UNEP

CBD

CONVENTION ON BIOLOGICAL DIVERSITY

Distr.
GENERAL

UNEP/CBD/GTE-ABS/1/3
20 October 2006

ORIGINAL: ENGLISH AND SPANISH

GROUP OF TECHNICAL EXPERTS ON AN INTERNATIONALLY RECOGNIZED CERTIFICATE OF ORIGIN/SOURCE/ LEGAL PROVENANCE
Lima, 22-25 January 2007
Item 3 of the provisional agenda*

COMPILATION OF SUBMISSIONS PROVIDED BY PARTIES, GOVERNMENTS, INDIGENOUS AND LOCAL COMMUNITIES, INTERNATIONAL ORGANIZATIONS AND RELEVANT STAKEHOLDERS REGARDING AN INTERNATIONALLY RECOGNIZED CERTIFICATE OF ORIGIN/SOURCE/LEGAL PROVENANCE

Note by the Executive Secretary

I. INTRODUCTION

1. At its eighth meeting, held in Curitiba, Brazil, the Conference of the Parties decided, in paragraph 1 of its decision VIII/4 C, "to establish a group of technical experts to explore and elaborate possible options, without prejudging their desirability, for the form, intent and functioning of an internationally recognized certificate of origin/source/legal provenance and analyse its practicality, feasibility, costs and benefits, with a view to achieving the objectives of Article 15 and 8(j) of the Convention".

2. In addition, in paragraph 5 of the same decision, the Conference of the Parties invited Parties, Governments, relevant international organizations, indigenous and local communities and all relevant stakeholders including the private sector, to undertake further work, including through research and submission of views, on the possible options for the form, intent and functioning of an international certificate of origin/source/legal provenance and on its practicality, feasibility, costs and benefits, with a view to achieving the objectives of Articles 15 and 8(j), including consideration of certificate models as an input for the work of the Expert Group.

3. In accordance with the above, by notifications 2006-043 of 29 May 2006 and notification 2006-048 of 30 May 2006, Parties, Governments, indigenous and local communities, international organizations and relevant stakeholders were invited to submit their views and other information on an international certificate of origin/source/legal provenance to the Secretariat by 1 September 2006. The contributions received, which are reproduced as they were received by the Secretariat, are annexed hereto. A further submission, from the Government of Italy, is being circulated as an addendum to the present document.

* UNEP/CBD/GTE-ABS/1/1.

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Annex

COMPILATION OF SUBMISSIONS PROVIDED BY PARTIES, GOVERNMENTS, INDIGENOUS AND LOCAL COMMUNITIES, INTERNATIONAL ORGANISATIONS AND RELEVANT STAKEHOLDERS REGARDING AN INTERNATIONALLY RECOGNIZED CERTIFICATE OF ORIGIN/SOURCE/LEGAL PROVENANCE

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I. SUBMISSIONS FROM PARTIES

ARGENTINA [ORIGINAL: SPANISH]

Al respecto, indudablemente la experiencia mas significativa acerca de la utilización de certificados internacionales, la constituye el trabajo cotidiano de esta Coordinación como Autoridad Administrativa de la Convencion sobre Comercio Internacional de Especies Amenazadas de Flora y Fauna Silvestres (CITES). Este tratado tiene por objeto fomentar la cooperación internacional para lograr la protección de ciertas especies contra el trafico excesivo, con el fin de asegurar su supervivencia.

Para el cumplimiento de sus cometidos, la Convencion cuenta con dos herramientas basicas: la clasificacion de las especies en Apendices con diferentes regulaciones en lo que concierne a su comercio internacional, y la implementacion de un sistema de permisos y certificados que emite la Autoridad Administrativa para acompanar la exportacion de ejemplares vivos y sus productos, sin los cuales el comercio no puede realizarse.

La Convencion posee tres Apendices, que contienen listas donde figuran los animales y plantas, de acuerdo con el grado de amenaza que sufre cada uno de ellos, de los cuales son mayormente utilizados los dos primeros.

El Apéndice I incluye las especies en peligro de extinción, para las cuales las transacciones internacionales solo se autorizan en circunstancias excepcionales. En el Apéndice II se enumeran todos los ejemplares que pueden llegar a encontrarse amenazados si no se regula su comercio internacional en forma estricta.

A traves de los anos, el sistema instituido por CITES se ha ido aceitando y estandarizando, resultando un eficiente sistema de cooperación nacional que guarda algunas similitudes con la implementacion de un eventual certificado de origen que acompane la salida del pais de recursos geneticos, asi como sus movimientos transfronterizos futuros, toda vez que impone en el interesado la carga de cumplir con las regulaciones vigentes y obtener el certificado, so pena infringir el regimen, con las consecuencias que correspondan.

Las similitudes y diferencias entre el sistema de permisos y certificados previstos en la Convencion CITES y un eventual sistema de certificados internacionales respecto de acceso y participación en los beneficios ha sido exhaustivamente analizado en el Taller realizado en Lima en noviembre 2003, cuyos resultados fueron transmitidos a la Septima Reunion de la Conferencia de las Partes. Muchos de estos conceptos han sido asimismo utilizados como base de discusiones ulteriores sobre el tema. Los aspectos que aun resta definir seran discutidos durante la proxima reunion del Grupo de Expertos acordada en Curitiba, donde esperamos poder contribuir a las discusiones sobre lo que, a nuestro entender, sera un importante mecanismo en le futuro regimen internacional.

English translation

Undoubtedly, the most significant experience with the use of international certificates is linked to this Coordinating Body's daily work as the Administrative Authority of the Convention on International Trade in Endangered Species of Wild Flora and Fauna (CITES). This treaty is aimed at fostering international cooperation to protect certain species from excessive trafficking, in order to ensure their survival.

CITES uses two basic tools to carry out its tasks: the classification of species in Appendices that have different regulations with regard to international trade in those species, and the implementation of a system of permits and certificates issued by the Administrative Authority to accompany exports of live specimens and their products, without which trade cannot take place.

CITES has three Appendices that contain lists of animals and plants, according to the degree to which each is threatened. The first two Appendices are the most commonly used.

Appendix I includes species threatened with extinction and for which trade is only permitted in exceptional circumstances. Appendix II lists all of the specimens that could become threatened with extinction if their trade is not strictly controlled.

Over the years, the system set up by CITES has become increasingly fine-tuned and standardized, resulting in an efficient system for national cooperation. The system shares certain similarities with the implementation of a potential certificate of origin that would accompany genetic resources leaving the country, and for future transboundary movements, insofar as it puts the onus on the interested party to comply with the regulations in effect and obtain a certificate in order to keep from infringing the system and incurring the corresponding consequences.

The similarities and differences between the permit and certificate system under CITES and a potential system for international certificates for access and benefit sharing were analyzed at length in the Workshop held in Lima in November 2003, the outcomes of which were forwarded to the Seventh Meeting of the Conference of the Parties. Many of these concepts have furthermore been used as the basis for discussions on the issue. The aspects that remain to be defined will be discussed at the next meeting of the Group of Experts in Curitiba, where we hope to contribute to discussions on what we understand will be an important mechanism of the future international regime.

AUSTRALIA [ORIGINAL: ENGLISH]

Many of the existing proposals for an "international certificate of origin/source/legal provenance" do not appear to be workable, nor consistent with Article 15 of the Convention on Biological Convention (the Convention). There are serious practical limitations which circumscribe the objective and scope of a system of certificates, including the differences in domestic implementation of Article 15 and the fact that many legitimate transfers of genetic resources are not subject to the Convention. In addition, the distinctions between a certificate of origin, source or legal provenance are not helpful and the idea of a certificate covering both genetic resources and traditional knowledge is neither workable nor consistent with the Convention. However, within these constraints, Australia believes that certificates of compliance issued by domestic authorities may be a viable means of supporting the effective implementation of Article 15. Such certificates could provide evidence of compliance with access requirements for genetic resources without undermining contracts, which should remain the means for stipulating conditions of utilisation and ensuring benefit sharing.

Objective

Australia's national experience with implementation of the access and benefit sharing provisions of the Convention, and its analysis of recent literature on the idea of an 'international certificate of origin / source / legal provenance', leads to the conclusion that a 'certificate of compliance' could support the effective implementation of Article 15. Such a certificate would be issued by domestic authorities to show that a user has fulfilled all access requirements as set out in domestic law. This would serve the paramount objective of ensuring that access is consistent with obligations under the Convention. It would not replace the need for contracts containing mutually agreed terms.

A certificate of compliance issued as the result of domestic procedures for granting access would assist both users and providers. For providers, the certificate could offer a simple means of stipulating that all access requirements, such as prior informed consent, had been fulfilled and it would support legal claims to any benefits that may have been negotiated under an associated benefit sharing agreement. For both scientific and commercial users, certificates would provide evidence during the stages of research and commercialisation that genetic resources had been initially obtained from a provider country in accordance with the Convention as implemented by its domestic law.

Certificates of compliance would thereby contribute to ensuring certainty, transparency and predictability about the basis on which the genetic resources were initially acquired throughout the

research and commercialisation process. It is important to remember that without research and commercialisation, there will be no benefits to share. Thus, the maintenance of incentives for research and development is crucial.

