

- Designation of national authorities to issue and ensure mutual recognition of certificates;
- Identification of conditions for verification and enforcement of certificates; that is, which materials, for which purposes, in which moment, and at which stage will they be checked, including the limits of obligations with regard to certification of derivatives related to the genetic resource;
- Exclusions, such as transfers of material covered by Annex 1 of ITPGRFA for purposes of food and agriculture;
- Provisions for cases where it is not possible to identify the origin of the genetic materials, including on benefit sharing;
- Differential treatment for specific sectors;
- Mechanisms to solve controversies;
- Creation of an international registry for certificates;
- Treatment of non parties;
- Provisions to deal with ex-situ pre-convention materials, to prevent them from becoming a loophole for any certificate system.[44]

2.3.2 Why "certificates of legal provenance"?

The proposal considers the term 'provenance' to be a more inclusive concept than either origin or source, which refers to the supplier of the material and not necessarily to the process of transfer and transformation that resources may undergo. Certificates of legal provenance,

it is suggested, would refer more to the history of custody of relevant material, from the original access, and would continue through multiple exchanges and transformations (from biological samples, to chemicals, to bio-information).[45]

Anticipated benefits of such a system are that it would:

- Discourage misappropriation of genetic resources;
- Facilitate monitoring by providers and interested third parties, through the use of a clearinghouse mechanism;
- Generate greater transparency and confidence for parties in transactions.

Potential limitations would include the fact that it:

- Does not resolve asymmetries in ABS negotiation capacity and strength;
- Is not a substitute for development of national access legislation;
- Depends on solving the management of ex-situ pre-CBD collections in order for it to be effective.[46]

2.3.3 Scope and Nature

A certificate of legal provenance has been characterised as:

- A legal guarantee issued by a government institution;
- That is internationally recognised;
- Certifying that the exporter has complied with the legal provisions (if existing) concerning ABS in that country;
- Requiring a clear concept of the term 'origin', of who is the provider of the resource and provenance - especially in the case of ex-situ collections.[47]

Proposals for certificates of legal provenance are focused solely on certification of genetic resources and do not refer to TK. Certificates would be issued by a designated national authority, based upon an internationally agreed standard, with a single certificate capable of covering multiple genetic resources.[48] Documentation would include a description of geographical origin, and evidence of compliance with ABS obligations arising under the CBD and national legislation.[49] Where products utilize genetic resources in a sufficiently substantive way so as to trigger benefit sharing obligations, they must be able to identify the relevant certificate or certificates of origin.[50]

It has been suggested that a certificate of legal provenance could allow provider countries to issue a certificate even where they are merely the country of source, so long as they are willing to certify that there is no country of origin that the user can name with sufficient certitude.[51] With regard to pre-CBD collections, the proposal notes the arguments made by some countries that post-CBD transfers of resources - from whatever source - should comply with the Convention and its ABS provisions.[52]

2.3.4 Certificates of legal provenance and TK

Proposals for a certificate of legal provenance have deliberately avoided the issue of TK - which, it is felt, will not lend itself to certification of the kind envisaged for genetic resources.[53] Firstly, due to the complexities associated with intangible knowledge, and secondly, due to concerns regarding potential for loss of rights over TK it if once documented it falls into the public domain. In the event of the development of a certification system for TK, further consideration would need to be given to the potential of certificates of legal provenance to achieve this end.

One of the major challenges facing those working on the development of a system to protect TK is the question of how to deal with TK which has fallen into the public domain. Applying a system of certification of legal provenance to TK could serve as a means to provide a legitimate title for TK which is validly in the public domain, and which should not have retrospective property rights extended to it. At the same time, TK that has come into the public domain following a breach of the rights of indigenous peoples and local communities, or of a breach of fiduciary obligation to them, would not be entitled to certification. This would provide a means to regulate the scientific and commercial use of TK held in databases beyond the control of indigenous and local community rights holders.

Accordingly a certification of legal provenance system may be designed to facilitate differential treatment of TK in the public domain. Thus where TK had come into the public domain as the result of the breach of any contractual or fiduciary obligations, or as the result of misappropriation or other unfair trading practices, certification could be withheld

2.4 Certificates of compliance

The most recent variation on the certification theme was made in a submission by Australia to the CBD,[54] proposing a system of 'certificates of compliance'. The proposal argues that a 'certificate of compliance' scheme could support the effective implementation of Article 15 of the CBD.[55]

2.4.1 The Proposal

A 'certificate of compliance' would be issued by domestic authorities to show that a user has fulfilled all access requirements set out in domestic law in the country in which resources are accessed. Certificates would not replace the need for ABS contracts, but would be

complementary to them, demonstrating that access is consistent with obligations under the Convention. The proposal argues against the development of any standardised international certificate, due to the multiplicity of national domestic measures which may be adopted for regulating ABS. However, it does envision the possibility of the establishment of an internationally recognised certificate conforming to agreed international guidelines. Information which may be included in such a certificate would be

> "…details of the provider and initial user, a description of the material covered (which could vary from a single gene to thousands of species depending on domestic law), a statement of compliance with the relevant domestic law, and reference to any benefit sharing agreement."[56]

The certificate of compliance proposal makes a significant break with all earlier certification proposals arguing against linking any certificate scheme to checkpoints, such as patent applications or product approvals procedures. The argument is made that pre-CBD collections that fall outside the scope of the CBD will make it impossible to establish a workable system which can "… comprehensively cover all transfers of genetic resources.[57]" What is proposed is a voluntary system of certificates, with no specific monitoring system, which applies only to material covered by the CBD.

2.4.2 Why "certificates of compliance"?

The principal arguments given in support of the use of certificates of compliance are that:

- Many of the existing proposals for an 'international certificate' of origin/s ource/legal provenance do not appear to be workable, or consistent with Article 15 of the CBD.
- There are serious practical limitations which circumscribe the objective and scope of a system of certificates, including the differences in domestic implementation of Article 15 and the fact that many legitimate transfers of genetic resources are not subject to the Convention.
- The distinctions between a certificate of origin, source or legal provenance are not helpful.
- The idea of a certificate covering both genetic resources and traditional knowledge is neither workable nor consistent with the Convention.
- Certificates of compliance issued by domestic authorities may be a viable means of supporting the effective implementation of Article 15.
- Certificates could provide evidence of compliance with access requirements for genetic resources without undermining contracts, which should remain the means for stipulating conditions of utilization and ensuring benefit sharing.[58]

The use of the term 'certificate of compliance' is explained by basing it upon a critique of the words 'origin', 'source' and 'legal provenance'. Identification of the 'origin' or 'source' of genetic resources is considered challenging and expensive to verify in many cases, particularly where a species exists in more than one jurisdiction.[59] Furthermore, the range of possible scenarios under which domestic authorities may issue a certificate to indicate compliance with Article 15 of the CBD are considered to be more extensive than could possibly be identified by either 'origin' or 'source'.[60] With regard to the use of the term 'legal provenance', it is argued that this could be interpreted as meaning evidence of compliance with domestic requirements for access. However, "… the term could possibly also be construed in some jurisdictions as constituting evidence of a legal title or ownership."[61] This, it argues, should be "… avoided because, depending on the domestic structure for legal ownership of genetic resources, governments may not have the authority to transfer ownership... [and]... may only have the power to grant the right to use a resource, in which case legal ownership is precluded from vesting in the user."[62] The proposal does not explore the possibility that certificates might serve to certify the existence of ABS agreements which do not involve a transfer of full legal title, but nonetheless establish a clear legal right to use resources.

Among the perceived benefits of a certificate of compliance scheme would be its role in assisting in the effective implementation of Article 15 of the CBD, benefiting both users and providers.[63] For providers, it would help to provide evidence of compliance with access requirements, such as PIC, and would support claims for benefit sharing. Benefits to scientific and commercial users would manifest themselves in the form of evidence that genetic resources were obtained from a provider country in accordance with the Convention.[64] Certificates would provide certainty, transparency, and predictability, and facilitate research and commercialisation - without which, it is argued, there will be no benefits to share.[65]

2.4.3 Scope and Nature

It is proposed that certificates of compliance would only apply to genetic resources provided by a country which has domestic ABS legislation: It would not cover TK. Certification would be voluntary, and certificates would not be harmonised, but rather, designed to be internationally recognisable.

2.4.4 Certificates of compliance and TK

The certificate of compliance proposal highlights the difference between PIC requirements under the CBD as they apply to genetic resources and the obligations relating to TK under Article 8(j) of the CBD, which are weaker. Accordingly, it proposes that TK and genetic resource issues be treated separately, and stresses the need to ensure that any certification system should

avoid arrogating to the State rights over TK.[66] It does not, however, suggest how TK should be addressed. Drawing upon Australia's own legislative experience may provide some guidance on the issue.

The Australian Government's *Environment Protection and Biodiversity Conservation Regulations 2000* requires that a benefit-sharing agreement:

".. must provide for reasonable benefit-sharing arrangements, including protection for, recognition of and valuing of any indigenous people's knowledge to be used, and must include:

1. a statement regarding any use of indigenous people's knowledge, including details of the source of the knowledge, such as, for example, whether the knowledge was obtained from scientific or other public documents, from the access provider or from another group of indigenous persons;

2. a statement regarding benefits to be provided or any agreed commitments given in return for the use of the indigenous people's knowledge;

3. if any indigenous people's knowledge of the access provider, or other group of indigenous persons, is to be used, a copy of the agreement regarding use of the knowledge (if there is a written document), or the terms of any oral agreement, regarding the use of the knowledge.[67]"

In light of these provisions, it would appear practicable to establish a means for the granting of certificates of compliance where statutory requirements exist in relation to the use of TK associated with genetic resources.

2.5 Group of Technical Experts[68]

With a view to determining the potential utility of a certification system as a means to help secure implementation of the CBD's ABS objectives and as a component of an international ABS regime, COP 8 established a Group of Technical Experts (GTE) to examine the idea in more detail. The group which met in Lima, in January 2007, had as one of its objectives: to analyse the distinctions between the options of certificate of origin/source/legal provenance and the implications of each of the options for achieving the objectives of Articles 15 and 8(j) of the Convention. The meeting also considered the proposal for certificates of compliance.

The GTE meeting identified a number of points common to all four proposals including, that a certificate:

- would be a public document to be issued by a competent national authority appointed in accordance with national law;

- it would serve to provide evidence of compliance with national access and benefit-sharing legislation, and;

- it could be required to be presented at specific checkpoints in user countries, established to monitor compliance in relation to a range of possible uses.

The GTE agreed that the basic role of any certificate system would be to provide evidence of compliance with national access and benefit-sharing regimes. This could be achieved by a system of national certificates with standard features to allow for their international recognition. These would be required to be shown at agreed checkpoints, which implies action on the part of both provider and user countries.

Depending upon the model of certification system adopted the report suggests it may assist in achieving a wide range of goals, including: legal certainty; transparency; predictability; facilitation of legal access with minimal transaction costs and delay; technology transfer; prevention of misappropriation; minimization of bureaucracy; compliance with national law and mutually agreed terms; cooperation in monitoring and enforcement of access and benefit-sharing arrangements; development of national access and benefit-sharing frameworks; protection of traditional knowledge; compliance with requirements of the Convention; fair and equitable sharing of the monetary and non-monetary benefits from the utilization of genetic resources and associated traditional knowledge; cooperation among different jurisdictions, and; simplification of access processes to genetic resources.[69]

Review of all models showed that they could cover all genetic resources, with a mandatory system restricted to the scope of the CBD, while a voluntary system might extend its scope beyond the Convention. As any international regime may include both binding and non-binding elements, it is possible a certification system could be mandatory for CBD resources and voluntary for non-CBD resources.

With regard to the format and content of a certificate the GTE took the position that a certificate identified by a codified unique identifier might contain the following minimum information:

(a) Issuing national authority;

(b) Details of the provider;

(c) A codified unique alpha numeric identifier;

(d) Details of the rights holders of associated TK , as appropriate;

(e) Details of the user;

(f) Subject matter (genetic resources and/or TK) covered by the certificate;

(g) Geographic location of the access activity;

(h) Link to mutually agreed terms;

(i) Uses permitted and restrictions of use;

(j) Conditions of transfer to third parties;

(k) Date of issuance.

The group identified a number of potential checkpoints where certificates might be required such as registration points for commercial applications (e.g. product approval processes; and, intellectual property rights offices (in particular patent and plant variety authorities). They also identified additional checkpoints for cases of non-commercial uses, which might be further explored such as entities funding research, publishers and *ex situ* collections. The group favoured a paperless system but recognised that differences in the capacities of the countries meant that any system should be flexible enough to allow for a mixture of paper and electronic formats.

With regard to traditional knowledge the GTE considered that its intangible nature poses practical difficulties and distinct implementation challenges requiring special consideration. The GTE suggested countries of origin should consider covering traditional knowledge in certificates. The group acknowledged that further exploration may be needed in order to determine whether any certificate system should be extended to TK. Indigenous peoples attending the 5th Working Group on ABS in October 2007 in Montreal drew attention to the fact that only one indigenous representative was invited to participate in the GTE meeting. They requested that efforts be made to provide indigenous peoples with the opportunity to have their own "experts' workshop" to address this and other key issues relating to TK and international ABS regulation.

With a view to aiding the work of the GTE, UNU-IAS in collaboration with the Peruvian National Council for the Environment (CONAM) and Environment Canada hosted the Lima ABS Dialogue on, "The Role of Documentation in ABS and TK Governance. That meeting, held back to back with the GTE meeting, was attended by over half the GTE experts. The meeting provided an opportunity to share practical experiences on key issues pertinent to the development of a certification system. These included case studies of documentation practices of industry, ex-situ collections and indigenous peoples; innovative contractual models for online licensing and the opportunities associated with new technologies, such as unique digital identifiers, to facilitate documentation of resources. A summary of the Dialogue's discussions was presented to the GTE at its opening session.

GTE members welcomed the input from the Lima ABS Dialogue and recognised the importance for their work of access to up to the moment information on existing documentation practices, experiences in the development of national certification models and of new technological opportunities for monitoring resources.

The GTE was informed by submissions from states, non-governmental organisations, indigenous peoples etc. One detailed study on the rationale for certification as part of ABS governance was submitted by the Government of Italy. This study identifies a broad range of functions and benefits associated with an international certification system, and their relationship to research, conservation, cultural integrity and commercial ends. (See Box 1).

Reports of national and regional expert meetings on certificates held in Canada and Germany,[70] respectively, were also important to informing the GTE`s work. Future work of the GTE and WGABS on certification will benefit from further initiatives of this kind. In designing expert meetings attention should be given to the outstanding issues facing the GTE and WGABS. The GTE has in particular indicated a need for further work on costs of a certification system, promotion of capacity building to aid national implementation of any certificate system, and consideration of the possibilities for a certification system to apply to TK.

The success of the GTE in agreeing on a basic list of common content elements for any system of certification suggests that real progress is possible. Further work is required to test whether that list of elements adequately meets the needs of all rights holders and stakeholders and serves to efficiently promote and safeguard access and use of genetic resources. To this end attention should be given to the impact of new technology and the increasingly global reach of existing technology. This includes:

- The utility of low cost publicly searchable certificate databases providing evidence of PIC and MAT
- The ability to record progressive compliance on such databases as conditions of PIC and MAT are met
- The spread of searchable patent application and registration databases
- Integration of genomic and morphological taxonomy to create species certainty
- Emerging low cost, portable, gene based bar-coding technology to create rapid attack taxonomy
- The opportunity to link unique identifiers to gene based bar-coding

Debate of certification proposals has been ongoing for more than 10 years, during which time it has been possible to identity a number of key issues that will need to be addressed if any system of certification is to be established. These, include:

- Practicality, feasibility, and costs of a certification scheme

BOX 1: PROPOSED FUNCTIONS OF A CERTIFICATE OF BIOLOGICAL/GENETIC RESOURCES

A Certificate of Origin of Biological/Genetic Resources - legally recognised at an international level - would have a range of functions that are social-scientific and/or institutional-economic in nature, and are interconnected:

1. It would satisfy needs of *Research, Science and Knowledge Systems* in general (informal/local and formal).
2. It would allow the *subject* (state, community) to be recognised as *responsible* for the *conservation-management* of those biodiversity dynamics and components whose origins fall within its territory.
3. It would legitimate the rights of a subject (state, community) to *manage-exploit* (and realise the full potential of) the interactions between local biodiversity dynamics and socio-economic systems. In concrete terms this would enable the entire life cycles of biological-genetic components to be managed/exploited, and bring *'value chains'* under control once again.
4. It would enable the state (and the community) to *gain increased awareness*, to *participate actively* and to *receive empowerment* through managing its biodiversity dynamic processes and *the entire life cycle* of its biological/genetic components.
5. It would enable the state (and the community) to acquire 'management tools' and know-how for formulating *effective local-national-international policies for the conservation-exploitation* of ecological-economic-commercial *'value chains'* of biological/genetic components.
6. It would make it possible for a state or community to avoid losing control over their own biological component/genetic resources, and to keep up to date with, and check, lines of research and scientific results based on these resources. In this context the Certificate would have the following objectives.
   i. Scientific objectives regarding conservation of 'centre of origin' ecosystem dynamics (of reproduction/production, of management/sampling etc.). Examples of this are: the discovery of previously un-known properties and applications, or the establishment of a connection between 'local phenotypical knowledge' and 'genotypical knowledge', leading to a better comprehension of a nutritional chain, or of interactions among ecosystem abiotic (i.e. soil acidity) and biotic elements.
   ii. Scientific objectives aimed at improving subsistence conditions of communities. An example of this may be research lines followed by pharmaceutical or cosmetics industries on the gene pool of an underutilized plant variety that has particular international commercial potential. Additional advantages might be obtained using the same plant variety in different applications and with alternative purposes, at local markets or self-subsistence level.
   iii. It would allow a state (or a community) to pursue further research, autonomously or in co-operation (even contractual) with interested countries and research centres. The provider country could agree, or impose in negotiations, specific lines of research which may not be of commercial interest. For example, we could imagine two lines of research on the same molecules; one on a neglected disease of local interest, and the other on a commercially viable pathology.
   iv. Scientific/commercial objectives to optimize sustainable exploitation of biological/genetic resources.
7. Economic objectives, aimed at reducing information asymmetries and transaction costs (moral risk, adverse selection).
8. Scientific objectives, aimed at reducing information asymmetries and transaction costs (moral risk, adverse selection). 'Scientific Research' is enhanced by increased knowledge on the origin of biological and genetic resources and their life cycles.
9. It enables legal certainty to be established. Legal certainty is a 'public good' not only in economic relationships, but also in scientific relationships.
10. It allows a state (and a community) to evaluate and control the dynamics, and the ecological-economic effects, deriving from the removal, the exploitation, and the market 'supply/demand' of a specific biological element/genetic resource.
11. It allows the knowledge associated with biological elements/genetic resources to be identified, as well as that associated with reference communities.
12. It allows the recognition and the legitimation of local/indigenous communities and of knowledge associated with biological/genetic resources.

