Certificates of origin come of age: the role of certification in International ABS and TK Governance

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I. ABSTRACT

Development of international regimes to regulate access to genetic resources and benefit sharing (ABS), and protection of traditional knowledge (TK) are two of the most challenging and pressing issues currently under negotiation by the international community. Based upon work in Peru in the early 1990's, proposals were made for a certificate of origin system including binding disclosure of origin obligations, which are now at the fore of international negotiations in this area. Proposals have subsequently been made for systems of certificates of source, legal provenance and compliance. This paper examines the similarities and differences amongst certification proposals and their potential role in international ABS and TK governance

II. INTRODUCTION

Securing fair and equitable sharing of benefits derived from the use of genetic resources and traditional knowledge (TK) has become an emblematic cause for developing countries, indigenous peoples and local communities. Equitable sharing of benefits is seen as a means to compensate countries for their efforts to conserve biological diversity. More importantly it is a necessary incentive for developing countries and their populations to continue to provide access to biological and genetic resources and associated traditional knowledge for scientific and commercial use.

Historically biological diversity was treated as the common heritage of humankind and TK was collected with little if any consideration of the rights of indigenous peoples and local communities. As a result the biotechnology, agricultural, pharmaceutical, cosmetics and natural products industries all benefited from the relatively low costs of raw materials.

Increasing use of intellectual property rights to secure monopoly control over the products of these industries raised concerns amongst developing countries at the inequities associated with free access and demands for participation in commercial and scientific benefits. The Convention on Biological Diversity (CBD), which came into force in 1993, had amongst its objectives the aim of securing fair and equitable sharing of the benefits derived from the use of genetic resources and TK

To date the CBD has had only marginal success in securing its objectives and there is little is any confidence, amongst most developing countries, in its ability to ensure equitable benefit sharing. As a result the international community is currently in the process of negotiating a new international regime on access to genetic resources and benefit sharing (ABS). This regime is likely to include a range of binding and non-binding measures, including measures in provider countries in the form of ABS and TK law and policy and measures in user countries to support compliance with the CBD's ABS objectives.

Negotiations to date on the international ABS regime are proving slow and there is little consensus on the nature, scope and elements for a regime. One area in which there has been substantial interest and much support has been for the establishment of some form of standardised system of documentation of resources and TK. This is seen as an important tool to help demonstrate compliance with national ABS laws and the legal provenance of resources and knowledge.

First proposed in the years immediately following the adoption of the CBD a variety of proposals now exists for systems of documentation based around what have been termed certificates of origin, source, legal provenance and most recently compliance. Interest in the potential role, which some form of certification scheme may play in international ABS and TK governance has been increasing over the years. The 6th Conference of the Parties (COP) to CBD which met in The Hague in 2002, called for further investigation of certificates. COP 8, in Curitiba in 2006 established an international Group of Technical Experts to investigate the practicality, feasibility and costs of a certification scheme.

As the variety of proposed schemes has multiplied debate has frequently diverted from the central issue of the potential utility and limitations of any certification scheme to an often unproductive discussion of which form of certification is to be preferred. This paper examines the principal elements of each of the main proposed certification schemes identifying the underlying similarities between them and their differences. The paper argues that attention should focus primarily on determining the purpose, nature, scope and elements of any certification scheme leaving a determination on what terminology to use to describe it for a later time.

This study notes the difficulties associated with certification of TK and proposes further analysis of modalities for ensuring that indigenous peoples and local communities are empowered to control access to and use of their knowledge.

The paper is set out in three sections. Section I, looks at the role of documentation in ABS and TK governance and the CBD. Section II examines and compares proposals for certification of source/origin/legal provenance/compliance schemes. Section III proposes how a certification system may be integrated into an international ABS regime. A final section sets out some general conclusions and proposals for future work.

II. THE ROLE OF DOCUMENTATION IN ABS AND TK GOVERNANCE

The Convention on Biological Diversity (CBD) adopted at the Earth Summit in Rio de Janeiro in 2002 has three objectives. The conservation of biological diversity, the sustainable use of biological diversity and, the fair and equitable sharing of benefits derived from use of genetic resources. An associated objective of the Convention is the fair and equitable sharing of benefits derived from use of traditional knowledge of local and indigenous communities.

Securing realisation of the CBD's objectives has to date proved elusive. Despite significant advances in biodiversity conservation an ever increasing number of species are in danger of extinction, according to the IUCN Red List. Meanwhile sustainable use of biological diversity is threatened by among other things extensive use of monocrop agriculture, genetic modification of resources and development of genetic use restriction technologies (GURTs). Achievement of the Convention's third objective has proved even more problematic.

2.1 CBD's role in fair and equitable Benefit Sharing

Although, almost half of all the decisions of the Conference of the Parties (COP) to the Convention are related directly or indirectly to the issue ABS[1] there is a widespread sense that the CBD has not and cannot alone secure its benefit sharing objectives. In 2002, negotiation of the voluntary Bonn Guidelines on ABS at COP 6 was hailed by developed countries as a positive step forward. Developing countries were sceptical and later the same year secured a call from the World Summit on Sustainable Development, in Johannesburg, for negotiation of an international regime on benefit sharing relating to genetic resources within the framework of the CBD.

In 2004, COP 7 gave a mandate to the Working Group on ABS (WGABS) to negotiate an international ABS regime covering not only genetic resources but also traditional knowledge (TK) under Article 8 (j)[2]. COP 8 in Curitiba, in 2006, tasked the WGABS with concluding its work by COP 10 in 2010[3].

The 5th meeting of the working group which met in Montreal in October 2007 commenced its discussions based upon a set of draft provisions prepared by the 4thWGABS, which covered such issues as the potential objectives, scope, nature and elements of a regime. Known as the Granada annex this document proved conflictive at the 5th meeting where delegates disagreed on how to proceed. While megadiverse countries sought to promote discussion of text, developed countries in general sought to avoid entering negotiations of text at this stage. This was perhaps to be expected with delegations taking a harder line than in previous meetings as the as negotiations begin in earnest. Some developed countries, for instance, appeared to be returning to the polarised positions of

1 Barber, C V, S Johnston and B. Tobin, User Measures: Options for Developing Measures in User Countries to Implement the Access and Benefit–Sharing Provisions of the Convention on Biological Diversity, UNU-IAS, Tokyo, March 2003.

2 CBD Decision VII/19D.

3 Para. 1 of CBD Decision VII/19D.

earlier years arguing that a contract based system was in itself adequate to secure the CBD's ABS objectives. This is despite a widespread belief that experience to date shows that a contract based system alone is incapable of ensuring fair and equitable benefit sharing. In fact many commentators take the position that reliance upon bilateral agreements has been responsible for increasing impediments to accessing genetic resources and the climate of distrust surrounding bioprospecting in general.

