







REGIONAL WORKSHOP ON THE SYNERGIES BETWEEN THE CONVENTION ON BIOLOGICAL DIVERSITY AND THE CITES REGARDING ACCESS TO GENETIC RESOURCES AND DISTRIBUTION OF BENEFITS:

THE ROLE OF THE CERTIFICATES OF ORIGIN

PRELIMINARY REPORT

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Note: This report will be circulated among the participants in the Workshop and will be finalized upon receipt of their comments and suggestions. It does not yet reflect the consensus among the participants.

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Introduction

This report presents a preliminary description of the results of the Regional Workshop on the Synergies between the Convention on Biological Diversity and the CITES regarding Access to Genetic Resources and Distribution of Benefits: The Role of Certificates of Origin organized by the IUCN's Environmental Law Centre, the National Institute of Ecology of Mexico and the Peruvian Society of Environmental Law (SPDA) in Lima, Peru on 17-18 November 2003. The organizers wish to acknowledge and thank the German Federal Ministry for Economic Cooperation and Development (BMZ) through the IUCN/BMZ "ABS Project".

The primary objective of the workshop was to analyze the relationship between CITES and the concept of access and benefit-sharing (ABS) under the CBD. CITES's experience in the administration of an export/import permit system and its approach – imposing and overseeing compliance in both exporting and importing countries – served as a basis for discussion of the practical factors relating to the development of a "Certificate of Origin" or "Certificate of Legal Provenance" of genetic resources, as an internationally recognized component of ABS. The meeting began with the idea that such a certificate if properly conceived and implemented could potentially play a positive role in the implementation of an effective and efficient manner the principles of access to genetic resources and benefit sharing in the CBD. For that purpose, the workshop convened a small group of specialists of both Convention for a day and a half meeting (see the list of participants in Annex II).

While the full report of the Workshop, along with other background papers will be available early next year; this preliminary report is presented to participants at the Ad hoc Open Ended Working Group on Access and Benefit Sharing as a contribution that may be found useful in their discussions.

Although somewhat constrained by time considerations, the workshop was successful in raising, discussing and reaching agreement on various issues. It suggested a number of key considerations that might help set a research and work agenda for the development of the Certificate of Origin or Legal Provenance. Some of the basic recommendations that grew out of that discussion are summarized below:

A. Do not limit application of this concept to intellectual property rights.

The discussion on the role of the certificates of origin or legal provenance should not be restricted to the field of IPRs. Many important developments have occurred in regard to IPRs, for instance, in the legislations of Brazil, Costa Rica and the Andean Community where evidence of legal access to the genetic resources is a precondition for the processing of IPR applications. The same principle, however, could be extended to other fields, such as marketing and network development.

B. Analyze the usefulness and application of the Certificate in the wider context of the international regime and its application to different areas.

The Bonn guidelines already incorporate specific elements on the responsibilities of providers and users of genetic resources. This recognition in the Guidelines (as well as in other Decisions by the COP of the CBD) forms part of the rationale for the development of the certificate of origin or legal provenance. The certificate could be a central piece of the international regime on benefit sharing, in the CBD and as mandated by paragraph 40(o) of the Plan of Implementation of the WSSD.

Such an approach could be an enabling tool for a number of user-country measures, and may also be relevant and useful within provider countries. Its impact and value could extend beyond the direct ambit of the CBD. They could easily become a coordinating elements clarifying, consolidating or assisting in the development of the relationships among many forums including the CBD, WTO, WIPO and FAO, all of which will be relevant in the implementation of the Certificate.

C. Incorporate a general clause in CITES certificates and other governmentally issued instruments, to safeguard the rights over genetic resources.

There is a similar need from the other side of the CITES-CBD equation, regarding the need, at the very least, to raise awareness among CITES-oriented users regarding the limits of their rights over biological resources. One suggestion is that a disclaimer such as "... This permit does not in itself authorize the use of this materials as genetic resources or for research and development of the genetic resources within.." in all CITES permits would constitute a warning that may be a deterrent against unauthorized use of genetic material. The same type of disclaimers could be used in other components of national legislation dealing with

biological resources. It will be important to implement this concept in a way that does not create inappropriate demands on CITES management authorities, and to educate them about the CITES-CBD relationship, as well.

While this kind of measures will not be the "magic bullet" solution, they contribute to the promotion of good behavior under both regimes.