Source: P. Bozzi, 2006.

- The manner in which pre-CBD collections may affect the implementation of any certification system
- Potential benefits and drawbacks of applying a certificate system to TK
- The role of certificates in access to justice and alternative dispute resolution
- Relationship between certificates and disclosure requirements in intellectual property applications procedures

These issues will be dealt with in detail in the following sections 3 and 4.

3. Practicality, feasibility and costs of certification

This section examines the issues of practicality, feasibility, and costs related with certification through consideration of existing practices and real life experiences in resource management.

3.1 Practicality

At present, collection of biological material is subject to a plethora of documentation requirements. These include documentation required by national authorities in provider and user countries; internal documentation requirements of ex-situ collections, research institutions and commercial companies; and obligations imposed by customers. Research into existing documentation practices demonstrates that almost all collections, accessions and transfers of biological and/or genetic material are subject to documentation. In a significant proportion of cases, information is already being stored regarding resources received, any internal use or modification of resources, and transfer of resources to third parties.[71] A study by UNU-IAS argues that rationalising documentation procedures would have many benefits, not least in monitoring compliance with requirements for PIC and MAT in ABS agreements. It states:

> "A certificate system common to all nations would help to harmonize procedures and prevent the need to interpret different contract provisions under differing legal regimes. It would also protect commercial confidentiality of sensitive contract details not required by the patent authorities. A uniform and recognizable certificate would also help to prevent the necessity for verification of the nature of the consent given."[72]

Development of standardized documentation procedures is not unique or even novel in the international context. Many industries have identified the need for documentation mechanisms along supply chains to assist compliance with environmental requirements. The auto sector, for example, has developed an International Materials Declaration System, to enable tracking and reporting of materials of environmental concern that find their way into their products. Similarly, the electronics industry, where a single product may contain thousands of components, is working to standardise documentation procedures with a view to rationalising existing record keeping systems.[73]

The benefits of harmonising documentation procedures has not been lost on ex-situ collections, which, under the International Plant Exchange Network (IPEN), have established a set of minimum standards that collections are required to keep, for material they bring within the collective (see Box 2). This information enables users to identify the origin and/or source of material, and the conditions relating to its use. Common guidelines regulate issues such as third party transfers, and require members to treat pre- and post-CBD collections equally.

BOX 2: RESOURCE DOCUMENTATION AND MTAS UNDER THE INTERNATIONAL PLANT EXCHANGE NETWORK (IPEN)

The International Plant Exchange Network (IPEN) was developed as a voluntary certification system to cover the transfer of plant genetic resources within the Botanic Gardens community, exclusively for non-commercial purposes. IPEN members are advised to treat all their plant material 'as if' acquired after the CBD came into effect; i. e. there is no distinction between pre- and post-CBD material.

IPEN distinguishes between two types of documentation: a 'maximum documentation' and a 'minimum documentation'. The 'maximum documentation' covers all relevant information about an individual plant accession, such as taxonomic and collecting data, type of material, source, permits related to the acquisition, and any conditions or terms of the country of origin. All this data is recorded on a documentation sheet by the first garden to introduce the plant material into IPEN. It is this garden which keeps the 'maximum documentation' sheet, and tags an individual IPEN-number to the plant material. This number is unchangeable, and sticks to the material and all its descendants through all further exchanges.

The IPEN-number represents the 'minimum documentation', which is sufficient for exchange of resources within IPEN. It facilitates tracing of the origin of material, and contact with the first garden to obtain further details on the material.

Exchanges with institutions that are not members of the IPEN network are carried out under a standardized Material Transfer Agreement, which binds recipients to the same terms and conditions as members. In the case of intended commercial use and other uses not covered by the IPEN Code of Conduct, the requesting institution has to look for a new Prior Informed Consent of the country of origin, and has to negotiate bilateral agreements regarding Access and Benefit Sharing.

Source: Adapted from A. Gröger, 2007.

The true test of practicality lies in the willingness and capacity of national authorities, ex-situ collections, research institutions, industry, indigenous peoples, and other stakeholders to establish and/or submit to any certification or other harmonized documentation system. The IPEN example is just one instance of the practicality of adopting harmonised documentation procedures. Another, ground breaking example is the Micro-Organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC)[74] - the result of a multiyear project to develop a harmonised documentation system for microbial collections. Inter-institutional collaborations such as MOSAICC and IPEN are important because of the size of the collections they embrace, and their impact on practices across national boundaries.

At the national level, countries such as Mexico, Costa Rica and Australia have adopted varying forms of certification procedures. The most technologically ambitious effort to date has been that of the Australian national government's Genetic Resources Information Database (GRID). This is based upon the concept of what has been called a virtual certificate of origin and provenance system[75] (see box 3). The system is built on open source software, with a view to its being offered to other countries for their own use at little or no cost.

BOX 3: AUSTRALIA'S VIRTUAL CERTIFICATES OF ORIGIN AND PROVENANCE SYSTEM

Unveiled at the 2005 ABS Cape Town Workshop, a virtual certificate of origin and provenance system integrates online processing, certification of PIC and MAT and public verification into a single low cost secure system.

Objectives:

1. Reduce ABS application and processing costs
2. Create a secure, searchable database of PIC and MAT records
3. Address due diligence needs of any party seeking to verify the existence of PIC and MAT - at no cost to the inquirer
4. Enable users or concerned parties to verify compliance with law
5. Enable collections to be traceable, through the use of unique identifiers, and reduce the need for expensive paper trails

Key System features:

- Based on flexible open-source software
- Transparent and searchable, but behind a secure firewall
- Low cost to operate
- Allows on-line applications and processing
- Allocates a unique identifier to each application and to biological material collected
- Provides evidence of compliance through public on-line access to evidence of PIC and MAT for collections of biological resources
- Creates a permanent but updateable Certificate of Provenance/compliance
- Maintains required confidentiality for agreed elements of MAT

Advantages:

- Low staff and administrative costs for provider and user
- Provides secure and reliable evidence of compliance
- Unique identifier replaces need for paper duplicates of permits
- Information can be updated and made public; e.g., third party transfers or additional post collection taxonomic identification
- Refutes biopiracy concerns
- Link through the unique identifier enables all forms of statutory disclosure in foreign national IP systems to be met
- Supports due diligence needs for biotechnology research and development
- Reduces risk of fraudulent documentation
- Creates legal certainty for users of genetic resources and derived products

Source: G. Burton and B. Phillips, 2005.

The practicality of systems such as IPEN, MOSAICC and GRID lies in their ability to bring about win-win opportunities for providers and users. Systems such as these, which help to facilitate access while providing greater certainty along the supply chain with regards to compliance with CBD principles, provide a firm basis for the development of a sound and stable certification system. If a certificate scheme is to facilitate access and ensure fair and equitable benefit sharing, it will need to keep bureaucracy and transaction costs to a minimum. To prove useful, certificates will need to provide evidence of compliance with obligations to obtain PIC and MAT. Where these have been complied with, a certificate should raise a presumption of the existence of fair and equitable benefit sharing. Under a global system, the burden of proof of users to demonstrate a legal right to use resources would be met by provision of a valid certificate. This places the onus upon provider countries to ensure their national regulations and access procedures are adequate to ensure sound negotiation of access agreements.

The current lack of ABS legislation in many countries poses difficulties for the implementation of a global certification system. This might, in part, be addressed by developing a system of standard MTAs, which could be utilized by providers and users where national ABS regimes do not exist. Development of standard MTAs might be carried out with the support of the CBD and with funding by GEF; these could be posted on the CBD clearing house mechanism. A system may be envisioned where potential users could enter into online contracts based on standard terms and conditions posted at a national website of provider countries. Such contracts would grant the user a licence to use resources, with necessary payments also being made online.[76] Users seeking special terms would be free to enter into negotiations with provider countries. Countries' sovereign rights would still entitle them to restrict or refuse access to resources as they see fit. Such a system would need some form of international oversight, and could be usefully supported by an international alternative dispute resolution mechanism linked to, but independent of, the CBD.

Indigenous peoples and local communities are possessors of vast virtual and actual libraries of information regarding biological resources. This may be stored orally or, increasingly, in various traditional, paper-based, recorded, and other electronic, formats. As TK is largely intangible, access and use requires greater attention if control over TK is to be maintained. Where TK is codified, the opportunities for control of disseminated knowledge are greater.[77] However, care needs to be taken to avoid the unintentional placing of TK into the public domain, with a consequent loss of rights to control future use.[78] The experience of the publishing industry, one of the leaders in the use of unique identifiers to track use of copyrighted material,[79] may offer examples on how TK might be more effectively traced, and its use identified.

As yet, the potential of certificate systems to protect TK is unclear. One group of local communities in the Peruvian Andes has, however, moved forward with the establishment of a system of local certificates of origin, which they are attaching to traditional potato varieties.[80] Further investigation will be required to determine the practicalities of applying certificates to TK. This may usefully begin with an examination of existing documentation practices of indigenous peoples and local communities and of PIC procedures under customary law and practice.

In developing any certification system, it will be necessary to be clear as to its potential and limitations. Asymmetrical negotiating power, fraud, and other breaches of good trading practices may still lead to inequitable agreements - even where certificates have been issued by national authorities. A certification mechanism cannot, by itself, prevent such practices. It may need to be complemented by other measures; for example, mechanisms to facilitate access to justice, such as the services of an international alternative dispute resolution mechanism.

3.1.1 Barriers to trade or facilitators of access

Certification schemes are sometimes portrayed as a potential barrier to trade. Industry representatives have pointed to possible impacts on a wide range of industries including the pharmaceutical, cosmetics, plant breeding, natural medicines, horticulture, industrial biotechnology, and seed sectors. This includes impacts on science, trade, and trade policy, especially if "derivatives" are to be included in a certification scheme.[81] A study of ABS and the pharmaceutical sector, on the other hand, argues that only by establishing binding legal obligations upon industry will the CBD's ABS provisions be met.[82] Any certification system will no doubt have impacts on industry; however, these may not necessarily be negative. A UNU-IAS study suggests that a certificate system will promote facilitated access; will help secure fair and equitable benefit sharing; and will reduce the need for highly restrictive ABS regulations in provider countries.[83] The study states that:

> "One of the main beneficiaries of a standardized system for demonstrating the origin of biological and genetic resources and of rights to use them would be the private sector. A certificate of origin system which provides evidence of a clean title for use of resources would enhance the value of resources and create greater private sector interest in the natural product market. At the same time, a system of certification would provide increased transparency; facilitate monitoring of use of resources and of compliance with ABS agreements, responding to the interests of provider countries."[84]

Determining the true costs and benefits to industry of a certification system will require greater awareness of the internal documentation practices of the private sector. To date, there has been very little independent research

on private sector management of genetic resources and TK within an ABS context. One recent study, by UNU-IAS, examined a multiyear biodiscovery partnership between Griffith University and AstraZeneca. This collaboration involved the collection and documentation of sample collections from Australia, Papua New Guinea, India and China.[85] The working practices adopted under the project required registration of all collections, and the maintenance of detailed information regarding the date, time, and location of collection, as well as taxonomic information and details of species abundance. (See Box 4).

BOX 4: SCREENING AND DOCUMENTING SAMPLES UNDER THE QUEENSLAND BIODISCOVERY COLLABORATION

For the Griffith University/AstraZeneca Natural Product Discovery Partnership, the Queensland Herbarium and Museum were contracted to collect specimens. These institutions, as part of the collection process, registered - and continue to maintain - a collection of voucher specimens of all samples collected, as well as providing samples to Griffith University`s Eskitis Institute. Institutions in China and PNG also maintain voucher specimens. Plant samples were air dried and ground to a powder, and marine samples were freeze-dried and ground. Eskitis maintains its collections in powder form. Funds to cover collections over the course of the AstraZeneca partnership have totaled $9 million, and the collections are entirely owned by Griffith University. The full scale of investment by AstraZeneca in the Queensland Biodiscovery Collaboration is around AUS$100 million.

Biota samples collected for extraction and screening were 100 grams. This is a great deal less material than previously required by screening programmes. Advances in screening technology, particularly in the field of miniaturization, means that 200mg of a sample can provide sufficient extract for screening. In contrast, the Roche Research Institute of Marine Pharmacology (RRIMP) in Sydney screened 2100 extracts against a panel of screens over seven years between 1974 and 1981. Sample collections were 10kg of wet marine organisms, in contrast to the 100 grams of today's samples (Camp and Quinn, 2007; Griffith University, 2007). Advances in technology support requirements in the Queensland Biodiscovery Act (2004) that collections be of the minimal amount of biota necessary (See Part 1 3(1) (a), Part 3 and Schedule to the Act).

Once samples were collected, they were numbered and information associated with the sample - e.g., on taxonomy, collection date and location, collecting institution and individual collector, and species abundance – was entered into a database. This assists with tracking and monitoring samples throughout the research process for access and benefit-sharing purposes, re-collection (including any concerns associated with sustainability), and identifying factors that contribute to bioactivity, such as season, location, and stage in reproductive cycle.

Source: S. Laird, C. Monagle, and S. Johnston, 2008.

There is a need for many more such studies, preferably across a range of industry sectors, if a true picture is to be created of the opportunities and limitations associated with developing harmonised documentation standards. In the long run, it will be in the better interests of industry to ensure that such studies are prepared and fully considered in the development of a certificate system.

3.1.2 Differentiating between commercial and non-commercial research activities

ABS laws have traditionally tended to establish similar conditions for both commercial and non-commercial research and collection activities. The result has been to impede access by both national and foreign researchers, often with unforeseen and undesired impacts. Concern at the impacts that strict ABS laws are having on basic science has inspired the adoption of a more "science friendly" approach to development of ABS regulations. New legislative developments in countries such as Australia, Brazil, Kenya and South Africa, for instance, all contemplate distinctions between access for commercial and scientific purposes. Providing for the issuing of a variety of certificates, depending upon the declared intended use, raises questions regarding the capacity of any system to ensure compliance with the terms granted for use. Securing compliance will often depend upon the capacity to enforce the conditions of any agreement in a foreign jurisdiction. For this reason, any system providing for distinctions between scientific and commercial research may need to adopt special conditions in relation to high value resources, such as endemic species. Even taking into consideration the additional complexities of a system involving a variety of certificates, a certification system is considered an improvement on the current situation, which entails multiple permitting procedures and no standardised system of documentation for genetic resources and TK.

The scientific sector is also likely to benefit from a certification system which brings legal certainty and enhances record keeping, enabling the rapid identification of resources, where they were obtained, and the conditions associated with their use. However, this sector will be more susceptible to any increased charges and bureaucracy which may adhere to collection and use of resources. Countries that face taxonomic challenges may choose to reduce or exempt non-commercial use from the imposition of access permit fees. Countries may, likewise, decide to keep permit fees to a minimum for the scientific sector, in the hope

of promoting wider investigation of their resources, and increasing the possibilities of discoveries which may lead to future benefit sharing opportunities. This has been done in Australia at federal level, with no fee charged for non-commercial use of resources, and only a nominal charge of AUD$50 for a commercial permit.[86] Their rationale is that the national interest is served by maximizing access to resources, while MAT protects the country's economic interests.[87]

Experts meeting at an international workshop on certificates of origin, in Vilm, Germany 2005, suggested that a two-tier system of certificates should be applied to commercial and non-commercial research - the idea being to facilitate access for scientific use while ensuring commercial use is subject to full PIC and MAT(see Box 5).

