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AD HOC OPEN-ENDED WORKING
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BENEFIT-SHARING

Fourth meeting

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**COMPILATION OF FURTHER STUDIES AND PILOT PROJECTS AND VIEWS ON THE
DESIGN OF AN INTERNATIONAL CERTIFICATE OF ORIGIN/SOURCE/LEGAL
PROVENANCE**

Note by the Executive Secretary

I. INTRODUCTION

1. At its third meeting, in recommendation 3/3, the Working Group on Access and Benefit-sharing recalled that existing other approaches could be considered to complement the Bonn Guidelines and are useful tools in assisting with the implementation of access and benefit-sharing approaches. It also recognized that an international certificate of origin/source/legal provenance could be an element of an international regime on access and benefit-sharing and deserved further examination.
2. The Working Group invited Parties, Governments, relevant international organizations, indigenous and local communities and all relevant stakeholders in particular the private sector, to prepare further studies and pilot projects and to report thereon to the Executive Secretary, and to submit their views to the Executive Secretary on the design of an international certificate of origin/source/legal provenance, including, *inter alia*:
 - (a) Its rationale, need and objectives;
 - (b) The desirable characteristics/features;
 - (c) The practicality, feasibility and costs at national and international levels.
3. The Working Group requested the Executive Secretary to prepare a compilation thereon for the consideration of the Working Group at its fourth meeting.
4. Notification 2005-044 of 14 April 2005 was sent to Parties, Governments, indigenous and local communities, international organizations and relevant stakeholders inviting them to submit further studies and pilot projects as well as views on the design of an international certificate of origin/source/legal provenance.
5. Submissions received from Canada, Costa Rica, the European Community and its Member States, India, Mexico and the Australian APEC Study Centre are compiled in section I.
6. Participants may also wish to refer to section III B of the note prepared by the Executive Secretary, for the third meeting of the Working Group on Access and Benefit-sharing

(UNEP/CBD/WG-ABS/3/5), which addresses the issue of an international certificate of origin/source/legal provenance.

II. COMPILATION OF VIEWS PROVIDED BY PARTIES, GOVERNMENTS, INDIGENOUS AND LOCAL COMMUNITIES, INTERNATIONAL ORGANIZATIONS AND RELEVANT STAKEHOLDERS ON THE FURTHER STUDIES, PILOT PROJECTS AND VIEWS ON THE DESIGN OF AN INTERNATIONAL CERTIFICATE OF ORIGIN/SOURCE/LEGAL PROVENANCE

A. Governments

Canada

Canada has read with interest the report of the United Nations University- Institute of Advanced Studies (herein UNU report) on the “Feasibility, practicality and cost of a certificate of origin system for genetic resources”, and agrees that:

Any certificate of origin scheme would need to protect the interests of resource providers without being so restrictive as to prevent desired flows of genetic resources for scientific purposes linked to the conservation objectives of the CBD. Access to genetic resources is also important for food security and to create commercial opportunities from which benefits may flow. Furthermore, any system must not be so bureaucratic or costly that the transaction costs effectively consume potential benefits.^{1/}

While the UNU report is a good start in thinking about the technical barriers to elaborating a certificate system and potential solutions, more research is needed to fully assess the technical aspects of this proposal as well as the capacity of countries and/or organizations to effectively implement such a system.

From Canada’s perspective, any certificate would have to be issued by the country of origin. The compliance burden would then fall on the country of origin and would depend greatly, for instance, on its capacity to issue the certificate. A lack of capacity within a country of origin may reduce its ability to compete in the marketplace of genetic resources. At the same time, neighbouring countries with transboundary resources will need to coordinate and harmonize the process of issuing certificates in order to ensure no incentives for avoiding ABS procedures exist in their region. If certain countries of origin, such as the Least Developed Countries, lack sufficient capacity to produce certificates of origin, then the international regime should contain measures to support capacity-building efforts in those countries.

Technological proposals relating to certificates of origin/source/legal provenance, such as proposals for an online certificate of origin, must be considered with due regard for the technological capacity of provider countries, particularly the least developed countries. Solutions for tracking genetic resources and associated TK should therefore take into account the technological capacity of some of the major provider countries.

Costa Rica

Other approaches, according to decision VI/24 b, including consideration of an international certificate of origin/source/legal provenance

Regulations for access to genetic resources and access to traditional knowledge are governed, in Costa Rica, by Executive Decree N° 31514 –MINAE. (Biodiversity Act Regulation N° 7788 respecting

1/ UNU-IAS certificates of origin working paper (Preliminary findings, December, 2004), p. 6.

access to genetic and biochemical resources and elements of biodiversity and access to traditional knowledge). In that regulatory document, “Certificate of origin or legal provenance” is defined as: “An official document issued by the *Oficina Técnica de la Comisión Nacional para la Gestión de la Biodiversidad* (CONAGEBIO - Technical Bureau of the National Commission for Biodiversity Management), which certifies the legality of the access to genetic or biochemical resources or elements of biodiversity, and compliance with the terms under which the corresponding access permit was granted to the interested party.”

