

## Elements for the Design of a Certificate of Legal Provenance

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The Convention on Biological Diversity (CBD) recognizes States' sovereign right to their natural resources and their authority to determine access to their genetic resources. As such, access to genetic resources is subject to the legislation of each country. However, the Convention does not consider the provisions needed to address the fact that genetic resources are often used internationally. Likewise it disregards the fact that violations to access conditions would likely take place outside the jurisdiction of the country providing such resources. In order to meet access conditions of source countries, the Convention does not establish obligations for countries with users of genetic resources under their jurisdiction. This omission in the Convention has created an imbalanced system in which the regulatory burden is taken up by source countries as opposed to the countries with users of genetic resources in their jurisdictions.

The problem is not only about who must regulate the country providing the resources or the country with the users, but it is also a matter of how, and what aspects of, the product development chain must be regulated. The fact is that most countries are designing their legislation with provisions made exclusively at the stage of biological material acquisition. This legislation neglects the following issues: control and monitoring issues at more advanced stages of genetic resources' development and innovation; development and trade of their derivatives; and failure to ensure the fulfillment of access conditions when resources are used in other countries. All of these aspects truncates the regulatory chain and reduces the credibility of any threat of legal action against illegal access or misappropriation of genetic resources.

What would happen if countries included measures to support the fulfillment of legislation of those countries that granted access to their genetic resources? In principle, ensuring the fulfillment of foreign legislation may involve high transaction costs. The basic principle underlying the Certificate is to serve as a means to send a legally recognized signal that access has taken place in agreement with legal conditions. In particular, these legal conditions would be those of the source country and access would take place in accordance with international obligations. This certificate would be issued as part of standard procedures for access granting in the source country and would have international validity. It is this feature that allows the certificate to act as a mechanism to convey credible and standardized information through the legal systems, and thereby reduce verification costs. Countries with users within their jurisdiction would take measures to monitor and verify the existence of a Certificate for genetic resources possession. To the extent that these countries enforce these measures a more effective balance of the regulatory cost would take place.

### What would be Certified?

There are several concepts that have been proposed, all of which are found in the decision of the CBD to initiate negotiations on the International Regime. These concepts are provenance,

origin and source. Origin and source are similar concepts, both referring to the supplier of the material and not necessarily to the process that the material underwent. In CBD jargon, the origin tends to be interpreted as the country that has certain genetic resource in in-situ conditions; whereas the source only denotes the organization or country that granted access to the material, where this could be an ex-situ material provider. In the case of *provenance*, this concept tends to be more inclusive. In fact it refers more to the history of custody of the material, described since its first access, including the changes that it has suffered.

Recalling the fact that genetic resources are materially transformed (from biological samples, to chemicals to information), it is important that the certificate be capable of adapting to these characteristics (ie., not only be passed along the various forms of the same genetic resource) and that it should be feasible to reproduce it if more than one product is derived from a single genetic resource. In this sense, it should be more of a tracking mechanism and, as such, it is truly a Certificate of Legal Provenance rather than source or origin? Because these transformations can occur at different instances and places and be done by different agents, the certificate must be internationally recognised - of simple transferability across different users - and use, as much as possible, the existing tracking and monitoring mechanisms to ensure that its administration costs are low.

Conceptually, the Certificate could simply take the form of a number or code that is attached to all documentation involving a particular genetic resource and that can then be checked against a central clearinghouse of certificates, available for verification purposes, and which would contain the specific conditions for accessing the genetic resource.

Reducing the Certificate to a code would greatly reduce administration costs, since it could be added to existing mechanisms used by academia and industry to keep track of their materials, while the Clearinghouse would enable not only providers, but third parties to contribute to monitor the process. There are, however some considerations worth noting at this stage. The fact that someone displays a Certificate or a certification code, does not necessarily mean that the conditions for access have been complied with, but merely that prior informed consent has been obtained and that some form of mutually agreed terms have been reached. Assessing whether the conditions have been satisfied requires further investigation and would require the use of the Clearinghouse to obtain the specific conditions for those materials. The next section discusses the desirability of different modalities of monitoring and verification of compliance.

### **Check-points for the Certificate: Where and How should the Certificate be Verified?**

Two criteria for the identification of Check-points are the transaction costs involved in the monitoring and the enforcement effort and efficacy of the specific checkpoint. In principle, excessive control across a multiplicity of checkpoints can inhibit transactions or even motivate illegal activities. With uncertainty and low success rates being part and parcel of the nature of new product development in biotechnology, the higher the costs of such searches and the more limited they are allowed to be would reduce the possibilities of success and of generating benefits. This could be particularly damaging for non-profit activities. On the other hand, too few check-points would translate into too few or no incentives for compliance. Therefore, the development of a certificate requires careful design to allow for limited but effective checkpoints.