BOX 5: PURPOSE AND MODALITIES FOR A TWO TIER CERTIFICATION SYSTEM

Proposals for treatment of certificates derived from conclusions of working group sessions at a European Experts meeting on certificates held in Vilm, Germany in October 2006.

Participants proposed a model, based on two different certificates, which would minimize costs. This model differentiated between:

i. A certificate or 'permit' necessary for non-commercial uses ('permit I' or 'PIC-light'), in essence a coordinated and simplified collecting/export permit, Permit-I would forbid the user to commercialize and to apply for IPRs. For this permit a fee could be required for access to the genetic resource at the moment of collection, but this would not be an upfront payment for future commercialization. This permit would be useful for noncommercial uses, e.g. by gene banks, universities, etc.

ii. Certificates for commercial use of genetic resources ('permit II'). At this stage full ABS negotiations would be required

Both permits could have a unique number and would be registered in a data base, so that it would be possible to check them. Documentation obligations would be restricted to a minimum; e.g., as in IPEN and MOSAIIC. Benefit-sharing would be non-monetary and could include, among other things, the exchange of good practice and cooperation with the host country. If a change of intent from a non-commercial to commercial use of the resource occurred, the user would need to negotiate PIC and MAT with the country of origin. Checkpoints would be necessary, at which PIC and MAT would need to be proven. National laws will be necessary to implement and enforce this two-tier system.

Adapted from: F. Ute and F. Wolff, 2006.

3.2 Feasibility

To be functional, any certification system will need to maintain a chain of custody linking resources and TK with the terms and conditions established for their use. This will require that end users be able to identify (trace back) the original provider and the conditions applying to use of resources. To this end, biodiversity collectors, ex-situ collections and other resource brokers will need to maintain secure records of resources collected, uses made of them, any replication of resources, and transfers to third parties. They may also be required, under the terms of the original access agreement, to inform providers or seek their prior consent before making any transfers to 3rd party recipients. In some cases third party transfers may be prohibited altogether.

3.2.1 Documenting a Chain of Custody

Opposition to certification has often been premised upon claims that it is not feasible to require users to keep extensive records on the resources that pass through their hands. This fails to recognise that at present almost all users of genetic resources for scientific and commercial use keep detailed records of the material collected, where it was obtained, as well as keeping internal records of how resources were used, replicated, or otherwise modified, and data on third party transfers. These records are not only kept as part of good scientific and commercial practice; they are at times obligatory as a condition for receiving resources in the first place.

INBio of Costa Rica has made a name as a leading proponent of sound biodiscovery activities. Since its inception, INBio has negotiated agreements with a wide range of resource users including, multinational corporations and top-level research institutions. As part of its business model it has developed internal documentation requirements that have shown the feasibility of labelling even individual insects given sufficient resources.[88] It has also established extensive documentation requirements for third party recipients of its resources (see Box 6). The willingness of its contractual partners and scientific collaborators to apply such documentation standards speaks volumes about the real status of documentation in the industrial and scientific sector.

BOX 6: CONTROL AND MONITORING MECHANISMS DEVELOPED BY INBIO

Accession and internal transfers
Material is collected in the field under a permit system with separate permits for export and domestic use. A standard agreement applies to taxonomic research while unique legal agreements are developed for bioprospecting research.

Specimens are often only identified to Family or Genus level in the field and so many specimens from a collection trip may have the same textual description on the label. This can be a collecting number, the name of the collector, the date and information about the location. As specimens are sorted in the laboratory, each receives a unique barcode which is physically attached to the specimen e.g. pinned to an insect or fixed to a vial of fungi.

All the information subsequently generated on a specimen is registered in a database with reference to the barcode number. Basic information includes collection data (where, when, methods etc), taxonomy, biology, history and GIS. All transactions are recorded including the loans and transfers of material and details of the researcher, objectives of the project, dates and list of materials.

The database (ATTA) is a relational database based on Oracle with a Powerbuilder interface. Separate databases store publicly available information on specimens and restricted information which includes documentation such as the MTAs.

External transfers for bioprospecting
All material leaving INBio's Bioprospecting Unit is labeled with a barcode and identification number. INBio uses legal and contractual mechanisms for the tracking of the Genetic Resources as follows:

1. Access is limited in time and quantity. Any transfer to a third party of a sample is made using a material transfer agreement (MTA) or under a collaborative research agreement (with companies, research institutions, etc). INBio agrees to transfer the materials specified in detail in the annex of the MTA or the contract.
2. The recipient may transfer the material only with prior written authorization. The terms and conditions of the original MTA shall apply equally to third party transferees. A letter usually accompanies all transfers stating, that:

   "This material has been received under a Material Transfer Agreement which includes terms and conditions for use by Third Parties."
3. The Recipient must assign a unique identification number to each of the materials obtained and to the resulting materials from the research, which will ensure traceability.
4. The recipient is usually obliged by the contract to maintain complete and accurate internal written records and reporting systems so as to keep track of all the materials and any research and/or development activities.
5. The recipient has the duty to allow INBio, upon request, to audit and/or inspect such records and reporting systems, from time to time, and to make such changes in such reporting system as INBio may reasonably request to ensure the accurate tracking of all materials.
6. INBio may have access to the lab notes on INBio material.
7. The recipient shall submit periodical reports to INBio on materials, stage of the research, IPR, research results, etc.
8. The monitoring of uses is provided by the Bioprospecting Unit. There is no Department or special personnel dedicated to the monitoring of contracts; it is done by the current scientific and technical personnel in charge of other Bioprospecting tasks.

External transfers for biodiversity inventory
In the case of inventory, in general, all the types of samples located in the INBio's collection can be transferred to a third party, using a MTA and only for basic non-commercial research. This is mostly taxonomic research which does not involve access to reproducible genetic resources. Transfers are made only to qualified collaborators. Each specimen has a bar code written in the sample form or MTA and monitoring is done through 1) reports from the recipient and 2) a requirement for the recipient to cite the barcode number of any specimens used in publications.

Conclusions: practical aspects of tracking genetic resources

The database and barcode system effectively enable tracking however the purpose of the system is not primarily for tracking, it is to associate information with the material to facilitate biodiversity research.

The unique barcode number allocated to each specimen leaving Costa Rica could potentially be linked to a certificate of origin number at minimal expense and with little technical modification to existing systems in INBio.

Source: J. Cabrera, 2006.

A study of user measures, carried out by UNU-IAS, has identified a list of information that may be incorporated in a certificate, these include:

- Particulars of the provider and user;
- Particulars of the indigenous or local communities parties to the agreement;
- Details of genetic resources or traditional knowledge;
- Details of the approved use which may be made of the resources;
- Details of any restrictions on use;
- Period of the agreement;
- Conditions relating to transfer of rights to third parties; and
- Details of the issuing authority.[89]

A subsequent collaborative study, coordinated by UNU-IAS – incorporating case studies prepared by The Royal Botanical Gardens at Kew, the Smithsonian Institution and INBio - examined both the challenges and opportunities posed for ex-situ collections arising from the development of a global system for documenting transfers of genetic resources. This study found that, in almost all post-CBD collections, all of the information listed above is available in some form, although, rarely in one place and often subject to some restrictions.[90] Even where all the information is available to an institution, in many cases it cannot be transferred to labels on specimens, and it may not, therefore, be passed on to third parties.[91] These difficulties are less prevalent with new collections, which are generally being entered into databases as they arrive.

Based upon the three cases studies and analysis of the documentation procedures of a number of European microbial collections, the UNU-IAS study proposes that any international certification system should, where viable:

- Use existing tracking procedures;
- Minimise the creation of new levels of bureaucracy;
- Promote automatic issuing of certificates upon compliance with specific criteria, such as completion of MTA or ABS agreement;
- Promote consolidation of existing permitting requirements with any new certification system;
- Promote paperless systems;
- Establish minimum standards for the recording of collections, to ensure a link between incoming and outgoing resources, without requiring harmonization of internal recording procedures;
- Provide economic support to developing countries to develop online systems to support an international documentation system.

These and similar studies help demonstrate the benefits and viability of establishing systems that promote synergies amongst existing documentation practices. The challenge does not appear to be to build acceptance regarding the need to keep detailed records of resource collections, their use and transfers. That appears to be the norm. What is, however, missing is acceptance of the benefits and need for greater transparency and harmonisation regarding the type of information to be kept and the responsibility to maintain a chain of custody between what is received, what is used, and what is passed on. Simplifying the process for maintaining a chain of custody and the demonstration of clear benefits for doing so will be crucial to gaining the support necessary for any certification system to succeed.

One option is for a system where each party in a chain keeps a minimum amount of information on resources received, how they use them, and to whom they have transferred resources or products developed using such resources. The Saskatchewan Herb and Spice Association have developed a system along these lines that creates a chain of custody involving all intermediaries from the original provider until the final user.[92] Requiring any party transferring resources to always include information regarding the original source of the resources will enable the end user to identify that source/origin.

Certificates would not replace the need for contracts demonstrating PIC and MAT; but they could serve as evidence of their existence. The certificate would demonstrate the existence of a legal right to use resources, subject to the terms and conditions of the contract under which they were accessed. The more they are used, the greater their utility and the possibility that they may facilitate (rather than limit) access to and use of resources. Where user measures create incentives for users to seek PIC and MAT, which may be evidenced by certificates the incentive for their use will grow. As it does so, provider countries will be in a position to utilise certificates as a means to link resources and TK with standard terms and conditions for their use. To the extent that certificates can provide legal certainty for users, there will be an incentive to use them. This utility also applies to users within the national jurisdiction concerned. This is because the use of certificates will facilitate the development of new, locally derived products, by easing any concerns about their origins and any attached conditions applying to the source material. This is especially valuable in regions where common genetic resources are distributed across national boundaries.

3.2.2 Persistent global unique identifiers

As the debate on certificates advances, increasing recognition is being given to the role of unique identifiers as a means to help identify resources and link them to relevant terms and conditions for their use.[93] It has been proposed that a persistent global unique indicator[94] could be used to identify a relationship between specific resources and their certificate.[95] Another proposal is for the issuing of a digital unique identifier to certificates themselves, which would serve as the link to relevant contractual terms and conditions relating to use of resources held on national databases.[96] Unique identifiers are already widely in use by a range of organisations as a means to track the flow and use of a wide variety of materials (see Box 7).

BOX 7: DOCUMENTING LIFE – POTENTIAL OF BARCODES, UNIQUE IDENTIFIERS

1. The Entomological Collection Network attempts to tie the data derived from a specimen to that particular specimen by using attached barcodes. According to them, barcodes, while still expensive, allow the identification of individual specimens and greatly reduce the cost of subsequent data handling.
2. Bar-coding of life (www.barcodinglife.com) is a project that uses DNA sequences as genetic barcodes. A 648 base-pair section of the mitochondrial cytochrome oxidase I (COI) gene has been shown to provide species-level resolution in varied animal phyla. The barcode of life consortium includes natural history museums, herbaria, biodiversity research oganisations, government oganisations and private companies.
3. The International Plant Exchange Network (IPEN, http://www.bgci.org.uk/abs/ipen) is an exchange system for botanic gardens for non-commercial purposes. All plant material supplied by an IPEN member needs to be accompanied by an IPEN number that remains connected with the material and its derivatives through all generations to come. With the aid of this number it is possible to track where and under which conditions the plant entered the network.
4. The World Data Centre for Micro organisms (WDCM, http://www.wdcm.org) assigns unique identifiers to the different registered culture collections. Collection acronyms followed by a number are used to refer to a certain strain and act as such as an identifier at the strain level. When strains are being exchanged between collections synonym acronyms may cause great confusion. This problem is resolved by WDCM, assigning a unique identifier to the collections or institutes that provide the strains.
5. The Organisation for Economic Cooperation and Development (OECD, www.oecd.org) has investigated the use of unique identifiers for transgenic plants. The unique identifier is seen as a key attributed to a biotech product, which could facilitate cross referencing information in different databases, and improve access to and management of information by regulators and other interested stakeholders.
6. 6. DNA or protein sequence databases make use of accession numbers as the identifier for a given sequence.

Source: P. Desmeth, 2005.

The MOSAICS program[97] is a multiyear project to develop a conveyance system to manage access and benefit sharing issues related to microbiological resources, in the context of the CBD and the enforcement of other relevant international rules. Based upon extensive research into options for harmonised documentation, researchers have proposed a system involving the use of persistent globally unique identifiers (GUID)[98] at its core. What is envisioned is a system, which would begin with coverage of microbial collections and then spread to other ex-situ collections. Under this vision:

- Unique identifiers would not replace traditional labeling of strains, genes or other data elements, but would allow them to be incorporated in a larger namespace that provides an extended unicity and interoperability.
- The WMCC would oversee a harmonised international system of global persistent unique identifiers.
- Digital Object Identifiers (DOI's) are considered the most appropriate system for tracking of microbial resources.
- DOIs can be assigned to any identity, for use on digital networks. Information about a digital object may change over time, including where to find it, but its DOI will not change.
- A similar procedure would be recommended, for biological resources (BR) other than microbial resources, so that most *ex situ* BR could be managed through one global system.
- Participation of professional networks and federations must be organized on a modular concept, allowing gradual connection of collections, institutions and scientists to a compatible permanent system, without making them interdependent.[99]

The potential of unique identifiers was not lost on the GTE and it is increasingly likely that any certification system will incorporate their use in some form or other. One of the drawbacks of a system which uses identifiers such as DOI's is the potential costs associated with a system in which the issuance of identifiers is in private hands. If any international certification system is to successfully incorporate the use of unique identifiers it will need to be based upon a mechanism which will not prove too costly. Research is needed to investigate the potential for establishment of a stand-alone system of identifiers which could be managed as part of an international ABS regime.

3.2.3 Standard MTAs and online licensing

The costs of ABS negotiations and the time taken to conclude even modest agreements for collection activities have become one of the principal impediments to access for both commercial and scientific ends. In the process, much potentially valuable pure scientific research and opportunities for collaborations between research institutions as well as with industry are being lost, with little noticeable benefit for either provider or user countries. Furthermore, the vast majority of access agreements focus on scientific uses with little immediate commercial value. In many cases resources are available from a variety of sources and their overall value as samples for preliminary research are likely to be low. Prolonged negotiations and face-to-face meetings between providers and users may prove prohibitively costly, where the amount of the resources and value of the transaction is relatively small. Resource providers are now looking for new resource management and business strategies which can protect national sovereign rights over resources; streamline contractual negotiation procedures; and facilitate access with a view to enhancing opportunities for benefit sharing.

One ABS business model that has received significant attention is that of Yellowstone National Park. Yellowstone actively facilitates collection of its resources and their use, for scientific purposes with little, if any, up-front benefit sharing. Yellowstone's philosophy has been that the more research which is carried out the greater the chance of a commercial hit.[100] In such cases the research collection license obliges the user to return to negotiate a full benefit sharing agreement. A potential weakness with such a system for global distribution of resources lies in the difficulties which may arise in enforcing agreements, once resources have left the provider countries jurisdiction. This is a difficulty that applies, however, to all contracting and as such is a question that will need to be addressed if any international ABS regime is to function effectively.

Proposals now exist for online licensing regimes which reflect the Yellowstone models underlying principles. That is, facilitated access for scientific research with obligations to return to negotiate full PIC and MAT and benefit sharing if commercial use is desired. An online system of standard MTAs, developed by the Science Commons, for the licensing of biological material for non-commercial purposes is of particular note.[101] The idea behind the Science Commons approach is to:

1. Enable potential users of biological research material to retrieve, via the Internet, comprehensive information on where specified biological material can be located and the conditions for access and use. Provide that users may enter into online agreements for resources.

2. Automatically record transfers and attach a licensing agreement to the biological samples to be shipped to the user. Subsequent users can easily identify the provider of resources from the licensing agreement.

3. Enable providers of biological research material to obtain information on subsequent uses of this material through Internet searches for the unique identifier linked to the specific research sample.[102]

The Science Commons licensing model incorporates three innovative steps. These compromise, the use of a menu of standard MTAs with limited choice of provisions, automatic translation of agreements into machine readable format, and utilisation of semantic web Internet language (see Box 8).

BOX 8: INNOVATIVE ASPECTS OF SCIENCE COMMONS ONLINE LICENSING SYSTEM

Science Commons has developed an innovative system for online licensing of biological materials which:

1. First, seeks to lower the time and energy spent on negotiations of MTAs by s*tandardising the possible choices providers and users can make*. Providers and users are offered a choice of standardised options on a few issues that typically consume most negotiating time.
2. Second, *automatically translates MTAs into an electronic machine-readable format*. Information on biological material and standard MTAs for their use may then be published on the Internet (which only requires a PC, software and internet access and thus can be done from anywhere in the world at low cost). This can be picked up by specially programmed search engines that crawl the web, and be used to update a virtual register of the internet-locations of biological materials and attached user conditions.
3. Third, makes use of a new generation of Internet language, the so called *semantic web*, which makes it possible to relate an entry on a specific research material to another entry on associated traditional knowledge or information on references to this research material in scientific journals. Such relations can then be extracted from the web through specific searches.

