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Monitoring Compliance under an International ABS Regime: The Role of an International Certificate Scheme

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Abstract: One area of compliance which has received significant attention over the years relates to a potential compliance monitoring tool viz. international certificate issued by domestic authorities. This paper provides a brief overview of existing proposals for an international certificate system and of the report of the Group of Technical Experts (GTE) established by the CBD to consider on the practicality, feasibility and costs of certificate proposals. In developing any certificate system the aim of negotiators should be to develop a bureaucratically light, inexpensive, flexible system. Work should focus first on identification of the elements and procedures for any regime, only then should attention be given to what any system will be called. In this way the system will define its own name and not vice versa. Certificates should be designed to provide the information necessary for monitoring at checkpoints

Keywords: ABS, Material Transfer Agreements, TK, CBD.

Introduction

Negotiation of an international ABS regime, which has stumbled along since 2004[1], got a much needed shot in the arm at the 6th meeting of the working group on ABS (WG ABS). Adoption of a novel working methodology enabled negotiators to agree on components requiring further elaboration with a view to their incorporation in an international regime. These components are set out in five blocks that comprise fair and equitable benefit sharing, access to genetic resources, compliance, traditional knowledge associated with genetic resources, and capacity.

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The inclusion by the WGABS of compliance as one of the principal components for elaboration of an international regime may prove a decisive step in the negotiation process. Compliance, an issue which has been surprisingly marginalized in debates on ABS over the years, is at the heart of developing country calls for negotiation of an international regime. This is, however, only a very preliminary step and compliance issues are likely to prove amongst the most controversial and challenging areas facing negotiators of an international ABS regime.

The 6th WG ABS identified three areas of compliance in which there is consensus regarding the need for further elaboration of measures[2]. These include:

1) Development of tools to encourage compliance:
   (a) Awareness-raising activities
2) Development of tools to monitor compliance:
   (a) Mechanisms for information exchange
   (b) Internationally recognized certificate issued by a domestic competent authority
3) Development of tools to enforce compliance

One area of compliance which has received significant attention over the years relates to what the 6th Working group has described as an international certificate issued by domestic authorities, a potential compliance monitoring tool. This paper provides a brief overview of existing proposals for an international certificate system and of the report of the Group of Technical Experts (GTE) established by the CBD to consider on the practicality, feasibility and costs of certificate proposals. It then suggests a model and highlights some of the challenges that will be faced in developing a functional international certificate system.

Certificates of Origin, Source, Legal Provenance or Compliance

Monitoring access to and use of genetic resources and traditional knowledge is considered crucial for effective ABS and TK governance. At present the collection, storage, use and transfer of such resources and knowledge is subject to an ad hoc system which often involves multiple forms of documentation. This includes government permits for the collection, export and import of resources, international obligations for sanitary and phyto-sanitary reporting, internal requirements of *ex-situ* collections, and reporting necessary to meet users demands. This plethora of documentation may provide a means to

track back and identify the country of origin or legitimate provider of resources. Too often, however, different standards in record keeping breaks the chain of custody, resulting in what may be considered a loss of identity of the resources. An inability to demonstrate the origin or source of resources affects the capacity of enforcement agencies to monitor resource use and to ensure it is legal and conforms to the terms and conditions for its use. This in turn diminishes possibilities for enforcing benefit sharing obligations under the CBD.

Proposals for some form of international standardized system to document genetic resources and/or TK emerged soon after the entry into force of the CBD. An initial proposal for a CITES style permitting system[3], was soon followed by a proposal for what was termed "certificates of origin".[4] The certificate idea in particular caught on and proposals now also exist for certificates of source, legal provenance and compliance.[5]

A certificate of origin[6] would identify the country of origin of resources and provide evidence of PIC for its use.[7] The CBD defines a country of origin as a country having resources *in-situ*, and for domesticated crops and animals, where they developed their distinguishing characteristics. Under the CBD provider countries includes countries of origin and countries which obtained the resources in accordance with the CBD (Pre-CBD collections would not be covered). The issuance of certificate of origin in cases where TK is involved would be subject to PIC of indigenous peoples or local communities.[8] Certificates would be monitored through a system of checkpoints, such as intellectual property (IP) applications and product approvals procedures.[9] A certificate of origin system would in effect transfer the burden of proof regarding rights to use resources from the provider to the user.[10]