One possible solution is to establish control-free areas where no verification would take place, although the Certificate would still need to be passed along. This area would need to be where transactions are more frequent, but involving the lowest-value genetic resources, i.e. those involving the most basic research up to the identification of potentially valuable derivatives. The creation of these areas of verification exclusion has a two fold rationale: on the one hand they will avoid high verification costs given the multiple transactions, but also, they will avoid verifying at a regulatory point where, given the low value of genetic resources at that stage, users would not face a great penalty and therefore have a lower incentive for compliance. It should be noted here that border controls, in the form of CITES permits, as a means of verification would not be desirable under any circumstance.

The fact that there could be areas of no verification does not mean that no changes in existing practice be needed. In fact, the Certificate or Certification code would still need to be passed along. The advantage is that it could be passed along using existing mechanisms that universities and industry use to track their materials, possibly as an annex to material transfer agreements. Likewise, there may be a need for incentives to obtain the required Certificate, particularly directed towards the academic community. For instance, requiring the Certificate when applying for research funding, or when submitting scientific papers for publication, could be considered as incentives for compliance.

Creating “hard” check-points at the end of the product development chain, however, reverses the considerations that limit the use of check-points at early stages of product development. Not only are genetic resources used at later stages of product development far less than those initially bioprospected, but they are also more valuable. This is true in at least two ways: the uncertainty over the value of a genetic resource has been partially resolved and the fact that the commercialization or appropriation is being sought indicates that there is some positive value to the genetic resource; and, in addition, past expenses in reaching to the product represents a sunk cost in the prior bioprospecting effort. This implies that non-compliance with access and benefit-sharing provisions would have a greater cost for the user, thus creating a greater incentive for them to comply with the legislation of countries providing such resources. Some of these hard check-points could include intellectual property applications and product approval procedures.

There are a number of issues related to the compatibility of requiring the Certificate with existing intellectual property principles that need to be addressed. To the extent that the certificate allows for a clearer description of the invention, the Certificate can be considered as compatible with IP principles and, as such, be part of a formal requirement, which would carry the greatest incentive for compliance. However, if it only becomes an administrative or formal requirement for patentability, the value of the requirement as an incentive depends on the consequences of non-compliance since they need to be sufficiently hard for applicants to face greater costs or, alternatively, lose significant benefits.

A related problem that needs to be solved for the requirement to become a credible incentive is the identification of the trigger points of the requirement itself, i.e. which inventions are sufficiently related to the genetic resource that the disclosure of the Certificate is triggered.

### **Elements to Consider in the Design of the Certificates**

As a result of the above considerations, there are several components that need to be defined for the clear an effective operation of the Certificate of legal provenance:

- designation of national authorities to issue the Certificate and that are mutually recognized;
- identification of conditions for verification and enforcement of the Certificate, that is, which materials, for which purposes, in which moment or at which stage will they be checked, including the limits to derivatives related the genetic resource;
- exclusions;
- provisions for cases where it is not possible to identify the origin of the genetic materials, including on benefit sharing;
- differential treatment for specific sectors;
- mechanisms to solve controversies;
- creation of an international registry for the Certificates;
- treatment of non parties; and
- provisions to deal with ex-situ pre-convention materials to prevent them from becoming a loophole for the Certificate system.

### **Advantages and Limitations of the Certificates of Legal Provenance**

The Certificate of legal provenance has various advantages that can positively contribute to solving some of the implementation problems of access and benefit-sharing provisions, internationally. For instance:

- It serves as evidence that genetic resources have been obtained in accordance with the access provisions of the providing country;
- It enables the effective application of user measures by reducing their cost of implementation;
- It discourages misappropriation of genetic resources to the extent that they are verified at key check-points;
- Facilitates monitoring by providers and interested third parties, through the use of the Clearinghouse mechanism; and
- Generates greater transparency and confidence for parties in transactions.

Despite this, there are also limitations of the Certificate, i.e. issues that cannot be resolved by the Certificate but which are key problems for the effective regime created around access to genetic resources. For example, the Certificate:

- does not ensure that mutually agreed terms have been complied with;
- does not create an equitable platform for the negotiation between the actors involved (asymmetries in capacity and information are not resolved);
- does not ensure, per se, a fair and equitable distribution of benefits, but represents a signal that mutually agreed terms have been reached;
- does not substitute the need to develop national access legislation, since they can only be issued by countries with national procedures for doing so;
- depends on solving the management of ex-situ pre-convention materials in order for it to be effective;

- it provides a solution only for those who can negotiate - i.e it excludes the large number of communities unable to enter into contracts; and
- it does not adapt equally well to all sectors

As a result, the Certificate represents an element of the RI that would still require additional measures to address the limits of the Certificate.

### **Final Remarks**

Certificates are undoubtedly an appealing instrument as an enabler of significant user measures and relevant check-points that will reduce uncertainties and increase transparency and confidence of providers. At the same time, it will provide greater certainty to the users of genetic resources, by giving them a means to proof that they are behaving according to the CBD and the legislation of the provider country.

However, a word of caution is in order, since not any design of the Certificate will be administratively and economically feasible. It should also be clear that the Certificate can only solve part of the problems surrounding ABS. There is no "silver bullet".