Source: M. Buck, 2005.

The Science Commons model offers a potentially low cost versatile means for managing ABS contracting, which if widely applied could reduce transaction costs and promote wider use of resources and increased benefit sharing opportunities.[103] It is not however, a complete answer and provider countries are still likely to want hold formal negotiations for access to and use of high end-value resources, such as those endemic to their territories. This will in all likelihood, however, be only a small percentage of overall transactions and it is conceivable that an online standard MTA model will appeal to many countries. Another benefit of using standard MTAs is their potential to help to level the playing field in what may otherwise be asymmetrical negotiations. This form of online licensing may prove of interest to indigenous peoples and local communities as a means for managing some TK related contracts. It is likely, however, to prove less useful where sacred or other culturally important TK is involved.

Use of Standard MTAs and online licensing has been adopted by the ITPGRFA. Under this system legal consent to the agreement is shown by 'clicking' online to order a seed or by ripping open a seed package ("click-wrap" and "shrink-wrap" respectively) in addition to a physical signature on a paper contract. Once signed, the contract would require the recipient to make benefit-sharing payments for covered products commercialised under restriction, and the money which would go into a fund administered by the Governing Body for distribution to farmers and other providers of genetic resources. The payment requirements are calculated as percentages of revenues from commercialisation minus thirty percent, with the latter deduction incorporated to allow for transportation, marketing and related costs.[104]

Online licensing will not itself overcome the problems associated with protecting rights over resources and TK once they have been transported to foreign jurisdictions. The adoption and maintenance of effective user measures will be crucial if the opportunities offered by online ABS contractual systems are to be realised. Measures will need to address issues such as contract enforcement, recognition of foreign judgments and provide accessible remedies in the event of breach of contracts or misappropriation of resources by third parties.

3.2.4 Carrots and Sticks: Incentives for use of certificates

Clear documentation of genetic resources and TK would appear to offer benefits for a wide range of actors, creating incentives for their use. Providers, for instance, need the means to track their resources and ensure compliance with national regulations on PIC and with MAT. Users need legal certainty that the resources they are using have been obtained in compliance with relevant ABS and TK laws. Administrative, regulatory and enforcement agencies need reliable information - in an easily recognisable format - to enable them to enforce relevant law and policy. Presently, that information may be obtained from a wide range of documents, including access and collection permits, export and import permits, sanitary and phytosanitary documentation, contracts (both written and oral), publications, and other sources. A standardised international system of documentation should, therefore, facilitate rather than impede access to and use of resources and TK, while ensuring compliance with obligations relating to PIC and MAT.[105]

It has been argued, that in order to be incorporated into an international ABS regime a certificate system, will need to "…integrate clear commercial benefits and tie the system in with existing commercial systems in a way that creates a clear incentive for users to comply with the system requirements."[106] Certificate proposals have tended to address this issue with what may be seen as a carrot and stick approach. An internationally recognised certificate providing legal certainty with regards to the right to make use of resources creates an incentive for their use (the carrot). A complementary system of checkpoints requiring evidence of PIC and MAT for use of resources and TK, brings the threat of some direct or indirect commercial loss or penalty where PIC and MAT cannot be shown (the stick).

Certificates will not, of themselves, serve as a means to enforce compliance with ABS laws or the terms of any agreement for access to and use of genetic resources or TK. However, when linked to a system of checkpoints, which provide means to monitor and control use of resources and knowledge, they may provide significant incentives for compliance. A variety of check-points have been proposed, at which a certificate may serve as evidence of the nature of subject matter, its origin and/or source, and rights of access and use. These include customs controls, intellectual property offices, and registration points for other commercial applications not covered by intellectual property rights.[107] Non-commercial checkpoints, such as the publishing houses of scientific journals, grants making bodies, and ex-situ collections may also be considered.

Checkpoints have an important part to play in securing compliance with ABS objectives of the CBD. Without them, opportunities for identifying the use of genetic resources and TK are diminished. In this case, countries of origin, indigenous peoples, local communities and other stakeholders will be reliant on their own capacity to regulate, control and monitor the use of their resources. This task is likely to prove impossible for all but a small minority of countries and other rightsholders. Checkpoints are amongst the user measures provided for in the Bonn Guidelines. It has been proposed that checkpoints should be focused more on the research and development phase of resource use, reducing pressures for strict monitoring and regulation during the access phase.[108] This would reduce the costs to provider countries of implementing and administering a certificate system and place the burden further along the chain of resource use where cost can be better absorbed by commercial users. This would also reduce the bureaucratic burdens for both providers and users of

excessive monitoring of low value early stage activities relating to collection and processing of resources. Resources and knowledge would still need to be the subject of ABS and TK agreements, appropriately certified and documented from the outset. However, while documentation would need to link through all those who had control of resources, monitoring checkpoints would be reserved for certain milestones in the research and development process, such as those related to product approval, IPR applications, publications, or the presentation of funding proposals.[109]

While checkpoints will eventually be needed in all countries, the priority should at first be to ensure their establishment in those countries where the biotechnological, pharmaceutical and agro-industrial industries are concentrated, and where the greatest markets for their products exist. To date, adoption of user measures - including functional checkpoints to appraise the use of genetic resources and TK - has been patchy. The most notable advances in this area have come with the progressive implementation of disclosure requirements in IP regimes. The issue of user measures, compliance and disclosure requirements will be discussed in more detail in section III, below. In design and implementation of user measures and any certification system care will need to be taken to avoid inappropriate impacts on trade, which may potentially lead to conflicts with the WTO.[110]

3.3 Costs

Despite the apparent practicality and benefits associated with standardising documentation, and the existence of experiences such as IPEN and MOSAICC, some major ex-situ collections have been slow to embrace proposals for an international certification system. This resistance is due in to a number of issues, not least of which are concerns at the potential costs and technical difficulties associated with harmonisation of record keeping. There is significant concern that a harmonsied system might, for instance, require ex-situ collections to re-catalogue their collections, a daunting prospect and a potentially unproductive use of scarce resources which would need to be diverted from other scientific activities.

These concerns cannot be lightly overlooked. The Royal Botanical Gardens at Kew (Kew Gardens), for instance, has estimated that a certificate scheme may require hiring between three to four persons just to maintain records of accessions.[111] Large biodiversity collections such as those at Kew Gardens and the Smithsonian Institution could potentially be overwhelmed by an inappropriate certificate system simply because of the numbers of specimens and transfers they handle. Kew's herbarium, for example, receives around 23,000 specimens per year from other collections, and distributes around 18,000 specimens. To retrospectively certify its collection of 7.5 million specimens would be enormously costly. The Smithsonian deals with even larger numbers of specimens. Such collections may hold material for extremely long periods - in some cases, upwards of a century or more. This raises questions regarding the length of time for which records would need to be kept. Any certification system requiring harmonisation of the internal record keeping practices of collections would involve significant costs, especially in relation to software and hardware retooling. This would imply that any system should focus on defining minimum criteria for recording material collected, and its use and transfer to third parties, rather than requiring harmonisation of internal record keeping practices.

A recent study has sought to identify the potential costs of a documentation/certification system for the ITPGRFA. This study suggests that between 41% and 97% of benefits derived from that system may end up being consumed by transaction costs.[112] The study calculated that between 50% and 100% of tracking costs would be associated with managing standard material transfer agreements.[113] If DNA fingerprinting is involved this may account for almost 45% of tracking costs.[114] The allocation of the majority of costs associated with tracking to contract management and DNA fingerprinting highlights the minimal costs associated with recording information regarding resources collected, their in-house use, and subsequent transfer.

The value of the above-mentioned study for the purposes of determining the costs of certification for a wider ABS regime is rather limited. The resources under the ITPGRFA are destined only for use for food and agriculture, and benefits will arise only in very limited instances. The study does show, however, that the bulk of costs associated with managing resources are likely to be related to contract management and the use - if at all - of high tech tracking mechanisms. At present the likelihood of massive DNA fingerprinting of genetic resources by provider countries is remote, given current costs. It is more difficult to avoid the costs of contract negotiations, they may, however, be reduced through the use of standard material transfer agreements (MTAs). Using online contracting procedures would further reduce transaction costs. A documentation system that facilitates the use of standard MTAs and online contracting for use of resources is likely to further reduce overall transaction costs rather than increase them.

One of the key issues addressed by the GTE was the implementation and other costs associated with setting up a certification system. These were anticipated to be high in the start up phase; however, it was felt that transaction costs may prove relatively low. The group agreed that costs were likely to escalate if a system involves excessive tracking, reporting and monitoring, or generates more bureaucracy than required. It also agreed that excessive bureaucracy could prove counterproductive if it unnecessarily slows down or discourages research and product development. The GTE noted the need to consider costs related to the establishment and maintenance of checkpoints in user countries. The existence of pre-CBD collections outside of any certificate system could in the GTE's view cause inefficiencies and potentially increase costs and overall loss to the system.[115]

To the extent that a system could lower transaction costs and provide flexibility and legal certainty, the GTE felt it could balance the costs of implementation and avoid the costs associated with the uncoordinated development of national regimes. The GTE's report notes that the level of legal certainty provided by a certificate system and its potential to secure the CBD's ABS objectives, are likely to increase as obligations to provide and monitor certificates in provider and user countries increases.[116] Conversely, the GTE felt, the level of legal certainty may decrease as any system becomes more discretionary.

Low cost functional documentation schemes for recording plant genetic resource collections and transfers do exist. One practical example is the case of the Saskatchewan Herb and Spice Association which has established a documentation system in order to secure the source and reliability of medicinal plants, where plant quality is crucial. Referred to as a "one up one down system"[117], members are required to maintain records of resources received, use of resources and transfer to third parties. Similarly, in a study of microbial collections in Europe, it was noted that a majority of collections kept information on what came in, what they did with it, and what went out.[118] A crucial difference between the record keeping practices of the microbial collections investigated and the one up one down model is that many microbial collections do not link the resources that come in with those that go out.[119] Failure to keep this information breaks the chain of custody necessary to identify the origin of resources. This in turn severs the link to the original terms and conditions, if any, governing use of such resources. Where multiple genetic resources are aggregated and it is technically impractical to make a link to the output, it may be necessary to find a way to put all related certificates under one common MTA and benefit sharing agreement.

Experiences in other industry sectors, such as the electronics sector, show that, where a multiplicity of record keeping systems proves overwhelming, the involvement of stakeholders in a meaningful way is crucial to exploring ways to integrate their record keeping activities. Securing the widest possible participation of rightsholders and stakeholders in the design of an international certificate system could go a long way towards mainstreaming documentation and reducing costs of any system for both providers and users of genetic resources and TK.

3.4 Pre-CBD Collections

There is a widely held belief that the CBD granted sovereign rights to countries over their genetic resources. In fact, this is not the case. What the Convention did was to recognize sovereign rights that countries had never relinquished. This is highly relevant to the debate regarding genetic resources collected prior to the CBD whose legal status remains unclear. For some, the fact that the Convention does not address pre-CBD collections implies that countries of origin no longer have any legal right over them. An alternative view is that any post-CBD transfer of resources must be carried out in conformance with the Convention, and this applies to material from pre-CBD collections. This issue is of particular significance to research institutions, ex-situ collections, and commercial actors with extensive collections of genetic resources and/or TK.

Requiring pre-CBD collections to produce evidence of a legal right to use resources, based on the existence of a sound legal title obtained from a country of origin, would have a significant impact on their commercial value. The wide distribution of genetic resources over centuries - many of which are mainstays of global food security - is frequently posited as a reason to avoid extending control over pre-CBD collections. There are, however, sound arguments in favour of preventing commercial use of resources originally provided for purely scientific purposes. There are similar reasons to impede use of resources obtained by theft, fraud, and/or misrepresentation, as well as where laws were not in place to secure equitable benefit sharing. The principle that a person should not benefit from his wrongdoing is an intrinsic part of the law of intellectual property enshrined in the common law *doctrine of unclean hands*, in jurisdictions such as the United States. To date, it has not been applied in relation to intellectual property rights arising from the use of genetic resources collected prior to the entry into force of the CBD. However, it has been proposed that it might be utilized to protect rights over TK, an issue closely linked to the genetic resource debate.[120]

Various approaches may be taken to overcome dilemmas associated with pre-CBD collections. Ex-situ collections could, for example, be provided with a period within which to sanitise their collections. This might involve one or more of a range of measures. For instance, an international agreement could allow for a general exclusion of all collections made pre-CBD, subject to registry of information about the resources held in an international database. Registered collections might be required to pay a percentage of benefits derived from their use into an international fund, established along the lines of the fund for distribution of benefits under the ITPGRFA. Benefits from the fund could then be distributed to support resource conservation and strengthening of traditional knowledge systems. One drawback of such a system would be the sheer volume of material held by some collections. In order to avoid unproductive bureaucratic and administrative burdens, and avoid the potentially ruinous costs of requiring the registration of all materials, requirements might only extend to specific resources intended or provided for commercial use.

In many cases, collections will be able to demonstrate a good legal title, entitling them to make commercial use of resources. In such cases, they should be encouraged to inform the authorities of the country of origin regarding the collections held, and the nature of the rights relating to its use. Countries of origin could have a fixed period within which to challenge a collection on its title, after

which the right to challenge would expire. The cost of attempting to find or establish good title for some historic collections may prove problematic. One solution would be for ex-situ collections to enter into agreements with countries of origin of the material to establish conditions for future maintenance of collections. Options would include an arrangement for ex-situ collections to agree to maintain collections, and provide free access to resources to the country of origin, in return for a grant of rights to use of them, subject to fair and equitable benefit sharing, for scientific and/or commercial purposes. Under such an arrangement, ex-situ collections would in effect act as resource brokers providing resources to third parties for scientific and commercial use subject to relevant benefit sharing with the country of origin. Such agreements might also be usefully applied to local ex-situ collections of material collected from within the same national jurisdiction.

Alternatively, pre-CBD collections could be deemed held under trust for countries of origin - where the origin of resources can be identified - and under trust for humanity, where their origin cannot be identified. Collections would be entitled to receive an appropriate share of any benefits derived from use of resources, with obligations on users to negotiate benefit sharing agreements directly with countries of origin before any IPR rights are applied for. This would be similar to the arrangements for management of the CGIAR international genebanks, which require commercial users to seek PIC and MAT of countries of origin.[121]

One potential solution would be for institutions holding pre-CBD collections to adopt the approach of IPEN's Common Policy Guidelines[122] that require member institutions to treat both pre-CBD and post CBD collections in the same manner. A mechanism to recognise such a commitment internationally could be agreed by the CBD and may form a part on an International ABS Regime. The IPEN experience provides an important example of the potential for development of minimum documentation standards and the potential role of voluntary codes of conduct to promote implementation of a certification system.[123]

An international ABS regime may seek to address the situation of pre-CBD collections, by creating a means to certify them as such. It has been suggested that a certificate of source might be used for documenting transfers of pre-CBD collections for non-commercial purposes.[124] This would help avoid a situation where pre-CBD collections circulate without any documentation, undermining the functioning of a certification system. It would not, of itself, however, resolve continuing discrepancies over the status of such collections.

3.5 Traditional Knowledge

There is growing recognition of the rights of indigenous peoples and local communities over their TK. These rights derive from a range of sources, including their own customary laws and practices, national sui generis laws, and constitutional law; as well as their moral rights under intellectual property laws, and under regional, national, and international human rights regimes. Rights over TK and biological resources - as well as to self-determination and to their traditional territories - are set out in the recently adopted United Nations Declaration on the Rights of Indigenous Peoples.

Indigenous peoples and local communities have consistently argued that any system for protection of their rights relating to TK should be based upon their own customary laws and practices. This raises many complex legal and technical issues, which are currently being researched and debated at the regional, national, and international levels.[125] Developing mechanisms to protect TK in a manner which accords with the rights, interests and priorities of indigenous peoples and local communities will require time, sensitivity, and, above all, respect. Effective implementation of any ABS and/or TK regime will depend to a great extent on its perceived legitimacy in the eyes of indigenous peoples and local communities. This in turn will depend on the extent to which it demonstrates respect for their legal institutions, decision-making practices, and the norms and practices upon which they are based. This should engender caution against the imposition of purely technical solutions on what is as much a cultural and social challenge as a legal and economic one.

Requiring PIC of indigenous peoples and local communities as a condition for accessing genetic resources on their traditional territories, where they have control over such resources, and for access to and use of TK, provides indigenous peoples with an opportunity to apply principles of customary law to the collection and use of their resources and knowledge. Establishing a system which requires evidence of PIC of indigenous peoples and/or local communities as a condition for the issuing of a certificate would act as an incentive for users to enter into benefit sharing agreements with them. Furthermore, requiring disclosure of evidence of PIC (as a condition for processing IPR grants and product approvals) would reduce the commercial value of collections of TK obtained without prior informed consent. The adoption of such a regime could serve as a means of preventing biopiracy, while truly participative processes for the design of international, national, and regional TK regimes are established and implemented. Existing collections of TK would need to develop mechanisms to govern their future use, benefit sharing, and so on. One suggestion is that such collections should be held in trust for indigenous peoples and local communities.[126]

Protection of TK will need to address the status of knowledge which has fallen into the public domain following misappropriation, unfair trading practices, breach of confidence or of a fiduciary position. This would not be the first instance of knowledge in the public domain being provided with protection. One such example is the case of databases under the European Union Database Directive of 1996, which enables

compilers of databases in the E.U. to assert ownership and demand payment for licensing the use of content already in the public domain, even where that material could not otherwise be copyright protected.[127]

The European database legislation has come under significant criticism for its restriction of the public domain.[128] Similar criticism is likely for proposals to restrict the public domain in order to give retrospective protection to TK. Significant distinctions can, however, be drawn between the information being protected under the European Database Directive and TK - most specifically in relation to the source of the information; its nature; the manner in which it came into the public domain; and, the moral, ethical and legal reasons for the protection of TK.

