

Certificates of Origin, Legal Provenance and Source: Mutually Exclusive or Complementary Elements of a Comprehensive Certification Scheme

Brendan Tobin¹. Coordinator Biodiplomacy Initiative, Institute Advanced Studies, United Nations University. tob@ias.unu.edu

David Cunningham and Kazuo Watanabe.

The secretariat to the CBD was tasked by COP-6 to undertake further information gathering and analysis of the feasibility of an international certificate of origin system, as evidence of MAT and PIC for the use of genetic resources. As discussion of the proposal has advanced, so too has debate about what should be certified and proposals have emerged for certificates of source and legal provenance as well. This led COP-7 in 2004 to decide to undertake further examination of an internationally recognised certificate of origin/source/legal provenance of genetic resources and associated traditional knowledge as part of the negotiation of an international regime on ABS. Once again the feasibility, practicality, operational functionality and costs of any international certificate system were identified as the key issues to be investigated. Investigation will also focus on the potential role certificates might play in a system regarding the disclosure of origin of genetic resources and associated traditional knowledge in applications for intellectual property rights.

Despite several preliminary investigations and many informal discussions at international meetings, however, there is still no clear understanding of how a certificate of origin system could operate in practice, or what should be the scope or nature of any such system.

The term 'certificate of origin' was originally coined in 1994 to describe a proposal for the use of patent applications procedures as a means for ensuring the existence of PIC for use of genetic resources. The original concept proposed the adoption of requirements for disclosure of the origin of genetic resources and associated traditional knowledge as a condition for receipt and processing of patent applications. It was suggested that the establishment of a standardized certificate of origin, which would act as evidence of prior informed consent, would exempt patent officers from the need to examine all of the documentation related to an ABS agreement to verify compliance with the CBD (Tobin 1994). The idea was quickly taken up by indigenous people across Latin America and the Declaration of Santa Cruz (1994) calls for further investigation of the potential of system of certification of origin to protect rights over traditional knowledge (TK). It was also included in proposed Draft Elements for a Regional Regime on ABS for the Andean Pact, prepared by IUCN/ELC and The Peruvian Environmental Law Society (SPDA) between 1994 and 1995 (Tobin 1997).

The term has since taken on a wider meaning which broadly encompasses the tracking flows of genetic resources and documenting evidence for the right to use genetic resources. It has also been proposed that such a system could be expanded to apply to product approval processes, scientific publications and other regulatory approval procedures.

Framework for a System of Certificates of Origin

In determining the potential framework of a certificate of origin system, a number of key issues need to be addressed, including:

- The purpose of certification;
- Nature of a certificate, ie. would it be mandatory or voluntary;
- Subject matter covered by the certificate;
- What it is certifying - origin, source, or legal provenance;
- When would it be required?;
- What format would a certificate take - physical hard copy, barcode or virtual online certificate?;
- Verification procedure;
- What terms and conditions would apply to material provided under a certificate?; and
- What verification and compliance mechanisms would be needed to support such a system?

These matters can be addressed only briefly here, and focus will primarily be given to addressing the issues of the subject matter to be certified and what is being certified. A proposal is also made for utilizing certificates as a tool for promoting a more flexible access and benefit-sharing procedure that incorporates elements of both liability and property regimes, as discussed by Ruth Okediji in her paper for this workshop.

Subject Matter of a Certificate

A preliminary list of the information that may perhaps be included in a certificate of origin, has been proposed by Barber *et al.* (2003), 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.

With regard to the provision of details of genetic resources or traditional knowledge the latter is less problematic as particular elements of TK could be clearly identified, while detailing genetic resources may prove more problematic - in particular where the material involved includes unidentified samples made in random bioprospecting collections.

