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Issues for consideration by the Group of Technical Experts concerning a Certificate relating to genetic resources

Submission of ICC to the CBD Secretariat pursuant to Decision VIII/4 paragraph 1 regarding the form, intent and functioning of an internationally recognized Certificate, including its practicality, feasibility and costs

Prepared by the Commission on Intellectual Property

Note: In the following paper, the term 'Certificate' is used in place of "certificate of origin/source/legal provenance". This is simply for convenience, and is not intended to pre-empt any decisions about what any certificate should certify, or what it should be called.

Introduction

There are many different types of genetic resources used by many different types of institutes and industries for many different purposes. Further, these genetic resources have been continuously exchanged, altered and improved. Genetic resources have an enormous range of uses: a few of these, from two important fields, are illustrated below.

Plant breeding

Increased food production over the last half-century owes much to innovations achieved through plant breeding by recombining existing resources.

In major crop species, a high to very high percentage of genetic resources has been freely exchanged and intermingled over the ages and over nearly all countries in the world. The resulting plant varieties are based upon multiple accessions: in general, only those accessions used by formal breeders in the last several decades have specific documented origins. Ultimately these varieties result from the screening of thousands of recombinations of genetic material.

Biomedical research

A wide variety of biological materials is used in biomedical research. These materials range from human materials, through non-human materials found in humans (such as bacteria and viruses), through animal and plant biological materials. Some materials are indigenous and unique: most are staple commercial products obtained through ordinary commercial channels.

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Diverse uses

Consideration of whether there should be a Certificate - and, if so, what it should be, how it should operate and its legal effects - must take account of reality: numerous and diverse uses and continuous intermingling of genetic resources in the past and at present. Any benefits of using a Certificate must be weighed against the practical impact of such a certificate on the real world use of genetic resources, the conservation of those resources and their sustainable use.

ICC welcomes the creation of a Group of Technical Experts to consider these issues and to clarify what role any Certificate might play in the International ABS Regime within the CBD. The widest consultation is essential. We look forward to participating in these discussions as they progress.

We give below an overview of issues that should be considered in the Group of Technical Experts on the Certificate. We note that the mandate for the discussions explicitly states that the desirability of any certification scheme is not to be pre-judged. We should therefore make clear that ICC is as yet far from convinced that Certificates are either useful or practical, whether applying universally or only in some technical areas. Accordingly ICC expects to make further comments if more specific proposals are developed.

A certificate is a tool rather than a goal

The concept of a Certificate as proposed in the CBD context is as a standard document or system of proof of conformity to access and benefit-sharing obligations between a provider of genetic resources and the recipient of those resources.

A Certificate is a tool that may be useful to reach a desired goal. However, what exactly is the goal intended? Is the Certificate for genetic resources "in the form received", does it apply to the presence of components or even to derivatives based upon (or even on knowledge from) the material accessed? Is the Certificate linked to a product, either original or final, or to a process? Or is it linked to traceability, benefit-sharing or to trade? Until the goal is precisely defined, questions such as these which relate to the scope of the scheme cannot properly be addressed. Answering these questions also involves identifying with precision what practical problems exist, how frequently they arise and the nature and extent of their consequences. Evidence as to the need for any certificate is vital. The report 'UNEP/CBD/WG-ABS/4/INF/6' analysed for example claims of "misappropriation of genetic resources" and concluded that many of the claims of biopiracy are disagreements arising out of uncertainties about ABS requirements. A certificate will not help this situation.

Defining the scope of the Certificate

Any certification scheme for genetic resources must take into account that they are not static and very broadly defined.

- Genetic resources are sometimes uniquely available from certain countries only, sometimes widely available commodities or staple commercial products.

- Genetic resources often have considerable "genetic overlap" between accessions or even complete duplication between different origins due to extensive interchange over the ages; this makes the value of any Certificate (whatever it certifies) questionable.
- Genetic resources are acquired for many different purposes by many different groups: ranging from those whose sole interest is to trade, to industrial users, to academic institutions, to conservation bodies etc.
- Genetic resources are used in many different ways by different users. They may be used as items of trade, as products into which research is conducted for commercial or academic purposes, in foods, etc.
- Genetic resources are changing continuously. For example, in plant breeding, during genetic recombination the specific identity of each original accession is lost (the accession is never exploited "in the form received"). To maintain the link with a Certificate, a formal "tracking system" during breeding and development would be needed. This could be a heavy burden on some smaller researchers.
- There are many different types of derivatives from genetic resources ranging from some pharmaceuticals through cosmetics through food products such as bread and wine. Sometimes, derivatives may contain no genetic resources or indeed biological materials; and the final product may be far removed (in function, structure and time) from the original genetic resource.