Indigenous peoples have begun examining the possibilities of developing some form of open access commons license for protection of TK.[129] Such a licensing system could enable TK to circulate in the public domain while restricting unapproved and uncompensated commercial use. It could also restrict other uses which might affect the spiritual or cultural integrity of the knowledge or otherwise degrade that knowledge or the knowledge holders. A commons licensing system for TK may conceivably be developed based upon principles drawn from customary laws and practices of indigenous peoples and local communities. This would in essence extend the remit of customary law as a tool for protection of TK by having users contract into custom.[130]

Certificates are only one of many tools which may be incorporated in an international ABS regime to aid in securing rights over TK. Another important tool are community TK protocols, which have been described as forms of contracts that draw upon aspects of customary law and practice as the basis for regulating rights to access and use TK.[131] A certificate might potentially serve to provide evidence of the existence of the relevant TK protocol. In order to ensure that TK protocols and certificates are mutually supportive, it has been proposed that the body certifying the existence of PIC be empowered to review whether the agreement has been obtained with good faith; that those entering into the agreement truly represent the custodians of knowledge; that indigenous peoples' customary law relevant to the provision of prior informed consent has been conformed with; and to sever or modify any terms of the Protocol that are inequitable, unfair or involuntary.[132]

For a certification system to be acceptable to indigenous peoples, it will need to be developed in a manner which, amongst other things:

- guarantees that indigenous peoples will be equal Parties to access and benefit sharing arrangements which incorporate their TK;
- sets out appropriate standards for obtaining prior informed consent of the relevant indigenous peoples;
- provides processes to ensure that Parties negotiate in good faith, including investigative and enforcement powers;
- sets out practical mechanisms for dispute resolution that include respect for applicable customary laws;
- provides for conflict of laws mechanisms that reconcile customary laws and national laws.[133]

Although not specifically required by the CBD, national and regional efforts to regulate ABS have consistently included requirements for PIC of indigenous peoples and local communities as a prerequisite for accessing TK and genetic resources on their lands. In some cases this has included clear guidelines for administrators to ascertain if PIC was freely and properly given. For example, section *8A.10 Informed Consent* of the Australian Environment Protection and Biodiversity Conservation Regulations 2000 provides:

> In considering whether an (Indigenous) access provider has given informed consent to a benefit-sharing agreement, the Minister must consider the following matters:
>
> (a) Whether the access provider had adequate knowledge of these Regulations and was able to engage in reasonable negotiations with the applicant for the permit about the benefit-sharing agreement;
>
> (b) Whether the access provider was given adequate time
>
> (i) to consider the application for the permit, including time to consult with relevant people;
>
> (ii) to consult with the traditional owners of the land, where the biological resources are in an area that belongs to indigenous people and an access provider for the resources is the owner of the land;
>
> (iii) to negotiate the benefit sharing agreement;
>
> (c) Whether the access provider has received independent legal advice about the application, and the requirements of these Regulations.

The PIC regulations set out above can be condensed into three key questions which, it is proposed should guide national authorities in defining PIC procedures relating to TK, these are:

- Was the consent fully informed?
- Was consent freely given?
- Did the process comply with any standards set out in law and custom?

Determining what national body or traditional authority may issue a certificate will have a bearing on both the legitimacy of the certificate and on its effectiveness to serve as evidence of a legal right to access and use TK. Developing a system as a whole will need to be done in a participatory fashion involving indigenous peoples, local communities, national authorities, NGOs, and other stakeholders. This is the case whether it is being done at the regional, national, or international level.

Indigenous peoples have raised many questions which need to be considered in determining the appropriateness and utility of any certificate system to protect TK, such as - who would issue a certificate? What would it certify? What information would need to be recorded in a certificate? And what rights would be associated with the use of TK covered by a certificate? The GTE too has noted the practical difficulties and distinct implementation challenges which may be associated with development of a certificate scheme for traditional knowledge, due to its intangible nature.[134] In order to advance consideration of this issue at the WGABS it will be necessary to carry out more detailed research into the possibilities for applying a certification regime to TK.

With a view to advancing analysis of the issue of certification of TK the CBD should encourage governments, international organisations, organisations representing indigenous peoples and local communities to convene national, regional and international meetings on certification and TK. These meetings should provide for the participation of indigenous peoples and local communities, as well as experts on documentation and certification issues. The CBD should in particular convene a meeting of experts on TK and certificates with a mandate to report back to the WGABS.

4. User Measures, Access to Justice and Disclosure of Origin

During negotiation of the Bonn guidelines, one of the principal demands of developing countries was that user countries[135] commit to taking steps to help identification and prosecution of cases of breach of contract or misappropriation. The 6th WGABS has identified compliance measures as being one of the main components of an international ABS regime. Under an international ABS regime, compliance measures will conceivably include requirements for adoption of user measures; mechanisms for monitoring compliance (such as an international certification system); and international dispute resolution mechanisms. In the development of the international regime's compliance provisions, attention will need to be given to the adequacy and accessibility of existing remedies under areas such as contract law, law of torts, and laws regulating misappropriation and unfair trade. Furthermore, consideration should be given to existing and potential models for mandatory and voluntary alternative dispute resolution (ADR) mechanisms, as well as the potential role of an international ABS/TK ombudsman's office.

This section briefly addresses the question of access to justice and alternative dispute resolution, before entering into a more detailed analysis of the most widely discussed user measure; i.e., disclosure requirements in intellectual property applications procedures.

4.1 Access to justice

Mechanisms already exist in many jurisdictions which would, in principle, entitle claimants to take actions for breach of contract or misappropriation of resources or knowledge. However, possibilities for indigenous peoples and local communities - as well as developing and, in particular, least developed countries (and their national research institutions and small companies) - to avail themselves of such rights may often be illusory. In reality, there are numerous practical, technical, legal, social and economic hurdles which may impede claimants from using these avenues of redress. These include difficulties in identifying a breach of contract or other cause of action; in securing necessary permits, visas and standing before a court to be able to take an action; and, in obtaining legal representation and sustaining the costs of fighting a case.[136]

Development of compliance mechanisms will require analysis of existing and potential mechanisms to prevent breaches of rights, identify and mitigate breaches where they occur, and to provide remedies and redress where appropriate. These may include mechanisms:

- requiring compliance with PIC procedures;
- securing equity in contract negotiations;
- identifying breaches of contractual obligations or misappropriation of resources or knowledge;
- bringing to the attention of rights holders and stakeholders any breaches of contractual obligations and cases of misappropriation;
- initiating and sustaining actions to prevent, mitigate or seek redress in cases of breach of contractual obligations or misappropriation;
- providing support for claimants in actions for breach of contract or misappropriation;
- applying alternative dispute resolution mechanisms to ABS and TK related disputes.

Whatever form compliance measures may take, their effectiveness will rely upon the capacity to identify the use of resources and knowledge, and to determine the existence (or otherwise) of rights for such use. Establishment of an international documentation system to provide evidence of PIC and MAT in an easily recognisable format has been proposed as a means of facilitating the demonstration of rights to access and use resources. This, it has been argued, will assist decision making regarding use of resources and benefit-sharing, compliance with access terms and conditions, as well as conformity with relevant international and national law. Evidence of compliance with relevant customary law and practice may also be required in certain cases, particularly those involving TK.

Existing national or regional regimes are unlikely to prove sufficient for ensuring access to justice in cases of asymmetrical relations involving local institutions, small developing country universities and companies, indigenous peoples or local communities, and foreign or multinational corporations. In order to provide effective mechanisms for resolving disputes involving indigenous peoples, local communities and/or developing countries, consideration will need to be given to the potential associated with alternative dispute resolution (ADR) and some form of international ABS/TK ombudsman's office.[137]

4.2 Alternative dispute resolution

Development of compliance measures for an international ABS regime is likely to include some form of alternative dispute resolution mechanisms. These may be set up at the national, regional or international level. The form and nature of any international alternative dispute resolution mechanism would depend upon its objectives, the parties who could come before it, and the extent to which its decisions are binding.

One option would be to establish a binding dispute resolution mechanism such as that used by the WTO. In this case, parties to any dispute would be countries, and enforcement of decisions would include the right of countries to impose sanctions against the country found to be non-compliant. This is less beneficial for developing countries than it might at first appear, however, as they may be dissuaded from taking actions and imposing any sanctions due to fear of reprisals in other areas.

Furthermore, in many cases developing countries would be in no position to impose any meaningful sanctions on developed countries. If a binding dispute resolution mechanism is adopted, it would need to provide for access by indigenous peoples and local communities seeking to protect their rights. Otherwise they may find the system a barrier to justice, where national authorities are reluctant to take cases on their behalf. Consideration needs to be given to the costs of establishing and maintaining such a system. These may be disproportionately high in relation to the economic significance of the matters involved.

An alternative model would be a form of arbitration mechanism accessible not only to countries but also to other aggrieved parties. This may include indigenous peoples, NGO's, research and commercial interests, and other providers and users of resources and knowledge. Amongst the aims of such a system would be the provision of opportunities for claimants and respondents to meet on more neutral and balanced ground. In order to make the system more accessible to potential claimants, it might be set up with regional offices. These should be able to work through the use of local languages and employ staff conversant with the cultural, social, economic, and environmental realities of the region.

Another potentially important step towards securing access to justice involves the establishment of an international ABS and TK ombudsman's office[138], possibly linked to but independent of the Secretariat to the CBD.[139] An ombudsman's office could be given responsibility for helping countries of origin, indigenous peoples, and local communities to identify breaches of their rights, and to provide aid in seeking fair and equitable resolution of disputes. An Ombudsman should be empowered to take an action on behalf of indigenous peoples or local communities through a binding dispute resolution mechanism. He or she should also be empowered to represent indigenous peoples in proceedings in a foreign jurisdiction, to take depositions from indigenous peoples and local communities, and to provide evidence of customary law and practice, as and where appropriate.

A fourth (low cost) option would be to create an Alternative Dispute Resolution (ADR) Panel - to be convened at the request of disputing parties - for the purposes of mediation and conciliation. The ADR should have the power to arbitrate a binding outcome with the consent of the parties, in the event that the parties are unable to find a resolution through mediation. Panels might be drawn from a list of experts previously nominated by CBD Parties for that express purpose. Such panels might receive administrative support from the CBD Secretariat, and draw on the good offices of the International Ombudsman Institute, or similar bodies involved in ADR.

Any dispute resolution mechanism and ombudsman's office would need to be guided in its work by principles of equity drawn from a wide range of legal sources, including customary law and practices of indigenous and local communities.

Certificates could play a role in helping arbitrators to identify a cause of action, and to determine an equitable remedy. They may help identify principles of equity and relevant sources of law for particular cases. Certificates issued for access to TK, for instance, may identify the custodians of knowledge whose customary laws and practices may be relevant in arbitration proceedings. A certificate may provide evidence on approved uses, and any limitation on the uses of resources. It should help to identify the terms and conditions and applicable law under which those resources were accessed.

The existence (or lack) of a certificate may, in certain cases, give rise to presumptions under law and allocation of the burden of proof regarding rights to use resources, as between users and provider countries, indigenous peoples or local communities. For instance, the issuing of a certificate may serve as evidence of PIC and MAT, and raise a presumption of fair and equitable benefit sharing. If the equity of benefit sharing is challenged, where a certificate exists, the burden of proof would fall upon the provider to demonstrate that sharing was not, in fact, equitable. Where procedures exist for granting certificates, the use of resources or TK without a certificate may, likewise, raise a presumption of misappropriation. In this case, the burden would fall on the user to show good legal title for use of resources and TK.

4.3 Disclosure of origin, source, legal provenance

Intellectual property (IP) regimes are amongst the principal tools employed to secure monopoly rights over products, processes, and plant varieties, developed utilising genetic resources and TK. The IP system relies on transparency to function effectively. This is because enforcement of IP rights is usually undertaken through civil litigation, or where criminal or improper conduct has been alleged, with the involvement of governmental agencies. In the case of the patent system, details of every invention must be publicly disclosed in return for the grant of a time-limited monopoly right over the use of the invention. The IP system is, therefore, uniquely positioned to serve as a means of monitoring the use of genetic resources and TK. In 1994, two proposals emerged suggesting use of IP applications procedures to help in ABS and TK governance. One, originating in Denmark, called for disclosure of the source of genetic resources used in development of the subject matter of IP applications.[140] The other, from Peru, called for disclosure of the origin of genetic resources and TK in IP applications, as well as evidence of PIC and MAT for their use.[141]

Initially, disclosure proposals found little favour. On the one hand, developing countries and NGO's were suspicious of proposals to use IP regimes as a tool to bring equity to ABS and TK governance. On the other hand, developed countries were, initially, firmly opposed to

proposals for any modification of the dominant IP regime - in particular, any modifications that would require users of genetic resources and TK to show they had obtained PIC and MAT as a condition for processing IP applications. Positions on disclosure proposals have changed significantly over the years, and become nuanced, with support for some form of disclosure requirements now widespread.

Disclosure obligations have now been adopted by both developing and developed countries. At the regional level, impetus to amend individual country patent law to provide for disclosure of origin/source in patent applications was first given by a European Union Directive on legal protection of biotechnological inventions.[142] This states that:

> "… if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents."[143]

In contrast to the voluntary nature of the European Union Directive, the Andean Community in Decision 486 of September 2000 introduced binding disclosure obligations. This requires patent applicants to demonstrate that PIC has been obtained for use of genetic resources from the region as a condition for processing patent applications.[144] At the national level, both developing and developed countries have now adopted disclosure requirements. First included in Peru's plant variety protection law in 1995, they were subsequently introduced by a range of countries including Brazil, Costa Rica, Denmark, Egypt, Germany, India, Norway, New Zealand, Romania, Spain, Sweden and Switzerland.

In 2002, COP 6 in The Hague adopted Decision 6/24, which encouraged governments to establish disclosure obligations in their IP legislation. Since the adoption of Decision 6/24, numerous proposals have been made for modification of the TRIPS Agreement to included disclosure requirements. This has included proposals by developing countries led by Brazil, India, and Peru, as well as by developed countries such as Norway.[145] Meanwhile, Switzerland has championed a proposal for modification of the Patent Cooperation Treaty (PCT) to include disclosure obligations.[146]

The Swiss proposal provides an explicit right for countries to adopt national legislation requiring patent applicants to declare the source of genetic resources and of traditional knowledge in patent applications.[147] Switzerland proposes the application of these requirements to international patent applications. In order to further strengthen the effectiveness of the requirement to disclose the source and to facilitate its working, Switzerland proposes the establishment of an on-line list of government agencies competent to receive information about the declaration of source. Patent offices that receive patent applications containing a declaration of source should inform the competent government agency about IP applications involving resources for which their country is declared to be the source.[148]

The European Community (EC) has made submissions to both the World Intellectual Property Rights Organisation (WIPO)[149] and the WTO, suggesting that a disclosure system should be mandatory.[150] The EC proposal calls for disclosure of the country of origin of genetic resources, where known; and that, where the country of origin cannot be determined, there should be disclosure of source.[151] In the view of the EC: "… a global and compulsory system creates a level playing field for industry and the commercial exploitation of patents, and also facilitates the possibilities under Article 15(7) of the CBD for the sharing of the benefits arising from the use of genetic resources."[152] The EC takes the view that, in order to achieve a binding disclosure requirement, amendment of the Patent Law Treaty (PLT), the Patent Cooperation Treaty (PCT), and, as the case may be, regional agreements such as the European Patent Convention will be necessary.[153]

Three of the principal challenges facing disclosure proposals include:

1. Definition of Scope
2. Possible conflicts with international IP law including TRIPS
3. Lack of capacity in patent authorities to police disclosure requirements

4.3.1 Defining the scope of disclosure requirements

In developing international law, careful wording of disclosure requirements will be necessary to ensure they are meaningful. That is to say, that they clearly state the obligations for IP applicants; are unambiguous regarding the information to be provided; are not unreasonable; and are capable of implementation by IP authorities. Distinct approaches to the form which disclosure should take are largely based upon the proposals for disclosure of origin and disclosure of source - reflected in the original certificate of origin proposal,[154] and the Swiss proposal.[155]

Developing countries have largely supported proposals for revision of TRIPS to include disclosure of origin requirements in patent applications procedures. Based on a series of submissions made by Brazil, India and Peru, with the support of others, they have called for a system which would require disclosure of origin, PIC, and fair and equitable benefit sharing.[156] At the TRIPS council meeting in Geneva on the 13th of March, 2008, a proposal by Brazil, India, Cuba, Peru, Ecuador, Pakistan, Thailand, and Venezuela for amendment of TRIPS[157] was supported by the group of least developed countries and

The Dominican Republic, as well as the group of African, Caribbean, and Pacific (ACP) countries. This means approximately 80 of the WTO's 151 members now support an amendment to TRIPS, to include mandatory disclosure requirements on origin, PIC, and fair and equitable benefit sharing.[158]

Despite growing acceptance for disclosure requirements, there has been resistance from many developed countries to proposals that include obligations to show PIC and fair and equitable benefit sharing as a condition for processing IP applications. Without an obligation to demonstrate PIC for use of resources, the potential effectiveness of any disclosure system would appear to be seriously debilitated. The situation with regard to fair and equitable benefit sharing is less straightforward. If IP applications and IP rights, are open to challenge on the basis of the fairness and equity of benefit sharing, this will lead to greater uncertainty for users of genetic resources. The threat of possible litigation over the adequacy of benefit sharing could lead to a reduced interest in natural products, with a consequent loss of benefit sharing opportunities for countries of origin and TK rightsholders. One potential solution would be to create a rebuttable presumption of equity and fairness that would work in favour of users where evidence of PIC and MAT exists.

