

2<sup>nd</sup> Paris Roundtable on ABS Governance – 9-10, November 2004

# Roundtable on Practicality, Feasibility and Cost of Certificates of Origin

*Workshop Summary*

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**ABSTRACT.** Proposals for establishment of an international standardized system of certificates of origin to document genetic resource transfers are attractive due to their apparent simplicity. However, if certificates are to play a significant role in international ABS governance they will need to be a part of a simplified and transparent permitting system for access which links access with mutually agreed terms on benefit sharing; secures traceability in the flow of genetic resources, especially to third (and fourth...) parties; provides mechanisms for ensuring accountability and enforcement of ABS rights and agreements; and facilitates the monitoring and prevention of illicit commercial and industrial use.

The Roundtable presented new perspectives on the potential of certificates, while highlighting many complex unanswered, questions on the practicality, feasibility and cost of any regime.

## I. Introduction

The 2<sup>nd</sup> Paris Roundtable on the Governance of Access and Benefit-Sharing (ABS) organized by United Nations University-Institute of Advanced Studies (UNU-IAS), the Institut du Développement Durable et des Relations Internationales (Iddri) and the Centre for Philosophy of Law (CPDR) of the Catholic University of Louvain-La-Neuve was held from the 9-10 of November 2004 at UNESCO in Paris. The roundtable, which focused on the practicality, feasibility and costs of certificates of origin, was chaired by Professor A. H. Zakri, Director of UNU-IAS and Laurence Tubiana, Director of Iddri.

The Paris roundtable brought together a wide range of experts from both developed and developing countries working on the issue of ABS governance, regulation of biological resource flows, intellectual property rights (IPR) and trade, including representatives of national governments, the European Union, the Group of Like-Minded Megadiverse Countries, industry, international organizations including the World Intellectual Property Right Organization (WIPO), the Convention on International Trade in Endangered Species of Wild Fauna

and Flora (CITES) and the World Customs Organization, representatives of indigenous peoples and non-governmental organizations as well as experts from academia.

The Paris roundtable was divided into four sessions focusing on:

1. The potential role of certificates of origin in ABS governance,
2. Challenges in developing an international certificate of origin system,
3. Certificates of origin and disclosure of origin, and
4. Certificates of origin and international trade rules.

Interest in the potential role of certificates of origin in the development of any international regime on ABS has increased since the 7th Conference of the Parties (COP VII) of the Convention on Biological Diversity (CBD). A number of research projects are now under way to prepare reports on this issue with a view to informing the work of the Ad Hoc Open-ended Working Group on Access and Benefit-Sharing in 2005. These include a study on the role of certificates of origin initiated by the German Federal Environment Ministry and the Federal Agency for Nature Conservation as well as work

This summary is based upon notes of the meeting taken by the rapporteurs and authors and as such may not fully reflect the opinions, concerns and proposals of all participants. The authors have endeavoured to take into account all comments received from participants following circulation of a preliminary draft.

by the Smithsonian Institution, which was presented at the roundtable. Likewise, Iddri prepared a preliminary report on the relationship between certificates of origin and WTO. Copies were distributed at the roundtable. A special issue on ABS, including the issues of certificates of origin and traditional knowledge, has been prepared by CPDR and will be published in *Ecological Economics* in spring 2005.

UNU-IAS has prepared a comparative study of procedures for documenting collections of biological and genetic resources in a number of major herbaria, genebanks, museums and microbial collections, with case studies from the Royal Botanic Gardens Kew, the Smithsonian Institution, the Instituto Nacional de Biodiversidad (INBio) in Costa Rica, and a number of microbiological collections. The preliminary results of this study highlighted the opportunities and difficulties of documenting genetic resource flows.

## **II. The potential role of certificates of origin in ABS governance and experiences in certification**

The rationale for a certificate of origin is to build bridges between national and international jurisdictions as well as between providers and users of resources. Certificates of origin can potentially provide evidence of legal title to use resources, simplify and harmonize existing ABS procedures and ensure compliance with ABS law and policy. As an instrument of a traceability system, certificates of origin can help to monitor the trade and movement of resources and discourage unapproved and illegal use of genetic resources.

During the workshop it was argued that one economic justification for certificate schemes was their ability to provide legal certainty for user of genetic materials for those doing the expensive and lengthy process of commercial research and development. By increasing the certainty of their value, a certificate scheme would create incentives for the provision of genetic resources, create a known link to benefit-sharing provisions, and support conservation. It was also suggested that a certificate of origin can convert simple commodities into differentiated products through the conveyance of information to users.