Despite the setbacks apparent in the fifth working group meeting there is a high probability that an international regime can and will be successfully negotiated and adopted within the next five to ten years. What the final makeup of this regime will be is as yet unclear. However, it is possible to identify a number of key elements which will be required of any regime if it is to be effective in securing the CBD's objectives. These will include measures to be taken by countries both as providers of resources and as users[4], including guidance on minimum standards relating to issues such as prior informed consent (PIC), mutually agreed terms (MAT), benefit sharing and, protection of traditional knowledge. One of the regime's main tasks will be to develop and implement international mechanisms to link provider and user measures.

Most importantly the regime will need to plug a major gap in the current international ABS and TK regime, the lack of compliance measures. This issue is proving to be highly controversial and opposition by some countries has impeded any meaningful debate to date on the topic. However, this opposition cannot be allowed to impede consideration of an issue which, if left unresolved, will undermine the whole negotiation process and bring into question the relevance of developing any international regime on ABS and TK.

2.2 The case for Compliance measures

Any international regime on ABS and/or TK will, to be effective, need to include a range of compliance related measures designed to ensure enforcement of obligations, protection of rights, and access to justice. It will not be enough for a regime to refer to rights to access justice or secure redress for wrongs. Any regime will need to establish clear obligations and outline practical steps for their achievement. In many jurisdictions avenues may already exist through which claims might be made to secure contractual rights and prosecute misappropriation of resources. However, in practice many claimants, in particular those from poor communities and developing countries, may be effectively impeded from using these avenues of redress due to a multiplicity of practical, technical, legal, social and economic hurdles. Impediments may include difficulties in identifying a breach of contract or other cause of action; securing necessary permits or visas; obtaining standing before a court in order to be able to take an action, and; obtaining legal representation and sustaining the costs associated with fighting a case. One of the key demands made by developing countries during negotiation of the Bonn guidelines was that user

4 The concept of "user countries" includes both countries as direct users of resources and as the jurisdiction in which use of resources is made by private parties.

countries take measures to address infringement of ABS agreements[5] and to discourage misappropriation of resources and knowledge[6].

Responsibility for development of compliance measures cannot be left to user countries alone and the international community will need to consider what measures it may take to support access to justice and redress for wrongs. Amongst the most promising areas for consideration will be some form of international alternative dispute resolution mechanism. Establishment of an international dispute resolution mechanism with regional offices would enhance accessibility. Also worth investigating is the possibility of establishing an international ABS and TK ombudsman's office, possibly linked to the Secretariat to the CBD[7]. An ombudsman's office might be charged with responsibility for helping countries of origin, indigenous peoples, and local communities identify breaches of their rights and provide aid in seeking fair and equitable resolution of disputes. Any dispute resolution mechanism and ombudsman's office would need to be guided in its work by principles of equity and benefit sharing drawn from many legal sources, including customary law and practices of indigenous and local communities.

The most widely supported and also one of the most controversial proposals for an international measure to help secure enforcement is for the inclusion of obligations to disclose the origin of genetic resources and TK in intellectual property rights applications procedures. Proposals for disclosure obligations emerged in the early 1990's for patent applications relating to genetic resources[8] and traditional knowledge[9] . Peru was the first country to introduce disclosure obligations with the adoption of its national plant variety protection law in 1995. Disclosure obligations were later incorporated in regional intellectual property legislation by Decision 486 of the Andean Community[10].

In Decision 6/24, which adopted the Bonn guidelines, COP encouraged governments to adopt disclosure obligations in national intellectual property (IP) legislation. Peru together with India, Brazil and other megadiverse countries has been amongst the strongest proponents of disclosure obligations at the international level. Individually and collectively they

5 Guideline II, C (d) (iv) Bonn Guidelines on Access to Genetic Resources and Fair and Equitable sharing of the Benefits Arising out of their Utilization, SCBD (Bonn Guidelines) available at http://www.cbd.int/decisions/?m=cop-06&d=24

6 Guideline II, C, (d) (vi) Bonn Guidelines.

7 Carrizosa, S., S. Brush, B. Wright, & P. McGuire (eds.) Accessing Biodiversity and sharing the Benefits: Lessons from implementation of the convention on Biological diversity. IUCN 2004 at 305.

8 See Hendryx F., V. Koester and C. Prip. Access to genetic resources: A legal analysis. In V. Sanchez and C. Juma (Eds.) Biodiplomacy: Genetic Resources and International Relations, ACTS Press, Nairobi, 1994.

9 Tobin, B. Alternative Mechanisms for Protection of Indigenous Rights, Paper presented at Symposium of Indigenous Peoples of Latin America: "Indigenous Peoples, Biodiversity and Intellectual Property," Santa Cruz, Bolivia, 27–30 September 1994. (Tobin 1994).

10 Ruiz, M. "The Protection of Traditional Knowledge: Policy and Legal Advances in Latin America", IUCN, BMZ, SPDA, Lima 2006.

have made numerous submissions on the issue in proposal for modification of the Trade Related Intellectual Property (TRIPS) Agreement at the World Trade Organisation.

Whatever form compliance measures may take it is clear that their enforcement will require provision of evidence to help identify resources and knowledge, their origin, and conditions regarding their use. Where proof of PIC and MAT is required, - whether as a condition for product approval, grant of intellectual property rights, publication of journal articles, for adjudicating disputes, or prosecuting alleged infringements of rights, - there will be a need for clear, reliable data regarding relevant biological and genetic resources and TK and rights and duties relating to them. In certain cases, in particular those involving TK, this may involve evidence of compliance not only with national and international law but also with relevant customary law and practice.

Documentation is a need of not only providers and users of resources and knowledge, but also of regulatory, administrative and enforcement agencies. Providers need a means to ensure that use of resources is based upon PIC and MAT. Users need a clear legal title to make use of resources. While, administrative, regulatory and enforcement agencies need reliable, recognisable information to enable them to exercise their functions and administer use of resources and knowledge in accordance with relevant law and policy. At present that information must be gleaned form a 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 in principle help to rationalise existing documentation requirements and facilitate rather than impede access to and use of resources and TK, subject to PIC and MAT.

III. SIMILARITIES AND DIFFERENCES OF CERTIFICATION SCHEMES

Proposals for development of measures for documenting resources were made almost as soon as the CBD was adopted. One of the earliest proposals was for the use of a CITES like permit to accompany resource transfers[11]. Despite its utility as a model a CITES style permit system may have limitations due to the vast quantity of material and the enormous number of transactions involved. The nature of the bioprospecting industry, where resources may be collected, subdivided, active components extracted and synthesised or reduced to digital codes and transferred across the internet, calls for a more flexible instrument. One which can enable identification of resources and TK and rights relating to them as they pass through multiple modifications and transactions to the farthest possible point at which rights to benefit sharing may still subsist. Search for such a flexible mechanism has led to a number of proposals for some form of system to certification system to provide evidence of compliance with relevant ABS laws. This includes certificates of origin, source, legal provenance and most recently compliance.

11 Downes, D., New Diplomacy for the Biodiversity Trade: Biodiversity, Biotechnology, and Intellectual Property in the Convention on Biological Diversity, Touro Journal of Transnational Law, Vol. 4. 1993.