D. Move beyond the Memorandum of Understanding

While the creation of a Memorandum of Understanding is not insignificant, the specific needs and impacts of ABS Regime development suggest a need for more concrete lines of collaboration between CITES and the CBD. In developing the Certificate of Origin or Legal Provenance, a more formal analysis of the workings of the CITES certificate system and its relationship to ABS issues could be a positive first step.

BACKGROUND

One of the central issues at the outset of the negotiations of the Convention on Biological Diversity was how to ensure that each country obtains a fair and equitable share of the benefits derived from access to genetic resources. In the end, this became one of the main objectives of the CBD. The discussions focused on the taking of genetic material from one country ("country providing the genetic resources" or "source country" which may also be a "country of origin" of the species) to be analyzed and used in another (sometimes called the "user country.") If that analysis should result in a new use or product that generates benefits (monetary and non-monetary), the CBD Parties were conscious of an equitable need to ensure that the source country would share in the benefits. The regulation of access to genetic resources and distribution of benefits in countries of origin was seen at that time as the best way to address this issue.

More than fifteen years later, the application of the CBD principles regarding access to genetic resources and the objective of "fair and equitable sharing of the benefits" is, as yet, rather limited and almost imperceptible beyond the existence of a handful of norms adopted in some (mostly developing) countries. In particular, and with the limited exception of a few provisions in documents from the CBD (such as the Bonn Guidelines), there are few advances at the international level. In particular, the countries that are primarily users of the genetic resources (i.e. industrialized countries with biotechnology industries within their jurisdiction) have done little to ensure that the uses and users within their jurisdiction comply with the provisions of the CBD.

The CBD has yet to develop a mechanism to guarantee that the flow of genetic resources across countries and institutions complies with its principles. The idea of a "Certificate of Origin (or Legal Provenance)" has emerged as a means to identify the legal origin of the resources, ensure the PIC from proper authorities within provider countries, create incentives for users to comply with access provisions, etc. If recognized internationally, the Certificates could be useful as a tool to ensure

that the principles of the CBD, as well as the implementing access legislation in provider countries, is effectively complied with. Moreover, the Certificates would enable a number of complementary measures in user countries⁴, thereby contributing to a more balanced burden of responsibilities among countries in the implementation of the CBD.

Despite its appeal, achieving a coordinated approach at the international level for the traceability of genetic materials is not an easy task. It not only involves the commitment of the countries that provide the resources, since it requires an equal commitment from user countries. In practical terms, it will also need the global agreement and acceptance of a unified or highly integrated institutional and administrative system. These issues need to be addressed from a practical point of view.

In this context, it is unavoidable that the debate centers at least momentarily, in the way in which certificates could work for genetic resources within the CBD to trace transboundary movements as well as in the relevance that the work of the Convention on the International Trade in Endangered Species (CITES) may have. CITES has more than 30 years of experience in regulating the transboundary movement of thousands of specimens, and parts and derivatives of protected species of plant and animal. Its lists of species now include than 10,000 species. The successes of CITES´ permit and certification system include the creation of a documented record and an oversight mechanism for transboundary movements of specimens, to ensure that they comply with the norms established by the Convention.

Although some specialists and meetings have addressed the relationship between the CBD and other multilateral environmental agreements (MEAs), the specific relationship between the CBD and CITES has not been explored at depth. The recent brief, but heated, debate during the last COP of CITES stands as one of the few instances where the specific issue has been addressed.

Understanding the way in which CITES operates, with the shared but differentiated responsibility it assigns to both exporters and importers, would allow the identification of specific links between access laws and regulations on access to genetic resources and benefit sharing (in the CBD context) and the CITES mechanisms. In particular, it would inform from experience and provide relevant insights into the design of similar mechanisms that could prove useful in the CBD context. This is particularly important in order to develop effective and efficient mechanisms for the regulation of genetic resources. At the same time, this discussion would positively contribute to the debates within CITES on the necessary conditions for trade in biological samples of species listed in its appendices.

This joint review of the issues surrounding genetic resources from the perspective of both Conventions is even more relevant given that the Conferences of the

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⁴ We will refer repeatedly to the term user countries, implying countries with users of genetic resources within their jurisdiction.

Parties of both instruments will convene during 2004 (CBD in February and CITES in November). At CBD COP-7, Parties will be taking important and long ranging decisions regarding the development of the International Regime for the Distribution of Benefits from genetic resources. Later in the year, at CITES COP-13, Parties will examine other questions relevant to collaboration with the CBD and, in general, explore means to enhance the two instruments' roles in achieving the global sustainable development goals.