Any regime will need to clearly define the scope of disclosure requirements, in order to avoid creating uncertainties regarding the status of patents and the introduction of requirements which patent examiners could not reasonably be required to process. One suggestion is for restriction of disclosure requirements to those resources whose use is required for the development of, or form an element of, the subject matter of an IP application.[159] Switzerland has proposed language to define the scope of disclosure obligations in a manner that aims to leave as little "grey area" as possible, in order to ensure that disclosure measures work in practice; that is, that patent applicants and patent offices will be able to determine when disclosure is necessary.[160] The Swiss proposal requires that, for disclosure requirements to kick in, inventions must be "directly based" on the specific genetic resources, i.e., that:

- They must make immediate use of the genetic resource; that is, depend on the specific properties of this resource.

- The inventor must have had physical access to the genetic resource; that is, its possession or at least contact which is sufficient to identify the properties of the genetic resource that are relevant for the invention.[161]

The European Community adopted similar language in its communication to WIPO outlining its position on disclosure.[162] A disclosure system based upon such criteria would respond, in part, to industry concerns that overly comprehensive disclosure requirements could involve unnecessary costs and effort. These concerns include the possibility of having to disclose information which has no relevance to the subject matter of the IP applications development. An example of such a situation would be the use for convenience of manufacture of genetic material from E.Coli which is not essential for an invention and has no significant utility or beneficial effect. In such cases, manufacturers have repeatedly argued that disclosure associated with such components should not be required. Reasonable limits will need to be set to avoid creating an onerous burden for patent applicants and, at least in some jurisdictions, opening the door to increased litigation through patent opposition challenges.

The wording of the Swiss and European Community proposals are not without difficulty. Terms such as "directly based", "immediate", and "physical access" may be open to interpretations which could exclude from disclosure requirements IP applications involving the use of new technologies, which make direct physical access to genetic resources unnecessary.[163] Advances in technological capacity - leading to what has been called the "decorporealization" of the gene trade[164] - must be fully understood and addressed in a future international ABS regime, if it is to be effective. Biological materials can now be transformed into a wholly informational form, such as a DNA sequence or tomographic scan. This makes the acquisition of information about the structure of an organism or its genetic composition possible through analysis of genomic sequence data or images that can be downloaded from centralized databases.[165]

One influential commentator has pointed out that, as "…the export (e.g. over the Internet) of a gene sequence from a nation is now the operational equivalent of the export of the organism containing the gene sequence … genetic resource issues may soon be outflanked by genomic information issues."[166] The implications of such technological advances will need to taken into consideration in the design of disclosure obligations. Most problematic may be the case of bioinformation products, which enable the use of genetic sequencing data in total isolation from the resources to which it relates. The extent to which the CBD applies to bioinformation is unclear,[167] demonstrating the importance of continuing work to clearly define derivatives and determine the extent to which they fall within the scope of the Convention and any international ABS regime.

As technology has developed, it has increased the importance and value of ex-situ collections as a source of material for commercial and scientific use, while reducing the need for access to in-situ resources. New technologies which enable the extraction of genetic information from dead matter, the storage of material for extensive time periods, and reproduction from the smallest of samples highlight the need to ensure ex-situ collections are fully incorporated into any international benefit sharing regime. The question on many people's minds is whether equity in the gene trade can actually be realized, in light of extensive pre-CBD collections which are not directly

regulated by the Convention.

The changing nature of the gene trade creates great challenges, but also new opportunities for tracking and monitoring use of resources and compliance with ABS law and policy. Negotiators at CBD, WTO and WIPO need to familiarize themselves with these changes, and ensure that they are factored into their efforts to regulate ABS and TK issues.

4.3.2 Capacity of patent authorities

Over the years, there has been opposition to disclosure requirements on the grounds that the IP system should not be required to police compliance with ABS laws of provider countries. Obliging patent examiners to review ABS agreements in order to identify compliance with national ABS laws and the equity of benefit sharing, it is argued, is beyond their capacities. Furthermore, patent examiners - already inundated with more applications than they can process - are unlikely to look kindly upon any modifications to patent applications processes which would greatly increase their workload. However, international IP law already requires compliance with a variety of formal and substantive obligations to disclose information relevant to IP applications. Disclosure obligations are pertinent to the examiner's subsequent consideration and decision to grant or deny a patent. Existing disclosure obligations already require provision of information on the origin/source of genetic resources, if it is required to replicate the subject matter of the application.

Recent laws establishing disclosure of origin/source requirements and proposals for modifications on international law in this area provide for varying levels of disclosure relating to use of genetic resources and/or TK. This includes:

(i) declaration of the use of genetic resources or TK directly or indirectly

(ii) the origin/ source of such resources or knowledge

(iii) evidence of PIC and MAT

(iv) evidence of fair and equitable benefit sharing

Requiring patent authorities to examine ABS agreements in order to ensure compliance with ABS and TK laws of provider countries, adequacy of benefit sharing, and existence of valid PIC and MAT would place an large burden upon them. Providing information on the origin/ source of resources and TK in an easily recognisable fashion, such as that proposed by certification models, would help alleviate this burden. Certificates which provide evidence of PIC and MAT would further reduce the pressure on authorities to analyse compliance with national ABS laws. It would be sufficient for the examiner to be satisfied that the use of genetic resources and/ or TK associated with an application is covered under the relevant certificate(s) provided with the application. Without a certification system, the possibility for successfully implementing a functional disclosure system is greatly reduced.

4.3.3 Conflict with TRIPS

Opposition to disclosure requirements often seeks to portray them as being in conflict with TRIPS. From the outset, attempts were made to address possible conflicts with TRIPS by framing disclosure requirements as formal requirements which must be completed as a condition for processing IP applications.[168] To date, countries have varied between adoption of voluntary procedures (e.g. Germany, Sweden, Romania, European Community), or mandatory requirements (e.g., Brazil, Denmark, Norway, Andean Community).

WIPO, in response to a series of carefully crafted questions formulated by CBD COP 6, has prepared a study of disclosure requirements. This shows that various forms of disclosure requirements may be legally incorporated in national IPR applications procedures.[169] A certificate system which serves merely to demonstrate compliance with the requirements of the laws of the providing country, and legal title to use resources and identify the rights and limitations attached to any access and use, would not appear to run counter to WTO rules.[170] There is, as yet, no consensus on the legality of establishing mandatory disclosure requirements, in particular where non-compliance may have a substantive effect on patent rights.[171] An influential study prepared for UNCTAD argues that "nothing in the existing international treaties prohibits such additional substantive conditions of entitlement from being imposed in national patent applications."[172] It is noteworthy that adoption of mandatory regimes by the Andean Community, Brazil, and other countries has not led to challenges at the WTO. Switzerland is also due to adopt mandatory disclosure provisions in its revised patent law, which is currently predicted to enter into force on July 1st, 2008.[173]

Peru has proposed an amendment of Article 27(3) of TRIPS designed to overcome the uncertainties regarding the legality of adopting disclosure obligations. The amendment would recognize the rights of members to exclude from patentability: "…. (c) products or processes which directly or indirectly include genetic resources or traditional knowledge obtained in the absence of compliance with international and national legislation on the subject, including failure to obtain the prior informed consent of the country of origin or the community concerned and failure to reach agreement on conditions for the fair and equitable sharing of benefits arising from their use."[174] The Peruvian proposal has considerable merit: It would send a clear signal that disclosure requirements do not conflict with WTO, and reduce pressure on developing countries to accept adoption of weak disclosure requirements at the international level.

One study of the relationship between certificates of origin and the WTO has suggested that in order to ensure consistency with WTO rules, any certification system

should:

- Be designed on a product basis - not on that of a country or a firm - with certification traveling with the resources along their useful life

- Be mandatory for the sale, use, export, import, and/or patenting of a product

- Ensure that where certificates attest not only to the source of resources, but also compliance with benefit sharing standards, those standards should be established by providing countries

International coordination of a certification system would improve its effectiveness, and reduce the risk of a WTO challenge.

5. Elements of a certificate system

Despite the most obvious difference amongst certification proposals, i.e. the use of terms, they demonstrate many similarities, and taken together provide a firm basis for the development of a system of certification. Comprehensive discussion of the multiple issues that will need to be considered in developing any certification system is beyond the scope of the current study. An extensive list of such issues is set out in Annexes I and II. Here we will focus on a number of key issues considered vital to framing future work on development of a certification regime. These include: objectives, nature, scope, issuing authority, pre-CBD collections, compliance, format, and TK. The positions taken by the various certification proposals with regard to these issues are brought together under these headings, creating a menu of options for consideration in the development of any international certification system.

51. Objectives

Amongst the most frequently asked questions regarding proposals for certification are: Why is it required? What gap in existing ABS governance is it intended to fill? In other words, what would be the purpose or objectives of a certification system?

All certification proposals view documentation of genetic resources as serving the interests of both providers and users of resources, and as a tool for transparency. Beyond these areas proposals differ on objectives.

The nature, content and utility of any certificate scheme will depend upon the intended purpose of certification. A number of possible objectives for establishing such a system may be identified, including:

- Identifying the origin and/or source of resources and/or traditional knowledge;
- Establishing a standardized international system for traceability of genetic resources, to be used by herbaria, museums and microbial collections, etc., including commercial collections;
- Consolidating national permitting procedures, and reducing bureaucratic delay regarding exploration, collection, movement and exportation of genetic resources;
- Tracking flow of resources and/or traditional knowledge;
- Providing evidence of legal provenance;
- Providing evidence of prior informed consent;
- Assisting customs control of transboundary movement of genetic resources and/or traditional knowledge;
- Providing legal certainty of rights to use resources
- Establishment of a market tool to control market use.

5.2 Nature

Certification is seen as a transparency mechanism that can help bring legal certainty to the trade in genetic resources. Certificates in each proposal would serve to demonstrate compliance with legal obligations relating to access to genetic resources. The certificate of origin proposal envisions a system which may be either compulsory or voluntary; proposal for certificates of compliance would favour voluntary regimes; while, the certificate of legal provenance and source proposals lean towards a binding regime. They all envision establishment of some form of standardised or internationally recognisable system of documentation to provide information on resources and/or TK covered by the certificate.

5.3 Scope and issuing authority

A certificate of origin system would apply to genetic resources obtained from countries of origin as defined under the CBD. Certificates would be issued by the authorities in the country of origin. The proposal on certificates of source would extend to genetic resources sourced from both primary sources, i.e. countries entitled to provide resources under the CBD, and secondary sources, such as ex-situ collections. It is unclear which authorities would be responsible for issuing certificates in the case of ex-situ collections based in countries other than provider countries as defined under the Convention.

Certificates of legal provenance would apply to genetic resources obtained from provider countries, as that term is construed under the CBD, i.e. countries of origin or countries that have obtained resources in accordance with the CBD. The resources covered would, therefore, be genetic resources which are directly or indirectly obtained from countries of origin. A certificate of legal provenance would be issued by the authorities in provider countries. Under the certificate of compliance proposal the genetic resources covered would be those obtained from provider countries with domestic ABS legislation. National authorities in provider countries would issue certificates.

Where specific national ABS legislation does not exist access may still be secured in accordance with the CBD through administrative action under the exercise of sovereign authority, and/or under other legislative provisions of domestic laws providing for use of natural resources (An example might be laws governing the management of protected areas or of government owned lands and waters). Countries without domestic ABS legislation may still, therefore, be in a position to provide certificates demonstrating compliance with PIC and MAT obligations, in a manner required for international recognition. The establishment of a certification system may thus empower countries that have not as yet adopted ABS legislation to control access and subsequent use of resources to the satisfaction of resource users and

interested 3rd parties.

Where access is given for non-commercial scientific research, countries can protect their interests in the event that a user wishes to change their intended use and commercialise their research. This may be achieved by recording on a certificate the obligation on users to return to negotiate MAT for commercial use of the material referred to in the certificate. This step has the benefit of providing clarity for all involved and enabling all parties to benefit from serendipitous discovery. Moreover, a certificates system provides public institutions acquiring samples from multiple sources with protection from 3rd party concerns about misappropriation and the ability to independently verify the provider of samples acquired.

5.4 Subject matter

The subject matter covered by a certificate is in many cases unlikely to be defined at the level of specific genetic resources. Often what will be certified will be the right to use material collected under a specified bioprospecting agreement, for instance, collection of insect samples from the forest canopy of a given country over a defined time period. This may be a single collection or multiple collections, it may be made on a single date or trip, or it may cover numerous collections over a period of years. A certificate may apply to all samples of a specific genus or species, or may be restricted to an individual sample.[175] Any certification system will need to be flexible enough to enable a certificate to adapt to coverage of material at such a multiplicity of levels.

Certification procedures will need to be both durable and flexible in order to ensure that resources continue to be linked back to the original access agreement as they go through multiple transformations. To consider how this might be achieved we could take a hypothetical example of a certificate granted to cover all genetic resources derived from plants and animals collected in a specified area of, say, Peru over a three year period. In the first place all collections of whatever nature would be recorded with the use of a coding system linked back to the access agreement. For example, PE08ABC, where PE defines the country of collection Peru, the year of the agreement 2008, and ABC identifies the access agreement. This code could enable location of the terms of the access agreement through a national register of ABS agreements, which may be available online. Additional information may be added to the code at various stages to more clearly identify the material and its relation to the original agreement. This could include code to identify:

- Specific collection activities, year, date, time, location
- Family, species, genus
- Extracts, active compounds, molecules, compositional matter, genes, etc.
- Expression of genetic resources as bioinformation

Users may be required to inform providers at various stages of research and development of advances in the extraction, isolation and identification of new taxa and genetic resources and their codification. This would enable providers to maintain centralized records of resources, their taxonomic classification, isolation of new compounds, and other derivatives.

5.5 Compliance measures

Certificate proposals have since their inception been closely linked to proposals for establishment of compliance measures, including disclosure obligations in patent applications and product approval processes. This is a fundamental element of proposals for not only certificates of origin, and legal provenance, but also for certificates of source. The certificate of compliance proposal argues that a diversity of national approaches to ABS regulation make it impossible to establish a standardised system to document resources. It concludes that a certification system could not, therefore, be associated with any system of checkpoints to review compliance with CBD obligations. The proposal acknowledges, however, the ability of certificates to provide evidence of rights to use resources. It also suggests that, while standardisation of certificates may not be feasible, international guidance could be given for national certificates in order to ensure that it is internationally recognised. A certificate of compliance could therefore, in principle, serve as part of a disclosure of origin/source system.

For any system of checkpoints to function, whether it is disclosure or origin/source or otherwise, it will require a capacity to review the existence of rights to access and use resources and identify whether there has been compliance with such obligations. Relevant authorities may carry out such review in a number of fashions including through the revision of contracts, collection, export, and import permits etc. It would appear to be in the interest of all parties that the information required to be provided to demonstrate compliance with PIC and MAT and give evidence of a legal right to use resources be kept to a minimum, An internationally recognised system of certification offers the possibility of rationalising such procedures, thereby facilitating the task of those responsible for monitoring and enforcing compliance with ABS and TK laws.

5.6 Format

All certification proposals appear to envision a form of documentation which would travel with resources and be transferable subject to the terms and conditions of the original certificate. Identification of the terms and conditions may be achieved by linking certificates to standard terms and conditions for use of resources accessible online.[176] The certificate of origin proposal suggests a form of passport that accompanies genetic resources, either through their entire history from

collection to use ('cradle to grave'), or only for certain transactions. In the certificate of legal provenance proposal certificates/codes would link users and providers through a central clearinghouse system. The certificate of source proposal envisions that national authorities, in countries where a certificate is submitted as part of a patent application procedure, would inform national authorities in the country of origin if identifiable of the application. The certificate of compliance proposal suggests attention be given to the existing practices of ex-situ collections with regard to documentation and argues that any system should be cost effective and easy for users to implement.