As the focus of the system will be to trace the flow of genetic resources it would seem at first glance that genetic resources themselves should be certified. This, however, is not only impractical it will be impossible in a vast majority of cases where the material collected still remains to be classified. Once again, the issue of the definition of 'genetic resources' also comes into play, because there are a multiplicity of possible collections which would fit the CBD definition, including isolated compounds, soil samples, insect collections and animal and plant specimens. Certificates could be granted for the access contract itself and all material collected under it, for a specific collection activity in a defined area for a defined period, for all samples of a specific species or genus, or for an individual collection or sample. At a different level, a certificate might be linked to a particular isolated compound, perhaps be given an individual barcode, as is the case with samples provided by INBio. What will be necessary is to identify the most practical level for the granting of a certificate and develop a system which enables collectors and or users to code the products of research and development in an identifiable manner which links back to the original certificate.

What is being Certified?

The term certificate of origin implies a certificate which identifies that a genetic resource that has been obtained from a country of origin, as that term is defined in the CBD. This has proved problematic for some as identifying the origin of resources may be impossible in many cases, thereby creating a legal limbo for resources whose origin cannot be identified. Proposals have now been made for alternatives such as a 'certificate of source' or a 'certificate of legal provenance'. These proposals are, however, also problematic and have not found acceptance with those who fear the potential implications for collections of genetic resources collected prior to the entry into force of the CBD, or subsequently without any PIC or MAT.

A certificate of source would track the genetic resource only as far as the place where the user obtained it, which may be a collection or depository and not necessarily the country of origin. A certificate of legal provenance would document evidence that the resources had been obtained from a legally entitled provider. In the face of continuing uncertainties regarding legal rights over resources and in the absence of a binding international regime on ABS (which clarifies the legal status of all pre-CBD collections and of those collected post-CBD but without PIC), legal provenance would fail to be decided by the laws of the country where the resources were sourced. This situation could potentially provide an opportunity for circumvention of the rights of countries of origin. A certificate of origin would be granted by a country of origin.

Attempting to secure international agreement on whether a certificate of source, legal provenance or origin is to be the preferred option is a difficult challenge and is, not necessarily, the best avenue to pursue. In fact, a system which employs a variety of certificates including both certificates of origin and legal provenance, as well as, potentially, certificates of source, may be the most effective way to expedite the establishment of a functional international system.

A certificate of origin would most likely be granted by a national competent authority while a certificate of legal provenance would more likely emanate from the provider of the relevant genetic resources such as a genebank, herbaria etc. Their right to grant such a certificate could be established by a national approvals procedure under which they are listed in a Register of those organizations entitled to grant certificates of legal provenance, for resources within their collection that meet determined criteria. This could include material collected prior to entry into force of the CBD, material collected in accordance with international agreements, or material obtained in accordance with national law in

countries not requiring PIC and MAT for access, and for which it can be shown that resources were obtained in full compliance with the national laws and policies of the provider country. Certificates of legal provenance might also be granted by a national authority for resources held by individuals or companies which are not registered, and subject to provision of evidence of their legal acquisition of the relevant genetic resources.

The value of having a separate defined certificate of origin would be to clearly establish a fresh chain of custody for genetic resources obtained in accordance with the CBD's provisions on ABS; add value to resources by ensuring legal certainty for users; and to distinguish material for tracking and for marketing purposes. It is conceivable that resources which are covered by a certificate of origin may in time become more valuable as users seek to ensure the legitimacy of the source and to avoid any potential claims of biopiracy.

Certificates of source would be issued by providers who are not registered for the purpose of issuing certificates of legal provenance. In such a case, the certificate of source would indicate where the provider had obtained the resources and would serve to provide a paper trail of resource transactions, which could be traced for the purposes of identifying whether the resources were legally held or not. This might for instance be utilized for exchanges between scientists for pure research. Certificates of source would therefore be required for all exchanges of genetic resources for scientific research purposes not covered by certificates of origin or legal provenance, and would help to develop a more responsible management of resource flows amongst scientists. Such certificates could not be used as the basis for commercial use of resources, and in the event of serendipitous innovation, it would be necessary to seek a valid certificate of legal provenance or origin prior to seeking a patent or product approval etc.