3.1 Certificates of origin

The term 'certificates of origin' was coined in a 1994 as part of wider proposal for a Market based system to help secure realization of the CBD's ABS objectives[12] and as a means to protect rights over TK. The development of the proposal was influenced and informed by three processes. Firstly, the adoption of the TRIPS agreement in Marrakesh, Morocco on 15 April 1994, and, with it, the increased potential for use of intellectual property rights (IPR) as tool for misappropriation of genetic resources and TK. Secondly, negotiation of a bioprospecting agreement for use of traditional knowledge of the Aguaruna people of the northern Peruvian Amazon, in the development of new pharmaceutical products. The agreement involving a consortium of universities and Searle & Co. then the pharmaceutical arm of the Monsanto Corporation was part of the International Collaborative Biodiversity Group Program (ICBG)[13]. A negotiation which demonstrated the vulnerability of indigenous peoples in negotiation processes based upon concepts of law and contract alien to them[14]. Thirdly, the negotiations in the Andean Community for a regional ABS regime, and the possibilities it provided for Andean countries to adopt measures to ensure that IPR regimes worked to support fair and equitable sharing of benefits derived from use of genetic resources and TK. Reference to a certificate of origin system was included in draft elements for an regional regime on ABS prepared in a joint project coordinated by IUCN-ELC and the Peruvian Environmental Law Society (SPDA) in 1994/5, at the request of the Andean Community [15].

A certificate of origin system was envisaged as including two principal components. Firstly, a requirement to disclose the use of genetic resources and or TK, and evidence of the right to make use of such resources and TK, in applications for patents[16]. This is widely referred to as a disclosure of origin requirement. Secondly, establishment of a standardized international system of documentation, which could provide evidence of the right to access and make use of genetic resources and TK. In the form of a certificate issued by national authorities demonstrating compliance with national ABS and TK laws.

The proposal is based upon a number of hypotheses. Firstly, that achieving the CBD's ABS objectives requires action by both provider and user countries. Secondly, equitable

12 Tobin, B. 1994, *Alternative Mechanisms for Protection of Indigenous Rights*. Paper presented at Symposium of Indigenous Peoples of Latin America: "Indigenous Peoples, Biodiversity and Intellectual Property," Santa Cruz, Bolivia, 27-30 September 1994 (Tobin 1994). A revised version of this paper was widely circulated under the Title: Putting the Commercial Cart before the Cultural Horse I (Manuscript) 1995 (copy with author) (Tobin 1995). See also Tobin, B., *Certificates of Origin: A Role for IPR Regimes in Securing Prior Informed Consent*, in Mugabe, J, et al. (eds.) *Access to Genetic Resources: Strategies for Sharing Benefits*. Nairobi: ACTS Press 1997 (Tobin 1997).

13 Information on the ICBG program is available on http://www.fic.nih.gov/programs/research_grants/icbg/index.htm, last visited 27 January 2008.

14 For discussion of the Peruvian ICBG Program see Tobin, B., K. Bannister and J. Render, Lessons of Bioprospecting Agreements: The Peruvian ICBG Agreements (forthcoming),

15 Caillaux, J. and M. Ruiz. *Acceso a Recursos Genticos: Propuestas e Instrumentos Juridicos*. Lima: SPDA. 1998.

16 Tobin1994 and 1997 note 15 above.

benefit sharing requires a means to monitor commercial use of resources and TK. Thirdly, Market tools are the best means to monitor and control Market use. Fourthly, placing the burden of proof on users to demonstrate a legal right to use genetic resources and TK creates an incentive for compliance with the CBD's ABS objectives. Fifthly, an effective and cost effective means to monitor commercial use of genetic resources and TK is at the stage of applications for intellectual property rights. Finally, a standardized means to provide evidence of a legal right to use resources and TK, in the form of a certificate of origin, will provide legal certainty and facilitate monitoring of whether a right to use genetic resources and or TK exists.

3.1.1 Certificates as incentives for compliance

A recent paper, part of an edited volume of studies on tracking and monitoring flows of genetic resources[17], identifies the greatest challenge in integrating a certificate system into an international ABS regime as being "… the 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"[18]. The certificate of origin proposal seeks to achieve this end. Firstly, it provides an incentive for users of resources and knowledge to seek PIC and MAT, in order to comply with disclosure of origin obligations. Secondly, it establishes a standardised system to document the existence of PIC and MAT in order to reduce the uncertainty for users regarding rights to use resources and TK.

The functionality of any compliance system will depend upon the capacity and preparedness of relevant authorities to apply it. Modifications to patent applications processes, creating obligations for review of ABS agreements in order to determine issues of compliance with national ABS laws and the equity of benefit sharing, would be likely to fall beyond the current competence and capacity of patent examiners. A certificate evidencing a right to use resources and TK for defined purposes would greatly facilitate the work of patent examiners and others required to identify the existence of PIC and MAT[19]. A certificate system would also offer providers and users of genetic resources and TK the opportunity of maintaining confidential the terms of ABS agreements. Certificates would not replace PIC and MAT requirements, but serve as evidence of their existence. A certificate scheme maybe designed as either a mandatory or incentive based system. Under an incentive based system certificates act to provide legal certainty for users and to facilitate access to and use of resources. The issuance of certificates of provides a means to add value to resources. It has been argued that: "One of the main beneficiaries of a standardized system for demonstrating the origin of biological and genetic resources

17 Ruiz, M., and I. Lapena A. *Moving Target: Genetic Resources and Options for Tracking and Monitoring their International Flows*, ABS Series N.º 3, IUCN, 2007 (Ruiz/ Lapena 2007)

18 Young, T. R,, Challenges ahead: Legal and Practical Prerequisites for the Development of a Certificate of Source, Origin or Legal Provenance for the CBD, Ruiz, M. and I. Lapena, A Moving Target: Genetic Resources and Options for Tracking and Monitoring their International Flows, ABS Series N.º 3 2007.

19 Tobin, 1997, note 15 above.

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."[20]

An incentive based system would not require providers to issue a certificate nor users to hold one. However, an international ABS regime is likely to require users to provide evidence of their right to use resources at various stages during resource use and to maintain records of resources received, how they are used and to whom they are transferred. A certificate system could help to simplify this process. Where a certificate was not available users would be required at various checkpoints to provide other information regarding compliance with ABS laws and agreements. Interestingly, some users have suggested that if a certificate system is adopted it should be mandatory to use standardisation documentation[21].

One potential embodiment of a certificate of origin may be likened to a passport that accompanies genetic resources, either through their entire history from collection to use ('cradle to grave'), or only for certain transactions. Possible check-points for a certificate could be at borders, patent offices or the registration points for other commercial applications not covered by intellectual property rights[22]. The passport information in a certificate, which may attached to the resources transferred or be linked to a digital unique identifier, would serve as the link to relevant terms and terms and conditions relating to use of resources held on national databases[23].