Certificates of source were suggested as an alternative to those of origin due to concerns that identification of the geographical origin of resources could prove impossible.[11] Sources to be certified would include primary sources (such as the Contracting Party providing resources, and the Multilateral System established by the FAO-ITPGRFA), and secondary sources (such as *ex-situ* collections, databases on genetic resources and traditional knowledge, and scientific literature).[12] Certificates would be linked to obligations for disclosure of the source of genetic resources and TK in patent applications. Patent authorities would be obliged to inform competent authorities of countries identified

as the source of genetic resources and/or TK of relevant IP applications where the source is declared.[13]

Certificates of legal provenance focus on the legality of use rather than on the issue of where resources are obtained.[14] They would provide evidence of the geographical origin of resources and of compliance with the access laws of the providing country.[15] Certificates would be recorded in an international clearing house, with users obliged to maintain the link between the certificate and genetic resources.[16] Certificates could be requested at specific check points related to grant of IP rights, product approvals, grant making, and journal publications. A recent paper suggests they may be worthy of consideration as a possible tool for distinguishing TK legally in the public domain from that which has fallen into the public domain as a result of breach of a contractual or fiduciary duty, or due to misappropriation.[17]

The most recent proposal is for what are termed certificates of compliance. The term, which has become immediately popular, is used in the proposal to apply to cases of compliance with domestic ABS regimes.[18] This proposal favours a system of internationally recognised certificates rather than a globally harmonised certificate. Its proponents have argued against the establishment of checkpoints to monitor certificates and resource use. The proposal would exclude TK from any certification system.[19]

The potential of a certificate system to form a part of an international ABS regime led COP 8 to establish the GTE which met in Lima in January 2007. The Group's report identifies a number of features common to all four proposals, including: (i) a certificate would be a public document issued by a competent national authority; (ii) it would serve to provide evidence of compliance with national ABS legislation; (iii) it could be required for presentation at specific checkpoints in user countries (iv) all models could cover all genetic resources.[20] Furthermore, the group considered that a mandatory system would be restricted to the scope of the CBD, while a voluntary system might extend beyond the Convention; potential benefits of a certificate system were likely to increase with greater participation of parties at both the user's and provider's end; and a paperless system is favourable, however, any system should be flexible enough to allow for a mixture of paper and electronic formats.[21] The Group took the position that due to its intangible nature TK poses practical difficulties requiring special consideration before development of a TK certification scheme.

The 6th WGABS took the decision to include an international certificate issued by domestic authorities within the areas for further elaboration with the aim of their inclusion in an international regime. To this end, it has been proposed that the WGABS be given a clear mandate to prepare a set of minimum standards and procedures for an international certificate system and to provide the results of its work for consideration by COP 10 in Japan in 2010.[22]

Potential Elements and Procedures for a Certificate System

This section provides a brief overview of issues which the WBAGS and GTE may wish to take into consideration in the development of minimum standard elements and procedures for an international certificate system. This is an indicative list of issues for consideration and is not intended to be exhaustive. The issues for consideration set out below have been prepared based upon analysis of: all four certification proposals and the report of the GTE; existing harmonsied documentation procedures such as those developed by the International Plant Exchange Network (IPEN)[23] and MOSAICC[24]; case studies on documentation practices of *ex-situ* collections, including the Royal Botanical Gardens Kew, the Smithsonian Institution and INBio[25]; innovative models for contractual procedures to govern resource management, such as those of the International Treaty on Plant Genetic Resources for Food and Agriculture[26], Science Commons[27], the Potato Park[28] and Yellowstone National Park; conclusions of a series of international expert meetings on certificates[29]; as well as review of the writings of numerous commentators[30]; statements by industry sectors; and reports prepared by international organisations.