A well developed certificate system has the potential to facilitate access if it reduces the number of permits and forms needed for research, collecting, and export. Existing procedures for these activities involve approval processes and permitting procedures involving numerous steps and ministries in most coun-

tries. This complex system creates numerous entry points and potentially inconsistent benefit-sharing concerns and obligations.

It was pointed out during the roundtable that a significant majority of requests for access to genetic resources are for basic research and are not directly intended to lead to use of resources for commercial purposes. For example it was claimed that based upon a research in Mexico it had been determined that 95% of resource use in Mexico is for basic non-commercial research. If this is the case, it is fair to ask whether a certificate system will add to the bureaucracy and costs of managing ABS systems or help to rationalize it. If it is the latter this will require political will in provider countries to streamline processes and overcome existing tensions amongst government departments for control over access issues.

Discussion of the experience in CITES and the World Customs Organization, which was supported by presentations by both institutions, tended to suggest that development of a computerized, paperless and centrally administered system would be preferable. CITES, for example, are currently examining how to move from a system of authorized signatures/seals, special paper or stamps to an electronic system that could be used by all Parties. One concern related to how to support such a system. It was pointed out that if there were a means for cost recovery for certificate administration by provider countries, these costs should not be so high that they will serve as a disincentive for basic research, which forms the vast majority of all access requests.

Experience in CITES also emphasizes the need for capacity-building, awareness raising and consideration of security issues for the managements of any system paperless or otherwise. These concerns will have to be addressed should a certificate system be developed.

Unlike in the case of CITES the material covered by a certificate may change substantially during research and development activity through processing, breeding and refinement. Moreover, while these customs-based permits basically terminate on use, proposals for ABS certificates would involve the creation of an instrument that follows the genetic resource or specimen (and all of its descendants, as well as all parts that are grown or divided from it) throughout their subsequent use and travels. This makes the transfer of certificates a potentially difficult process. Flexibility within any scheme is needed therefore to adapt to the changing nature of resources as they move through various stages of research, development and transformation, thereby modifying the circumstances under which the certificate was originally granted. The question to ask is

whether a system capable of responding to such changing circumstances will meet the test of feasibility, practicality and cost necessary for the development of a viable system.

It was pointed out during the roundtable that promoting more value added research and development activities in provider countries would make it easier to certify the resources being accessed. This issue linked helped to highlight the fact that any certification scheme is only one tool amongst a range of potential measures which together will make up an international ABS regime.

### III. Challenges in developing an international certificate of origin system

The concept of ABS promoted by the CBD poses some serious challenges for policy relevant research. Indeed, it combines in one framework issues of conservation of biological diversity and issues of equity and property rights, which are usually dealt with in separate disciplines and regulated in distinct political institutions. So any progress on the creation of a system of certificates of origin that could foster the implementation of the ABS requirements depends on furthering fruitful collaboration between disciplines and involvement of relevant stakeholders in the discussion.

Users of genetic resources from the public sector stressed that a system, whether involving certificates or other mechanisms, needs to ensure traceability, transparency and tractability in order to be effective. Any system needs to protect the interests of resource providers without being restrictive and preventing desired flows of genetic resources for scientific purposes linked to the conservation and sustainable use objectives of the CBD. Participants noted the importance of access to genetic resources for food security and the need to create commercial opportunities from which benefits may flow.

One challenge will be how to develop a clear system that provides certainty for all new genetic resource collections and flows, while finding acceptable mechanisms to support the transboundary movement of both pre-CBD and pre-ABS collected specimens, each which are bound by different obligations. One possible model that would develop this type of comprehensive coverage would be a creative use of Certificates of Origin (for new collections), Certificates of Source (for pre-CBD materials) and Certificates of Legal Provenance (for post-CBD, pre-ABS materials). For such a system to work the legal status of all pre-CBD collections will have to resolve.

From an economic point of view the balancing of costs and benefits of a certificate system seems to be the major challenge. Put simply, the transaction costs should not outweigh the potential benefits. The costs of documenting resources and implementing a regime to monitor resource flows need to be carefully evaluated, especially as the vast majority of resources being collected will never become the subject of research for commercialization purposes. Placing onerous requirements for certificates at the point of collection could then prove counterproductive both for science legal implementation and could place onerous burdens on providers of biological resources who could find themselves with large administrative costs.