To certify the legality of access, the Technical Bureau of CONAGEBIO (the Competent Authority) issues to the applicant or interested party a certificate of origin, also called “certificate of legal provenance.”

Its characteristics (information, elements or content) are determined in Costa Rica’s regulation on access as follows:

- Place and date of access.
- Owner of the biodiversity resources.
- Material obtained, in what quantity
- Person, community or communities that have contributed or will contribute their related knowled, innovations and traditional practices.
- Indication of whether the interested party has complied with established regulations or legislation regarding prior informed consent, and regarding compliance with mutually accepted terms for the proposed access to genetic resources.
- Date and number of the resolution granting the access permit.

With regard to the characteristics that a certificate of origin/source/legal provenance should include, we agree with the characteristics listed by the experts who participated in the “Regional Workshop on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising from their Use, and Associated Traditional Knowledge”, held in Havana, Cuba, on 21 and 22 June 2005:

- i. Should be reviewed fundamentally, but not exclusively, in patent applications;
- ii. Should be used for review at the end of the process, not for step-by-step tracking;
- iii. Must state the legality of the access;
- iv. Must be a positive signal, and must therefore be used as a positive incentive for users.
- v. Must remain a simple concept.
- vi. Must be practical and inexpensive.
- vii. Must be issued by whoever is granting the access permit.

The overall objective of Costa Rica’s legislation with regard to the issue of a certificate of origin or a certificate of legal provenance arose from the concept of legal provenance, since that is the central idea.

Costa Rica is currently drafting a regulation for access to *ex situ* genetic resources, and there is a preliminary draft of the initiative to ensure that, when there is an attempt to access genetic resources in *ex situ* conditions, but, for various reasons, the interested party wishes to export the material for use outside of the country, the interested party must apply for a certificate of origin/legal provenance that must accompany the material at all times. Said certificate will be issued according to the terms set out in Executive Decree 31514-MINAE: General Regulations for access to genetic or biochemical resources and elements of biodiversity.” It is considered appropriate to discuss the need for and purpose of requiring that the material be accompanied by a certificate of origin/legal provenance in such cases, and to discuss the certificate’s content and other possible uses. The issue awaits the discussions and decisions of the Open-ended Working Groups on ABS at its fourth meeting.

With regard to recognizing certificates of origin/legal provenance at the national and international level, the Open-ended Working Group on ABS must establish criteria for international recognition, which must be part of the elements of the international regime, one of which could be international recognition for certificates of origin that are backed by national legislation. In other words, if a Party's national legislation addresses the issue of certificates of origin/legal provenance, said certificates should be recognized internationally.

European Community and its Member States

The European Community and its Member States were among the Parties that responded to the invitation in decision VI/24 B and, *inter alia*, submitted their views and relevant information on an international certificate of origin/source/legal provenance to the third Ad Hoc Open-ended Working Group on Access and Benefit-sharing. The relevant part of this submission is found in an information document (UNEP/CBD/WG-ABS/3/INF/1, pages 25-26).

A certificate of origin could potentially be relevant to the ABS process under the CBD by bringing more transparency to transactions related to genetic resources and facilitating the monitoring of national access laws. However, core issues of this new concept still require a careful evaluation: the objective of such a certificate; exactly what should be certified; the relationship of such certificate with the objectives of the Convention on Biological Diversity on conservation and sustainable use; its practicality; and cost effectiveness, etc.

The EU is convinced that discussions on the concept and details of a certificate of origin will greatly benefit from practical implementation studies. In this regard the European Commission is financing a project to test the feasibility of an integrated conveyance system to manage access and benefit sharing issues related to microbiological resources. The project develops tools to evaluate the economic value of microbial resources and model documents to enable the tracking of microbiological resources that can widely be used by microbiologists in the public and private sector. Results should be available by the end of 2005.

The German Environment Ministry has commissioned a comprehensive and informative study on the role of certificates of origin, source and legal provenance as one of the instruments under discussion within an International ABS Regime. The study has been sent to the CBD secretariat and has been made available to participants of WG ABS3.

India

Rationale

The certificate of origin can be used to fulfill the requirement of the disclosure of the origin of genetic resources and associated traditional knowledge as a condition for receiving applications for grant of patents. Certificate of origin can act as evidence of prior informed consent (PIC) and Mutually Agreed Term (MAT) thus can reduce the load of patent offices by exempting them from the need to examine all of the documentation on ABS agreement. Further it will be useful in tracking flows of genetic resources and documenting evidence for the right to use genetic resources.