Establishing a system of certification which provides for certification of source, legal provenance or origin from a predetermined date may prove more feasible as a means for launching a comprehensive system for tracking resource flows than trying to establish a single form of certification to fit all situations.

How would a Certification System Operate?

One potential mechanism would be to grant a certificate for all samples collected under a particular contract. The contract would be registered with the competent national authority and would be accessible for consultation with regard the terms and conditions applying to samples covered by the particular certificate.

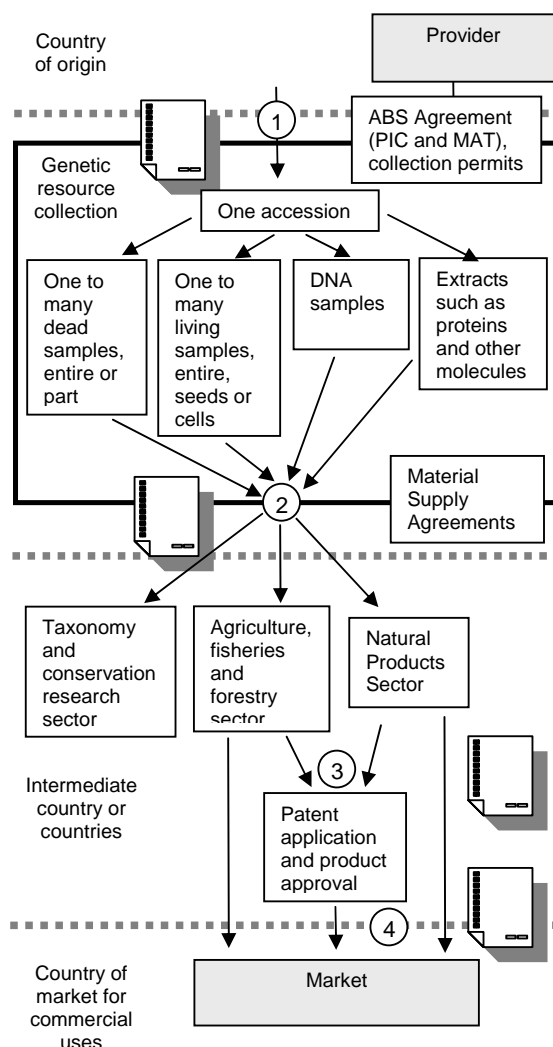


Figure 1. A simplified pathway for genetic resource flows. Transfers of genetic resources may pass through one or more national borders (dotted lines). Biological material is acquired by a company or institution at Phase 1 and partitioned into different types of resources; at Phase 2 some of these may be provided to third parties - some carry out biodiversity and conservation research and others may develop commercial products. A new product could be patented or registered for a commercial use at Phase 3 and traded at Phase 4. A certificate of origin may be useful to prove compliance with ABS laws at one or more of these stages.

In such a case the original certificate would specify a contract number which would accompany all subsequent transfers of relevant genetic resources. Transfers would be conditional upon a commitment to notify the competent national authority in the providing country. Under such a system an obligation could be established so that all collections made under the relevant agreement would be coded with the certification number applying to the original contract, to which would be added a number to identify specific collections, samples etc. At subsequent stages in research and development additional codification would be added to identify specimens, isolated compounds, etc.

Under such a system, the transfer of resources to third parties, where allowed under the original agreement, would be made subject to the terms and conditions of the original agreement or a set of standard terms and conditions established by the providing country's competent national authority. In this case, a certificate of origin might be likened to a MTA and the certificate of origin would serve to put the recipient on notice that use of the relevant resources is governed by these terms and conditions. In this sense the certificate of origin would serve as a form of shrink wrap licensing regime. The result could be to significantly free up the flow of genetic resources while ensuring legal certainty for users as to their rights to us resources and security for providers that their resources were covered by legal obligations.