Scope of a certificate

There are practical limitations which circumscribe the scope, function and form of a system of certificates under the Convention.

First, while certificates can provide a supplementary form of evidence of compliance with access requirements, they cannot replace the need for 'mutually agreed terms' (or a contract) which stipulates terms for use, subsequent transfer and benefit-sharing. A certificate issued at the point of access cannot provide evidence of subsequent compliance by a user with the terms of a contract, and any certificate system that cast doubt on the value of contracts would undermine benefit-sharing.

Second, the significant variation in proprietary rights over genetic resources in different countries makes a 'one-size-fits-all' approach unworkable. For example, in some countries all genetic resources are owned or controlled by the government, whereas in others, genetic resources in ex situ collections and on privately-owned land are controlled by the collection or land owners. For this reason, implementation of Article 15 obligations varies considerably from country to country. Thus, the scope of genetic resources covered by domestic law and the particular requirements for access will necessarily be different. The variety of domestic systems for implementing Article 15 precludes the development of any standardised certificate.

Third, many of the proposals for 'international certificates of origin / source / legal provenance' contained in published literature presuppose that certificates could cover all transfers of genetic resources. This is not in fact possible. Article 15(3) provides that the genetic resources covered by the access and benefit sharing articles of the Convention are 'only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with the Convention'. Accordingly, many transboundary transfers of genetic resources are outside the scope of the Convention, most significantly transfers of material obtained before the Convention entered into force. In many countries, there may also be a range of genetic material that is not subject to a prior informed consent process, as is recognised in Article 15(5), and over which domestic authorities do not exercise control. The consequences of this are clear: no system of 'checkpoints' could be workable since no system of certificates could comprehensively cover all transfers of genetic resources.

Fourth, as a mechanism for providing evidence of prior informed consent, it is important to note that certificates could only attach to physical property and not the scientific or traditional knowledge employed in the use of those genetic resources. This flows from the wording of the Convention itself and in particular, the difference between the Convention's access and benefit sharing provisions (mostly in Article 15) and the obligation under Article 8(j) for parties to 'respect, preserve and maintain knowledge innovations and practices of indigenous and local communities'.

Whereas Article 15 governs access to physical material, Article 8(j) is concerned with information and knowledge. And while Article 15(5) provides that the prior informed consent of the state providing resources must be granted for access to occur, Article 8(j) obliges parties (subject to their national legislation) to 'promote the wider application' of traditional knowledge 'with the approval and involvement of the holders'. Proposals in the existing literature for certificate systems that cover genetic resources and traditional knowledge do not correspond to the obligations contained in the Convention, and in some cases appear to arrogate to the state significant roles in authorising access to traditional knowledge. Accordingly, additional measures to support the implementation of Article 15 and Article 8(j) should be considered separately, respecting fully the different obligations in the Convention, and

responding to the specific practical and policy challenges pertaining to genetic resources and traditional knowledge.

Origin, source or legal provenance?

Existing literature refers to an 'international certificate' or 'internationally-recognised' certificate and a range of options have been mooted including certificates of origin, source and legal provenance. The differences are significant and need to be assessed carefully.

In the existing literature, certificates of origin or source or legal provenance reflect differing interpretations of the Convention and sometimes differing objectives. It is widely agreed that identification of the 'origin' is challenging and expensive to verify in many cases, particularly where a species exists in more than one jurisdiction. Proving which country is the origin of a particular sample can be equally difficult. Identification of the 'source' could present similar problems.

Australia contends that these distinctions are not helpful in conceiving and designing a certificate system that improves implementation of Article 15. The range of possible situations in which domestic authorities may issue a certificate to indicate compliance with Article 15 as implemented in domestic law cannot be reduced to either 'origin' or 'source'. The material covered by Article 15(3) is sometimes provided by the country of origin and sometimes by a country that obtained the material in accordance with the Convention. In addition, some proposals for certificates of 'origin' or 'source' appear to presuppose an extension of the actual provisions contained in Article 15 especially proposals that would require the 'origin' of all material transfer to be identified.

And, although 'legal provenance' could be interpreted as meaning that acquisition of genetic resources had met domestic requirements for access, the term could possibly also be construed in some jurisdictions as constituting evidence of a legal title or ownership. This should be avoided because, depending on the domestic structure for legal ownership of genetic resources, governments may not have the authority to transfer ownership. In such cases, they may only have the power to grant the right to use a resource, in which case legal ownership is precluded from vesting in the user. For this reason, the term 'legal provenance' does not appear useful and could be misleading.

Australia therefore suggests that these terms not be used, and that debate focus on a domestic 'certificate of compliance' which augments, but does not supplant, contracts.

A domestic or an international certificate?

There have also been some proposals for an 'international certificate' in the form of a standardised certificate that might be the same in all countries or might even be issued by a single intergovernmental body. An international certificate in this sense is neither workable nor desirable. As pointed out previously, the variability of domestic systems to implement Article 15 precludes a single, 'one size fits all' approach to documenting compliance with requirements under those systems. As such, it is difficult to imagine how an intergovernmental body could effectively supervise the application of domestic ABS laws in all countries and issue certificates. Such a system would inevitably require substantial institutional infrastructure which could be prohibitively expensive.

Although the variability of domestic ABS systems prevents the adoption of any single format for a certificate, it may be possible to provide guidance for countries when developing certificates. In this sense it could be considered to be 'internationally recognised'. This might include details of the provider and initial user, a description of the material covered (which could vary from a single gene to thousands of species depending on domestic law), a statement of compliance with the relevant domestic law, and reference to any benefit sharing agreement.

Many ex situ collections already require documents that are tailored to the particular type of species and the administrative systems in place to manage the collections. It is important that any new certificates system will be easy and cost-effective for users to implement. In the case of small user companies, a complex and costly system could have the unintended effect of discouraging biodiscovery. Given the overwhelming majority of acquisitions are for scientific purposes, the prospect of passing the costs on to commercial users is limited. There are real risks that an administratively intensive system would add costs to basic science and taxonomy without contributing significantly to ensuring compliance and the return of benefits.

Australian experience

The Australian Government has put in place a legislative framework for biodiscovery to demonstrate acquisition of genetic resources in Commonwealth areas, which aims to give investors confidence and security when committing to large and sustained investment in research and development. Regulations under that legislation ensure that Australia's genetic resources are used for the purposes they are acquired, on mutually agreed terms that provide an equitable return to Australia, with prior informed consent, while ensuring the environment is protected.

The regulations apply to the taking of biological resources of native species in Commonwealth areas for research and development on any genetic resources, or biochemical compounds, comprising or contained in the biological resources. Where the regulations apply, gaining access will involve entering into a benefit-sharing agreement with the owner or manager of the biological resources as a pre-condition to obtaining a permit. A permit issued under these regulations provides evidence of compliance with Australian law in accordance with Article 15 of the Convention.

Please see the following link for more information about Australia's permit system: *http://www.deh.gov.au/biodiversity/science/access/permits.html*. Australia would also be willing to provide further information on its domestic experience in implementing a permit system should that be of interest to other parties.

In Australia's federal system of government, constitutional authority over land use and genetic resources in held primarily by the state and territory governments. As such, legislative and administrative action to implement Article 15 is required in nine jurisdictions in Australia. A full report on the status of Australian implementation will be provided in a further submission to ABS Working Group 5.

BRAZIL [ORIGINAL: ENGLISH]

1. Through the notification contained in document SCBD/SEL/VN/VP/54835, dated May 5th, 2006, the Secretariat of the Convention on Biological Diversity (CBD) invited Parties, governments, International Organizations, indigenous and local communities and relevant stakeholders to submit views on the possible options for the form, intent and functioning of an international certificate of origin/source/legal provenance and on its practicality, feasibility, costs and benefits, with a view to achieving the objectives of Article 15 and 8(j), as an input to the work of the Expert Group on the issue established by decision VIII/4 C, paragraph 1, of the Conference of the Parties.

2. In reply, the Brazilian Government would like to present some preliminary views with respect to the establishment of such certificate.

3. Brazil regards a certificate of origin/legal provenance as an important tool to ensure enforcement of the provisions of the CBD. Such a certificate could be considered in the context of the establishment of a legally-binding international regime on access and benefit-sharing that would guarantee the rights of countries of origin of genetic resources as well as those of indigenous and local communities in relation to their associated traditional knowledge according to national legislation, as established by the CBD, thus avoiding the misappropriation and misuse of genetic resources, derivatives and/or associated traditional knowledge.

4. The main objective of a certificate of origin, whether as part of or in addition to an international regime on access and benefit-sharing, should be to ensure that the access to genetic resources, derivatives and/or associated traditional knowledge is made in compliance with national legislation on access and benefit-sharing of the countries of origin and that the conditions that led to granting of access can be enforced at the international level.

5. A certificate should apply to genetic resources and derivatives from countries of origin and associated traditional knowledge of local communities and indigenous people. In order to avoid overlapping of regulatory frameworks, genetic resources that fall under the scope of the International Treaty on Plant Genetic Resources for Food and Agriculture, when utilized for the purposes of that agreement, should, in principle, not be covered.