Desirable Characteristics:

A preliminary list of the information that may perhaps be included in a certificate of origin, has been proposed by Barber *et al.* (2003), these include:

- Details of the provider and user;
- Details of the indigenous or local communities;
- Details of genetic resources or traditional knowledge;
- Details of the approved use which may be made of the resources;

- Period of the agreement; and
- Details of the issuing authority.

There is a need to make a distinction between certificate of origin, certificate of source and certificate of legal provenance.

While certificate of origin would be issued from designated national authority of the country of origin of resource and TK, certificate of source/legal provenance could be alternatives to certificate of origin in instances where country of origin is difficult to be known. A certificate of source would track the resource to the place from where the user obtained it, which may not necessarily be the country of origin. Certificate of legal provenance would show evidence that the resource is legally held, or had been obtained from a legally entitled provider. Hence, a certificate of origin is more important than certificate of source/legal provenance.

The elements of the legally binding instrument on ABS should include an internationally recognized certificate of legal provenance of genetic resources that should include evidence of compliance with access legislation (including prior informed consent and mutually agreed terms). Further, the requirements to obtain the Certificate should be nationally defined, considering the provisions in the CBD. Criteria for international recognition of the certificate should be established in the legally binding instrument.

Operational functionality

A bar code based on internet based system of certificate would work better than certificate in a paper form. Further, the verification/monitoring of the certificate would have to be at the patent examiner level, rather than at the country's border, since it is extremely difficult to regulate physical movement of biological resources across borders. It was also felt that the cost of international certification system would not be prohibitive, and in any case, such a system is essential to ensure benefit sharing and prevent biopiracy.

Mexico^{*}

Considerations for the design of an international certificate of origin/source/legal provenance

Despite being the subject of multiple discussions in expert meeting, the proposed Certificate of legal provenance/source/origin has not been analyzed to detail in the context of the international Regime. Mexico would like to provide some comments as a contribution to the discussions to be held in Granada in 2006.

A.I Rationale, need and objectives

To regulate the access to genetic resources, from its collection to its utilization, implies the regulation of a process involving multiple actions and actors. These processes tend to take significant time.

In addition, it involves regulating a process that is inherently uncertain. In particular, there is uncertainty with regards to the type and reach of the results and benefits that could be derived from a specific access to genetic resources.

As an additional feature, the biotechnological industry, in its pharmaceutical, agricultural and industrial areas, tends to be a globalized one, with research and development activities occurring in different social contexts and legal frameworks.

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The following English translation was provided by Mexico.

In the absence of a coordinated regulatory response there is a risk to lose our capacity to ensure compliance with access and benefit-sharing provisions as well as the risk to increase transaction cost to the extent that different jurisdictions try to regulate the process in an uncoordinated fashion.

What is the certificate of legal provenance?

The certificate of legal provenance (CLP) is a legal instrument that provides evidence of compliance with the CBD as well as national access laws. It also serves as evidence of mutually agreed terms for the fair and equitable distribution of the benefits.

This instrument has to be international in nature to ensure that it can follow the entire process of research and development up to the point of utilization, i.e. along the entire reach of CBD obligations.

The Certificate of legal provenance constitutes a central part of the contractual approach within the Regime. It allows for a speedy and effective coordination between jurisdictions. This coordination involves a lower regulatory burden, and as such, a reduction in transaction costs.

A.2 *Desirable features*

Among the most important features of the Certificate, we propose:

- a. Issued by a designated national authority
- b. Simple and homogenous format
- c. Easily verifiable, either by environmental authorities or relevant stakeholders
- d. Low administration costs
- e. Include minimum check points in stages near the commercial applications of the biotechnological products in order to promote its compliance. One such key check point are in the granting of intellectual property rights.
- f. Clear triggers to activate the disclosure requirement should be developed to provide certainty to users
- g. Has to be flexible enough to accompany both the genetic materials as well as the derived information
- h. Requires credible and effective mechanisms for national authorities to act upon infringements

In order to identify more clearly the role of the Certificate, it is worth mentioning some of its undesirable features:

- a) It does not have to be verified in all stages and in all transactions along the R&D process;
- b) Disclosure of the Certificate is not in itself equivalent to verifying compliance with its associated conditions, but only that permitting/authorization requirements have been met. As such authorities in charge of check points, such as intellectual property offices, should not be in charge of verification, this has to be done by environmental authorities or any other authority designated by Parties.

In its more concrete form, the certificate will consist of a standardized electronic code that should be linked to samples and sub-products derived from it, including intangibles ones (i.e. relevant information, derivatives).