KEY CONSIDERATIONS

Beyond these basic conclusions and recommendations, the workshop's fruitful discussions produced a list of key considerations relating to ABS and Certificates of Origin. This Interim Report only gives the most basic summary key considerations. A more complete discussion will be provided once all participants have a chance to comment, amend and add to this initial draft. As mentioned earlier, the full report will be ready early next year.

The concept of a "Certificate of Origin": an accepted and recognized idea

Although there is still much to be clarified in terms of the legal nature, scope, essential characteristics, economic viability and practicality, among others, it is clear that the notion of a certificate or document (certificate of origin, legal provenance, etc.) is well recognized and accepted. The Certificate could provide a legally valuable statement of compliance with the requirements for legal acquisition of the genetic resources, i.e. that the implementing norms and legislation on access to genetic resources of the country of origin have been complied with. It may be seen as a means to resolve in a practical – and relatively "simple" way – the basic CBD principles. Moreover, it is appealing because its rationale rests on the principle that no one should acquire or seek to acquire rights over products or materials that were not obtained by legal or legitimate means.

♣ The need for precision in the objective and purpose of the Certificate

It is of the outmost importance to first identify the main objective or set of objectives of the Certificate of origin or legal provenance and hence, define its nature, scope, elements and characteristics as well as its implementing bodies, and its integration into the essential processes of ABS. The Certificate should not be confused with instruments that are part of the national procedures through which one can access and utilize genetic and biological materials, such as contracts, permits, authorizations and others). The certificate is simply a kind of "passport" that travels with the resources along their useful life and that can be monitored and verified at various stages of access and use as well as across various jurisdictions beyond that of the providing country that issued the certificate.

Definition of concepts

At present, one of the main problems at the international level is how to develop a common language that allows for clear boundaries to be drawn for concepts such as "biological resource", "genetic resource", "access", "derivative", "certificate", "origin", "legal provenance", "fair and equitable benefit sharing", among others. Some of these concepts must be sufficiently clarified and agreed upon at the international level in order to develop the Certificates or origin or legal provenance since they have a bearing on the scope of a mechanism such as the Certificate. Take for instance the concepts of "access" and "derivative", while the first one will determine the range of activities that fall under the certificate regime, the second has a bearing on the persistence of rights for the provider of the genetic resource along the process of product development.

The use of the Certificate of Origin or Legal Provenance in Intellectual Property Rights procedures

The Certificate could potentially be a very important tool in addressing the needs of an "international regime on access", depending on the objectives and needs of the regime. Various examples demonstrate the manner in which IPR systems may be used to avoid the granting of rights that directly or indirectly use or incorporate materials — or associated traditional knowledge — that may have been obtained illegally or illegitimately. Such examples may also deter applicants who would not qualify under these standards from seeking IPRs at all. In countries such as Brazil, Costa Rica and the Andean Community, this has taken the form of required documentation — some form of "certificate" — to show the legal provenance of the genetic materials or the traditional knowledge, prior to the granting of rights. India and Brazil have made this into a proposal before the World Trade Organization. The *Group of Like minded Megadiverse Countries* has also defined a common position on this issue.

In developed countries, Denmark now requires the disclosure of the geographical (only) origin of materials used in products and processes that are the subject of patent applications. The European directive on biotechnology also generally alludes to this idea. The plain justification lies in the principle that no rights should be granted nor obtained from illegal acts, such as the illegal acquisition of genetic materials (the so-called "Clean Hands Doctrine" as expressed in some countries' common law.) This is equally true where the specific "certificate" required is merely a call for disclosure of geographical origin, as it is when a "proof of legal acquisition" is required.

For some experts, the point of IPR-application, as a primary checkpoint for disclosure of origin is very attractive, for one reason, because it significantly limits the number of transfers. At any of the thousands of international border areas and other points of transportation, hundreds or thousands of specimens or samples may be exchanged in any given month, only some small percentage of which are relevant to ABS. By contrast, in intellectual property we are concerned primarily with three main IP offices: the USPTO, the EPO and the Japanese, and at the time of application, the innovations using natural genetic material will be more clearly defined. Hence it will be interesting to is the use of the Certificate during

the PCT searches patent applications carried out by the Search authorities. Tying the Certificate of origin or legal provenance into the work of these authorities may be a cost-effective way to administer the system given the small number of Search authorities currently recognized. Such a solution might contribute to discouraging "biopiracy".