6. A certificate of origin/legal provenance should be emitted by the country of origin of the genetic resources, derivatives or associated traditional knowledge. In case of genetic resources obtained from "ex-situ" sources, a certificate must be issued in accordance with CBD provisions, in particular those related to the rights of countries of origin to regulate access to their genetic resources, derivatives and/or associated traditional knowledge. Other situations that should be taken into account include cases where the origin of some genetic resources, derivatives and/or associated traditional knowledge may not be known.

7. A certificate should attest that the national legislation on access and benefit-sharing of the country of origin has been complied with. It should have an internationally recognizable format, though not necessarily standardized. Ideally, a certificate should be sent to the institution that intends to use the genetic resources, derivatives and/or associated traditional knowledge, after issuance by a competent national authority.

8. The use of genetic resources obtained prior to entry into force of the CBD should not be under the scope of a certificate of origin/legal provenance. This condition, however, must be adequately justified by the user of such resources.

9. The implementation of a certificate should be as simple as possible and avoid burdensome or costly management schemes, although some form of management system may need to be put in place.

10. In principle, a certificate could be used as one of the means to comply with the disclosure requirements on applications for intellectual property rights, in particular patents, as well as for commercial registration for the launching of new products or processes in the market. Implementation of a certificate should be carried out in a manner that does not unduly restrict trade. Its central purpose is to ensure compliance with the national legislation of the country of origin on access to genetic resources, derivatives and/or associated traditional knowledge.

11. The following elements, among others, should also be considered in discussions on a certificate of origin/legal provenance: international serial listing; country of origin; user country; taxonomic identification; holder of the associated traditional knowledge; issuing authority and institution of user country contact information; issuing date."

INDIA [ORIGINAL: ENGLISH]

The discussion on the need to develop an International Certificate of Origin/Source / Legal Provenance has become quite engaging in recent years because of the attempts that are being made to lay down the contours of such a mechanism.

An instrument of the kind that is being proposed would no doubt add to the transparency with which the key elements of the CBD, viz. access, based on prior informed consent, and fair and equitable benefit sharing, can be implemented. However, a number of critical issues need to be considered before such an instrument is put into effect. The discussions that have taken place during the past few years have revealed the nature of complexities that can accompany the establishment of this instrument. These

aspects need careful consideration, particularly in light of the costs and benefits of establishing an "International Certificate".

At the outset, however, the CBD Contracting Parties would need to assess the practicality of establishing the International Certificate. It would appear, as is briefly indicated below, that basic concept of an International Certificate is still in a melting pot and that a common understanding about its structure is yet not clear. This problem, in our view, stems from the fact that although there is a general idea about its utility, the precise nature of advantages that this instrument would bring forth remains nebulous. It is therefore imperative that these issues are discussed thread-bare, which would, in turn, help in designing the International Certificate in manner that facilitates implementation of the CBD in an expeditious and transparent manner.

The Rationale for Establishing an International Certificate of Origin/Source and or Legal Provenance

The justification for an International Certificate was laid down in the context of the requirement to disclose the origin/source of genetic material and/or associated TK in the patent applications. It has been argued that the establishment of a standardised certificate of origin, having acceptance of all Parties to the CBD, would help in harmonising the procedures followed by different national authorities while they exercise their rights of their respective States that the CBD provides. In its simplest form, an International Certificate could be a passport that accompanies genetic resources.

Certificates of origin has been conceived of as evidence of legal title to use the resources, and also as an instrument of a traceability system, which can help monitor the trade and movement of resources and discourage unapproved and illegal use of genetic resources. A further proposal in this regard has been that such a system could be expanded to apply to product approval processes, scientific publications and other regulatory approval processes.

International Certificate: Major Issues for Consideration

Several issues needs to be considered while establishing the International Certificate. The more important of these are: (i) the design of the International Certificate, (ii) the information that may be included in the International Certificate, and (iii) assessment of the costs and benefits of an International Certificate.

The design of an International Certificate, it has been proposed, should be based on a number of considerations. These include *inter alia*, (i) the purpose of certification; (ii) nature of a certificate, i.e. mandatory or voluntary; (iii) subject matter covered by the certificate; (iv) content of the certificate, viz. origin, source, or legal provenance; (v) verification and compliance mechanisms needed to support such a system. Each of these issues need detailed consideration before a decision on the International Certificate can be taken.

The ongoing discussions on the International Certificate have brought out the fact that a complex set of issues may have to be dealt with while implementing an International Certificate. A glimpse of the nature of complexities that could be involved can be had from one of the suggestions relating to the nature of information that may be included in an International Certificate. It has been suggested that an International Certificate could include the following information:

(i) Particulars of the provider and user;
(ii) Particulars of the indigenous or local communities parties to the agreement;
(iii) Details of genetic resources or traditional knowledge;
(iv) Details of the approved use which may be made of the resources;
(v) Details of any restrictions on use;
(vi) Period of the agreement;

(vii) Conditions relating to transfer of rights to third parties; and

(viii) Details of the issuing authority

The above-mentioned issues point to the fact that the CBD Contracting Parties would need to develop common understanding on the content of a possible International Certificate, and this would in turn be based on its uses from a practical standpoint. The Contracting Parties need to be mindful of the fact that it is the implementation of the CBD in an expeditious and transparent manner which deserves focused attention and therefore, any instrument that is developed for implementing the CBD must help in facilitating the process.

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.

The requirements to obtain the Certificate may be nationally defined, considering the provisions in the CBD. Criteria for international recognition of the certificate may be established in the legally binding instrument.

An important issue that needs to be considered is the justification of this instrument from an economic point of view. 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. CBD Contracting Parties need to assess whether the balance of costs and benefits justifies establishment of such an instrument. More specifically, the transactions costs of having such an instrument in place must be assessed in light of the potential benefits that it may give rise to.

Countries would have to consider carefully the resources: physical, financial and human, that they would require for implementing an International Certificate. Besides, they would have to put in place institutions that would be essential for effective implementation of this instrument.

MEXICO [ORIGINAL: SPANISH]

Propuesta de México del Certificado Internacional de Origen/Fuente/Procedencia Legal

A. Consideraciones para el diseño de un certificado internacional de origen/fuente/procedencia legal

1. El Certificado de legal procedencia/fuente/origen ha sido sujeto de múltiples discusiones en foros de expertos, aunque todavía no ha sido analizado a detalle en el marco de las negociaciones del Régimen Internacional. En este documento, se incorporan algunas consideraciones sobre el mismo como una contribución a la discusión que deberá de tenerse en la próxima reunión del Grupo de Expertos Técnicos sobre un Certificado internacional de origen/fuente/procedencia legal que se reunirá en enero de 2007.

A.1 Su fundamento, necesidad y objetivos

2. Regular el acceso a los recursos genéticos, desde la colecta hasta su utilización, implica regular un proceso dentro del cual ocurren múltiples acciones, involucra a múltiples actores y tiende a ser por un largo periodo.

3. Adicionalmente, implica regular un proceso que es inherentemente incierto, es decir, no existe certeza sobre el tipo ni el alcance de los resultados ni de los beneficios que pudieran derivarse de un acceso.

4. Como una característica adicional, la industria biotecnológica, en sus áreas farmacológica, agrícola e industrial, tiende a ser una industria globalizada, por lo que el proceso ocurre en diversos contextos sociales y marcos jurídicos.

5. En ausencia de una respuesta regulatoria coordinada se corre el riesgo de que se pierda la capacidad de hacer cumplir la ley al tiempo que puede resultar en un régimen con altos costos de transacción, en la medida que las diferentes jurisdicciones donde ocurre el proceso pretendan regular todo el proceso de manera independiente.

¿Qué es el certificado de legal procedencia?

6. El Certificado de Legal Procedencia (CLP) se refiere a un instrumento legal emitido por la autoridad competente que será muestra del cumplimiento de las disposiciones pertinentes que regulen el acceso a los recursos genéticos nacionales y que existen, así como de las disposiciones – contractuales o de otro tipo – que permitan identificar los mecanismos necesarios para la distribución justa y equitativa de los beneficios derivados del uso de esos recursos.

7. Para que este instrumento sea efectivo y cumpla cabalmente con los objetivos de su implementación, es necesario que esté sustentado en un régimen internacionalmente vinculante, con el fin de estar en posibilidades de dar seguimiento a todo el proceso de investigación y desarrollo y hasta la utilización del recurso (tomando en cuenta aspectos de confidencialidad que pudieran repercutir o comprometer aspectos de derechos de propiedad industrial); es decir, hasta el punto en el que cumple cabalmente con todas sus obligaciones emanadas del CDB.

8. En este sentido, el Certificado de legal procedencia constituye un elemento central del componente del Régimen basado en un enfoque contractual, ya que habilita la coordinación ágil y efectiva entre jurisdicciones. Esta coordinación se traduce en una menor carga regulatoria y por tanto, una reducción en los costos de transacción asociados con la regulación del acceso y la distribución de beneficios.

