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AD HOC OPEN-ENDED WORKING GROUP ON
ACCESS AND BENEFIT-SHARING
Sixth meeting
Geneva, 21-25 January 2008
Item 3 of the provisional agenda*

COMPILATION OF SUBMISSIONS PROVIDED BY PARTIES, GOVERNMENTS, INDIGENOUS AND LOCAL COMMUNITIES AND STAKEHOLDERS ON CONCRETE OPTIONS ON SUBSTANTIVE ITEMS ON THE AGENDA OF THE FIFTH AND SIXTH MEETINGS OF THE AD HOC OPEN-ENDED WORKING GROUP ON ACCESS AND BENEFIT-SHARING

Note by the Executive Secretary

INTRODUCTION

1. At its fifth meeting, the Ad Hoc Open-ended Working Group on Access and Benefit-sharing invited Parties, Governments, indigenous and local communities and stakeholders to submit by 30 November 2007, concrete options on the substantive items on the agenda of the fifth and sixth meetings of the Working Group and requested the Secretariat to circulate a compilation of those options as soon as practicable prior to the sixth meeting of the Working Group.

2. In light of the above, notification 2007-132 dated 26 October 2005 was sent out to Parties, Governments, indigenous and local communities and stakeholders and a reminder (notification 2007-152) was sent out on 23 November 2007.

3. This compilation contains submissions received by the Secretariat as of 12 December 2008. They have been reproduced in the form and language in which they were received. In addition, contributions provided in a language other than English have been translated into English.

* UNEP/CBD/WG-ABS/6/1.

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CONVENIO DE DIVERSIDAD BIOLÓGICA
GRUPO DE TRABAJO ESPECIAL DE COMPOSICIÓN ABIERTA SOBRE ACCESO Y DISTRIBUCIÓN DE BENEFICIOS

NOTIFICACIÓN SCBD/SEL/VN/GD/60541

INTERNATIONAL REGIME ON ACCESS AND BENEFIT-SHARING

In accordance with the Convention on Biological Diversity,

Objectives

a) To ensure the effective implementation of the CDB provisions regarding the fair and equitable sharing of the benefits arising out of the utilization of genetic resources.

b) To prevent the misappropriation and misuse of genetic resources, their derivatives and associated traditional knowledge, innovations and practices.

c) To support compliance of national legislations on access and benefit sharing of the Contracting Party providing genetic resources, including countries of origin, in Contracting Parties with users of such resources under their jurisdiction.

d) To ensure that patents or any other intellectual property rights, subject to national legislation and international law, are supportive of and do not run counter the effective implementation of this international regime.

e) To respect the rights of indigenous and local communities over the traditional knowledge, innovations and practices associated to genetic material subject to access and benefit sharing legislation.

f) To contribute to the conservation and sustainable use of biological diversity;

Scope

All genetic resources, their derivatives and associated traditional knowledge, innovations and practices covered by the Convention on Biological Diversity and benefits arising from the commercial and other utilization of such resources should be covered by the guidelines, with the exclusion of human genetic resources.

Benefit-sharing

a) Benefits arising out of the use of genetic resources and their derivatives should be directed in such a way as to promote conservation and sustainable use of biological diversity in their countries of origin.

b) Benefit sharing includes monetary and non-monetary benefits.

c) Minimum conditions and standards for the fair and equitable sharing of the benefits arising out of the use of genetic resources, derivatives and associated traditional knowledge shall be stipulated in national legislations and be based on prior informed consent and mutually agreed terms.

d) Mutually agreed terms must cover the conditions, obligations, procedures, types, timing, distribution and mechanisms of benefits to be shared.

e) Parties should consider near-term, medium-term and long-term benefits, including up-front payments, milestone payments and royalties.

f) Benefits should be shared fairly and equitably with all those who have been identified as having contributed to the resource conservation and management. The latter may include governmental, non-governmental or academic institutions and indigenous and local communities.

g) The user country of genetic resources must take measures with the aim of sharing results of research and development with the country of origin.

h) The user country of genetic resources must take measures with the aim of sharing the benefits arising from genetic resource utilization with the country of origin.

i) The user country of genetic resources must provide the country of origin, with access to and transfer of technology which makes use of its genetic resources, under fair and most favourable terms, including on concessional and preferential terms where mutually agreed and where necessary.

j) Access to and technology transfer must also support the generation of social, economic and environmental benefits in the country of origin of the genetic resources accessed and used.

k) The user country shall establish national legislation to facilitate access to joint development and transfer of those technologies to the country of origin of such resources, derivatives and associated traditional knowledge under mutually agreed terms.