A certification scheme may serve as a means to facilitate access to resources where it assists users to obtain access with a minimum of bureaucracy, and cost. To this end a certificate should provide access to information identifying the terms and conditions applying to use of resources, including if necessary obligations to enter into a new agreement for their use. Standard terms and conditions for use of resources may, for instance, be placed on a national website of provider countries. Provision may be made for online contracting, in certain cases, with users required to accept terms and conditions of a standard licence and

20 Tobin, B., D. Cunningham, and K. Cunningham, *The feasibility, 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*, United Nations University, Institute of Advanced Studies. UNEP/CBD/WG-ABS/3/INF5 2005, (Tobin et al. 2005).

21 Conversation with Leonard Hirsch of the Smithsonian Institution, Cuernavaca Mexico, October 2004. While opposed in principle to proposals for any system of certification, he argued that where documentation is required it should be standardised to avoid confusion. To do otherwise would likely further complicate the lives of customs authorities and those involved in the collection, use and transfer of genetic resources.

22 Cunningham, D., B Tobin, and K. Watanabe. Tracking genetic resources and international access and benefit sharing governance: The role of certificates of origin, Background paper for Smithsonian/UNU-IAS Roundtable on certificates of origin, 9 September 2004, UNU-IAS, 2004 (Cunningham et al 2004).

23 Tobin et al 2005, note 222 above.

make any necessary payments as a condition for using resources[24]. Where users wish to negotiate more favourable terms they would be free to enter into negotiations with provider countries and/or indigenous peoples and local communities as appropriate. Such freeing up of resource access will of course be dependent upon the existence of adequate compliance mechanisms to protect the rights of countries of origin and other legally entitled providers, including, indigenous peoples and local communities.

3.1.2 Why certificates of origin, why not certificates of access?

The use of the term certificate of origin has proven controversial from the beginning. . It has been criticised by those who argue it is not possible to identify the origin of many resources which are already circulating in the world. It was also considered potentially confusing as the term is also used to designate certification of origin of goods under customs treaties[25]. The term was, however, purposefully chosen to highlight that the resources the subject of any certificate were resources covered by the CBD and obtained in accordance with its ABS provisions. The difficulties with identifying the origin of resources historically transferred over centuries apart, the origin of any collection of genetic resources made since the adoption of the CBD should be readily identifiable[26]. The question then becomes what is the purpose of certification, is it to certify all genetic resources or only those covered by the CBD?

The CBD defines the genetic resources covered by the Convention for the purposes of ABS as "… only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention."[27] It defines "a country of origin of genetic resources as being "the country which possesses those genetic resources in *in-situ* conditions"[28]. In-situ genetic resources are in turn defined as those which are found within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties. Certificates of origin could therefore be issued for all resources which were provided by a country which had relevant genetic resources in-situ, or which had obtained the resources in accordance with the Convention. For resources collected in accordance with the Convention but prior to the establishment of a certificate system some form of retrospective certification would be required. Such resources might perhaps be certified under a certificate of legal provenance, which will be discussed below. .

One objective of a certificate of origin system is to make it commercially unviable to use genetic resources and TK not obtained in accordance with the CBD, and for which evidence

24 Ibíd.

25 This led to one early suggestion for use of the term certificates of access, conversation with Begona Venero, INDECOPI, Lima, 1995.

26 Conversation with Philippe Desmeth, **Belgian Coordinated Collections of Micro-organisms (BCCM)**, Lima, January 2007.

27 CBD Article 15.3.

28 Article 2 CBD.

of legal right to make use of such resources or knowledge cannot otherwise be demonstrated. A certificate of origin scheme would, therefore, reduce the value of those pre-CBB collections for which evidence of a valid agreement entitling their commercial use does not exist. . This is considered crucial in order to prevent the unjust enrichment of those holding collections of genetic resources and TK directly or indirectly obtained as a result of some form of misappropriation. Collections for which clear legal title exists would not of course be affected. Nor would this imply any impediment to continuing scientific use of resources for pure research. It would however, apply to scientific research which has as its objective commercial gain. The result would be to create clear incentives for all users to seek legitimate providers of genetic resources and TK, in particular countries of origin and those countries which have obtained resources in accordance with the Convention. The result would be to link users and providers more directly and increase possibilities for equitable benefit sharing.

3.1.3 Certification as an Interim Measure for Protection of TK

Where TK is involved a certificate of origin system proposes that evidence of PIC of indigenous and local communities be a condition for granting access and use[29]. Granting of a certificate would be dependent upon that PIC. Support by indigenous peoples for the idea of a certificate of origin system came as early as 1994 in the form of a call for further study of the concept as a means to protect TK[30]. One potential limitation of a certificate of origin for protection of TK is that origin as defined by the CBD relates to countries and there is concern to ensure that states do not appropriate rights over TK. For this reason it has been proposed that certification should refer to compliance with PIC procedures of indigenous and local communities in effect respecting their customary laws and practices[31].

A TK based certification scheme would seek to create incentives for users to seek out PIC of indigenous peoples and local communities and to enter into benefit sharing agreements with them. Requiring disclosure of evidence of PIC for use of TK, as a condition for IPR grants and product approvals, would reduce the commercial value of collections of TK, obtained without prior informed consent of indigenous peoples or local communities Existing collections of TK, such as those held in databases and registries would, need to determine the status of their collections and the existence or otherwise of rights to make them available for scientific or commercial use. One suggestion is that databases to declare their collections of TK to be held in trust for indigenous peoples and local communities, in a manner similar to the way in which genebanks of the International Plant Genetic

29 Tobin, B. An Interim Solution, in K Whimp & B Mark, Protection of Intellectual, Biological & Cultural Property in Papua New Guinea, Asia Pacific Press, 2000 (Tobin 2000)

30 Declaration of the Symposium for Indigenous Peoples of Latin America "Indigenous Peoples, Biodiversity and Intellectual Property", Santa Cruz, Bolivia, 28-30 September, 1994, COICA, 1994

31 Alexander, M. The Role of Traditional Knowledge Protocols in conjunction with a Certificate of Origin/Source/Legal Provenance ABS Regime: A Preliminary Aboriginal Perspective, paper presented at the International Expert Group Meeting on the Convention on Biological Diversity's International Regime On Access And Benefit-Sharing and Indigenous Peoples' Human Rights 17 – 19 January 2007, New York, 2007. (Alexander 2007).

Resource Institute (IPGRI), hold its plant genetic material in trust for humankind[32]. One of the main challenges associated with developing a system to protect TK is the need for review of application of the principle of the concept of the public domain and its conflict with rights over TK. Application of the concept of the public domain to TK may serve otherwise as a means to legitimise its historic expropriation.

Threatened by misappropriation of TK indigenous peoples are being forced into debates on TK protection which do not respect their timeframes. Nor does it provide them with opportunities and means to ensure full informed debate of key issues at the community level. The result may be imposition of technical solutions to what is as much a cultural and social challenge as a legal and economic one. A certificate of origin system incorporating disclosure of origin requirements in patent law would serve to reduce that pressure and provide indigenous peoples and local communities interim protection while they developed their own proposals and mechanisms for securing rights over TK[33].