A.2 Sus características/aspectos deseables:

9. Dentro de las características más importantes del Certificado están:
    a. Ser emitido por una Autoridad Nacional Competente. Cada país puede designar más de una autoridad competente, de acuerdo con la relevancia de las diferentes dependencias en cada país para cada grupo de especies.
    b. Debe tener un formato simple y homogéneo (definir idioma o idiomas de trabajo).
    c. El formato deberán existir medidas de seguridad que permitan verificar la autenticidad del mismo.
    d. Debe ser fácilmente verificable, difundible o inspeccionable, según sea el caso, ya sea por la autoridad ambiental o por los propios interesados.
    e. Debe tener una administración de bajo costo.
    f. Debe contar con puntos de revisión y/o difusión mínimos en etapas cercanas a la aplicación comercial de productos biotecnológicos, a fin de inducir su cumplimiento. Los puntos de revisión y/o difusión pueden incluir procesos de autorización comercial, procesos

fitosanitarios, trámites aduanales y procesos de otorgamiento de derechos de propiedad intelectual, entre otros.

g. Deberá contarse con criterios claros para detonar la obligación de presentar el certificado a fin de dar certeza a los usuarios.
h. Debe acompañar tanto al recurso genético como a la información derivada, de forma que se mantenga la rastreabilidad.
i. Debe haber mecanismos ágiles para que las autoridades competentes de cada país puedan tomar acciones sobre los usuarios que no cuenten con el certificado o que contravengan las obligaciones asociadas al mismo.
j. Se debe determinar si el certificado tendrá vigencia o no.
k. De acuerdo con la legislación nacional, debe contar con información suficiente que permita identificar el material, y salvaguardar aquella información que es considerada reservada o confidencial de acuerdo a legislación nacional.
l. Deberán existir mecanismos de sanciones y compensaciones en caso de cumplimiento.
m. Obtener el Certificado debe ser un instrumento obligatorio para el usuario que desee acceder a un recurso genético nacional.

10. A fin de delimitar claramente el papel que debe tener el Certificado, vale la pena también mencionar algunas características NO deseables del mismo:

    a. No debe de ser verificado o requerido en TODAS las etapas ni en TODAS las transacciones.
    b. La revisión o inspección del Certificado no equivalen a la verificación del cumplimiento con las disposiciones de acceso, el Certificado es evidencia de que se ha cumplido con los requisitos solicitados para su obtención, por lo que, en principio, las autoridades revisoras (i.e. puntos de revisión) no pueden ser verificadoras del cumplimiento, esto compete a las autoridades ambientales especializadas o a quién designe cada país.

11. En su versión más concreta, el certificado consistirá en un código electrónico estandarizado otorgado por la autoridad competente que deberá acompañar a las muestras y los subproductos derivados de los mismos, incluyendo los productos intangibles (información) derivados.

12. Las condiciones específicas del certificado, y los aspectos mínimos de su contenido, serán incluidas en un Mecanismo de facilitación de información (Clearing house-CHM) vía Internet, que podrá ser libremente consultado y en su caso verificado. Para estos elementos se requiere que haya total armonización de los formatos y asegurar no duplicar códigos. Esto se resolvería fácilmente designando los códigos desde el seno mismo de CDB, en un proceso en el que participaran todas las Partes.

13. Los puntos de revisión deberán de exigir la presentación del código del Certificado y almacenarlo en sus las bases de datos oficiales para confirmación de vigencia, autenticidad y descripción de los productos transportados y transmitirlo al CHM a quien corresponda la administración de dicha información.

14. En lo que se refiere a los requisitos para la emisión del certificado, estos dependerán de la legislación nacional vigente y podrán variar entre países Las condiciones o características de dichos requisitos incluyen aspectos tales como: consentimiento informado previo —en particular si se accede a conocimiento tradicional- y aspectos que establezcan las condiciones de distribución de beneficios derivados de ese acceso. Cabe mencionar, sin embargo, que verificar el cumplimiento sería menos costoso en la medida que los contratos sean más similares. En este sentido, se reconoce el valor de explorar la posibilidad de desarrollar y acordar contratos modelo de acceso.

15. Dado que todos los países cuentan con usuarios de recursos genéticos en diversos niveles, todos deberán implementar puntos de revisión para verificar el cumplimiento con las disposiciones de

acceso y la legal procedencia de los recursos genéticos. Una alternativa para implementar esta mecánica pudiera ser el diseño de mecanismos de revisión *global y/o regionales.*

A.3. Factibilidad, viabilidad y costos a nivel nacional e internacional

16. La principal carga *adicional* a lo dispuesto en la legislación nacional derivada del Certificado, se desprende de la necesidad de generar y mantener un registro sistematizado del mismo y transferirlo a quienes hagan un uso posterior de los recursos genéticos. Tiene por tanto, dos componentes básicos para evaluar su practicidad, viabilidad y costos: su almacenaje y su transmisión.

17. Desde el punto de vista del almacenaje, es importante notar que las demandas del certificado son una simple adición a las enormes necesidades en cuanto a capacidad de almacenamiento y herramientas de bases de datos bioinformáticas. La explosión en información biológica, genética y biología molecular asociada a las nuevas tecnologías ha detonado la búsqueda de nuevas herramientas que agilicen su manejo. En este sentido, el Certificado representa un campo adicional de información y generación de estadísticas con miras a ser incorporado en las crecientes bases de datos.
18. Adicionalmente, las bases de datos, debidamente curadas, requieren contener información básica sobre el organismo, muestra o información que mantienen. Por ejemplo, mantener información sobre la institución que proporcionó el material, la ubicación donde fue colectado del medio silvestre y los datos del responsable, entre otros. Un usuario, sea institución académica o empresa, que pueda mantener esta información sobre sus muestras, puede de igual modo ya sea mantener un registro del Certificado asociado o, alternativamente, le permitiría rastrear dicho Certificado de sus proveedores de ser necesario El registro y rastreo de las diferentes etapas que siga el recurso podría tenerse en la base de datos global.

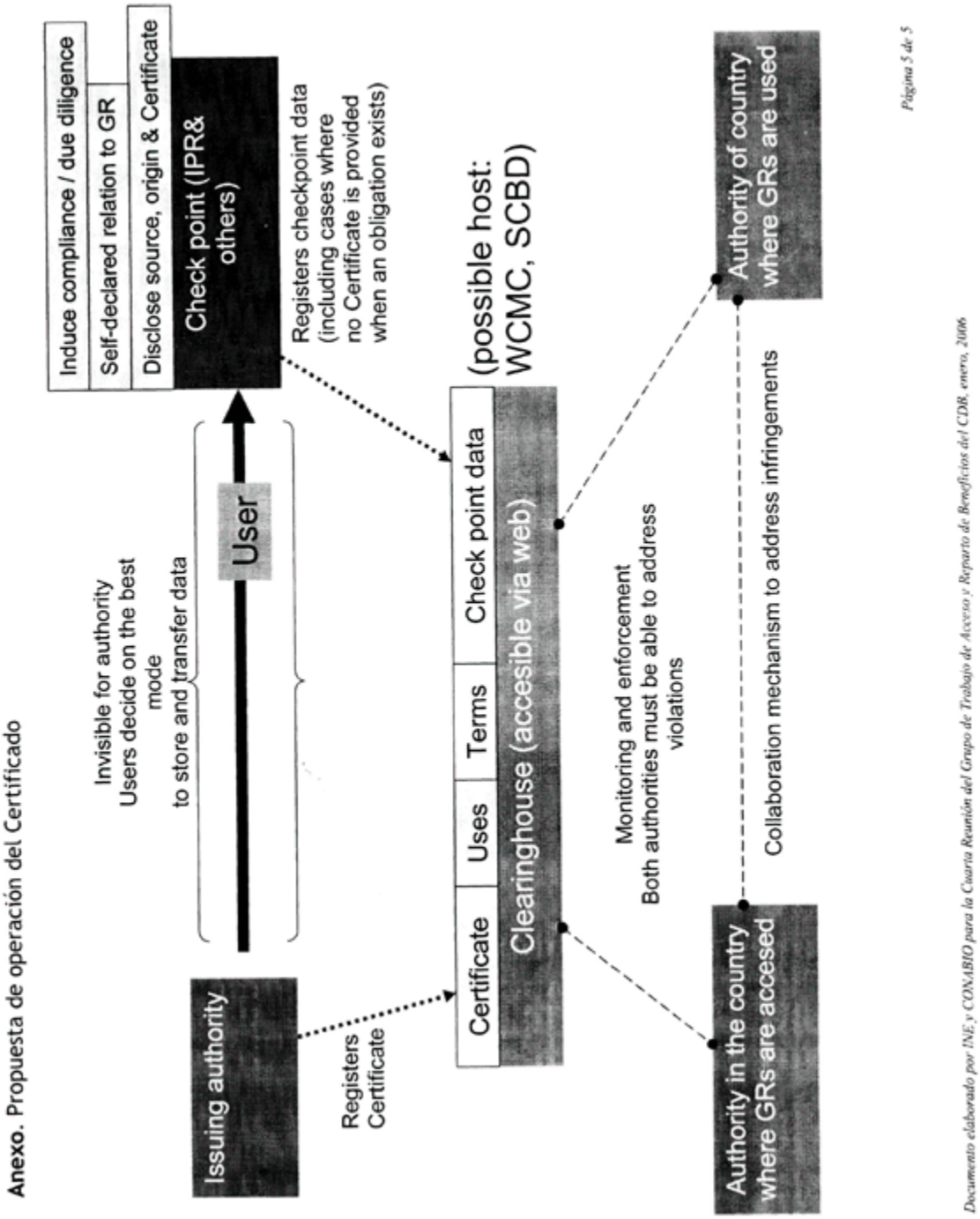
19. En cuanto a la transferencia de la información, la razón por la cual se propone un código electrónico es para facilitar que éste acompañe no sólo a muestras físicas, sino también a la información intangible; de la misma manera en como se hace referencia a la literatura en un artículo científico, reconociendo al autor. El certificado obligaría a cualquier usuario del recurso genético o de una idea derivada del mismo, a referirla adecuadamente.