There is increasing support for a certification system which would make use of globally persistent unique identifiers travelling with genetic resources or TK. Unique identifiers would be managed by an international online registry. The identifier would provide a link to certificates and terms and conditions governing use of resources and/or TK. Such a linkage would reduce cost, complexity and enable instant verification. Significantly, it would also reduce the opportunity for the fraudulent use of false documentation.

The determining factor regarding the relevance and utility of any regime will, in the long run, depend upon, what is being certified, why it is being certified, and what incentive and enforcement mechanisms are used to ensure compliance? In all events, certificates will need to include information on the origin and/or source of genetic resources. They may also require inclusion of information on the legal right to use resources (legal provenance). This legal right, in so far as it relates to genetic resources covered by the CBD will require compliance with national ABS laws of provider countries. Any certification system should therefore be compliance based and cover the issues of origin, source and legal provenance.

A comprehensive certification system might involve the use of more than one form of certificate. Under such a system certificates of origin would be used to designate resources obtained from countries of origin. Certificates of legal provenance would designate resources obtained from provider countries as defined by the CBD, which are not countries of origin, or from ex-situ collections with good legal title to resources. Certificates of source would be provided with resources from pre-CBD collections, for which clear legal title cannot be determined and only for non-commercial scientific use.[177] Each certificate would in effect serve as part of an overall system for ensuring compliance with ABS laws and the provisions of the CBD.

5.7 Pre-CBD collections

All proposals acknowledge the inextricable link between any certification system and pre-CBD collections. The proposal for certificates or origin excludes pre-CBD collections held in countries other than the country of origin. The certificate of source proposal, in its most expansive interpretation, would allow for certification of any resource from whatever source without any restriction whatsoever. The certificate of legal provenance proposal argues that the legal status of pre-CBD collections must be resolved if any certification system is to function effectively. Certificates of legal provenance might be applied to pre-CBD collections, which can show a good legal title demonstrating rights for commercial use. The certification of compliance proposal would exclude all pre-CBD resources from coverage. Whatever system is developed, there are likely to be incentives for ex-situ collections with pre-CBD genetic resources to bring them within the system and increased pressure to deal with them on the same basis as post-CBD genetic resources. IPEN`s common policy guidelines which require members to treat pre and post CBD collections equally is an example which may equally be applied to certification of resources.[178]

5.8 TK

From the outset certification was seen as having a potential role to play in protection of TK. The certificate of origin proposal was first fully described in a paper on alternative means to protect rights over TK.[179] Later again it was proposed a dual certificate of origin and disclosure of origin system could be seen as an interim measure for protection of TK.[180] Certificates of source were also designed as part of a system which would require disclosure of source of TK in IP applications.[181] Later proposals have been more circumspect on this issue. In development of the proposal for certificates of legal provenance it was decided not to propose certification of TK, at the present time, for a number of reasons, these included:

- Lack of clear support by indigenous peoples and local communities for any certification scheme;
- Complexities associated with defining the parameters of any system to document and monitor transfer and use of intangible TK;
- Concern to ensure that a certification system does not inadvertently undermine rights over TK by promoting increased collation and placement of TK in the public domain.[182]

The proposed certificate of compliance system has also taken the view that TK should not be subject to a certification system, but for very different reasons. These are, that:

- TK is not subject to the same level of PIC requirements as apply to genetic resources, making certification unnecessary;[183]
- Certification if carried out by a state body may be seen as arrogating to the state rights over TK which should be avoided.

Indigenous peoples have taken varying positions on the matter with some expressing support for the concept in principle,[184] while others have pointed to conceptual

difficulties with proposals, such as the potential difficulties of certifying the origin of TK.[185] In both cases it has been argued that there is need for further research into the potential modalities for a certificate system to certify TK. Indigenous peoples and local communities have called upon the CBD to provide opportunities for their full and effective participation in debates regarding protection of TK. They have pointed out that only one indigenous representative was invited to form part of the GTE, and they have requested the CBD to organise a TK experts meeting on certificates of origin/source/legal provenance in order to examine questions of the practicality, feasibility and costs, of an international certificate system for TK.

In order to analyse the potential of any certificate system to protect rights relating to TK consideration should be given to the range of possible certification models offered by certificates of origin, source, legal provenance and compliance. Towards this end the following discussion of TK and certificate proposals, examines treatment of TK under existing proposals and makes some suggestions regarding the manner in which certificate proposals might address TK in the future. This discussion is intended to promote debate and is not intended to demonstrate a preference for any particular model or indeed for the establishment of a certification system for TK. That is a decision to be taken based upon the full and informed decision of indigenous peoples and local communities working in collaboration with the international community.

The certificate of origin proposal suggests that certification related to TK be based on compliance with requirements for PIC of indigenous peoples and local communities. Under this proposal, certificates would provide evidence of PIC. In order to identify the origin of TK more clearly, certification could be of the "originators of TK" - i.e., the indigenous people or local community which has developed the TK, or received it as part of their cultural patrimony. Where TK is too widely disseminated to enable a definitive identification of the true originators, certification could be of "cultural origin Certification of the "originators of TK" or the "cultural origin" of TK should be managed in close collaboration with, or by and on behalf of indigenous peoples and local communities, with attention to relevant customary law and practice.

A certificate of source would literally be just that a certification of the source of TK and nothing else. In this it differs from all other certification proposals, which to varying degrees are focused on certification of compliance with the ABS laws of provider countries. The disclosure of source/certificate of source system is primarily a transparency measure designed to bring to light the use of genetic resources and/or TK. Once brought to light it will be up to countries of origin and indigenous peoples and local communities, as appropriate, to take steps to protect their rights.

In contrast to other proposals a certificate of source would not certify either compliance or the legal provenance of resources or TK. As such, it does not presume to define the existence or otherwise of rights to use TK; would not presume to certify the adequacy or otherwise of any PIC procedures; and, could not be seen as arrogating any rights over TK to the state. The certificate would serve as a statement of the source of resources and TK, nothing else, and any remedies or penalties for failure to provide a valid certificate or for provision of false information would lie outside the IP system. It is conceivable that, under a certificate of source system indigenous peoples and local communities - through their representative organisations or through the establishment of their own certification organisation - could issue certificates of source for TK.

In the event that any certification system is to apply to TK, the concepts of certification of legal provenance and of compliance warrant consideration. A certificate of legal provenance could provide an interesting mechanism to distinguish between TK which has been knowingly placed in the public domain by indigenous peoples or local communities - or which is held in private, non-indigenous databases, under legal agreements which allow for its commercial use and/or distribution to third parties – and TK which has fallen into the public domain, or is held in private databases as the result of a breach of contract or fiduciary obligation, or as the result of misappropriation and other unfair trading practices. Users of TK could be obliged to seek out legitimate providers which can supply them with a certificate of legal provenance for use of TK; without such a certificate, the use of TK in the public domain might be restricted to non-commercial purposes.

Certificates of compliance could be used for certification of compliance with national legal obligations to obtain PIC and MAT from the holders of TK, and/or of compliance with the customary laws and practices of indigenous peoples or local communities.[186] For any system to function effectively, indigenous peoples will need to play a decisive role in determining the conditions for certifying compliance with PIC procedures, and customary law and practice. Compliance assumes the completion of an act or conformance with a set of obligations. A certificate of compliance is, however, likely to be granted at the earliest stage in the life of an agreement for use of TK, whereas any breach will occur later in the life of the agreement. One possible remedy would be to enable rescission of certificates of compliance in the event of non-compliance with the terms of the agreement upon which access to TK was given. A power of this nature would have the effect of empowering indigenous peoples and local communities to exercise control over the future use of their TK, even after it has entered a foreign jurisdictions and without the need for recourse to distant and often inaccessible enforcement bodies.

As with genetic resources, any system for certification of TK may apply a number of different certificates depending upon the actual source of TK - i.e., certificates of origin where the originators of TK are identified; certificates of legal provenance for TK in the public

domain or in private databases; certificates of source that might apply to TK provided by communities other than the "originators of TK"; and/or TK held in public or private databases which cannot demonstrate a clear legal title for their commercial use (in which case, certificates of source could be limited to situations involving non-commercial use). All certificates would, in essence, be a form of certificate of compliance, demonstrating conformance with national ABS and TK laws and/or customary law and practice of indigenous peoples and local communities. A certificate of compliance system for TK could apply to all TK wherever found, provided that access was with PIC and in conformance with the customary laws and practices of the relevant custodians of knowledge.

Considering the complex nature of TK systems, a special meeting of TK experts should be convened in order to weigh up the merits and drawbacks associated with applying any certification system to TK.

5.9 Origin, source, legal provenance or compliance

To some extent, determining what any certification system should be called is a distraction from the main issue of determining what the elements of any regime should be, and then deciding what to call it. All four proposals are for certificate systems, and not merely a recognizable certificate. The terms origin/source/legal provenance and compliance, as they have been applied to certification proposals, do not in themselves convey fully the complete nature of the systems proposed. Furthermore, proponents of various systems have sometimes failed to demonstrate the commonalities between proposals, focusing more on perceived differences. This has sometimes led to long and unproductive debates on the meaning of the terms employed to describe each proposal, rather than on the content and merits of the proposals themselves. The GTE has helped move the debate forward by identifying the commonalities between proposals, and, where convenient, by separating the use of terms from the content of the proposals.

This study has attempted to look beyond the terms involved, and examine the content of the proposals themselves; and it is considered appropriate that future work should focus first on developing the elements of any certificate system, and allow the identification of the appropriate name to follow after. This will help to avoid trying to shape the system to fit the name (as opposed to the other way around). Having said that, at this point in time it is worth reflecting a little upon the use of terminology to date, and the extent to which it has shaped the debate (and at times, perhaps, clouded or confused it).

The first certificate proposal was based upon what was termed "certificates of origin" - with the intention of identifying that what were being certified were resources from "countries of origin" as that term is defined under the CBD. The proposal was designed to cover only those transactions falling within the remit of the CBD`s provisions on ABS. Concerns regarding the use of the term were based upon perceived difficulties in identifying the origin of resources, primarily those of pre-CBD collections held in ex-situ facilities. A certificate of origin system, as proposed, incorporates requirements for disclosure of both origin and PIC in IP applications. This would create an obligation for users to show a legal right to use resources - based upon compliance with the CBD's obligations on PIC and MAT - as a condition for processing patent applications. In essence, this is a requirement to show legal provenance based upon compliance with the laws of a provider country, as defined by the CBD.

The term "certificate of source" is self-explanatory. It was chosen to describe a disclosure and certification proposal developed as an alternative to the proposed certificate of origin/disclosure of origin system. In this case, the system is designed to be inclusive, requiring disclosure of use of both pre- and post-CBD genetic resources in IP applications procedures, and potentially (on the face of it) allowing for their certification. This has led to concern that a certificate of source system could serve to expand the notion of provider under the CBD to include pre-CBD collections. However, a closer reading of the proposal demonstrates that sources should be those which are contemplated by the CBD and the Bonn guidelines, effectively excluding pre-CBD collections other than those held in the country of origin. Furthermore, a certificate of source system would only certify the source of genetic resources and/or TK. As such it serves only as a transparency tool and nothing more. It could not be taken to indicate or define any rights over either genetic resources or TK the subject of a certificate.

The certificate of source proposal deserves consideration as a clear alternative to compliance based systems. Analysis of the practicality, feasibility and costs of a certificate system should consider the potentially low cost nature of a source based system and the relative simplicity associated with its implementation.

The term "certificates of legal provenance" was adopted to define a proposal which focuses not so much on where resources are obtained, as on whether or not a legal right exists for access and use. The proposal argues that what is required is a flexible certificate system which can help establish and maintain a chain of custody for genetic resources, and an online registry system to facilitate the tracing and tracking of resources. One important question regarding this proposal is the issue of who defines the legality of provenance. If this is left to the country where resources are obtained, it may lead to widely diverging rules on what is considered legal provenance. A case in point is the status of pre-CBD collections. Some commentators take the view that their legal status has not been determined. Accordingly they argue that, in order to be legal, any transfers made post-CBD should be carried out in accordance with the Convention. Others have expressed the opinion that they fall outside the CBD and are, therefore, legally held.

One study of certificate proposals suggests that certificates of legal provenance could be used to certify pre-CBD collections.[187] However, the original proposal appears to take a different position, requiring certification of compliance with the laws of provider countries, as defined in the CBD, which would not extend to pre-CBD collections for which the country is not a country of origin.

Considering that most certificate proposals focus on certifying compliance with ABS laws of provider countries, it is not surprising that the concept of a "certificate of compliance" system, quickly found favour. The term has already been embraced by the GTE which has taken the view that any certification system will be primarily compliance based. What is surprising, however, is the extent and breadth of initial support for the concept (and by inference of the proposed compliance system behind it) in light of the restrictive nature of the proposal itself. The certificate of compliance proposal would, for instance, only apply to resources from provider countries with domestic ABS laws - thereby excluding all but a small minority of countries. It would also, exclude TK from consideration as a potential subject for a certificate scheme. Notwithstanding the foregoing, the certificate of compliance proposal, as has been discussed elsewhere in this paper, is capable of further development to address these two matters.

The GTE has shown that, despite differences in perspectives, the four certificate proposals contain many common elements. Building upon these common elements, it should now be possible to embark upon the development of a set of minimum standards and procedures for the development and implementation of an internationally recognized certificate. Collectively, existing certificate proposals provide a comprehensive array of options from which such standards and procedures can be developed. The WGABS, with the support of the GTE, should now begin working to identify the optimal combination of measures necessary to develop a practical, feasible and cost effective system.

6. Future Work and General Conclusions

The 6th meeting of the WGABS has identified an international certificate as being one of a number of issues requiring further work for the elaboration of an international ABS regime.[188] In order to advance work in this area, it is proposed that COP consider calling upon the WGABS to develop a set of minimum standards and procedures for an internationally recognized certificate system. COP may request the WGABS to finish this work in time for its consideration by COP 10 in Japan, 2010.

This section provides some suggestions on future research, capacity building, and pilot projects to support the development of a set of minimum standards and procedures for an international certificate system. A final sub-section sets out a number of general conclusions that may be drawn from this research.

6.1 GTE and WGABS

The GTE has provided the WGABS with valuable information on the practicality and feasibility of a certification system, and preliminary views on the issue of costs. In its role as a technical advisory body, the GTE might be tasked with advising the WGABS on the development of a set of minimum standards and procedures for an internationally recognized certificate of origin/source/legal provenance. This work should consider the outcomes of the first meeting of the GTE and WGABS 6, and engage in further examination of the implementation challenges of such a certificate for different types of users.

The WGABS and GTE should be guided in their work by the need to develop a form of integrated certificate system required to meet the needs of the scientific community, commercial actors, and the interests of provider countries, indigenous peoples, local communities, and ex-situ collections. The future work of the GTE will require more in-depth consideration of a wide range of technical, legal and economic issues relating to the establishment and implementation of a certification scheme.

Among the issues that the WGABS and GTE may be asked to consider (and further refine) in the development of a certificate system are:

- The principal elements of an international certificate system;
- The nature, content and format of an internationally recognized certificate;
- Modalities for the administration and monitoring of a certificate system;
- Minimum conditions which must be met for the (i) certification of origin/source/legal provenance of genetic resources and/or TK, and (ii) certification of compliance with provider countries' ABS and/or TK regulations;
- Options for differential treatment for non-commercial and commercial activities;
- The content, nature and format required for a certificate to serve as evidence of PIC and MAT, and of the information incorporated in a certificate in administrative, judicial, and alternative dispute resolution processes;
- Conditions necessary if a certificate system is to apply to TK;
- Modalities and mechanisms for a certificate system to support realization of ABS objectives in the absence of domestic ABS law;
- Modalities for addressing pre-CBD collections;
- Options for monitoring of certificates at commercial and non-commercial checkpoints such as product approval and IP authorities; and non-commercial checkpoints such as entities funding research, publishers, and ex situ collections.

In addressing its work the GTE and WGABS may also be invited to look at supplementary issues such as:

- How a certificate system relates to biological resource centres and other ex-situ collections;
- The potential role of online searchable certificate databases;
- The differing nature of certificates of origin/source/legal provenance and compliance and their utility as a means to secure compliance with the CBD's objectives relating to ABS and TK;
- Circumstances where retrospective issuance of a certificate is desirable and feasible;
- The degree to which certificates meet the needs of differing classes of stakeholders;
- The extent to which recent changes in the form and cost of information technology can assist with the establishment and operation of an internationally recognised certificate system, in particular as a capacity building tool to assist developing countries;
- The benefits of national certificates being searchable on public access data bases.