Access

a) Parties have sovereign rights over their own genetic resources and derivatives and the authority to determine access rest with national governments and is subject to national legislation.

b) Access to genetic resources and their derivatives shall be subject to the prior informed consent of the country of origin, in accordance with its national legislation.

c) Prior informed consent is linked to the requirement of mutually agreed terms.

d) Permission to access genetic resources does not necessarily imply permission to use associated knowledge and vice versa.

e) Encourage Parties for the adoption of clear, simple and transparent access procedures, in order to provide legal certainty to different kinds of users and providers of genetic resources for the effective implementation of article 15 of the CBD.

f) Parties that are not countries of origin of genetic resources or their derivatives they hold shall not give access to those genetic resources without the prior informed consent of the countries of origin of those resources.

g) Where the country of origin cannot be identified, the Party in whose territory those genetic resources or derivatives are located in ex situ conditions will grant access to users on behalf of the international community, and the benefits arising out of their use will be directed towards conservation and sustainable use programs approved by the Conference of the Parties.

h) Mutually agreed terms for access to and specific uses of genetic resources or derivatives may include conditions for transfer of such genetic resources or derivatives to third parties, subject to national legislation of countries of origin.

i) Parties must only use genetic resources, their derivatives or associated traditional knowledge for purposes consistent with the terms and conditions under which they were acquired.

j) User countries must ensure that uses of genetic resources, their derivatives for purposes other than those for with they were acquired, only take place after new prior informed consent of the country of origin and mutually agreed terms are given.

k) User countries must ensure that uses of associated traditional knowledge for purposes other than those for with they were acquired, only take place after new prior informed consent of the indigenous or local community and mutually agreed terms are given.

l) Parties must only supply genetic resources, their derivatives and/or associated traditional knowledge when they are entitled to do so.

m) User countries of genetic resources should take appropriate legal, administrative, or policy measures to ensure the compliance with prior informed consent of the Party providing such resources and mutually agreed terms on which access was granted.

n) User countries of genetic resources should adopt mechanisms to prevent the use of genetic resources obtained without the prior informed consent of the country of origin.

o) User countries of genetic resources, their derivatives or associated traditional knowledge must adopt measures to encourage the disclosure of the country of origin of the genetic resources and associated traditional knowledge in applications for intellectual property rights.

Associated traditional knowledge

a) Access and benefit sharing arrangements relating to associated traditional knowledge should be regulated according to national legislations.

b) Parties should recognize and respect the rights of indigenous and local communities regarding their associated traditional knowledge, innovations and practices.

c) Parties must obtain the prior approval and involvement of indigenous and local communities before the access and use of their associated traditional knowledge, innovations and practices.

d) Indigenous and local communities have the right to participate in the fair and equitable sharing of benefits arising out of the use of their associated traditional knowledge, innovations and practices.

e) User countries must ensure that the commercialization and any other use of genetic resources and their derivatives will not prevent their traditional use by the indigenous and local communities, as appropriate.

f) Access to genetic resources and their derivatives will respect customs, traditions, values and customary practices of indigenous and local communities.

g) Encourage Parties to develop, adopt or recognize national and/or local *sui generis* systems for the protection of traditional knowledge, innovations and practices associated with genetic resources.

Compliance

a) Parties shall take appropriate legal, administrative, or policy measures, as appropriate, to support effective compliance with national legislations regarding prior informed consent of the Contracting Party providing genetic resources and their derivatives and mutually agreed terms on which such access was granted. These countries shall consider, *inter alia*, the following measures:

- Mechanisms to provide information to potential users on their obligations regarding access to genetic resources;

- Measures aimed at preventing the use of genetic resources obtained without the prior informed consent of the Contracting Party providing such resources;

b) Parties are shall report on access applications through the clearing-house mechanism and other reporting channels of the Convention.

c) Parties shall only use genetic resources for purposes consistent with the terms and conditions under which they were acquired.

d) Parties shall maintain all relevant data regarding the genetic resources, especially documentary evidence of the prior informed consent and information concerning the origin and the use of genetic resources and the benefits arising from such use.

e) Parties agree to provide information to potential users on their obligations regarding access to genetic resources.

f) Parties shall develop and adopt modern communication tools to facilitate traceability of the use of genetic resources, their derivatives and associated traditional knowledge.

g) Parties shall establish mechanisms to promote accountability by all stakeholders involved in access and benefit sharing arrangements, especially regarding reporting and disclosure of information.