20. Esta obligación a referir el Certificado requiere de criterios claros para que el usuario sepa con toda claridad cuándo tiene la obligación de mostrarlo. Sin embargo, esta transmisión, entendida así, no debiera tener complicaciones más allá de hacer un esfuerzo de comunicación con los usuarios para que estén conscientes de dicha obligación.

21. Por supuesto que el Certificado permite al receptor del material o de la información verificar las obligaciones y derechos que tiene sobre los mismos. En este sentido, el Certificado facilita al usuario el mejor conocimiento de la situación jurídica de sus activos, contribuyendo así a dar mayor claridad de una manera más ágil. Por lo anterior, el certificado contribuye a reducir, más que a aumentar costos de transacción.

22. La distribución de costos, a nivel nacional o internacional, dependerá del diseño final del Certificado. Si cada país establece sus propias autoridades de revisión y verificación, entonces el costo multilateral será reducido, siendo el costo más importante el ampliar las capacidades del Mecanismo de Facilitación de Información para albergar la base de datos de certificados.

23. Las instancias responsables de administrar un punto de revisión deberán tener acceso a las bases de datos de los Certificados.



English translation

Mexico's Proposal for an International Certificate of Origin/Source/Legal Provenance

A. Considerations for designing an international certificate of origin/source/legal provenance

1. The Certificate of legal provenance/source/origin has been the object of several discussions in expert forums, although it has not yet been analysed in detail as part of the negotiations for an international

regime. The present document includes some considerations on the matter, as input into the discussions that will take place at the next meeting of the Group of Technical Experts for an International Certificate of Origin/Source/Legal Provenance, to be held in January 2007.

A.1 Rationale, objective and need

2. Regulating access to genetic resources, from the time they are collected to the time that they are used, means regulating a process that is made up of multiple actions, involves multiple actors and tends to cover a long period of time.

3. It also means regulating a process that is inherently uncertain. In other words, there is no certainty regarding the type or scale of the outcome or benefits of a case of access.

4. An additional characteristic is that the biotechnology industry, in its pharmacological, agricultural and industrial sectors, tends to be a globalized industry, and therefore the process takes place within various social contexts and legal frameworks.

5. In the absence of a coordinated regulatory response, there is the risk of losing the ability to enforce the law, while creating a regime with high transaction costs, in which the different jurisdictions involved attempt to regulate the entire process independently.

What is the certificate of legal provenance?

6. The Certificate of Legal Provenance (CLP) is a legal instrument issued by the competent authority, which will provide evidence of compliance with the relevant existing provisions regulating access to national genetic resources, as well as with provisions – contractual or otherwise – making it possible to identify the necessary mechanisms to achieve a fair and equitable distribution of the benefits derived from the use of said resources.

7. In order for this instrument to be effective and fully meet its implementation objectives, it must be based on an internationally binding regime, so that it will be possible to track the entire research and development process, through to use of the resource (taking into account confidentiality considerations that might have an impact on or compromise elements of industrial property rights); in other words, up until the point at which it fully complies with all obligations under the CBD.

8. In this respect, the Certificate of Legal Provenance is a central component of a contract-based Regime, since it enables quick and effective coordination among jurisdictions. This coordination will result in a lighter regulatory burden and, therefore, lower transaction costs associated with the regulation of access and benefit sharing.

A.2 Desired characteristics/features:

9. Here are some of the Certificate's most important characteristics:

   a. It must be issued by a Competent National Authority. Each country may appoint more than one competent authority as relevant, depending on the various departments in each country for each group of species.
   b. It must have a simple and uniform format (define working language or languages)
   c. The format must have security features that make it possible to verify its authenticity.
   d. It must be easy to verify, disseminate or inspect, either by the environmental authority or by stakeholders.
   e. Related administrative costs must be low.

f. It must feature minimal check and/or issuance points in phases nearing the commercial application of biotechnology products, in order to encourage compliance. The check and/or issuance points may include commercial authorization processes, phytosanitary processes, customs procedures, and intellectual property rights granting processes, among others.
g. It must feature clear criteria for triggering the obligation to present the certificate in order to provide certainty to users.
h. It must accompany both the genetic resource and derived information, so that tracking is maintained.
i. There must be flexible mechanisms to allow the competent authorities of each country to take action with regard to users who do not have a certificate or who violate the associated obligations.
j. It must be determined whether the certificate will be valid or not.
k. In accordance with national legislation, it must feature enough information to make it possible to identify the material, and to protect any information considered reserved or confidential under national legislation.
l. There must be compliance-related sanction and compensation mechanisms.
m. Obtaining the Certificate must be a mandatory instrument for users wishing to gain access to a national genetic resource.

10. In order to define the Certificate's role clearly, it is also worth mentioning some characteristics that would NOT be desirable for said Certificate:

    a. It should not be verified or required at ALL steps, nor for ALL transactions.
    b. Review or inspection of the Certificate is not equivalent to verifying compliance with access provisions; the Certificate is evidence that the requested requirements for obtaining the certificate have been fulfilled. Therefore, in principle, the reviewing authorities (i.e. checkpoints) may not verify compliance, since this is the responsibility of the specialized environmental authorities designated by each country.

11. In its most concrete form, the Certificate will consist of a standardized electronic code, issued by the competent authority, which must accompany the specimens and their derivative sub-products, including intangible derivatives (information).

12. The specific conditions of the certificate, and the minimum aspects of its content, shall be included in a Clearing House Mechanism (CHM) on the Internet, which will be freely accessible and verifiable as needed. This will require full harmonization of formats and it will be necessary to make sure that codes are not duplicated. This could be resolved easily by assigning codes directly from within the CBD, through a process in which all Parties would participate.

13. The checkpoints must require that the Certificate's code be presented, and saved in their official database to confirm the certificate's validity, authenticity and the description of the transported products. The code must also be transmitted to the CHM, to the person in charge of administering said information.

14. With regard to the prerequisites for issuing the certificate, this will depend on national legislation in effect, and may vary from one country to another. The conditions or characteristics of said prerequisites include aspects such as: prior informed consent – in particular for access to traditional knowledge – and aspects that establish the conditions for the sharing of benefits derived from said access. It is worth mentioning, however, that verifying compliance will be less expensive to the extent that contracts are similar. In this respect, there is admittedly value in exploring the possibility of developing and agreeing on model access contracts.

15. Seeing as all countries have users of genetic resources at various levels, all countries must implement checkpoints to verify compliance with the provisions on access, and the legal provenance of genetic resources. An alternative for implementing this mechanism would be to design both *global and/or regional* review mechanisms.

A.3. Practicality, feasibility and costs at the national and international level

16. The main burden, *in addition* to certificate-related provisions in national legislation, arises from the need to generate and maintain a systematized record of the certificate, and to transfer this record to those who use the genetic resources at a later date. There are therefore two basic components involved in assessing the certificate's practicality, viability and costs: storage and transmission.

17. From the point of view of storage, it is important to note that the demands linked to the certificate are a simple addition to the vast needs with regard to biocomputing storage and database tools. The biological, genetic and molecular biology information explosion associated with new technologies has triggered the search for new tools to make handling all of this information easier. In this respect, the Certificate represents an additional field of information and statistics generation to be incorporated into growing databases.

18. Furthermore, properly managed databases must contain basic information on the organism, specimen or information maintained. Examples include maintaining information on the institution that provided the material, the location where it was collected from the wild, and the contact information of the person in charge, among other information. A user, be it an academic institution or a company, that can maintain this information on its specimens, can also maintain a record of the associated Certificate or, alternatively, will be able to track said Certificate for its suppliers, if necessary. The record and tracking of the various steps of the resource's itinerary could be kept in the global database.

19. With regard to the transfer of information, the reason for proposing an electronic code is to make it easier for the code to accompany not only physical specimens, but also intangible information, much in the same manner as reference is made to the author when citing the literature in a scientific article. The certificate will oblige any user of the genetic resource, or of a derivative idea, to cite the proper reference.