3.1.4 Potential content

A preliminary list of the information that may perhaps be included in a TK certificate could include:

- Particulars of the indigenous or local communities parties to the agreement;
- Particulars of the user
- Details of the traditional knowledge covered,
- Details of the approved uses ;
- 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.[34]

3.2 Certificates of source

According to proponents of a certificate of source approach both "country of origin" and "geographic origin" are terms which may be difficult or impossible to determine in practice[35]. Both concepts are seen as being too restrictive to fully take into account the

32 Alexander, M., K. Chamundeeswari, A. Kambu, M. Ruiz, B. Tobin. **The Role of Registers in the Protection of Traditional Knowledge:** From Concept to Practice, UNU-IAS, 2003.

33 Tobin 2000, note 31 above.

34 Adapted from Barber, C V, S Johnston and B Tobin, *User Measures: Options for Developing Measures in User Countries to Implement the Access and Benefit–Sharing Provisions of the Convention on Biological Diversity*, UNU-IAS, Tokyo, March 2003.

35 Girsberger, M., *Certificates of Source – Disclosure of Source*, in Proceedings of the International Expert Workshop on Access to Genetic Resources and Benefit Sharing, October 24-27, 2004, Final Report, Environment Canada and CONABIO, 2004 (Girsberger 2000) available at http://www.canmexworkshop.com/papers.cfm.

multitude of entities that may, according to the CBD and the Bonn Guidelines, be involved in access and benefit sharing. As an alternative it is proposed that the term "source" be used, to cover all potential "sources" of genetic resources and traditional knowledge allowed for in the CBD and the Bonn Guidelines.

The 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. Depending on the genetic resource or traditional knowledge in question, there may be "primary" and "secondary" sources: Primary sources would be the Contracting Party providing genetic resources (see Arts. 15, 16 and 19 of the CBD), indigenous and local communities (see Art. 8(j) of the CBD), and the Multilateral System established by the FAO-IT (see Arts. 10-13); secondary sources would be *ex situ* collections such as gene banks and botanical gardens, databases on genetic resources and traditional knowledge, and scientific literature."[36] The position of pre-CBD collections is not discussed and it is unclear whether providers of such resources are to be considered secondary sources for purposes of certification. This might prove problematic if certification was deemed to confer legitimacy upon all those with pre-CBD collections to dispose of them as they will.

This proposal was developed as part of a wider Swiss proposal which suggests that patent applicants should be required to declare the "source" of genetic resources and traditional knowledge in patent applications[37]. It argues that if a certificate is to have a role in relation to disclosure requirements both transparency measures should be congruent with and mutually supportive of each other. Using the same terminology and based on the same concepts.[38]

Questions have been raised by industry regarding the value of disclosure of source as a means to forward the objectives of the CBD[39]. However, many experts working on the development of national and international ABS regulation favour some form of certification. In the view of one influential commentator disclosure of source in patent applications would benefit all parties. In his words "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 it 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 contacts 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 the IP, it enables them to undertake due diligence, addressing commercial and legal uncertainty and, to more accurately determine the Market value of the

36 Ibíd.

37 Girsberger, M.A., 2004. *Transparency Measures Under Patent Law Regarding Genetic Resources and Traditional Knowledge: Disclosure of Source and Evidence of Prior Informed Consent and Benefit Sharing*, Journal of World Intellectual Property, Vol. 7 N.º 4, July 2004,

38 Ibíd.

39 Chartered Institute of Patent Attorneys, CIPA, http://www.cipa.org.uk/pages/GeneticRes last visited Wednesday, 11 July 2007.

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. Most importantly for the patent applicants, it allows them to obtain full measure of Market reward for their compliance with their legal obligations surrounding their acquisition of the source material from which their inventions derive."[40]

Experts from Latin American countries meeting in Lima at the invitation of the Andean Community and the government of Peru, in advance of the GTE meeting, did not lean towards a certification of source based system[41]. A certificate of source based system could conceivably give legitimacy to pre-CBD collections, even where obtained illegally. It has been suggested that a certificate of source might be utilised to document transfers for non-commercial purposes of resources collected pre-CBD[42] Some commentators, however, have expressed the position that although pre-CBD collections do not fall within the remit of the CBD, post CBD transfers of resources from whatever source should comply with the Convention and its ABS provisions[43].

The certificate of source proposal is closely linked with Swiss proposals for a system of disclosure of source. This proposal envisions a system under which patent authorities in a country where an application is made would inform the authorities of countries of origin if their resources are relevant to the application.

3.3 Certificates of legal provenance

Proposal of a certificate of legal provenance based system was offered as an alternative to both certificates of origin and source which it was argued both referred to the supplier of the material and not necessarily to the process that the material underwent[44]. The proposal is based upon the premise that the purpose of a certificate system should be to provide a history of custody rather than merely identify the origin or source of the material.

40 Burton G. National Access Laws: Challenges, Benefit-Sharing, Monitoring and Enforcement – Disclosure of Information: Patent Applications, in Proceedings of the International Expert Workshop on Access to Genetic Resources and Benefit Sharing, October 24-27, 2004, Final Report, Environment Canada and CONABIO, 2004 available at http://www.canmexworkshop.com/papers.cfm

41 Conversation with Monica Rossel January 2007.

42 UNEP/CBD/WG-ABS/3/INF5 Tobin, B., D. Cunningham, and K. Watanabe, *The feasibility, 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*, United Nations University Institute of Advanced Studies

43 Fernández, J.C. *Tracking and Monitoring of International Flows of Genetic Resources: Why, How and, Is it worth the Effort?* In Ruiz, M. and I. Lapena, *A Moving Target: Genetic Resources and Options for Tracking and Monitoring their International Flows, ABS Series N.º 3* 2007 (Fernández 2007)

44 Fernández, J.C. *Elements for the Design of a Certificate of Legal Provenance in Proceedings of* the International Expert Workshop on Access to Genetic Resources and Benefit Sharing, October 24-27, 2004, Final Report, Environment Canada and CONABIO, 2004 (Fernández 2004) available at http://www.canmexworkshop.com/papers.cfm

A certificate of legal provenance would provide evidence that resources or TK had been legally obtained. As resources are transformed the certificate would travel with the transformed resource continuing to provide evidence of legal provenance[45]. Under the proposal certificates would serve as evidence of compliance with the access provisions of the providing country[46]. Certificates would be issued by a designated national authority according to an internationally agreed standard, with a single certificate capable of covering multiple genetic resources[47]. Documentation of resources would include a description of their geographical origin and, evidence of compliance with access and benefit sharing obligations arising from the CBD and from national legislation[48]. The proposal does not, therefore, suggest so much a change in the nature of the certificate itself as in its perception.