Disclosure

a) Intellectual property rights applications whose subject matter makes use of genetic resources, their derivatives or associated traditional knowledge, shall disclose the country of origin of such resource or associated traditional knowledge, as well as, evidence that provisions regarding prior informed consent and benefit sharing have been complied with, in accordance with the national legislation of the country of origin of such resources, as one mechanism to prevent misappropriation and unauthorized access and use of genetic resources, their derivatives and associated traditional knowledge.

In case the applicant ignores the country of origin, the applicant shall inform this to the intellectual property national authority.

b) National legislations shall provide for remedies to sanction lack of compliance with the requirements set out in the above paragraph which must include, inter alia, revocation of the intellectual property rights in question.

c) Applicants shall state what part, if any, existing rural, local and indigenous knowledge, innovations or techniques, were used in identifying the properties, and location of relevant samples, including samples that were helpful in the research even though these do not form the basis of the final product or process.

d) Applicants shall submit an undertaking confirming that to the best of their knowledge, all national laws relating to access to genetic resources, conservation and use of natural resources, customary laws of rural and indigenous peoples and any biodiversity prospecting arrangements entered into by the prospective patentee have been complied with.

e) Failure to fulfill these requirements shall bar the grant of a valid patent and subsequent discovery of false or negligent information should invalidate a patent and lead to appropriate legal proceedings against the patent-holder.

International Certificate of Compliance

a) Parties establish hereby the International Certificate of Compliance with the Access and Benefit Sharing national and international legislation, in order to guarantee that requirements to the legal acquisition of genetic resources in the country of origin or provider country has been met, and to contribute to build trust among users and providers of genetic resources.

b) The International Certificate of Compliance will indicate that prior informed consent has been obtained and that mutually agreed terms have been reached according to the national legislation of the provider country.

c) The International Certificate of Compliance is a permit which accompanies the genetic resource(s) along its life cycle and can be verified at various points of its life cycle, from the collection phase until the marketing of the product.

d) Parties agree that the verification of the International Certificate will be carried out at various “check-points”, including at least the border national authorities; patent or other intellectual property rights offices, when the claimed rights include the use of the genetic resources or information or knowledge related to them; applications for research funding or for publication of scientific papers.

e) Parties agree to create an International Registry, to be administered by the Secretariat of the CBD, in which the Compliance Certificates issued by the respective national authorities will be registered for verification purposes and to provide information regarding the specific conditions under which the genetic resource was accessed and may be transferred.

f) Each party will designate a competent national authority with the needed institutional support, with the responsibilities to issue the Compliance certificate and monitor and recognize certificates of origin delivered by competent national authorities in foreign countries.

g) Contracts registered by the competent national authority in the provider country could be consulted by a third party, in order to obtain information with respect to the initial terms and conditions under which the resources were accessed.

h) All genetic materials screened should be covered by access contracts and should include benefit-sharing, IPRs and technology transfer arrangements where appropriate.

i) The country of origin will be mentioned in relevant publications and patent applications".

j) The international certificate will not replace the need for countries to develop national legislations on access and benefit sharing.

Sanctions and remedies

a) The misappropriation of genetic resources, their derivatives and associated traditional knowledge shall be punished not only in those countries that fall victim to the unlawful act, but also in those countries where the products resulting from the act are commercially exploited.

b) Parties agree to take appropriate, effective and proportionate measures, for violations of national legislative, administrative or policy measures implementing the access and benefit-sharing provisions of the Convention on Biological Diversity, including requirements related to prior informed consent and mutually agreed terms.

c) Parties agree to cooperate to address alleged infringements of access and benefit-sharing agreements;

d) The non disclosure of the country of origin, prior informed consent and mutually agreed terms in intellectual property rights applications, whose subject matter makes use of genetic resources, their derivatives and associated traditional knowledge, shall lead to significant sanctions, ranging from penalties for false, misleading or fraudulent statements, to refusal, invalidation or transfer of the patent right.

e) False or misleading information regarding the country of origin of genetic resources, their derivatives or associated traditional knowledge, evidence of prior informed consent through approval of authorities under the relevant national regimes; and evidence of fair and equitable benefit sharing under the national regime of the country of origin, in intellectual property rights applications will lead to the rejection of an application or the invalidation of a granted patent.

f) The non compliance with the international regime shall lead to the following sanctions:

a) fines

b) seizure of samples

c) suspension of the sale of products resulted from genetic resources, their derivatives or associated traditional knowledge

d) revocation/cancellation of the permission or license of access

e) revocation of mutually agreed terms

f) ban on undertaking prospecting of biological and genetic resources

Access to justice

a) In case of infringement with the prior informed consent and mutually agreed terms, the provider must have access to information and justice in the countries where the users are located. In this respect, countries' access and benefit-sharing focal point could play a facilitator role by providing information, including on the legal system of their country.

b) Providers will have access to courts located in the user country, in order to safeguard their rights over genetic resources, derivatives and associated traditional knowledge.