The paper seeks to avoid the often unproductive debate over what any certification regime should be called, and focus attention instead on the objectives, nature, content and scope of a certification system. Leaving what it should be called to emerge from the nature of the system itself.

What is the Purpose of Certification?

In order to determine the purpose of certification it is first necessary to consider what certification is and what it is capable of. Generally a certification system serves as a system for confirming the accuracy of something, or guaranteeing the meeting of a standard.[31] The certificate

itself may serve to provide evidence of a legal right such as in the case of a certificate of title to a car[32], or act as a mark designating the quality or nature of goods or services as, for example, the "AAA Approved" sign found at hotels.[33]

In the context of ABS and TK it has been suggested that a certificate system may certify such issues as the origin of genetic resources, the source which provided resources, their legal provenance, i.e. that they have been obtained in accordance with the CBD, and compliance with relevant ABS laws.

Scope

Certificates will need to be flexible to enable certification of anything from a single sample to multiple collections under a single ABS agreement. The CBD will need to define derivatives to ensure that as resources undergo transformation documentation will continue to be held linking transformed resources and the certificate which covers such resources. This should be held at least up to the stage when benefit sharing rights are exhausted.

Further work is required to determine whether certificate should cover associated TK, and/or whether a stand-alone system for certification of TK is appropriate.

Nature

Certificates if they are to play any serious role as a tool to monitor compliance, should demonstrate compliance with relevant ABS legislation of provider countries as defined under the CBD. To this end they will need to certify the origin, source, and/or legal provenance of resources. Certificates will need to provide evidence of PIC and MAT in order to provide legal certainty which will be the principal incentive for their use by industry and the research sector. Certificates will prove more useful if they raise a presumption of fair and equitable benefit sharing. This presumption will need to be rebuttable in cases of fraud, misrepresentation and other unfair trading practices.

A system of certificates may be either mandatory or voluntary. If mandatory it is possible that it may be restricted to resources covered by the CBD. A voluntary regime could also potentially be extended to pre-CBD collections and resources collected outside national jurisdiction, such as Antarctica, the high seas, and deep sea-bed (these will be discussed further below). An incentive based system would seek to promote use

based upon the benefits for users of legal certainty arising from certification.

With regard to TK certification should be based upon PIC of indigenous peoples and local communities, and should be made with due regard for customary law and practice.

Format

The certificate of origin proposal suggests a form of passport that accompanies genetic resources, either through their entire history from collection to use ('cradle to grave'), or only for certain transactions.[34] The GTE supports a paperless system, but recognizes the need for any system to incorporate paper based certificates as well due to differences in technological capacity of countries.

There is growing use by a wide range of actors of systems of unique identifiers, including barcodes, and digital object identifiers (DOIs) as a means to identify resources and aid in their future tracking. Where DOIs are in use, these are usually managed by an international online registry. Use of identifiers would enhance the possibilities for maintaining a link between resources and the certificate and terms and conditions applying to them. Such a linkage would reduce cost, complexity and enable instant verification and reduce the opportunities for the fraudulent use of false certificates.[35]

Certificates may be designated as non-transferable; transferable upon agreement to be bound by the same terms and conditions as applied to the original access; or, transferable only upon due notification to the provider country or indigenous peoples or local community, and their acceptance of such transfer. Provider countries and indigenous peoples and local communities may develop online systems to administer such transfers.

Issuing Authority

Certificates would be issued by a competent national authority in a provider country, as defined by the CBD. Certificates of legal provenance might also be issued by international genebanks of the CGIAR system for transfers covered by the ITPGRFA; this would avoid the placing of bureaucratic constraints on transfers covered by the Treaty. Potential authorities for issuing certificates for pre-CBD collections and collections from outside national jurisdiction are discussed below. In order to avoid delays and further bureaucracy certificates should be automatically issued

upon completion of an agreement based upon mutually agreed terms (MAT) in compliance with national ABS laws. An exception would be in cases where the contract's validity itself is challenged in accordance with national law. Certificates should be issued with little if any charge.