The innovative element of the proposal resides in the suggestion that certificates be recorded in an international clearing house which would enable not only providers, but third parties to play a role in monitoring use of resources[49]. This is where the majority of information on certificates would be stored, with only the registry number or a code associating the material or information being exchanged with the information in the clearing house[50]. The user would be legally obliged to maintain the link between the certificate and the material/information by whatever means necessary, and to convey it to recipients of material or information derived from the genetic resource[51]. This certificate/code could be requested a specific check points such as applications for intellectual property rights and product approvals[52].

Amongst the anticipated benefits of such a system would be that it would:

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

While, its limitations include that it:

- does not resolve asymmetries in ABS negotiation capacity and strength;
- is not substitute for development of national access legislation, and;
- depends on solving the management of ex-situ pre-convention materials in order for it to be effective.[53]

45 Ibíd.

46 Ibíd.

47 Fernández 2007, note 45 above.

48 Ibíd.

49 Fernández 2004, note 46 above.

50 Fernández 2007, note 45 above.

51 Ibíd.

52 Ibíd.

53 Fernández 2004 note 46 above.

3.4 Certificates of compliance

Based upon national experience and analysis of recent literature on the idea of an 'international certificate of origin/source/legal provenance', Australia prepared a national submission to the CBD on certificates. This proposed that a 'certificate of compliance', issued by domestic authorities to show that a user has fulfilled all access requirements set out in domestic law, could support the effective implementation of Article 15[54]. The certificate would, not replace the need for contracts, but would be complementary to them having the primary objective of ensuring that access is consistent with obligations under the Convention.

A certificate of compliance is seen as benefiting both users and providers. For providers, it would show that access requirements, such as PIC, had been fulfilled and would support claims for benefit sharing. The proposal sees certificates bringing benefits to both scientific and commercial users in the form of evidence that genetic resources were initially obtained from a provider country in accordance with the Convention[55]. This it is argued will help bring certainty, transparency and predictability and facilitate the research and commercialisation, without which there will be no benefits to share[56].

The proposal argues that the variety of domestic systems for implementing Article 15 precludes the development of any standardised certificate; however, a recognised certificate, which conformed to international guidelines, could be envisaged. This it suggests "… might include 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."[57] The proposal makes the case that the transboundary transfer of pre-CBD collections, which are outside the Convention's scope, cannot be covered by a certification scheme. As a result the argument is made that "… no system of 'checkpoints' could be workable since no system of certificates could comprehensively cover all transfers of genetic resources."[58]

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 proposes that TK issues be dealt with separately from those relating to genetic resources, and that any system avoid arrogating to the State rights over TK[59].

The submission argues that "… identification of the 'origin' is challenging and expensive to verify in many cases, particularly where a species exists in more than one

54 Australia's National Submission on Certificates of Origin, Source or Legal Provenance, available on http://www.dfat.gov.au/environment/geneticresources/certificate-submission.html

55 Ibíd.

56 Ibíd.

57 Ibíd.

58 Ibíd.

59 Ibíd.

jurisdiction."[60] Identification of the 'source' it feels could present similar problems. It also argues that the range of possible scenarios under which domestic authorities may issue a certificate to indicate compliance with Article 15 of the CBD, cannot be reduced to either 'origin' or 'source'[61]. This argument is premised upon the kernel of the Australian proposal which is that implementation of the CBD will be dealt with in different ways in different countries making a one size fits all solution unworkable.

While recognising that 'legal provenance' could be interpreted as meaning evidence of compliance with domestic requirements for access, the certificate of compliance proposal says "… the term could possibly also be construed in some jurisdictions as constituting evidence of a legal title or ownership."[62] 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."[63]

3.5 Comparative analysis of Certification proposals

Certification proposals demonstrate a number of underlying similarities. They all see documentation of genetic resources serving the interests of both providers and users of resources, bringing transparency and legal certainty to the trade in genetic resources. They all envision the establishment of some form of standardised or internationally recognisable documentation which would include a certain amount of information regarding the resources covered by the certificate. The proposals also agree in general that a certificate would provide evidence of compliance with obligations relating to access to genetic resources. There are however differences in relation to what resources and whose laws are being complied with.

Proposals for certificates of origin and legal provenance both define the resources to be covered as those which are obtained from providers as that term is construed under the CBD. The scope of coverage would therefore be genetic resources obtained from countries of origin or parties who had obtained resources in accordance with the CBD. The proposal on certificates of source would extend to both primary sources, being countries entitled to provide resources under the CBD and secondary sources, such as ex-situ collections. Under the certificate of compliance proposal all resources not covered by the CBD would be excluded from its coverage, also excluded would be resources which are not subject to ABS regulations under the domestic legislation of the country providing them. Negotiators will need to review these various proposals with care to ensure that the scope of any certification scheme is sufficient to ensure the relevance of documentation. Ambiguities will reduce the utility of any system as a tool for helping to secure compliance with CBD ABS objectives.

60 Ibíd.

61 Ibíd.

62 Ibíd.

63 Ibíd.

Certificate proposals have since the inception been closely linked to proposals for disclosure of origin/source obligations in patent applications procedures. 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 as presented in the Australian submission, however, breaks with this tradition. It argues that the diversity of national approaches to domestic ABS regulation would 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.

For any system of checkpoints to be functional, it will need the capacity to review the existence of rights to access and use resources and identify whether there has been compliance with any obligations relating to such access and use. Relevant authorities may carry out such review in a number of fashions including through the revision of contracts, collection permits, export and import permits etc. Certificates it has been suggested would help to facilitate that process. The certificate of compliance proposal acknowledges 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 they might be internationally recognised. This it is submitted would most likely be adequate for the purposes of review of rights to use resources at internationally established checkpoints or checkpoints established in line with international guidelines. A certificate of compliance could therefore in principle serve as part of a disclosure of origin/source system.

All proposals acknowledge the inextricable link between any certification scheme and pre-CBD collections. The proposal for certificates or origin envisions a system where certificates must be issued by a country of origin as defined by the CBD, thereby excluding all pre-CBD collections. The certificate of legal provenance proposal would enable both countries of origin and countries which have obtained resources in accordance with the CBD to issue certificates. This would allow for the certification of resources from ex-situ collections obtained in accordance with the Convention. It would not, however, cover pre-CBD ex-situ collections. The certificate of source proposal in its most expansive interpretation would allow for certification of any resource from whatever source, without any restriction whatsoever. This could include pre-CBD collections, although it is unclear that this is the intention of the proposal. The certification of compliance proposal takes the position that pre-CBD resources are not covered by the CBD and cannot be included in any certification scheme. As a result it argues any attempt to apply checkpoints to the scheme will be inoperable.

It is increasingly clear that any certification scheme which does not address pre-CBD collections, either by inclusion, specific exclusion, or by sanitising collections (e.g. by international agreement), will prove less than useful for either providers or users, and even less so for regulatory bodies. It has been proposed that a comprehensive certification system might involve the use of more than one certificate. Under such a scheme 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 under such a scheme would be reserved for pre-CBD collections for which there is no clear legal title. A certificate of source would only be provided with resources for non-commercial scientific use[64].