20. This obligation to cite the Certificate requires clear criteria, so that the user will know, with complete certainty, when he or she is under the obligation to show the Certificate. However, this transmission, as such, must not be more complicated than making an effort to contact the users so that they are aware of said obligation.

21. Of course, the Certificate allows the receiver of the material or of the information to verify the obligations and rights that he or she has over them. In this respect, the Certificate provides users with a better understanding of the legal situation of their assets, thus helping to provide greater clarification more quickly. The certificate therefore contributes to lessening transaction costs, rather than increasing them.

22. The cost breakdown, at the national or international level, will depend on the Certificate's final design. If each country establishes its own review and verification authorities, the multilateral cost will be reduced, with the highest cost being that of building the capacity of the Clearing House Mechanism to house the certificate-related database.

23. The bodies responsible for administering a checkpoint must have access to the Certificate database.

Annex. Proposal on how the Certificate should work
(follows the Spanish language submission, see page 14 above)

NEW ZEALAND [ORIGINAL: ENGLISH]

New Zealand does not operate a certification regime in support of domestic policy on access to genetic resources, or the sharing of benefits from that access. In the further development of a domestic regime, however, certification is an issue that could be considered. Key considerations in such a decision would be practicality, and extent to which it provides benefits, and cost-effectiveness.

Purpose:

New Zealand considers that the most compelling rationale for a certification system should be to promote compliance with national ABS regimes, specifically PIC and MAT.

Taking this a step further, it is important that consideration of a certification system not close off consideration of other measures for inclusion in the international regime, such as the mutual recognition of national ABS regimes. Other measures may prove equally or more useful in ensuring compliance with national ABS regimes.

Principles:

New Zealand is of the view that the following principles should be considered in determining the practicality, feasibility and costs and benefits of certificates:

- Certificates should not substitute the need for states to implement national ABS regimes. For instance, national ABS regimes are best placed to determine conditions on access to genetic resources relating to:
    - benefit-sharing
    - the transfer of genetic material to third-parties
    - the exchange of information about genetic resources
    - the export of genetic material
    - the treatment of derivatives
    - intellectual property rights
    - traditional knowledge
    - environmental impacts of collection
- Certificates must be sufficiently flexible to accommodate a range of different models for national ABS regimes.
- Any obligations under the certification regime must be able to be implemented in a simple fashion, to prevent exploitation of countries with limited capacity to implement, and enforce, a certification regime. Providing for flexibility is one way to achieve this.
- Compliance costs should be kept to a minimum so as not to discourage research by creating financial disincentives through high compliance costs for certification.

Practical considerations:

New Zealand is of the view that there are many factors that affect desirability of implementing a certification system. In particular, New Zealand would like the following practical considerations to be examined:

- The practical consequences of certificates of origin, source or legal provenance. Origin may prove a challenging aspect to certify, particularly with regard to ubiquitous, introduced and migrant populations, and situations where origin is not established or in dispute. Source appears to be a much more practical basis for certification, unless these questions can be resolved in a simple fashion.

- To what extent does the effectiveness of a certification system depend on certificates being produced to verify disclosure of origin in IPR applications? If disclosure for IPR applications is not introduced what are the implications for the working of a certification system? For instance, when would checks then take place? Who would be responsible? What incentives would there be for complying with a domestic ABS regime? Would a certification system still be useful?

- When would the certificate be issued? Obvious options are at the time access is granted, or when material is collected. But certificates could also be issued when genetic resources are to be taken out of the country, or when IPRs are applied for.

- How would a certification system deal with non-commercial research, and its relationship to commercial research? What about situations where non-commercial research later results in commercialisable discoveries?

- How would a certification system ensure the continued approval and involvement of traditional knowledge holders in accordance with national legislation, and in particular after access to the material? For instance in situations where mutually agreed terms around traditional knowledge prohibited some uses as offensive to the knowledge holders?

NORWAY [ORIGINAL ENGLISH]

The Bonn Guidelines encourages countries *inter alia* to consider voluntary certification schemes for institutions. Within the context of the international regime, multilateral mechanisms could be developed such as an internationally recognised certificate of origin. This could be a certificate accompanying the genetic resources from the collection phase until their commercialisation, as a measure to increase transparency, traceability and predictability.

Important features of an internationally recognised certificate:

- It should encourage benefit sharing, and strive to reduce bureaucratic burden both for users and providers
- To be issued nationally according to internationally agreed features under the CBD. It could be voluntary or subject to national legislation
- To be complementary and without prejudice to other nationally and internationally recognised certificates, such as the standard Material Agreement under the International Treaty on Plant Genetic Resources for Food and Agriculture
- Taking into account the origin of traditional knowledge

Moreover, a certificate of origin could have a role to play in the patent application process. For those countries which have introduced disclosure of origin requirements and PIC requirements in patent applications related to genetic resources, a certificate could make it easier to enforce the disclosure requirements. The patent application would then serve as a checkpoint to verify whether such a certificate exists.

The clearing-house mechanism (CHM) could have a role as receiver of notifications of disclosure of origin in patent applications and unique identifiers of genetic resources under a system for international certificates of origin/legal provenance.

In Norway, draft legislation on access to genetic resources was presented by an expert committee in December 2004. This proposal is still subject to changes. The draft legislation contains provisions to ensure that collection and utilisation of genetic material from other countries is carried out in accordance with the provisions of the CBD and national legislation in countries of origin/providing countries when used in Norway. It would be possible to enforce the requirement for prior informed consent in Norway through checkpoints in the research process and when used for commercial purposes. A certificate of origin would make it easier to enforce this requirement. The government will present a legislative proposal on access to genetic resources to the Parliament by the end of 2007.

We believe that the concept of an international certificate of origin should be further developed within the concept of the international regime.

II. SUBMISSIONS FROM NON-PARTIES

UNITED STATES OF AMERICA [ORIGINAL: ENGLISH]

The United States appreciates the opportunity to participate in the discussions on the possible options for the form, intent and functioning of international certificates of origin/source/legal provenance. The United States would like to submit the following issues for consideration by the group of technical experts.

Regarding the practicality and feasibility of an international certificate:

(a) The United States encourages the panel of technical experts to focus on the implications of a system of certificates for the practice of science, and assess if the model of certificates actually can be effectively used in the many areas of utilization of genetic resources—(e.g. taxonomy and systematics, conservation science, ecology, agricultural research, and new products research.) The panel might then identify explicitly the objective, scope, and goals of a system of international certificates to facilitate both access and the sharing of benefits from the utilization of genetic resources. What types of genetic resources will require certificates and for what purpose?

(b) The United States believes a clear identification of the objective, scope, and goals of an international certificates system should precede any consideration of the design of such a system;

(c) The United States underscores the need for an objective, fact-based assessment of the full costs and benefits associated with any proposed certificates system to ascertain if a system can be developed such that the costs of the system will not outweigh the benefits for most countries. This includes an analysis of: the volume of materials which will fall under this system; a life-cycle analysis of specimens and certificates; models for developing e-certificates and the legal impediments to adopting this in individual countries; and personnel and systems needs for both users and providers to implement and maintain the system;

(d) Further, we encourage the panel to look beyond existing regulatory models.

Regarding the possible options for the form, intent and functioning of an international certificate of origin/source/legal provenance:

(a) The United States believes there is a need to make a clear distinction between a certificate, a tool for traceability and possibly enforcement, and the process of certification, a process of certifying that an institution or field operation is complying with an agreed set of standards for accessing and using genetic resources. Certification, by definition, requires a mechanism for tracking the chain-of-

custody of the resource or materials. Introducing a certificate does not necessarily imply that one is aiming for a certification system;

(b) In considering the form and functioning of international certificates, the United States believes it is important to note that genetic resources are broadly defined and take many forms. The panel of experts should consider whether a possible certificate would be linked to a product or to a process;

(c) Further, any possible certificate should foster innovation, research and encourage trade, use, and the sharing of benefits arising out of the utilization of genetic resources.

III. SUBMISSIONS FROM RELEVANT ORGANIZATIONS AND STAKEHOLDERS

THE WORLD CONSERVATION UNION, ENVIRONMENTAL LAW CENTRE (IUCN-ELC)

[ORIGINAL: ENGLISH]

IUCN, together with its partners, has undertaken substantial research on this issue. The latest results of this work are currently being compiled in a publication IUCN's Environmental Law Centre, which analyses the complex of tracking and tracing of the use, movement and transfer of genetic resources.

Chapter 4 of the book, in particular, will provide an extensive analysis of the legal and practical prerequisites for the development of a certificate of source, origin or legal provenance for the CBD. The book is going to be published by the end of this year. However, pre-publication versions of several chapters may be made available to the Secretariat earlier.

The details and table of contents are provided below.

"A Moving Target: Genetic Resources and Options for Tracking and Tracing their International Flows"

Manuel Ruiz and Isabel Lapena (Editors and Lead Authors)

The ABS Series (a sub-series of *IUCN Environmental Policy and Law Papers*)

Book 3

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Final remarks

THE BRITISH PHARMA GROUP (BPG)

[ORIGINAL: ENGLISH]

Introduction

There are many different types of genetic resources (GR)s used by many different types of industries for many different purposes. Consideration of whether there should be a certification scheme and, if so, what it should be, must take account of this reality. Any benefits of a certification scheme must be weighed against the practical impact of such a scheme on the real world use of GRs.