In the event that TK is to be covered by certificates, these may be issued by a national authority to demonstrate compliance with national legislation regarding PIC and MAT of indigenous peoples and local communities, for use of their knowledge and resources. Procedures for certification of TK should be managed where possible by a competent national authority representing and/or administered by representatives of indigenous peoples and local communities.

Indigenous peoples and local communities may also seek to develop their own certification authorities to demonstrate compliance with their customary laws and practices. Community protocols establishing clear procedures for certification of compliance could help to empower community control over PIC and MAT procedures.

Distinction between Commercial and Non-Commercial Use

Any certification system should avoid creating unnecessary costs and deals for pure scientific research, which covers a majority of access applications. Certification procedures may usefully adopt a two-tier system for commercial and non-commercial research. Researchers would be obliged to return to the provider country or indigenous people or local community for further PIC and MAT in the event of a desire to move to commercial related research and development activities. The terms and conditions for access may, in some cases, allow for such a change in use subject only to notification, where subsequent commercial use is governed by standard terms and conditions established by the rights holders.

Standard Material Transfer Agreements

Adoption of online access contracting systems employing standard material transfer agreements (MTAs) could greatly facilitate access to resources and TK. Increased access will increase the possibilities for discoveries of scientific and/or commercial importance and benefit-sharing opportunities for rights holders. Online systems may allow for click-licensing. Shrink-warp licensing systems may also be envisaged where receipt of resources and opening of their packaging amounts to acceptance of contractual provisions. The use of standard MTAs would benefit providers in what may often be asymmetrical negotiations with

users. Online systems may be established with a minimum of infrastructure which would benefit developing countries, and indigenous peoples and local communities wishing to manage their resources and provide them for access to a wider market. A set of standard agreements for non-commercial and commercial research could be developed by the CBD as has been done under the ITPGRFA.

Provider countries and other rights holders may decide to limit online licensing to resources which are widely available, or which are considered to have little commercial value. Obtaining access to endemic resources and high value resources such as extremophiles may require face-to face negotiations. Likewise, indigenous peoples and local communities may designate TK which may be accessed over the Internet and restricted knowledge which can only be accessed following face-to-face negotiations, if at all. Any decision to provide for online licensing of resources or TK would be the sole prerogative of relevant provider countries and indigenous peoples and local communities themselves.

The viability of online systems will depend to a large extent upon the existence of a robust system of user measures to ensure that contracts are complied with and where there is a breach there are effective and accessible remedies. Contract law alone will be insufficient to ensure protection of rights against third parties not party to a contract for use of resources. User measures such as disclosure requirements in IP applications will also be required to can help prevent misappropriation of resources and TK.

Clearing House Mechanism

A clearing house mechanism may be established to provide for register and tracking of all certificates.[36] This would bring transparency to the system and enable both providers and users to identify valuable resources. This may assist provider countries to regulate more effectively their resources, both for commercial purposes as well as to direct more effectively their scarce funds for conservation purposes.[37] Where there is online management of resources these systems may be networked providing greater access to information on resource use complementing a CHM, or in essence establishing a virtual CHM, through remote nodes.

Checkpoints

A majority of certificate proposals envisage their use in conjunction with one or more commercial and/or non-commercial checkpoints such

as intellectual property and product approval application procedures, other statutory approvals procedures, as well as in grant making and publications.

Checkpoints should be linked to high end use of resources and should not burden non-commercial users with unnecessary and costly procedures.[38] Placing checkpoints late in the stage of research and development will reduce costs for provider countries of any system and place the costs more firmly upon the users. If checkpoints are to prove effective in creating incentives for users to seek out PIC and MAT they will need to have substantive effect on procedures for granting of intellectual property, product approval, etc.