All 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. The certificate of origin proposal has evolved to include suggestions that certificates be linked to standard terms and conditions for use of resources. The certificate or legal provenance proposal envisions a system in which certificates/codes would link users and providers through a central clearinghouse system. The certificate of source proposal would provide for national authorities in countries where a certificate is provided as part of a patent application procedure to inform national authorities in the country of origin if identifiable of the application. The certificate of compliance proposal refers 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.

Certification is seen as having a role to play in protection of rights over traditional knowledge in proposals for certificates of origin, source and legal provenance. The certificate of origin proposal was designed primarily as part of a system to protect TK rights. It proposes that certification related to TK be based on PIC, and that user measures be established to ensure that use of TK requires evidence of PIC. The certificates of source and certificate of legal provenance proposals provide for certification of the source and legal provenance of TK respectively. The certificate of compliance proposal does not provide for certification of TK. It highlights the differences under article 15 and 8(j) of the Convention with regard to issues of PIC arguing that traditional knowledge and genetic resource issues should be dealt with separately and differently.

TK unlike genetic resources cannot be referred to in terms of origin as that term is used in the CBD. The terms legal provenance and compliance may more readily lend themselves to proposals for certification schemes to provide evidence of PIC relating to TK[65].

IV. CERTIFICATES IN INTERNATIONAL ABS AND TK GOVERNANCE

Consideration of certificate proposals have been a part of the international political process surrounding implementation of the CBD's ABS objectives since 1999 when it was incorporated in the report of the first Expert Panel on ABS. COP called for further investigation of the practicality, feasibility and cost of certificate proposals[66]. COP 8 went further establishing a technical group of experts to advance investigation of certifications possibilities as a tool to aid ABS regulation. This section reviews the work of the group of experts and considers a number of key challenges to be faced in developing any cer-

64 Tobin et al 2005.

65 Alexander, M. 2007, note 33 above.

66 CBD Decision 6/24 C.

tificate scheme. These include practicality, feasibility and costs, pre-CBD collections and certifying TK.

4.1 Group of Technical Experts on Certificates of Origin/source/legal provenance[67]

The potential utility of a certification scheme as a means to help secure implementation of the CBD's ABS objectives and as a component of an international ABS regime, led COP 8 to establish 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 GTE meeting identified a number of common points 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 report of the GTE meeting recognises that a certificate system forming part of a broader ABS regime could play an important role in helping to support national legal systems. Depending upon the model of certification scheme 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[68].

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. 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[69].

67 This analysis of the GTE's work is based directly upon and draws heavily from the Group's Report. See UNEP/CBD/WG-ABS/5/2.

68 UNEP/CBD/WG-ABS/5/2.

69 Ibíd.

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[70]. The issue was not considered in depth, and the group acknowledged that further exploration may be needed in order to determine whether the certificate should be extended to traditional knowledge. 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 issues relating to international ABS regulation.

One of the key issues addressed by the GTE was the implementation and other costs, associated with setting up a certification scheme. These were anticipated to be high in the start up phase; however, it was felt that the transaction costs may prove relatively low. The costs were likely to escalate if a system involves excessive tracking, reporting and monitoring, or generates more bureaucracy than required, and will be counterproductive if it unnecessarily slows down or discourages research and product development. Other costs to be considered relate to establishment and maintenance of checkpoints in user countries. There was also a perceived cost and potential loss to the system in the event that resources coexisted both inside and outside the system[71].

To the extent that a system could lower transaction costs and provide flexibility and legal certainty the Group felt it could balance the costs of implementation and avoid the costs associated with the uncoordinated development of national regimes. It was noted that the level of legal certainty provided by a certificate system may increase as obligations to provide certificates in provider countries and request certificates in user countries increased. Conversely, the level of legal certainty may decrease as any system becomes more discretionary. The potential benefits of a certificate system to achieve the access and benefit-sharing objectives of the Convention were also considered likely to increase with greater participation of parties at both the user and provider end[72]

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;

70 Ibíd.

71 Ibíd.

72 Ibíd.

(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[73].

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.

The GTE 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[74].

4.2 Challenges for implementation of certification schemes

Based upon the review of the certification proposals and the GTE report of its meeting three major outstanding issues can be identified. These are the costs and practicality of establishing certification systems, how to deal with pre-CBD collections and, how, if at all, might a certification system help in protection of TK. These issues will be briefly considered below

4.2.1 Practicality, feasibility and costs of certification

The lack of standardised system of documentation for identifying resources and knowledge greatly hinders the development of a more fluid process for facilitating access and benefit sharing. At present collections of biological material is subject to a plethora of documentation requirements. This includes documentation required by national authorities in provider and user countries, internal documentation requirements of ex-situ collections, research institutions and commercial companies as well as obligations imposed by customers. Research into existing documentation practices demonstrates that almost all collections, accessions and transfers of biological and or genetic material is subject to documentation. This includes, in a significant percentage of cases, information of resources received, any internal use or modification of resources, and transfer of resources to third parties[75].

Despite the apparent practicality and benefits associated with standardising documentation there is significant opposition to such proposals in part due to the potential costs and technical difficulties of documenting resources. There are also fears that standardisation may affect existing internal record keeping practices, and major costs if existing software

73 Ibíd.

74 Ibíd.

75 Tobin et al 2005, note 22 above.

and hardware infrastructure needs significant modification. These concerns cannot be lightly overlooked. The Royal Botanical Gardens at Kew for instance has estimated that a certificate scheme may require hiring of from 3-4 persons just to maintain records of accessions[76]. Questions have also been asked about the length for which records would need to be kept with Institutions such as the Smithsonian holding material for upwards of a century.

Recent work to identify the potential costs of a documentation/certification scheme for transfers of plant genetic resources for food and agriculture (PGRFA) under the International Treaty for PGRFA, suggest that transaction costs could amount to between 41% and 97% of benefits derived from that system[77]. These costs assumed that up to … % would be taken up with costs associated with managing standard material transfer agreements, while at the upper end of the scale almost 45% of costs would be associated with DNA fingerprinting. The likelihood of massive DNA fingerprinting by provider countries is indeed remote while the costs of contract negotiation and adoption cannot be avoided, in particular in the case of CBD ABS agreements. However, the costs of contracting may be reduced through the use of standard material transfer agreements (MTA's) and the possibility of using online contracting to facilitate agreement making for access to and use of resources.

Low cost functional documentation schemes for recording plant genetic resource collections and transfers do exist. One such example is the case of the Saskatchewan Herb and Spice Association, established to secure the source and reliability of medicinal plants, where plant quality is crucial. Referred to, as a "one up one down system"[78], 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.

A crucial difference between records keeping by microbial collections investigated and the one up one down model of the Saskatchewan Herb and Spice Association was that in many cases microbial collections did not link the resources that came in with those that went out[79]. This in effect breaks the chain of custody which would enable tracing of the origin of resources and linking them to any relevant terms and conditions associated with their original collection. Development of any certification system will need to consider the minimum levels of record keeping necessary to maintain a chain of custody linking resources and TK with the terms and conditions established for access and use.