The value-creation chain from genetic resources to a final product can therefore involve a number of diverse steps and players; many of the steps and players are invisible to third parties and, indeed, invisible to others participating in the value-creation chain.

The number of transactions involving genetic resources – including legal transactions (trading) and functional transactions (use) – may run into millions every day. If derivatives (however defined) are included, the numbers of transactions are multiplied. Indeed, every time a loaf of bread or bottle of wine is purchased, a legal transaction occurs using a derivative of genetic resources. We illustrate this below with examples from two sectors only.

Plant breeding

To illustrate the volume of certificates that might be needed in plant breeding alone: schemes for certification of agricultural crops list 37,000 plant varieties from 191 species; the number of seed productions produced and traded is a multiple of that. In the research phase, many samples of trial varieties are shipped for local testing or seed multiplication; at a rough estimate this will be between 10 and 100 million samples shipped per year.

The FAO International Treaty on Plant Genetic Resources for Food and Agriculture (PGFRA) recognizes these complications and has created a structure that does not apply the Country of Origin concept nor ABS agreements based on individual accessions and recipients. Individual certificates are therefore not required under this treaty.

Human health

Biological materials used for the medical sector are also used in very different ways and for very different purposes. For example:

- It is very rare for a biological material to be used in its natural form as an active component of a pharmaceutical. More usually, the active compounds in products like aspirin and Taxol, are derivatives of biological materials, in other words, the materials were the "starting point" from which the final product was derived. This process of developing it into a finished product is difficult, expensive, time-consuming and commercially risky. Use of biological materials in this way, and bioprospecting to collect them, is diminishing.
- Biological materials are also commonly used as tools in the research process. For example, CHO cells (derived from hamster ovaries), yeasts and other micro-organisms are used in screening assays.
- Biological materials are used in production processes. Gelatine, derived from cattle, is often used in capsules. Some viruses used in vaccine production are grown in chicken eggs.
- Some research is based on information about a genetic resource, although the resource itself is never used in the research. For example, the genetic code of a malaria parasite is needed to make a malaria vaccine: it is available from a US government authority which has isolated the parasite from a US citizen who contracted the disease after visiting several countries in Africa.

Legal ownership of genetic resources can be in many different hands due to their wide diffusion in the course of history.

- Genetic resources commonly used for the development of new plant varieties are resources from both public and private material. They may exist in the public domain, or in public or private genebanks. Moreover, a breeding process typically takes 10-15 years. Genetic resources used in breeding currently commercialized varieties were almost all obtained before the CBD came into force, when free exchange of such resources was customary.
- The same is true of large numbers of genetic resources and materials derived from them. Although many years ago they may have been indigenous to and found only in a particular geographical area (sovereignty over which may differ now from what it was then), they may now be widely available from many countries through common trade channels.

Feasibility

A full feasibility study is essential. Important criteria that must be considered are noted below. In addition, questions that should be answered to obtain relevant information on the criteria are presented in Annex 1.

1. It is essential that objective and scope are clearly and specifically defined. That precision is required to define what type of Certificate or certification scheme should be established.

2. To make a Certificate work, operational issues should be elaborated. The items, activities or processes that need a Certificate should be clearly defined. In addition, it should become clear at what stage in production chains it should be available (e.g. at first commercialization, etc). Duplication of effort should be avoided.

3. Once it is known what is to be certified, who provides the Certificate, and also who needs one, would have to be clearly specified. Presumably, the Certificate would best be provided by the official authority which has the legal control over the material accessed and who is available in case of enquiries about the Certificate and the circumstances of access. Recipients of genetic resources are of many kinds; as indicated before, they may use the genetic resources for many purposes, be it commercial or non-commercial. All recipients would need to know if they required a certificate, and, if so, of what type. A specimen-based system like CITES cannot be used as a model for ABS certificates because it operates under very different circumstances. The CITES system works only because it applies to a concrete and relatively limited list of species and parts that are "readily recognizable," including by customs officials.

4. The next step in making the Certificate operational would be a decision on the form and manner of using it. This should be simple, practical and minimize administrative burdens. Would a single Certificate serve for all the different transactions, providers and users? Or would different types be needed? In naming the Certificate, confusion with existing systems [1] must be avoided.