The British Pharma Group (BPG) is the trade association representing the interests of the UK-owned R&D based pharmaceutical companies, AstraZeneca and GlaxoSmithKline. We have a particular interest in the access and benefit sharing policy developments associated with the CBD. We therefore welcome the creation of an Expert Group to consider what role a Certification Scheme might play in the International ABS Regime under discussion within the CBD. We look forward to participating in these discussions as they progress.

Genetic Resources (GRs)

GRs are sometimes uniquely *available* from certain countries only; sometimes they are widely available commodities or staple commercial products.

GRs are *acquired* by many different groups ranging from those whose sole interest is trade, to industrial users, to academic institutions, to conservation bodies etc.

GRs 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 other purposes, as elements of production processes such as foodstuffs.

There are many different types of *downstream* products which are *derived* from GRs ranging from pharmaceuticals through cosmetics through bread and wine. Sometimes the link between the "downstream" product (for example, bread or wine) is far closer than for other products. Sometimes the downstream product may contain no GRs or indeed biological materials.

The value-creation chain from GR to final product can therefore involve a number of diverse steps and players; and there may be numerous transactions from GR to consumer. Many of the steps and players are invisible to third parties and, indeed, invisible to others participating in the value-creation and trading chain.

The number of transactions involving GRs – including legal transactions (trading) and functional transactions (use) – runs into many millions per day, every day. If derivatives (however defined) are included, the numbers of legal and functional transactions are multiplied. Indeed, every time a loaf of bread or bottle of wine is purchased, a legal transaction occurs using a derivative of a GR.

Many transactions will be at cost or free of charge (e.g. MTAs between academics, and indeed often between commercial entities, commonly involve no payment) so consideration needs to be given to how a global certification scheme will impact such transactions.

Given these realities, a detailed cost/benefit analysis of any certification scheme must be undertaken. Such an analysis is inherently required by the COP-8 decision of March 2006 to establish an Expert group "without prejudging [the] desirability of the options for a certification scheme". The BPG welcomes this approach and we hope that the following considerations will prove of value to the Group in their deliberations.

Objective of the Scheme

- 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 for doing so?

Scope of the Scheme

- To what materials will the scheme apply? Will it apply to all GRs? For example, will plants sold in nurseries or live herbs sold in supermarkets be within the scheme?
- Will human GRs be excluded? Will non-human GRs 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 a GR, included? If not, on what grounds will they be distinguished from products which are to be included. Definitions of what will and will not fall within any scheme must be clear in practical terms to providers and users.
- 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 GR/covered derivatives changes? Is it to apply to particular functional events, such as changes to the genetic or other characteristics of the GR? Where the GR is propagated or reproduced, will, and if so how, the scheme apply to the units which are the result of the propagation or reproduction?

Certification Criteria

- What will be certified? Countries of source or origin? 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?
- What scrutiny will there have to be of any certification?

Application of the Scheme

- Will the scheme apply to GRs acquired before the CBD came into force? If so, how will it apply to GRs acquired before CBD came into force but which are traded or developed thereafter?
- Will (and if so how will) the scheme apply to GRs acquired from or originating in a country which is not a CBD member but which is processed and or traded in a CBD member?
- Where a GR is modified into another GR which is then modified into a 3rd GR will certification be needed in relation to each form of the GR?
- Will the scheme apply to GRs acquired after the CBD came into force but before the new scheme is implemented? If so, how will it apply to GRs acquired before the new scheme is implemented but which are traded or developed thereafter?
- How will the scheme apply to GRs obtained from countries whose laws do not regulate access to GRs.
- 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? What will be the impact in terms of the effectiveness of the scheme of it not applying to some major countries?
- Will the scheme only apply to dealings with the physical GRs, or is it intended to apply to publications or other transfers of knowledge about the GRs?

Legal Effects of the Scheme

- What will be the legal effect of a certificate?
- What will be the legal effect of not having a certificate? Will any sanctions be punitive or compensatory? Will the nature and level of sanctions be internationally mandated or will this be left to national discretion?

- What will be the nature and extent of obligations of those in the transaction chain to conduct due diligence as to the need or otherwise of a certificate. In this regard, as elsewhere, it should be borne in mind that many staple commercial products in conventional trading channels may have been derived in some way from or using a GR but that will not and cannot be known by the purchaser.

Operational Issues

- 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 GR or any derivatives covered by a scheme?

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?
- To what extent will the scheme impact trade in and use of GRs and their derivatives (including derivatives which are not themselves covered by the scheme)? If such trade will be hindered (due, for example, to the scheme over-regulating trade or development activity or causing unacceptable uncertainty for users of GRs), 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 the scheme facilitate access to GRs for environmentally sound uses or will it impose restrictions that run counter to the objectives, including benefit sharing, of the CBD?
- What mechanisms should there be to monitor the effect of any scheme and adapt it as appropriate?

THE EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES AND ASSOCIATIONS (EFPIA) [ORIGINAL: ENGLISH]

Background

The eighth Conference of the Parties to the Convention on Biological Diversity decided to establish a group of technical experts with the following overall brief:

"to explore and elaborate possible options, without prejudging their desirability, for the form, intent and functioning of an internationally recognised certificate of origin/source/legal provenance and analyse its practicality, feasibility, costs and benefits, with a view to achieving the objectives of Articles 15 and 8(j) of the Convention".

Certification is viewed by the Parties to the Convention as one possible means of achieving the objectives of the Convention in relation to Access and Benefit-Sharing. The concept itself was first proposed in 1994, effectively before the impact of the Convention had been felt. The reference to the articles determines that the remit of the Group extends to ABS in relation to genetic resources and to the customs, knowledge and cultural expressions of indigenous people. The Group has been asked to report back to the Ad Hoc Open-ended Working Group on Access and Benefit-sharing. The Ad-Hoc group has been in existence since 2000 and is responsible for the elaboration and negotiation of an International Regime on Access and Benefit-sharing. The Ad-Hoc Group has been asked to finaliz work on the regime

before the 10th Conference of the Parties in 2010. The work of the Expert Group will assist the AD-Hoc Group in determining the role that certification should play in the International Regime.

Addressing the remit

There are some significant challenges in the remit of the Expert Group. One challenge will lie in the area of **expert input**. The bulk of the members of the Expert Group will be nominated by governments. This will guarantee a high level of expertise regarding the implementation of legislation and the difficult issue of achieving the right balance in any proposal between actions at national and international level. However, this regulatory and legal expertise can contribute less to questions of practicality and feasibility without the input of users. There is a risk that the Group will lack input from those who will be impacted by the system, users of genetic resources. EU industries likely to be affected by any proposal include cosmetics, seeds, natural medicines, horticulture and pharmaceuticals. In addition to industry, academic researchers and others will also need to contribute. It is important that the Group has access to expertise from these industries on a sustained basis outside of formal consultation exercises in order to enable it to assess practicality and feasibility. EFPIA would welcome proposals from the EU and other delegations to establish continuous contact processes with affected industries and other stakeholders. We encourage delegations to share their plans in this respect within the Expert Group.

A second challenge is that the remit does not expressly reflect the overarching objectives of the International Regime of which a certification system may form a part. Particular attention should be paid to the view of the COP that *the regime should be practicable, transparent, and efficient and avoid arbitrary treatment, consistent with the provisions of the Convention,*

Transparency and avoidance of arbitrary treatment are intimately connected. The Regime must both respect national and cultural sovereignty and be based on rules which are readily intelligible to all actual or potential users. EFPIA urges the Expert Group to make a thorough inventory of existing experience among the members of the Group and to examine the extent to which existing regimes have met the expectations of regulators and users.

Transparency is also an important desideratum in international trading rules. To the extent that the Expert Group is discussing trade in materials, there are obvious trade policy implications from any failure to secure transparency. To this extent, the Group should ensure it has the relevant expertise available to elaborate how the system would be treated for the purposes of trade policy, including the resolution of disputes.

Third, the remit of the Expert Group is to provide technical input to the Ad Hoc Open Ended Working Group on Access and Benefit Sharing. Implicitly, therefore, its work should take into account the **underlying rationale** of the International Regime being considered by that Group. In this respect, it is important to note the evolution that has taken place in understanding of the issues faced by the CBD and that this is likely to affect the direction of debate on the International Regime.

The impetus to create the regime came in part from the concern that some developing countries might be resource-constrained in their ability to police ABS effectively and the associated concern that without an international element, policing would be impossible because users and providers are often based in different national jurisdictions. These original ideas have been progressively overshadowed politically by concerns about the need to prevent “rampant biopiracy”. However, as substantive analysis continues to confirm that biopiracy is not as prevalent as some believe and consensus grows that the initial wave of post-CBD regulation had effects contrary to the objectives of the convention, it becomes important to critically evaluate whether and how certification, as an element of any international regime, can address the initial and more substantive concerns. The tension between the scope and ambition of any certification system and its feasibility of practical implementation is a key matter for the Group. Further,

whatever contribution to the goals of CBD may be made by the International Regime, its foundations unavoidably rest on effective national systems in countries of origin.