An obvious dilemma is the fact that, while some collection activities are carried out for the express purpose of commercially oriented research, – in which cases certification of compliance with ABS regulations would be relatively simple – there are many cases where material initially collected for basic research is later requested by third parties for use in commercially oriented research. If certificates are only required for commercial research, then such users will need a mechanism to either apply *ex post facto* for a certificate or find that their costs of demonstrating rights to use resources may be prohibitively high at the end of the commercialization process.

If, on the other hand, certification at source is required for all collection activities, there is a danger that the costs of maintaining such a system is likely to fall disproportionately on scientific users and provider countries. Thereby subsidizing the private sector in the provision of a scheme to ensure legal certainty for use of genetic resources. The challenge therefore is to find the optimum balance of rights, responsibilities and costs between certification at source and the responsibility to demonstrate rights to use resources.

One proposal suggested that a certificate could accompany genetic resources like a passport through their entire history from collection to use, but the obligation to produce a certificate would only arise only at specific trigger points, such as for transboundary movements, patent and product approval authorities as well as the international depository system within the Budapest Treaty. Participants noted that in order to determine the viability of any system it will be important to consider where possible the use of existing infrastructure, human resources and existing checkpoints.

Some participants highlighted the existence of significant practicalities that need to be considered reflecting the reality of biodiversity research that have important implications for determining the feasibility, practicality and the

cost of either a “passport” concept or others. Examination of these issues will require careful mapping out of how research and commercialization processes actually occur, with full and active participation of the scientific and private sectors, as well as administrative bodies, resource providers and other stakeholders.

The workshop highlighted the importance of a bottom up approach to governance. In the current context of the crisis of the system of multilateral governance it is important to have stakeholders more involved. The commitment of industry associations and research institutions to the building of a system of certificates of origin is seen as a key element in reaching acceptability. Indeed, for efficient and legitimate governance of a system of certificates of origin one has to look beyond the law, in direction of the network of institutions on which the implementation will depend. Institutions such as national focal points, traditional knowledge registries as well as experimental contractual and licensing schemes as those suggested by the creative commons are examples of steps in that direction.

From the legal perspective there are many questions regarding the regulatory framework which have to be answered. For instance, what can be certified? Will it be the gene, sample, species, or batch which is certified, or should the certificate be of a defined collection activity or of all the collections made under a specific bioprospecting agreement? Who can issue a certificate? Will it be a national authority, and if so will there be the political will to designate a single authority or will there be multiple authorities granting certificates? Who can certify rights to use traditional knowledge? When would obligations to provide a certificate terminate? How would compliance be enforced? Will disclosure of origin requirements in patent or product approval procedures be a sufficient enforcement and control instrument to enforce a certificate system? The status of pre-CBD collections for the purposes of any certificate system is another complicated matter, which has to be resolved.

Pilot studies (country- and sector-based) should be promoted to assess the feasibility of certificate of origin systems in countries with different infrastructure and evaluate further commercial practices and systems including those of intermediaries and end users of genetic resources. However, concern was expressed that we cannot postpone the development and implementation of ABS tools, but should go ahead in the modeling of a certificate system to test for tractability, recognizing that there are many practical and cost implications still to be understood. Development of any certification system is therefore likely to be an ongoing process allowing for review and modification in order to respond to the needs of both providers and users.

#### **IV. Certificates of origin and disclosure of origin**

Disclosure of origin requirements are being adopted into law both in developing and developed countries to attempt to include the concerns of the evolving access and benefit sharing regime. A variety of measures have to date been employed with a view to restore the balance between public and private law, and rebalance patent law to meet social as well as commercial ends. Certificates of origin were originally proposed as a means to support a disclosure of origin regime, by providing evidence of a right to use resources for specified scientific or commercial purposes. Certificates it was suggested during the roundtable would help to simplify the role of patent authorities in determining questions regarding compliance with disclosure requirements relating to the origin/source/legal provenance of resources in any IPR application procedure. Existence of a certification scheme would not prejudice rights to provide the source or origin or legal right to use resources by other evidence, such as ABS contracts, scientific collection permits allowing for commercial use, etc.

There is a need to distinguish between disclosure of origin requirements in intellectual property law and any system for proof of origin and most importantly of the right to use resources and of the equitable sharing of benefits.