76 Ruiz/Lapena 2007, note 19 above.

77 Eaton, D., and B. Visser, *Transaction Costs of Tracking and Monitoring the Flows of Genetic* Resources, in Ruiz, M. and I. Lapena, *A Moving Target: Genetic Resources and Options for Tracking and Monitoring their International Flows, ABS Series N.º 3* 2007.

78 Presentation of Connie Kehler President of the Saskatchewan Herb and Spice Association at the Lima ABS dialogue on the role of Documentation in ABS and TK Governance, organised by UNU-IAS, IDDRI and CPDR, Lima January 2007, on file with author.

79 Tobin et al 2005, note 22 above.

4.2.2 Pre-CBD Collections

Although it is widely presumed that the CBD granted sovereign rights to countries over their genetic resources, in fact, it merely recognized rights that countries had never in fact relinquished. This is of much importance with regard to genetic resources collected prior to the CBD which are not covered by the Convention and 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 transferred from pre-CBD collections.

The right to use genetic resources collected prior to the entry into force of the CBD, in particular for commercial purposes is, arguably, dependent upon the ability to show a good legal agreement allowing for such commercial use. This would require the provision of evidence that a legal right to collect and use resources had been obtained at some stage from a provider entitled to grant such rights. This proposition is of much significance for research institutions, ex-situ collections and commercial actors with extensive collections of genetic resources and or TK. Requiring collections to produce evidence of a legal right to use resources based upon the existence of a sound legal title obtained originally from a country of origin would have a significant impact on their commercial value. The result would be to impede commercial use of resources which were provided for purely scientific purposes, or were obtained by theft, fraud, misrepresentation etc.

The principle that a person should not benefit from his wrongdoing is an intrinsic part of the law of intellectual property enshrined in the doctrine of unclean hands. To date it has not been applied in relation to intellectual property right applications 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 rersource debate[80].

Various means to overcome the dilemma associated with pre CBD collections exists. Collections could 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 the registry of information in an international database of the resources held. 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 in the International Treaty on PGRFA. Benefits from the fund could be distributed to support resource conservation and strengthening of traditional knowledge systems.

Where collections can demonstrate a good legal title entitling commercial use of resources they may be encouraged to inform the authorities of the country of origin of the existence of the collection and the source of the rights relating to its use. Countries of origin

80 Carvahlo, N. 2000. *Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications Without Infringing the TRIPS Agreement: The Problem and the Solution*. Washington University Journal of Law and Policy, N.º 2, 371.

could have a fixed period within which to challenge a collection on its title, after which the right to challenge would expire. Collections, holding resources which do not have a full title could seek to enter into an agreement with countries of origin. Such agreements might entitle to act as a broker of resources providing them for scientific and commercial use subject to relevant benefit sharing with the country of origin.

Alternatively, all pre-CD collections could be deemed held under trust for the countries of origin, where the origin of resources may be identified, and for humanity where origin cannot be identified. Collections would be entitled to receive an appropriate share of any benefits derived form use of resources, with obligations on users to negotiate benefit sharing agreements directly with countries of origin before any IPR rights are applied for.

4.2.3 Traditional Knowledge

The intangible nature of traditional knowledge poses practical difficulties and distinct implementation challenges[81] for the development of a TK certificate scheme. These difficulties, coupled with a general feeling that indigenous peoples should be the ones to design proposals in this area, have restricted commentary to date on the possible elements of a TK certification scheme.

Indigenous peoples have raised many questions which will need to be considered in determining the appropriateness and utility of any certificate system to protect TK. These include matters, such as: who would issue any 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?

One recent paper on the issue has presented an indigenous perspective from Canada which deserves citing in detail. The paper argues that a certificate is only one of many tools, which together may go to make up an ABS regime, and proposes that any regime should also include tools, such as traditional knowledge protocols, which serve as evidence of PIC[82]. TK protocols may be described as forms of contracts which draw upon aspects of customary law and practice as the basis for regulating rights to access and use TK. A certificate might 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; indigenous peoples' customary law relevant to the provision of prior informed consent has been conformed with; and in order to sever or modify any terms of the Protocol that are inequitable, unfair or involuntary[83].

81 UNEP/CBD/WG-ABS/5/2

82 Alexander, M. 2007 note 33 above.

83 Ibíd.

For a certification scheme to be acceptable to indigenous peoples it has been proposed that it must be developed in manner, that amongst other things:

- guarantees that indigenous peoples will be equal Parties to access and benefit-sharing arrangements that incorporate their traditional knowledge;
- sets out appropriate standards for obtaining prior informed consent of the relevant indingeous peoples;
- provides processes to ensure that Parties negotiate in good faith, including investigative and enforcement powers;
- sets out practical mechanisms for dispute resolute that include respect for applicable customary laws; and
- Provides for conflict of laws mechanisms that reconcile customary laws and national laws[84]

The foregoing are just some of the issues which will need to be addressed in designing a TK certificate system. Most importantly any system will need to be flexible enough to serve as a means for providing evidence of compliance with PIC procedures in multiple countries and cultures following a variety of customary laws. Determining what national body or traditional authority may issue a certificate will have a bearing both on the legitimacy of the certificate and also on its effectiveness to serve as evidence of a legal right to access and use TK. Developing a system will need to be done in a participatory fashion with indigenous peoples, whether it is being done at the national, regional, or international level.

V. CONCLUSIONS

Certificate schemes are now a central part of negotiations relating to the development of an international ABS regime. Over the years a range of different proposals have emerged each adding a new perspective on how a certification system may support implementation of the CBD's objectives. Despite the external differences of these proposals they all display a number of the same fundamental principles. Most importantly they all perceive the role of certificates to be to certify compliance with national ABS laws. Albeit, in varying degrees.

For the main part certificate proposals are seen as being an integral part of compliance mechanisms which will need to be implemented by user countries. The principal potential for checkpoints at which certificates might be sought are commercial regulatory agencies (e.g. product approvals bodies) and 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.

Any system will need to be flexible, cost effective and easy to implement if it is to be successful. 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 received, how

84 Adapted from Alexander, M. 2007, note 33 above.

they are used and what resources, derivatives or products incorporating the foregoing are transferred to third parties.

A major impediment to the successful development and implementation of a certification scheme relates to resources which may fall outside its scope. Action needs to be taken to resolve the status of pre-CBD collections. This may be achieved by international action establishing means for payment of compensation for use of pre-CBD collections, or by bringing them within any system. This may be done through distinct certifying of pre-CBD collections. Failure to address this issue will seriously undermine the establishment of an international system to regulate the use of genetic resources and associated TK.

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.

Although, implementation of a global certification system may still be some way off it seems only a matter of time until a system becomes part of international ABS and TK law governance. . When that happens it will matter little what terminology may finally be used to describe it. What will be important are the content, nature and scope of any system. This is what negotiators should focus on. When that system comes into being whatever it is called then it will be fair to say that certificates of origin have indeed come of age.