Fourth, the Expert Group will have to work within the familiar constraints of the CBD working groups that there is no **consensus** on the legal meaning of some of the concepts that will underpin the Group's work. Nor is the overall scope of the regime clear (for example, how will pre-CBD acquisitions be treated and how should it deal with derivatives) This work of clarification will continue at national and international level in parallel with the work of the Expert Group, but it is clear that the conclusions reached will significantly influence the work of the Group. By addressing initial questions such as "what should be certified", the Expert Group will, in its turn, have to engage in examination of the fundamentals of the Regime. For EFPIA, it is unclear that the work of the Group can proceed beyond the development of comparative models of certification under different circumstances until there is greater clarity of these underlying issues.

Certification and value

The comments above deal with the organization of the work of the expert group. Consideration of the substance of the Group's remit reveals a series of complex and interlocking factors. EFPIA encourages the Expert Group to recall that the overarching definition of the components of the International Regime remains extremely broad and includes concepts of voluntary participation as well as mandatory systems. The nature of the certification system is no more pre-determined than any other element of the International Regime. In this situation where the possible parameters of discussion are almost unlimited, and in addition to specific proposals made above, EFPIA considers that the best underlying guide to the Expert Group's deliberations to consider purpose. Without pre-judging the conclusions that the Group might draw, the following are suggested as pointers to the boundaries of discussion.

Any system should promote the responsible use of genetic resources. This suggests that as well as examining the feasibility of different models of certification, the Expert Group must address the ability of a certification system to meet this objective in a way that reflects the realities of the growth of commercially-driven knowledge creation and use in relevant industrial sectors. In particular, the Group will have to consider the following:

- **Derivation.** Most commercial products derive from thousands of inputs, whether we speak in terms of knowledge or physical inputs. Biodiversity-relevant resources that have a one-to-one relationship with a final product are rare.

- **Branding** Where 'pure' products exist, they are normally sold as "natural" products and, in complete contradiction to the idea of biopiracy, their origin is an intrinsic part of the way they are marketed.

- **Volume.** The number of transactions involving genetic resources must run into the millions per day, particularly if "derivatives" are included. Few are traded as knowledge-based goods.

- **Public domain.** Thought will also have to be given to the way that knowledge functions within the global economy. The global model of development of knowledge is driven by publication and subsequent free circulation. Knowledge that has been proprietary becomes public, thus stimulating further research. It is undesirable to police this growth in the public domain.

- **Limits of certification.** The function of a traditional knowledge certificate is a case in point. A certificate can only record a sub-set of a body of indigenous knowledge while the commercial user of that knowledge is likely to draw inferences from it never considered by its original holders. The certificate will never contain the totality of the originator's knowledge nor can it encompass the

scientific enquiries that a researcher may derive from it. It is unrealistic to imagine that such a certificate can realistically serve as a retrospective basis for attributing value in any formulaic way. It seems clear that a certificate can only be a record.

- **Alternative models.** The heavy emphasis that has been placed in the debate on establishing equitable benefit-sharing in final products stands in contradiction to industrial experience of developing industry priorities. Whether the Expert Group considers emerging industries such as biotech or emerging industrial sectors in developing countries, it is likely to see that the priority for these industries is current investment for growth not the promise of rewards from the sale of future products. The latter is a more relevant model when critical mass and significant capacity for value-added have been achieved through the emergence of a national industrial or research base. For many developing countries, the critical priority is to be able to establish positive models of national legislation and support the legislative model with funding to move their scientific capabilities up the value chain. To the extent that weight is attached to certification in policy objectives, it may be to the detriment of what can be achieved through a more flexible negotiating framework in which specific goals can be discussed. Industrial experience suggests that development policy and the allocation of funds to biodiversity are enhanced through greater focus on the point of direct interaction between partners in a research initiative rather than their respective downstream activities.

- **Sectoral carve-outs.** Many commentators on certification have attempted to create a differentiation between commercial and non-commercial research, primarily with the objective of creating a reduced level of regulation for non-commercial research. The Expert Group will need to examine whether this is realistic, given the extensive and productive interactions between the two domains. The same point about activities that can be carved out may need to be made in relation to certain industrial products that are usually thought of as commodities.

Conclusions

EFPIA intends to support the work of the Expert Group. The success of the Group will depend on the extent to which it maintain the breadth of perspective contained in its remit and the extent to which it is able to reach out beyond the immediate membership of the Group.

INTERNATIONAL CHAMBER OF COMMERCE (ICC)

[ORIGINAL: ENGLISH]

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 preempt 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.

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 focusing 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.

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 Expert 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-regulatingtrade 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

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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.

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.
Document n° 450/1020
15 September 2006

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?

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA [ORIGINAL: ENGLISH]

Members of the Pharmaceutical Research and Manufacturers of America (PhRMA) welcome the opportunity to provide comments and views on the consideration of an international certificate of origin/source/legal provenance. PhRMA represents the leading pharmaceutical research and biotechnology companies of the United States. PhRMA members are committed to the research and development of medicines that enable patients around the world to live longer, healthier and more productive lives.

As noted in decision VIII/4, a group of technical experts will be established "to explore and elaborate possible options, without prejudging their desirability, for the form, intent and functioning of an internationally recognized certificate of origin/source/legal provenance and analyse its practicality, feasibility, costs and benefits, with a view to achieving the objectives of Articles 15 and 8(j) of the Convention."

It is certain that several issues will need to be considered by the experts committee as they determine the desirability, practicality and feasibility of a certificates system. Some of these issues are discussed below.

One of the first considerations for a certificate system is revealed in its description. That is, will the certificate relate to the "origin" or "source" of a genetic resource, or will it serve as an indicator of "legal provenance"? "Source" generally refers to the "country providing genetic resources", defined in the Convention on Biological Diversity (CBD) as the country supplying genetic resources, including *ex situ* sources from which the genetic resource did not originate. In contrast, "origin" refers to the "country of origin of genetic resources" which is the country in which the genetic resource is found in *in situ* conditions. It is not clear to what a certificate of legal provenance would attach or how that is to be defined.

If the certificate will be used to identify the country of origin, the expert group will need to consider who is responsible for accurately determining the country of origin of a particular genetic resource – a new implementation body within the CBD, the national focal point within the country of origin, or the party wishing to acquire the genetic resource.

As the expert group will be aware, many genetic resources have been transported from their country of origin hundreds, or perhaps thousands, of years ago either through natural means or via human intervention. Thus, in many instances, it may not be possible to identify a single country of origin for particular genetic resource. In such instances, will parties wishing to acquire a genetic resource be requires to apply for a certificate only from the country providing the genetic resource or from every country in which that resource is now found *in situ*?

Many species of genetic resources may also have acquired distinctive characteristics in a provider country that were not found in the species in its country of origin. In such instances, if a party wishes to acquire genetic resources from a provider country in which those resources offer some distinct characteristic, will the acquirer also be required to obtain a certificate from the country of origin, or form every country in which the genetic resources are found or to which they may have been transported over time?

The Conference of the Parties has previously affirmed that certain genetic resources are not included within the framework of the Convention. For example, Article 15 of the Convention refers specifically to "genetic resources", which are defined as "material of plant, animal, microbial or other origin containing functional units of heredity". In addition, human genetic resources fall outside the scope of the CBD, as reaffirmed in decision II/11. Thus, Parties must clarify whether the scope of a certificates regime will coincide with the scope of the CBD, which is limited *to non-human genetic resources.*

If the scope of a possible certificates system is maintained in concert with the scope of the CBD, materials such as chemical substances extracted from plants, including essential oils, wine and other foodstuffs would not be encompassed. Such materials are available commercially, and evidence suggests there are no restrictions on their sale (see for example, the comments of the Government of Peru in WIPO/GRTKF/IC/5/13, which indicate that *Lepidium meyenii* is actively traded by Peruvian exporters, in full recognition of the Government). However, the use of these commodities in trade is often criticized as "biopiracy" or "misappropriation". In this context the expert group will need to consider how such a broad certificates system, applied in a non-discriminatory manner, would have a significant impact on trade of goods and foodstuffs.

The more comprehensive the envisioned certificates system is, the more likely the cost of the system will significantly increase, and its practicality and feasibility will significantly decrease. Many genetic resources are the subject of purely academic or taxonomic research. Will acquisition of such genetic resources for the purpose of knowledge-sharing be negatively impacted? It is also not clear which parties will bear the costs associated with such a certificates system. Will each member State have the resources to implement a certificates system for genetic resources (or biological materials) found within its borders?

The expert group must also consider the legal effects of a certificate. Who will be authorized to issue certificates and on what bases? Will biological materials, such as chemical extracts and essential oils, be freely useable without a certificate? What will be the sanction for use of a non-certified genetic resource (or biological material)?

PhRMA hopes that the expert group on certificates will take into consideration these and other concerns as it attempts to determine whether a certificates system is necessary and feasible. We welcome the opportunity to provide our assistance to the expert group and the Secretariat.