There is at least some basis for compatibility of this certificate concept with existing IP principles, which mandate a full disclosure of relevant information on claimed inventions. This enhances the attractiveness of tying the certificate to "checkpoints" in IPRs procedures, particularly since the decision to seek IPR protection is a solid indication of commercial intent. There are other types of commercial intent, however, and it will be important to consider the cases in which there may be commercial intent without IPR. The identification of complementary "check-points" outside of the realm of IP procedures and institutions also deserves further exploration.

Training considerations for professionals and officials managing the certification system

The success of implementation of an international regime on access that includes the certificates of origin or legal provenance will inevitably turn on training and capacity building needs for the certificate issuing authorities, and officials at "check-points." It will also depend on the heightened level of awareness of those institutions and individuals that participate in access activities.

Training and capacity building costs should be borne in mind in the design of the Certificate. To reduce costs it may be possible to utilize existing authorities that undertake similar functions. This is another possible area for finding synergies with the CITES system.

However, while CITES authorities responsible for issuing permits may have similar functions, they may not be able, with current authority and training, to verifying an ABS certificate of legal provenance, or even to determine when one is needed. Moreover, given the difference in mandates between CITES and ABS, it seems clear that border controls may not always be the only or the most effective "checkpoint". These factors still suggest the need for training a variety of other officials, including those in patent offices.

Identify and develop incentives for Parties and stakeholders

Depending on how it is incorporated into the international, regional or national ABS regimes, the certificate of origin or legal provenance could serve as an incentives – for countries to mutually cooperate and collaborate, and for individuals to comply with CBD principles and access legislations. It could be one components of a process whose clarification would serve to reduce pressures in provider countries to pass restrictive legislations on access to genetic resources.

Individual users, now faced with the uncertainty regarding the "legality or legitimacy" of their activities, might find the certificate a "positive signal" that enhances their public reputation as "good actors." Similarly, the adoption or recognition of the Certificate by for user countries, would strongly signal their commitment to meeting their ABS obligations in the CBD.

In short, the certificate alone will not solve the various implementation challenges of ABS, but it could play a significant positive role as a signaling device and incentive.

Implications for ex situ collections for both conservation and research

Ex situ centers for conservation and research not only house significant collections of germplasm, but need to access and transfer those materials as part of their routine operations. One aspect to consider is how the certificate system would operate for those centers. While it is true that the FAO Treaty on Plant Genetic Resources for Food and Agriculture may provide a more adequate platform for those resources, it should be considered that only a limited list of crops will be covered by the Treaty and many questions relevant to coordination between the two instruments were not addressed in the Treaty. Hence, the Certificate may be applicable to many plant genetic resources with important ex situ collections.

In any case, as a core principle, it is suggested that the certificate carefully analyze and specifically address its relationship with the International Treaty. The Certificates and modalities of application should not limit the exchange of materials that were obtained in accordance with CBD principles.

Beyond this, it should recognize that the activities of *ex situ* collections are conducive to the realization of CBD objectives should be promoted. However, the exchange of pre-Convention materials from *ex situ* collections should not hinder the efficacy of the certification system for other materials.

Means to incorporate traditional knowledge considerations in the Certificate

While the specific components of the issue are not as well defined and their discussion is not as well advanced, the relationship of ABS and Traditional Knowledge issues is undisputed. Accordingly, it should be contemplated that certificates of origin or legal provenance, might ultimately also be used to provide evidence of compliance with national legislations and norms for the use of associated traditional knowledge. This area, too, deserves further exploration.

Of course, although, the certificate of origin or legal provenance could complement other regulatory instruments for traditional knowledge, it could certainly not replace key TK initiatives, such as the development of a *sui generis* system of protection.

Channeling the benefits to in situ conservation

Neither the CBD (in the case of genetic resources), nor CITES (in the case of the captive bred species or ranched species) have been effective in channeling economic resources to *in situ* conservation. While the CITES Convention does not have a mandate to address that issue, its parties have integrated relevant concepts into key CITES documents and processes such as the CITES listing criteria and the significant trade processes. There is, of course, no doubt that benefit sharing is an explicit mandate of the CBD. At a minimum, this suggests the need for some of the economic benefits derived from ABS activities should be channeled to *in situ* conservation.