It would of course be essential that "user measures" are in place to ensure compliance with licensing conditions. Failure to comply with the terms and conditions of the licences associated with relevant genetic resources would amount to a clear case of biopiracy.

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 for certain transactions such as patent applications or product approval procedures. Possible check-points for a certificate could be at borders (Figure 1), patent offices or the registration points for other commercial applications not covered by intellectual property rights.

The actual format of a certificate could either be paper, barcoded or perhaps, for organizations carrying out high levels of transactions, by way of virtual online certificates. Notification of transactions and transfers to the providing country by way of an online register of resources would potentially reduce the administrative burden of such a system while ensuring the maintenance of a clear trail of resource disbursements. It may be necessary to develop a system by which resources may be retired and reporting obligations terminated with regard to certain resources, when they are no longer in use.

Disclosure of Origin

Proposals for the establishment of disclosure of origin and traditional knowledge have become part of the mainstream debate on implementation of ABS and TK regimes, across many important forums including CBD, WIPO and the WTO. Mechanisms have been adopted requiring disclosure in numerous countries of the developing world including the Andean community, India, and Costa Rica, as well as in a growing number of developed countries, most notably Denmark and Norway - the latter requiring disclosure of both origin and of evidence of PIC. Proposals have been made by India and Brazil and a host of developing countries at WTO, for amendment of TRIPS to include a mandatory requirement on disclosure of origin. Meanwhile, Switzerland has proposed an amendment to the Patent Cooperation Treaty for a voluntary regime.

The functioning of any disclosure regime will require patent officials to determine whether the origin of resources has been adequately disclosed, and, where appropriate, whether PIC for use of resources existed. It is not hard to see that patent officers will be uncomfortable

about assuming responsibilities that may lead to the burdensome and time-consuming evaluation of issues beyond their area of capacity.

A standardised international system of documentation to record the origin of resources and, where appropriate, PIC for their use, would make their task much easier as the document would serve as evidence of both origin and PIC. This does not mean that providers of resources are bound to provide certificates of origin as a condition for granting access to resources, nor that applicants for patents are bound to provide them as evidence of origin or PIC, which could be evidenced by other forms of documentation. However, a streamlined process involving standard documentation is likely to be welcomed by patent officials.

Many products are not covered by patents, however, and other regulatory processes such as drug, seed and other product approval systems, also lend themselves to controlling the use of resources and may help promote compliance with ABS laws. Similarly, if scientific journals were to require evidence of rights to work on relevant genetic resources or traditional knowledge, as a condition for acceptance of articles, this would prove an important inducement for scientists to ensure they have obtained rights to use relevant resources. In all such cases, a certificate of origin could serve to demonstrate the right to use resources.

The benefit of certificates for the private sector would most clearly be to provide legal certainty regarding the right to use resources. Such a system could also help provide greater security for providers when linked to a licensing regime such as has been described above. The development of any certificate system should be carried out with an eye towards promoting greater transparency, flexibility and mobility in the international flow of genetic resources.

Feasibility, Practicality and Cost

Any certificate of origin scheme would need to protect the interests of resource providers without being so restrictive as to prevent desired flows of genetic resources for scientific purposes linked to the conservation objectives of the CBD. Access to genetic resources is also important for food security and to create commercial opportunities from which benefits may flow. Furthermore, any system must not be so bureaucratic or costly that the transaction costs effectively consume potential benefits. There is already evidence that pharmaceutical companies are withdrawing from natural products research because of uncertainty over access (Dalton, 2004). The number of new accessions to international agricultural genebanks has declined sharply since the CBD was ratified (Falcon and Fowler, 2002), raising concerns for food security. A key question to be addressed, therefore, is whether a certificate of origin scheme would serve to facilitate or further impede access and benefit-sharing.