The principal checkpoint proposed by certificate schemes is for disclosure requirements in IP applications procedures. Proposed disclosure requirements range from a transparency measure in the form of disclosure of source[39], to more substantive measures including disclosure of origin and of evidence of PIC.[40] Disclosure requirements in national law have now been adopted by both developed and developing countries, including Brazil, Costa Rica, Denmark, Egypt, Germany, Norway, New Zealand, Romania, Spain, Sweden, Switzerland, and India. At the regional level, the European Community has opted for voluntary disclosure while the Andean community has adopted mandatory obligations. At the international level proposals have been made for amendment of World Trade Organisation (WTO) TRIPS Agreement to include disclosure requirements, covering origin, PIC and fair and equitable benefit sharing. A majority of WTO member countries now support such proposals.[41] Switzerland has proposed amendment of the Patent Cooperation Treaty to establish mandatory disclosure of source requirements.[42]

Care will need to be taken to ensure any disclosure requirements are drafted in terms which reflect the rapidly advancing pace of technological change. Advances such as those such as genomics and bioinformation now enable significant use to be made of genetic information without the need for physical access to genetic resources themselves.[43] Disclosure requirements will need to be couched in terms which address such indirect use of resources.[44]

Users providing a valid certificate should be presumed to have a legal right to use resources for the purposes identified on the certificate or related terms and conditions of contract. They should also be presumed to have complied with national requirements on PIC, MAT

and fair and equitable benefit sharing. This presumption as stated above should be rebuttable under certain circumstances.

Traditional Knowledge

Indigenous peoples and local communities are as yet undecided on the appropriateness of applying certification to TK. If certification is to occur consideration will need to be given to the potential and limitations of different types of certificate systems. Certifying origin would require identification of the originators of TK or its cultural origin; certificates of legal provenance for TK may provide means to distinguish information which has fallen into the public domain due to breach of contract or of a fiduciary obligation or as the result of misappropriation; certificates of source might apply to TK held in public or private databases which cannot demonstrate a clear legal title for their commercial use (in which case, access should be limited to non-commercial use). All certificates would, in essence, be a form of certificate of compliance demonstrating conformance with national ABS and TK laws and/or customary law and practice of indigenous peoples and local communities.

Considering the complex nature of TK systems, a special meeting of TK experts should be convened in order to weigh up the merits and drawbacks associated with applying any certification system to TK.[45]

Pre-CBD Collections

Where genetic resources and knowledge are in circulation outside the scope of an international ABS regime and certification system this may undermine their effectiveness, creating legal uncertainty and loopholes for unscrupulous users. The CBD does not explicitly extend its provisions to pre-CBD collections, though some countries have argued that all post CBD transfers of resources should be carried out in compliance with the CBD's provisions on PIC and MAT.[46]

The proposal for certificates or origin would, in effect, exclude pre-CBD collections held in countries other than the country of origin. The certificate of source proposal might allow for certification of resources from pre-CBD collections held in provider countries. It has been argued that as pre-CBD collections are not explicitly addressed by the CBD, they are legally held and could, therefore, be granted certificates of legal provenance.[47] The certification of compliance proposal would exclude all pre-CBD resources from coverage. The GTE has suggested

that resources which fall outside the CBD may be incorporated in a voluntary system of certification. Whatever form a certification system might take there are likely to be incentives and pressure for *ex-situ* collections with pre-CBD genetic resources to bring them within a system of certification.[48] One potential solution would be for institutions holding pre-CBD collections to adopt the approach of IPEN's Common Policy Guidelines[49] that require member institutions to treat both pre-CBD and post CBD collections in the same manner.

Commercial bioprospecting activities in Antarctica, the High Seas and the deep seabed remain largely unregulated. Discussions are now ongoing in various international forums regarding the development of measures to regulate bioprospecting activities in areas beyond national jurisdiction. It has been proposed, for instance, that the Antarctic Treaty System (ATS) might be extended to include regulation of bioprospecting.[50] If this is done the ATS could also assume responsibility for certifying the legal provenance of resources. Bioprospecting activities on the High Seas are at present subject to flag State jurisdiction.[51] Therefore, the flag state may be entitled to certify the legal provenance of resources. This has the dangers of having the flag country act as both judge and jury of legitimacy of collections. With regard to deep seabed resources the mandate of the international seabed authority could be amended to cover bioprospecting activities. Alternatively amendment of the CBD might be sought to encompass bioprospecting of resources collected on the high seas and the deep seabed.[52]