To the extent that the certificate of origin allows for more effective contracting and better monitoring of obligations, the certificate could contribute to a more effective channeling of resources to *in situ* conservation. The Costa Rican experience is an example of how effective contracting leads to more resources for *in situ* conservation. Its numerous contracts have created a precedent and send a positive signal to interested users. A certificate system could give other countries a "shortcut" to a better contracting environment from the start.

Complementarity possibilities in the complex relationship between CITES and the CBD

CITES and the CBD have somewhat different objectives, scopes and aims. However, both regulate, directly or indirectly, biological (and genetic) resources. As variously noted above, there may be many possible ways in which the conventions could complement each other.

Among other things, CITES provides an example that sheds light on the potential cost and structure of a Certificate system. At the time CITES was created, costs were not a primary concern, since that Convention's whole purpose was to discourage an economic activity. In contrast, in the case of genetic resources, the CBD seeks to maintain the economic use of genetic resources. If the certificate is too costly (structurally, or to the parties seeking certificates), the market will suffer. Perhaps the most important recommendation of this workshop is that measures should be analyzed from a cost-benefit perspective, learning from the experience at CITES and seeking complementarities and synergies whenever possible.

ANEXO 1. Diferencias entre el régimen CITES y los posibles certificados de origen y legal procedencia.

Sin lugar a dudas que la experiencia de CITES en la administración de un sistema de certificados es de gran valor para el análisis del certificado de origen / legal procedencia para los recursos genéticos. No obstante, aunque a primera vista pareciera que los objetivos del certificado de origen / legal procedencia es muy similar al CITES, en una lectura más fina de ambos, resaltan diferencias importantes que deberán tomarse encuenta a fin de rescatar la experiencia más relevante y pertinente de CITES. En la tabla siguiente se presenta un cuadro comparativo entre las características de los permisos CITES y los elementos que parecen más evidentes de un certificado para recursos genéticos.

Permisos o documentos CITES	Certificados de origen o legal procedencia
Objetivo central: la no extinción de especies	Objetivo central: cumplir procedimientos de
amenazadas y la promoción del uso	acceso (consentimiento informado previo y la
sustentable	justa y equitativa distribución de los beneficios
	derivados derivados de los mismos)
Se aplica exclusivamente a materiales /	Se aplica inicialmente a una muestra biológica
especímenes en el comercio	transferida, pero continua con efectos sobre su
	progenie sus derivados e incluso sobre la
	información (incl. invenciones) derivadas de la misma
Termina con la introducción al país importador	No tiene fecha de terminación definida en
	cuanto a sus efectos
Cubre una sola transferencia (salvo re exportación)	Puede cubrir múltiples transferencias
Previene y mitiga impactos negativos del	Promueve relaciones más justas entre
comercio	proveedores y usuarios
Incluye precautoriamente "especies	Deberá adecuarse para casos de recursos
semejantes"	genéticos obtenidos en condiciones ex situ
Una agencia gubernamental determina que	Una agencia gubernamental evalúa si se ha
cumple con criterios para exportación /	cumplido con el procedimiento de acceso
importación	(verifica PIC y distribución de beneficios)
Acto regulado se inicia y termina en el	1 , 5
comercio	implica regular un proceso.
Oficiales de aduana como verificadores	Evaluación a nivel de oficina de patentes, aduanas, sanidad, etc.
Solicitante conoce el valor del especimen	Solicitante no necesariamente conoce el valor
	del material, se habla del valor potencial
Producto homogéneo o por lo menos bien	Producto muchas veces no conocido
descrito	(considerense por ejemplo, las muestras
	biológicas codificadas o las muestras de suelo)
Requieren acciones en países usuarios y	Requieren acciones en países usuarios y
proveedores	proveedores

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IUCN – The World Conservation Union

Founded in 1948, The World Conservation Union brings together States, government agencies and a diverse range of non-governmental organizations in a unique world partnership: over 1000 members in all, spread across some 140 countries.

As a Union, IUCN seeks to influence, encourage and assist societies throughout the world to conserve the integrity and diversity of nature and to ensure that any use of natural resources is equitable and ecologically sustainable.

The World Conservation Union builds on the strengths of its members, networks and partners to enhance their capacity and to support global alliances to safeguard natural resources at local, regional and global levels.

This publication expresses the views of the author based on expert research and collaboration under the ABS project, and does not necessarily reflect the opinion or the policy of IUCN in this field.