5. The time of implementation should be carefully chosen. For technical areas such as drug development and plant breeding, the development period is often ten years or more. This suggests first focussing on the creation and national implementation of the international regime for access and benefit sharing, since in the absence of such a regime, Certificates will have limited value.

6. Genetic resources have been used, exchanged and altered extensively in the past. It is essential to realize that those genetic resources that were obtained before the CBD went into force were obtained legally. Any certification scheme would therefore need clearly to exclude such materials and materials derived from them. A practical way of distinguishing between such materials and genetic resources acquired after the CBD came into force would be needed. Solutions may also be needed for materials that were obtained between the CBD coming into force and the introduction of the Certificate. There is also the problem of how to deal with materials obtained from countries that have not yet implemented access and benefit-sharing rules, or even not ratified the CBD.

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[1] For example, the Certificate of Origin (CO) - used since at least 1923 (see 1923 Geneva Convention relating to the Simplification of Customs Formalities (Article 11) - is a document widely used in international trade to attest that goods in a particular export shipment are wholly obtained or produced or manufactured or processed in a particular country (country of origin). Virtually every country in the world considers the origin of imported goods when determining what duty will be assessed on the goods or, in some cases, whether the goods may be legally imported at all. This certificate is issued by mainly chambers of commerce to help customs authorities make this determination. As such certificates apply to natural resources (eg. coal, wheat) as well as manufactured goods, using the same term for any "certificate" that might issue from this process would lead to great confusion.

7. The legal effects of the Certificate should be implemented appropriately to assure that the system becomes functional, and gives sufficient legal certainty to both provider and user. What are the legal effects of having a Certificate - and of not having one? In designing the system, all potential benefits to both providers and users of resources should be considered. One possible benefit to users of a Certificate would be as evidence of title, in the sense of the right to use the certificated material without being accused of bad faith. A clear title for access and subsequent development could be an advantage to users. It would help users if a Certificate could be regarded as conclusive in the absence of fraud. However, absence of a Certificate could not be evidence of lack of title unless all the other issues set out above are fully and clearly resolved.

8. Given the realities, a detailed cost/benefit analysis of any certification scheme must be undertaken, in which both costs for users and providers should be considered, as well as those to society as a whole. This is the more important because the system could be extremely costly. Such an analysis is inherently required by the COP-8 decision of March 2006 to establish an Experts Group "*without prejudging* [the] *desirability of the options for a certification scheme*". ICC welcomes this approach and we hope that the points made in this paper will help the Group in their deliberations.

9. Lastly, the overall impact of the Certificate on the objectives of the CBD must be carefully considered. Implementing a Certificate should not oppose the objectives of the CBD. Conservation of genetic resources should be guaranteed, and sustainable uses be promoted. ICC believes that use is essential for the first two objectives of the CBD. For an access and benefit-sharing regime to work well, firstly access must be made as easy as possible, after which benefit-sharing arrangements can be made. Without access, there are no benefits to share.

If a Certificate is put in place, it must not hinder research, beneficial trade, or use of genetic resources and their derivatives. If trade, for example, were hindered (due to the Certificate over-regulating trade or development or causing too much uncertainty for users of genetic resources), it would impede creation of the benefits which the CBD seeks. In the case of plant breeding in particular, breeders see no significant advantages to anyone and enormous operational and other difficulties: for example, the system seems quite incompatible with the recently negotiated and vitally important International Agreement on Plant Genetic Resources. Developing countries in particular, who depend strongly on breeding by public researchers and farmers, should consider if Certificates could really help them.

Conclusion

To develop and implement a Certificate appropriate to all situations would be very complex, if not impossible. Different technical areas and types of use are would require tailored solutions. The objectives of the Certificate have not been defined yet. The problems that the Certificate is to solve are as yet unspecified: this leaves a big hole in the discussion and broadens its scope indefinitely. What's more, Certificates may only have any value once ABS regimes has been established and implemented. Hence at this stage a better approach may be to concentrate on

developing ABS guidelines and conforming national laws to them. National ABS laws are so far few and far between.

If a Certificate is to be successfully developed, it is not only the objectives and scope of the system that needs to be defined, but many other questions need to be solved. These are linked to:

- Variation of genetic resources;
- Intermingling of genetic resources;
- Different uses and users of genetic resources ;
- Stages in the development chain that genetic resources pass through;
- Legal implications;
- Implementation of access and benefit-sharing legislation; and
- Cost/benefit analysis.