Certificates of origin might perhaps be integrated into the existing system of requirements for disclosure of information in the patent system. In such a case proof of origin or right to use resources could come from a certificate issued by the competent authority of the country providing the resources.

According to the experts and countries promoting disclosure requirements such as Belgium, Switzerland and Norway, such disclosure of origin requirements are compatible with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in a system where

- disclosure of origin is not a substantive criteria for patentability, which determines the eligibility of the invention such as novelty, invention, innovative step, etc.,

- the disclosure obligation only applies if the origin is known (so that the patentee is not required to do further research on the origin),

- and where the sanctioning mechanisms lie primarily outside the patent system (for example a system of fines for commercialization on basis of non certified genetic resources or financial advantages for the certified ones).

Sanctions outside the patent system for non-compliance with disclosure requirements could

include criminal and civil sanctions. By placing sanctions outside the patent system it may be possible to impose them without paralyzing research and development activities (i.e. without invalidating the patent or exposing the holder to a loss of the financial potential of its work). In some cases sanctions might require the transfer of rights over a patent to an aggrieved party, in particular an indigenous or local community whose knowledge had been appropriated. Developing countries such as the Andean community have developed more rigorous requirements on disclosure with sanctions which fall within the patent system. The Swiss proposal for amendment of the PLT and for incorporation of disclosure requirements into Swiss law also allows for a sanction within the patent system by enabling an application to be denied. These systems have not yet been tested in courts of law.

As many commercial uses of genetic resources are non-IPR related any system must consider a range of regulatory and non-regulatory procedures for ensuring benefit-sharing in product development and commercialization. If certificates are required for patent application procedures there is a question over what should happen with pre-CBD collections and pre-certificate resources. Proposals for a comprehensive certification regime covering both pre and post CBD material could help to resolve this dilemma. However, the status of collections, and the legal right to provide material for commercial use would require an extensive research into contractual rights pertaining to material collected pre-CBD or pre-certificate, or a multilateral agreement on the status of all such collections.

## **V. Certificates of origin and international trade rules**

During discussion of the relationship between certificates and trade it was argued that a system of voluntary certificates would not raise any conflicts with international trade rules. The case with regard to mandatory certificates is however, likely to be different and a number of key issues need to be considered. For example what is the subject matter of transboundary movement of genetic resources or products including genetic resources? It may be very complex if obligations extend to products which incorporate genetic resources. Another important issue relates to where compliance is being required, i.e. in the provider or recipient/user country. If it is in the user country it is more complicated and may violate WTO rules. It was suggested that care should be taken not to artificially construct a link to the WTO and Process and Production Method (PPM) regulations. If

there is national legislation in the provider country relating to access then requiring compliance with such legislation in the user country will be less problematic. In the absence of national legislation in provider countries there will be a need for an internationally approved system.

Building an international consensus for a certificate regime is therefore important as a means for ensuring it does not become the subject of a challenge under WTO. One means to ensure the legitimacy of any system and to avoid any potential conflicts with WTO would be for WTO members to adopt an authoritative declaration that a certificate system was held to fall within the ambit of GATT Article XX (The General Agreement on Tariffs and Trade). It was stressed during the debate that the WTO need not be considered as an opponent of the CBD. Participants took the view that efforts should be made to promote the design of any system with a view to functionality and practicality while avoiding any unnecessary impacts on trade.

In the light of these considerations it appears that a multilateral regime is probably the most appropriate to overcome potential concerns with regard to WTO and to cover for countries which do not have relevant national legislation.

## **VI. Traditional knowledge and certificates of origin**

Concerns were raised regarding the lack of clear recognition of the rights of indigenous peoples over their traditional knowledge and the lack of necessary mechanisms to ensure that access to traditional knowledge conforms to customary law and practices of indigenous and local communities.

A system of certificates of origin may potentially have a positive influence in the light of ongoing measures to develop means to protect traditional knowledge. It was suggested that a certificate system could serve as an interim measure to help protect rights over traditional knowledge, in particular where associated with a system requiring the disclosure of origin of traditional knowledge and of prior informed consent for its use as a condition for processing patent and other IPR applications. The manner for ensuring that certificates of origin for resources associated with traditional knowledge had been approved by relevant indigenous and local communities is a question requiring further consideration. Any proposals for establishment of a certificate system which involves traditional knowledge will need to be developed with full participation of indigenous peoples and local communities.