For both conservation and commercial use, the benefits of any certificate of origin system would have to outweigh the costs. The main benefit for commercial users would be certainty of title to a genetic resource. This is critical to ensure that large R&D investments can be recouped. For non-commercial conservation uses, such as basic biodiversity research, there are many more international transfers of specimens compared to commercial users because no single country has the taxonomic expertise to identify the majority of organisms. In this sector, there are no monetary benefits to support an expensive tracking system and one option that has been proposed is to exempt these uses by creating a special category. Care would need to be taken with this approach to ensure that any exemptions did not create a loophole in the legal system that allowed genetic resources to flow to commercial uses via the exempt sector without renegotiation of an ABS agreement.

To some extent, technologies developed in other industry sectors may be applicable for achieving traceability of genetic resources. For example, systems for monitoring IPRs over electronics, computer software and even music are well developed although instances of illegal use still occur. For some biological products, like agricultural commodities, there are quality assurance systems capable of tracking food from the farm to the supermarket. There already exist a range of international standards for biological products such as sanitary and phytosanitary (SPS) standards, food safety and labelling laws. For some other biological resources that are or have been traded, there is a certification system - the Convention on International Trade in Endangered Species (CITES). This is limited to border crossings of a selected number of species when transferred among the 164 countries which are members of CITES, while cases of illegal trade outside the system continue.

For most bioproducts, however, the supply chain arrangements are different to these sectors, the value of most genetic resources is poorly defined hence it can be difficult to demonstrate the benefit of an expensive tracking system, the timeframe from acquiring a resource to deriving any benefits may extend for decades or longer, and, in many cases, it is more difficult to detect unauthorised uses of a genetic resource.

Future Directions for Certificates of Origin

Key questions about certificates of origin include what event would trigger the issuing of a certificate, who could issue it, what happens when a resource may be obtained from a range of countries and knowledge from a range of local communities in one or more countries, would it apply to individual samples or all samples covered by a particular contract or even individual genes, how could the information be stored and accessed, how far could a resource be traced in practice and what measures could be put in place for penalties, liability and redress. A fundamental question is what a certificate system is for, would it help users and regulators to facilitate the continuous flow of genetic resources while at the same time respond to demands for rights to resources and associated traditional knowledge under the CBD? If not, are there alternatives to achieve these outcomes?

UNU-IAS has initiated a comprehensive research program on certificates of origin, which involves collaboration with major collections of biological resources around the world including the Smithsonian Institution (USA), the Royal Botanic Gardens, Kew (UK), INBio (Costa Rica), commercial users of genetic resources in Japan and selected microorganism collections. Case studies of a range of plant, animal and microbial genetic resources are being used as the basis for a comparative analysis of how different institutions are tracking the receipt, storage and dispersal of various kinds of genetic resources. Preliminary results have shown a range of technological and legal approaches to tracking genetic resources. This investigation intends to shed light on the feasibility, practicality and cost of a variety of potential systems for tracking genetic resources, with a view to determining the viability of wider application of these measures to achieve the objectives of both facilitated access and equitable benefit sharing.

The results of UNU-IAS research on certificates of origin will be presented at the Working Group on ABS under the CBD, in Thailand, February 2005. Further information on UNU-IAS work on certificates of origin is available at www.ias.unnu.edu

References

IV. Instruments/tools/measures which could assist in achieving the IR:
Products and process certification

Barber, C.F., S. Johnston & B. Tobin. 2003. *User measures: Options for Developing Measures in User Countries to Implement the Access and Benefit-Sharing Provisions of the Convention on Biological Diversity*. 2nd Edition. United Nations University Institute of Advanced Studies, Tokyo.

Falcon, W.P., Fowler, C. 2002. *Carving up the Commons – Emergence of a New International Regime for Germplasm Development and Transfer*. *Food Policy* 27, 197-222.

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, B., 1997. *Certificates of origin: A role for IPR Regimes in Securing Prior Informed Consent*. In Magube, et. al. (eds) pp. 329-343, *Access to genetic resources: Strategies for sharing benefits*. ACTS Press: Nairobi. Available on www.ias.unu.edu

Dalton, R., 2004. *Bioprospects less than Golden*. *Nature* 429, 598-600.