Above all, it is vital that a possible Certificate does not undermine the objectives of the CBD, by inhibiting rather than promoting research, trade and use of genetic resources. More widespread use of a broader base of genetic resources increases opportunities for the generation and sharing of benefits. This encourages the conservation of genetic resources, so that they are available for use in the future.

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Annex 1.
Questions to define the feasibility of a Certificate

Objective and scope of a Certificate

- What precisely is any scheme intended to achieve? This involves identifying with precision what practical problems exist, how frequently they arise and the nature and extent of their consequences. Evidence as to the need for any scheme is vital.
- How will any scheme achieve those objectives and what other means are there of doing so?
- To what materials will the scheme apply? Will it apply to all genetic resources? For example, will plants sold in nurseries or live herbs sold in supermarkets be within the scheme? How is the adventitious presence of genetic resources (e.g. micro-organisms) in other products to be dealt with?
- Will human genetic resources be excluded? Will non-human genetic resources found in humans be excluded?
- Will derivatives fall within the scope of the scheme and, if so, how are they to be defined? For example, is a loaf of bread or a bottle of wine, each of which is clearly a derivative of genetic resources, to be included?
- To what transactions will the scheme apply and how? Is it to apply, and if so how, to all transactions in which legal title or physical possession of individual units of the genetic resources or their derivatives changes? Is it to apply to particular functional events, such as changes to the genetic or other characteristics of the resource? Where the resource is propagated or reproduced, will the scheme apply to the products which result, and if so how?

Operational issues

- What will be certified? Countries of source or origin, or other providers? Compliance with national laws? Existence of use restrictions? Legal provenance (and what does that mean?)?
- Who will be responsible for certifying which transactions? The country of origin? User countries? Users themselves? Individual providers?
- What will be the form of a certificate? Will it be a unique identifier held on a database? Will it be paper-based? Will it be physically annexed to a product or its packaging? Will it have to be available in respect of each unit of a genetic resource or any derivatives covered by a scheme?
- Are different schemes appropriate or practicable for different situations?
- Will the scheme apply to genetic resources acquired before the CBD came into force? If so, how will it apply to genetic resources acquired before CBD came into force but which are traded or developed thereafter?
- Will the scheme apply to genetic resources acquired after the CBD came into force but before the new scheme is implemented? If so, how will it apply to genetic resources acquired before the new scheme is implemented but which are traded or developed thereafter?

- How will the scheme apply to genetic resources obtained from countries whose laws do not regulate access to genetic resources.
- Will the participation in the scheme be compulsory or optional for CBD members?
- How, if at all, will it apply to countries which are not members of the CBD? How effective will the scheme be if it does not apply to some major countries?
- Will the scheme only apply to dealings with the physical genetic resources, or is it intended to apply to publications or other transfers of knowledge about the genetic resources?

Legal effects of the scheme

- What will be the legal effect of a Certificate? Will it clearly establish the right to deal in and develop the genetic resource? Will it have a limited life, or be valid indefinitely?
- What will be the legal effect of not having a Certificate? Will any sanctions be punitive or compensatory?
- If a Certificate is granted in error, can it be challenged, and (if so) how?
- What will be the nature and extent of obligations of those in the transaction chain to conduct due diligence as to the need for a Certificate? Many staple commercial products in conventional trading channels are genetic resources: or are derived in some way from, or using, a genetic resource. Most purchasers will know little about the origin of such products..

Enforcement

- What scrutiny will there be of any certification?

Costs of the scheme

- What will the financial costs of setting up and implementing the system be to individual countries and any relevant international institutions?
- What will the costs be to individual holders and users of genetic resources?
- To what extent will the scheme impact trade in and use of genetic resources and their derivatives (including derivatives not themselves covered by the scheme)? If such trade is hindered (due, for example, to the scheme over-regulating trade or development activity or causing unacceptable uncertainty for users of genetic resources), to what extent will it hinder the creation of the benefits which the CBD seeks to ensure will be shared?

Overall impact of the scheme

- Will the scheme promote the wider application of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity?
- Will this be done with the consent of the communities in question?
- Will the scheme facilitate access to genetic resources for environmentally sound uses or will it impose restrictions that run counter to the objectives, including benefit-sharing, of the CBD?

- Is it desirable for a pilot scheme to be set up to monitor its impact before any international regime is mandated?
- What mechanisms should there be to monitor the effect of any scheme and adapt it as appropriate?