The specific access and benefit sharing conditions associated with each certificate should be uploaded on a clearinghouse via internet, which could be freely verified. Harmonization of the formats and means to ensure no duplication of codes is essential.

Check point should require disclosure of the Certificate code, store it in its public databases and/or transmit this information to the Clearinghouse.

Requirements for the issue of access permits and the associated Certificate fall under national jurisdiction and could be on a case by case basis. Such requirements include: prior informed consent (unless decided otherwise), traditional knowledge, and distribution of benefits. Verification of compliance with access conditions would have lower costs if conditions were simpler and more standardized. In this regard, it would be worth exploring the possibility of developing model contracts/conditions/structure that could help to at least partially codify access and benefit sharing conditions in the Clearinghouse.

Given that all countries have users of genetic resources, check point should be created in all of them, unless a global one is developed. One alternative for this could be the use of the international phase of the Patent Cooperation Treaty (PCT) as a platform to establish the disclosure requirements as part of preliminary evaluation done by the search international authorities.

A.3 Viability and costs at a national and international level

The main additional burden of the certificate is the obligation to keep a record of the certificate and transfer it to those who make use of genetic resources. It has therefore two basic components to evaluate its practicality, viability and costs: its storage and its transmission. It should be noted that, under current conditions, the alternative to this is for users to keep unstructured data on a wide variety of individual contracts/permits with the associated complexity of identifying its rights and obligations.

From the point of view of storage, it is important to notice that the demands for the certificate are a simple addition to the significant storage and data management needs and challenges of current bioinformatics databases. The explosion in biological, genetic and molecular information associated to new technologies has prompted the search for new tools to facilitate their management. The certificate would represent an additional field for these growing databases.

These growing databases require well curated information about organisms, samples and/or information that they held. For example, information about the institution that provided the material, the collection site, information of the researcher/company responsible for the material, etc. The user, either an academic institution or an enterprise, that is capable of keeping this information of its samples, will be able to keep a register of the associated certificate, or alternatively track the certificate to its suppliers. The certificate will in fact, facilitate storage of such information.

About information transfer, the reason why an electronic code is proposed is to facilitate this code to accompany both physical samples as well as intangible information. The way in which the certificate could follow information is through a similar to making reference to scientific work in a publication. The user of a genetic resource would have to acknowledge all genetic resources that contributed in an essential way to the information/invention through the disclosure of the certificate code in relevant check point and to other users.

This disclosure obligation should be based on clear and simple criteria so as to provide certainty to users and facilitate verification. The transmission of this information requires of an effort of convey users their obligation to disclose. The means and methods by which to transmit such information outside the checkpoints should be left to the individual arrangements.

The certificate allows the receptor of the material or information to verify the obligations and rights that he has over them. In this sense, the certificate makes it easier to the user to know the legal situation of his assets. Therefore, the certificate contributes to provide transparency and certainty. Thereby, the Certificate contributes to a reduction of transaction costs.

The distribution of costs at national and international levels will depend on the final design of the certificate. If every country establishes their own verifying authorities, then the multilateral costs will be

reduced. The most important cost will be then the cost to enlarge the capacities of the Clearinghouse to handle the Certificate database.

If a multilateral mechanism is employed as a point of revision, such as the PCT, then in addition to the latter, the capacities of the International Search Authorities will have to be enlarged.

B. Organizations

The Australian APEC Study Centre, Monash University

The following views were provided by the Australian APEC Study Centre regarding the concept of an international certificate of origin/source/legal provenance.

Requirements for certification of legality of genetic resources are unnecessary and will impede investment

Systems to determine the legal origin of a genetic resource (such as a certificate of origin) - and presumably to support regulations outlawing sale of uncertified products - are unnecessary if the right to prospect and the right to ownership of the property rights from prospecting are properly awarded and protected in law.

Either prospecting is legal or it is not. If it is not, any product of prospecting is illegal. No certificate of origin to establish legality is required.

If it is legal to prospect, any product of that activity is legal: no system of certification of the legality of a product is necessary.

Imposing a system of regulation to verify the legal origin of a genetic resource would deter bioprospecting and investment in biotechnology, unless the industry was lucrative and the cost and inconvenience of compliance was affordable. Bioprospecting is not so far lucrative.

A legal requirement to verify legality would also raise problems in international trade law when any product was traded. The Kimberley Accord which requires Governments to require that diamonds are certified as legally acquired before they be sold, required a formal waiver from the WTO that international trade rules would not apply to trade in diamonds. The cost of such a waiver is loss of valuable rights to protect trade from political interference.

The Australian APEC Study Centre also submitted to the Executive Secretary a document entitled: "Developing an effective international regime for access and benefit-sharing for genetic resources – Using market-based instruments". This paper includes a section relating to the international certificate of origin and is available as an information document.