The lack of a clear regulatory framework and procedures for regulating commercial bioprospecting on the deep sea-bed has been seen as a deterrent to investment in such research on the deep seabed[53] and in Antarctica.[54] Bringing such resources within the ambit of an international ABS regime and certification system could help to bring greater legal certainty and boost investment. One potential means for doing so would be through disclosure requirements in IP legislation. A blanket requirement obliging IP applicants to disclose the origin or source of resources and provide evidence of a legal right for their use could be applied equally to resources covered by the CBD and resources which do not fall within its remit. This is not a decision which could be taken by the CBD alone. However, an amendment to TRIPS requiring disclosure of origin, PIC and fair and equitable benefit sharing could be framed so as to apply to all genetic resources wherever obtained.

Further analysis of the relationship of a certificate system with genetic resources which are not covered by the CBD is required, including

investigation of: (i) modalities of an international certificate system which could create incentives for voluntary inclusion of non-CBD resources; (ii) measures for mandatory application of a certification system to pre-CBD collections and/or genetic resources collected beyond national jurisdiction; (iii) options for exemption of resources from any system; (iv) measures to mitigate the impacts of trade in genetic resources outside any international ABS regime and certification system.[55]

Capacity Building and Further Research

There is a need for further information on current practices in the documentation and management of resources and TK, in particular regarding the practices of industry and the research sectors as well as indigenous peoples and local communities. There is also a need for targeted case studies and pilot projects on implementation of certificates at the national level and across whole chains of use from cradle to grave. Funding for GEF medium sized projects on ABS capacity building could provide a means for carrying out of pilot studies.

Conclusions

Certificates have a potentially important role to play as a compliance tool in an international ABS regime. They are, however, only one of a range of tools which will be required to establish a functional regime. They cannot be expected to resolve all the problems associated with current ABS and TK governance. Certificates in themselves are not an enforcement tool but when linked to a system of checkpoints they may play a significant role in protection of rights over genetic resources and TK.

The WGABS and GTE should begin work to prepare a set of standard elements and procedures for an international certificate system to be considered by COP 10, in Japan in 2010. To inform its work the WGABS should promote the carrying out of case studies and pilot projects. COP should call upon GEF as well as governments, international organizations and aid agencies to make funding available in the short term for necessary research and capacity building in this area.

In developing any certificate system the aim of negotiators should be to develop a bureaucratically light, inexpensive, flexible system. Work should focus first on identification of the elements and procedures for any regime, only then should attention be given to what any system will be called. In this way the system will define its own name and not vice versa.

Certificates should be designed to provide the information necessary for monitoring at checkpoints. To this end consultation should be carried out with authorities who may be called upon to enforce any system such as customs, patent authorities, police, judiciary etc.

Analysis of certification proposals and a wide range of related projects and experiences demonstrate that certificates can be practical, feasible and cost effective. Efforts should be made to secure the full and effective participation of all rights holders and stakeholder groups in the design of a certification system.

Endnotes

1 The WG ABS was given a mandate to negotiate an international regime on ABS and related traditional knowledge (TK) by the 7th meeting of the Conference of the Parties (COP) to CBD, held in Kuala Lumpur in 2004.
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20 Report Of The Meeting Of The Group Of Technical Experts On An Internationally Recognized Certificate Of Origin/Source/Legal Provenance UNEP/CBD/WG-ABS/5/7 .
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[27] See Buck, M. (2005).
[28] See: http://www.parquedelapapa.org/
[29] See Dedeurwaerdere et al. (2004), Ute and Woolf (2007).
[30] See generally attached bibliography.
[31] http://www.thefreedictionary.com/certify
[32] Certificate of title n. generally, the title document for a motor vehicle issued by the state in which it is registered, describing the vehicle by type and engine number, as well the name and address of the registered owner and the lien holder (financial institution that loaned money to buy the car). http://legal-dictionary.thefreedictionary.com/certificate+of+title
[33] See definitions at http://www.discusslaws.com/terms/161/certification_mark.html
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