## To learn more

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Information on the 2nd  
roundtable on ABS  
governance available at  
www.cpdr.ucl.ac.be/  
paris.php

The 2<sup>nd</sup> Paris  
Roundtable on ABS  
Governance, held  
from the 9-10 of  
November 2004,  
brought together over  
fifty experts from  
states, international  
and regional  
institutions, academia,  
NGO's and civil  
society to discuss  
the issue of  
certificates of origin  
and their practicality  
feasibility and cost  
as a tool for ABS  
governance.  
The roundtable is  
the second annual  
roundtable on ABS  
governance organized  
by the Biodiplomacy  
Initiative of the  
United Nations  
University – Institute  
of Advanced Studies,  
the Institut  
du développement  
durable et  
des relations  
internationales (Iddri),  
and the Centre de  
philosophie du droit  
of the University of  
Louvain-La-Neuve  
(CPDR).

## VII. Conclusions

Depending upon how it may be ultimately configured, a certificate of origin scheme could help create economic incentives for complying with ABS requirements, and in this help promote the conservation of biological diversity by increasing the value of biological and genetic resources. It has the potential to support the CBD's objectives and to facilitate the exchange of genetic resources by tracking flows, providing evidence of legal title to use resources, simplifying and harmonizing existing ABS procedures and promoting compliance with ABS law and policy. The apparent simplicity of certification masks a potential for complexity and further bureaucratic, monitoring, compliance and other cost implications for both users and providers, if not carefully thought through. It also carries with it the possibility of creating highly charged intersectoral conflicts within provider countries, where rationalization of procedures brings with the potential for loss of power and income.

Capacity building has an important role to play in ensuring that the development and implementation of ABS law and policy, including measures such as a certification scheme are done in a manner which creates incentives for rationalization of national permitting procedures and enhances equitable benefit sharing with providers.

Clear objectives of a certificate system have to be identified and formulated to establish the basis for an effective system. Objectives have to be linked to the conservation objec-

tives of the CBD and address trust, transparency, traceability, and tractability.

A certificate system has to be cost-effective. Increased and expected benefits need to outweigh transaction costs arising out of the system's implementation. The use of existing infrastructure, check-points and human resources as well as the avoidance of increased bureaucracy and administrative complexity should guide the development of any system. What is required is a simple and flexible scheme which can address the nature of genetic resources in the innovation process and can be used by different stakeholders for different purposes, e.g. in material transfer agreements, in patent applications or in the process of product approval for commercialization. Any system should be designed without unnecessary impacts on trade to avoid any conflicts with the WTO.

A certificate of origin scheme will need to consider and balance the heterogeneity of users and providers of genetic resources by addressing the interests of the research community, the business community, local and indigenous communities and provider countries. The approach has to be developed with full participation of all stakeholders. Only then it can protect the interests of resource providers, in particular with regard to traditional knowledge, without being restrictive and preventing desired flows of genetic resources.

A certificate system will need to meet these challenges if it is to provide a viable mechanism to effectively support the ABS objectives of the CBD and advance the development of an effective international ABS regime.

## The ABS Governance Program

The ABS Governance Program is a collaborative research and outreach program established by the Biodiplomacy Initiative at UNU-IAS, Iddri and the biodiversity research unit at CPDR to provide the opportunity for reflection and debate on cutting edge issues relating to international ABS governance in an informal setting. The Program began with a first roundtable held in Paris in November 2003, on the subject of User Measures. The results of this roundtable were presented at a side – event during the Working Group on ABS in Montreal in November 2003. The second roundtable on the Feasibility, Practicality and Cost of Certificates of Origin were informed

by the preparation of two policy papers including a comparative analysis of Certificates of origin, prepared by UNU-IAS and a study of certificates of Origin and the World trade Organization prepared by Iddri.

Future research activities to be carried out in relation to the program will be focused upon forthcoming workshop and roundtable themes. In this manner it is hoped to both inform events organized as part of the program and provide an opportunity for critical review of research results. A workshop on IPR and Bioinformatics is scheduled for July 2005, and the 3rd ABS Governance Roundtable for November, 2005 in Paris.

One of the principal aims of the program is to bring together participants from the international negotiation processes and academic experts frequently absent from the political debate. The organizers are supported in the guidance of Program activities by a steering committee, drawn from among a range of stakeholder groups, and are seeking to ensure the best possible mix of participants and methodologies with a view to providing optimal setting for discussion of cutting edge issues relating to ABS governance issues, with a view to informing and facilitating international negotiations and implementation of ABS law and policy.