6.2 Targeted research and pilot projects

As debate on certification advances, awareness of the need for increased investigation of the technical and administrative issues associated with development and implementation of a certification system has come to the fore.[189] This has led to a spate of new studies on such issues as the development of national

certification systems in Australia;[190] research on existing documentation practices of leading ex-situ collections, including the Royal Botanical Gardens Kew, Smithsonian Institution, and INBio;[191] development of guidelines for documentation of microbial collections under the MOSAICS project in Europe;[192] and analysis of industry practices, such as the study of collaborative research involving Griffiths University and AstraZeneca.[193] This research has helped to identify challenges and opportunities associated with documentation of genetic resources and TK.[194]

However, there are still significant gaps in knowledge regarding resource management, documentation, use, and distribution by industry, research institutions, indigenous peoples and local communities. In order to respond to such gaps and provide a firm basis for the work of the WGABS and the GTE, a series of research projects, pilot projects, and capacity building activities are proposed. These would include:

1. Analysis of current practices in documentation of genetic resources and TK. This work should have as its goal development of a proposal for a certification system which can, to the greatest extent possible, build upon existing documentation practices. As part of this endeavour, a wide-ranging survey of existing practices - with regard to documentation of collection, use, and transfer of resources and TK - will be required. This should cover the activities of government bodies, ex-situ collections, industry, research institutions, indigenous peoples and local communities. Information from such a survey should be compared and, if possible, presented in a user-friendly fashion in order to provide a clear snapshot of documentation practices across a wide range of actors. Questions for such a survey should be specific enough to obtain clear responses from participants. A range of potential questions from which a questionnaire may be developed can be found in Annexes I and II.

2. Preparation of case studies on innovative experiences in development of harmonised documentation procedures, simplified systems for processing and managing ABS contractual relations, and national certification systems and laws. The utility of case studies will be enhanced when based upon a common set of questions and terms of reference, in order to ensure the possibility for comparative analysis of the information obtained. Development of a detailed questionnaire may usefully draw upon existing lists of questions, such as those set out in Annexes I and II of this paper.

3. Investigation of the role of certification as a tool in facilitating access to genetic resources subject to PIC and MAT, securing fair and equitable benefit sharing, and promoting the wider use of TK with the consent of indigenous and local communities. This should include consideration of how certification may aid the development of simplified systems for managing ABS agreements based upon use of standard MTAs and online licensing. Case studies of experiences such as the Australian GRID system, ITPGRFA, Science Commons, Yellowstone National Park, the Potato Park in Peru, and INBio (etc.) could be usefully collated, and a comparative study prepared.

4. Particular attention needs be given to engaging with industry and research institutions in the preparation of case studies of genetic resource and TK management, documentation, and contractual practices. Studies of the tracing/tracking of genetic resources and TK across whole supply chains from geographic source to end use and marketing will help to identify the practicality, feasibility, and costs of certification. This should address a range of sectors, such as biopharmaceuticals, cosmetics, horticulture, and other agriculture and processed food. Research is also needed regarding the growing bioinformatics sector and the possibilities for certification in this area. The feasibility of implementing a certificate of origin system by commercial users could be investigated through case studies of large companies, small companies and multinational companies who trade in, but do not use, genetic resources. Initiatives such as the UNU-IAS coordinated International Dialogue with Industry may provide a platform for promotion of industry studies in this area. Stand-alone research projects along the lines of the AstraZeneca study should also be promoted.

5. In-depth analysis of the potential and limitations of certificates schemes to assist in the protection and management of TK. Collaboration should be sought with IIFB and UNPFII to design and execute case studies on how certification may be best utilised to support indigenous peoples and local communities' resource and TK management practices. An international meeting of experts on TK issues is one practical way for indigenous peoples and local communities to participate more fully in discussion of the pros and cons of applying certification to TK.

6. Analysis of options for an internationally recognised certificate system will need to examine the opportunities and challenges for developing countries and least developed countries in the implementation of any system. The best way to test certification models will be through pilot projects. These could be conducted with a range of genetic resource provider countries, to see how - and if - countries could implement a certificate system. Analysis of possible low cost, flexible, and user-friendly mechanisms and modalities for administration of a certificate system should be investigated.

7. Analysis of the relationship of a certificate system with genetic resources, which are not covered by the CBD, and of measures to resolve the potential conflicts between a certificate system and such

resources. This work should include investigation of: (i) Modalities of an international certificate system which could create incentives for voluntary inclusion of non-CBD resources; (ii) Measures for mandatory application of a certification system to pre-CBD collections and/or genetic resources collected beyond national jurisdiction; (iii) Options for exemption of resources from any system; (iv) Measures to mitigate the impacts of trade in genetic resources outside any international ABS regime and certification system. Research should address pre-CBD collections and genetic resources from outside of national jurisdiction, including those from Antarctica, the high seas, and the deep sea-bed.

The CBD Secretariat should be called upon to coordinate with governments, international organizations, industry, research institutions, ex-situ collections, indigenous peoples, local communities, and civil society organizations in the preparation of case studies, pilot projects and background materials to inform future meetings of GTE, WGABS and COP.

6.3 Capacity building, funding and technical support

Concerted efforts will be necessary to build capacity to implement national, sectoral and local systems for implementation of any certification system. COP may invite support from governments, international organisations, aid agencies, research institutions, industry, indigenous peoples and local communities and the wider civil society to build and enhance such capacity.

As part of the process of capacity building, support should be given for informal expert meetings and stakeholder encounters on the issue of certification. One possible step would be to convene an international stakeholder meeting prior to a future WGABS, during which participants would be asked to assess and discuss the relevance and usefulness of the various certification models for their respective industry sectors.

UNEP/GEF could usefully provide support for the study of the practicality, feasibility and cost implications for developing countries wishing to introduce an integrated certificate system. Funding could be made available through GEF for studies testing a variety of national systems, including paper-based and electronic systems. Proposals to GEF for medium sized projects on ABS capacity building are a means for the carrying out of pilot studies. A medium sized project for a regional ABS capacity building project for the Andean Community, submitted to GEF in 2006, incorporated proposals for pilot projects involving (among other things) the development of a national certification system. Peru included a proposal for a medium sized project, focusing on development of a national certificate of origin system as part of ABS capacity building, in its list of potential GEF projects for the period 2008-2009.[195]

Examination of the opportunities and challenges associated with providing simple robust certificate software to developing countries should be carried out. The Australian GRID system, for example, was developed using open source software so it could be shared with other interested countries at minimal cost. Helping countries to introduce simple, integrated searchable certificate systems is something that both developing and developed countries may find attractive as practical capacity building measures.

6.4 General conclusions

Certificate schemes have now become a central part of negotiations relating to the development of an international ABS regime. A range of different proposals have emerged over the years, each one adding a new perspective on how a certification system may support the implementation of the CBD's objectives. Despite apparent differences, these proposals actually display significant similarities, and are largely based upon the same fundamental principles - the most important of which is the role of certificates as a tool for certifying compliance with national ABS laws.

To be successful, any system will need to be flexible, cost effective and easy to implement. To this end, it may adopt a 'one up, one down' structure, where each user is responsible for keeping a minimum amount of information on resources and TK received, and how they are used; and on resources, derivatives, or products developed using genetic resources or TK which are transferred to third parties.

If a certificate scheme is to facilitate access and benefit sharing, it will need to keep bureaucracy and transaction costs to a minimum. Its utility will prove even greater if it can help to rationalise existing permitting and documentation procedures. The capacity of any system of certification to promote rationalisation of existing documentation practices and permitting procedures will be influenced by the level of protection afforded to providers through compliance mechanisms, at the national and international level.

A majority of proposals view certificates as an integral part of compliance mechanisms involving checkpoints, which will need to be implemented in user countries. Checkpoints at which certificates might be sought include the conduct of legal "due diligence" prior to any dealing with the material or investment in its development; review by commercial regulatory agencies (e.g., product approvals bodies); and within the intellectual property rights system (i.e., patent and plant variety protection application procedures). Non-commercial checkpoints, such as publishers and grant approvals bodies, may also be utilised.

Rapid development of searchable IP databases, and of easy-to-use software to conduct such searches, has increased the opportunities for provider countries to monitor use of their genetic resources in the development of patentable products and processes.

Access to such information also sends important market signals to researchers regarding which species are of potential value, and where they may be found. This helps foster innovation, raises the importance and value of biodiversity, and may ultimately help developing countries decide where to spend their scarce conservation dollars.

Innovative contractual and business models and technological capacity to identify resources and knowledge offer interesting opportunities for development of streamlined ABS access procedures, and may increase benefit sharing opportunities. The use of online contracts based on standard terms and conditions posted at a national website of provider countries could empower even small and least developed countries to manage ABS contract negotiations with a relatively low cost system. Users seeking special terms would be free to enter into negotiations with provider countries. Resources and certificates may be linked through the use of globally persistent unique identifiers. Such a scheme - with online application and a database providing a publicly accessible means to verify details related to legal provenance of genetic resources - has been successfully deployed in Australia.[196] An international register utilising some form of globally unique identifiers, linked to a central clearing house mechanism (CHM) or a decentralised virtual CHM network, would increase traceability of resources and rationalisation of documentation procedures.

A potential impediment to the successful development and implementation of a certification system will come from resources which fall outside its scope. These may include pre-CBD collections and resources from outside of national jurisdiction including those from Antarctica, the high seas, and the deep sea-bed. Any certification system will need to address these collections - either by inclusion, specific exclusion, or by sanitising collections (e.g., by international agreement). Failure to do so could seriously undermine the implementation of an international certificate system.

Applying certification schemes to TK will require consideration of the special nature of intangible property and of the distinct cultural, social, and spiritual aspects of TK. It will also require that attention be given to the customary laws and practices of indigenous peoples and local communities. The full and effective participation of indigenous peoples in the design of a certification system should not only be seen as a moral right, but as an absolute necessity if any system is to be effective.

Determining what to call any certificate system prior to defining its component elements and procedures for its implementation is considered a distraction and potentially counter-productive. Terms may easily prove interchangeable. Compliance with the national ABS laws of provider countries would, for instance, raise the presumption of legal provenance of resources. Provider countries as defined under the CBD will have to be countries of origin or countries which have obtained resources in accordance with the CBD, i.e. from countries of origin. A certificate of origin would therefore imply both compliance and legal provenance. A legitimate source for resources would, in order to be compliant with the CBD, also have to be a country of origin or country which had obtained resources in accordance with the CBD. Although the actual provider of genetic resources may be an ex-situ collection or indigenous people, landowner, etc., to be a legitimate source they must still be providing resources for which that country is considered a provider country.

Although each proposal has provided differing interpretations of the scope of any certification system, it is clear that to be CBD compliant they must fall within the same defined parameters regarding who can provide resources and under what terms, including PIC and MAT. Furthermore, all of the proposals could be applied in either a voluntary or mandatory system, making distinctions in nomenclature even less significant. Deciding what any certificate system is to be called is very much secondary to defining what a certificate system is meant to do and how it is to do it. Pressure to adopt a specific term to designate a future certification system may inhibit full and informed debate of all options. That way the name will describe the system rather than having a system defined to fit the name. In the long run it's not what a certificate is called that will matter but rather how - and if - it does what it is supposed to do.

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its proposals regarding disclosure of source: document WIPO/GRTKF/IC/11/10, entitled "Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications: Proposals by Switzerland," available at http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_11/wipo_grtkf_ic_11_10.doc.

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[182]Pers. Comm., Jose Carlos Fernandez –Ugalde, April 6th 2008.

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[184]COICA. 1994, above, n.18.

[185]Alexander, M. 2007, above, n.20.

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Annex I Issues for consideration in development of certification schemes[197]

What is the purpose of certification?

- Rationalise and facilitate access
- Ensure fair and equitable benefit sharing
- Track all genetic resource flows
- Prevent the unapproved use of genetic resources
- Prevent unapproved use of resources and TK resulting in the patenting of products
- Provide evidence of a legal right to use resources
- Empower local and indigenous peoples over their traditional knowledge

Scope

Genetic Resources

- All genetic resources
- Post CBD genetic resources
- All genetic resources collected after entry into force of an international certification scheme

Traditional knowledge

- All traditional knowledge
- All traditional knowledge not in the public domain at the date of entry into force of a scheme
- Traditional knowledge which indigenous and local communities designate as being part of any scheme

Nature

- Voluntary
- Mandatory

What should be certified?

- The source of genetic resources and/or TK
- The country of origin of genetic resources
- The existence of an agreement with the country of origin to access/use Genetic resources
- The existence of an agreement with local or indigenous communities to access/use TK
- The existence of a legal right to use Genetic Resources and/or TK in the country where they are sourced and/or where they are used
- Compliance with an internationally agreed set of standards for the granting of certificates

What would be the subject matter?

- Gene
- extract
- Active compound
- All collections of a specified species
- individual samples
- Specific collection
- All collections covered by a Contract
- Should decisions on what is to be certified be taken by the certifying agency on a case by case basis?

When would certification take place?

- In advance of collection - e.g. Upon entry into an ABS agreement
- At the time of collection - expensive
- Subsequent to collection – Certifying compliance with collection procedures, and collection permits – administrative delay possible
- When scientific research changes into commercial research – return for recertification?
- In advance of applications for patents,, product approvals etc. – lets the user decide based upon commercial criteria when to seek certificate -

Who would be responsible for Certification?

- National authorities in country of origin
    - All bodies entitled to enter in ABS agreements – what would happen with overlapping jurisdictional issues
    - A centralized – automatic certification or another layer of bureaucracy?
- Independent certification bodies
- Entitled providers – individuals or others recognized under law as having proprietary rights over resources.
- Indigenous Peoples – local communities – for certification of the origin and legal provenance of

traditional knowledge

- National Authorities in countries other than countries of origin –e.g. for certification of source and legal provenance of genetic resources
- Collections – e.g. international genebanks, herbaria etc, with extensive collections.- certify the legal provenance of resources
- Countries holding ex-situ collections

When might certificates be utilized?

- To show a right for collection
- As part of export / import processes
- As part of Patent applications process
- As part of product approvals process
- In other regulatory approvals processes
- Scientific review processes –
    - Research grants
    - Research institutions monitoring of research activities
    - journal publications
    - review of compliance with professional codes of conduct
- Commercial sector
    - Compliance with industry codes of conduct
    - Contract negotiations
    - Dealings with resource brokers
- As evidence in legal proceedings

Who would be responsible for monitoring Certificates?

- Providing countries
- User countries
- All parties to CBD
- Customs authorities –
    - national authorities
    - is there a role for the World Customs Union?
- Patent offices
- Product approvals authorities
- Research institutions
- Scientific journals
- Ombudsman – SCBD

What information would need to be included in a certificate?

- Source
- Country of origin
- Legally entitled provider
- Recipient
- Resources
- Traditional knowledge
- Terms and conditions – governing access and use
- rights of use – e.g. for development of new medicinal products
- Limitations on use – e.g. no use for other purposes

What format would a certificate take?

- Hard copy – paper
- Barcode
- Electronic – paperless
- Mixture
- Unique digital identifiers

Who would maintain record of certificates?

- Countries of Origin
- Providers
- Research institutions genebanks, herbaria, etc.
- Private Sector

Who would monitor compliance?

- Countries of origin
- Provider countries
- user countries
- SCBD

- International monitoring body

What enforcement measures would be needed?

- Civil - Economic
- Criminal – penal
- Other

When would the need to demonstrate certificates end?

- Should the need to show a certificate be linked to the proximity of the end product to the original resource?
- What happens when a genetic resource has no major commercial value for a product?
- What about products which are derived from products which included a genetic resource but do not use it directly?
- Herbaria have collections which are hundreds of years old. – How long need records be kept?

What costs would be involved?

- Issuing a certificate
  - administration
  - labeling
  - revision of contracts
- Maintaining records of certificates
  - administration
  - databases
- Monitoring compliance
  - administration
  - enforcement

What possibilities are there to minimize costs and bureaucracy?

- Use existing human and institutional resources
- Rationalise existing access procedures
- Avoid adding new layers of bureaucracy
- Minimise administrative burden for existing collections
- Establish general requirements for record keeping
- Link certificates with standard terms and conditions for ABS.

Annex 2 Draft List of Questions from Canadian Meeting on ABS and the Issue of Certificates of Origin/Source/Legal provenance

- Would a certificate system be retroactive and apply to GR acquired prior to its entry into force or entry into force of the international regime? If so, how far back would it go?
- Would a certificate expire at some point?
- What would happen if for some reason, a given country is not in a position to issue a certificate?
- Who would be responsible for administering costs associated with a certificate system?
- Would a certificate be valid to access the same resource many times or would a new one be required every time?
- What relationship would the certificate system have with the international regime?
- What form would a certificate take? Would it be a paper document, or an electronic record?
- What type of information would appear on a certificate?
- Would a certificate be proof of compliance with PIC? Then what happens if countries don't have PIC systems in place?
- Would a certificate system be voluntary or mandatory?
- What would be the legal status of a certificate, is it a public document or subject to confidentiality clauses?
- Who would have access to the information contained on the certificate? How would this information be transferred? How can it be used and by whom?
- What would the relationship be between a certificate and the WTO agreements? Could a certificate constitute a barrier to trade?
- What are the most appropriate and efficient checkpoints for a certificate? How feasible and burdensome would it to have the borders as checkpoints?
- What is the relationship between a certificate and traditional knowledge? How should TK be reflected on a certificate?

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UNU-IAS

Institute of Advanced Studies

United Nations University
Institute of Advanced Studies
6F, International Organizations Center
Pacifico-Yokohama, 1-1-1 Minato Mirai
Nishi-ku, Yokohama 220-8502
Japan

Tel: +81 45 221 2300
Fax: +81 45 221 2302
Email: unuias@ias.unu.edu
URL http://www.ias.unu.edu

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