[ENGLISH TRANSLATION]

COSTA RICA

CONCRETE OPTIONS ON THE SUBSTANTIVE ITEMS ON THE AGENDA OF THE FIFTH AND SIXTH MEETINGS OF THE WG/ABS

Negotiating the International Regime on Access and Benefit-Sharing

1. Nature, scope and objectives of the International Regime

The International Regime must be a binding international legal instrument.

In accordance with the relevant provisions of the Convention on Biological Diversity, the International Regime's scope must include principles and legal measures linked to access to genetic resources, the fair and equitable sharing of benefits arising from access, and the protection of the traditional knowledge, innovations and practices of the men and women in indigenous and local communities, related to the use of elements of biodiversity and associated knowledge aimed at covering the most significant gaps at the international level.

This instrument must cover measures or elements that enable countries to establish and develop their own regulations. It must also provide for the establishment of minimum penalty or enforcement measures, establish measures to guarantee dissemination of information and public awareness on the issue of access and benefit sharing, and promote reciprocal support between the Convention on Biological Diversity and other international legal frameworks, such as: the World Intellectual Property Organization (WIPO), the FAO's International Treaty on Plant Genetic Resources for Food and Agriculture, and the International Union for the Protection of New Varieties of Plants (UPOV).

In the event that countries should establish an International Regime with minimum access procedures that fit their situation, capacity building will also be required to ensure that certain actions to implement and monitor said measures or obligations are carried out, and to provide consistent experience at the international level.

The instrument's objectives must therefore include: fulfilment of the Convention's three objectives and the effective application of its articles 15 and 8j), facilitated access to genetic resources, and support for the application of and compliance with national and international legislation.

It is of the utmost importance to promote compliance with the participatory mechanisms of prior informed consent (PIC) and mutually agreed terms (MAT) according to a gender perspective, and make sure that women in provider countries and indigenous and local communities are represented.

Furthermore, fair and equitable benefit sharing must be promoted and safeguarded, the rights and obligations of genetic resource users must be ensured and reinforced, and the rights of men and women in indigenous and local communities over their traditional knowledge associated with genetic resources must be protected. That will guarantee that the International Regime on ABS will function in accordance with human rights frameworks and with international and national agreements on gender equity and equality, including the Convention on the Elimination of all Forms of Discrimination against Women (CEDAW).

2. Fair and equitable sharing of benefits

During the process of drafting the Convention on Biological Diversity, negotiations on the issue of sharing benefits arising from the use of genetic resources was seen as a necessary counterpart to the issues of conservation and sustainable use of biodiversity.

Despite the fact that the Convention establishes obligations for the Parties with regard to fair and equitable benefit sharing, fulfilment of the Convention's third objective still has not occurred. The sharing of benefits has therefore not been satisfactory for all of the actors involved. For the most part, regulations have been issued by developing countries that provide the resources. However, generally speaking, developed-user countries have not put into effect the corresponding legislation, which is why it is important to establish ways of monitoring compliance with national regulations, and of supporting procedures that effectively guarantee the fair and equitable sharing of benefits.

In accordance with paragraph 2 of Decision VIII/4B, Costa Rica sent the Convention Secretariat its report on the following topic:

"Experiences in Developing and Implementing Article 15, Including Obstacles and Lessons Learned", which was included in Document UNEP/CBD/WG-ABS/5/INF/2.

The Secretariat's document reflects the need for the International Regime to encourage action on the part of user countries to achieve the fair and equitable sharing of benefits, aimed at building capacity to reach and implement the Convention's objectives through access regimes.

The International Regime for access must contain functional and consistent measures on the specific issue of benefit sharing, guaranteeing the equitable sharing of economic, social, environmental, scientific or spiritual benefits, including potential commercial gain in the short, medium and long term, for both men and women.

It must also encourage measures promoting joint research into genetic resources, as this will facilitate the application of benefit-sharing measures. Such research must be carried out in provider countries, guaranteeing the supply of technical assistance and access to technology and technology transfer, consistent with the conservation and sustainable use of components of biodiversity.

Finally, in applying the International Regime, user countries must issue appropriate national laws, including the binding compliance instruments established under the Regime. This will grant legislation more certainty and flexibility, with measures in user countries that make it possible to generate greater confidence on the part of all stakeholders.

However, the International Regime must not sidetrack national or regional activities carried out to better apply existing access and benefit sharing instruments. We therefore encourage parties to continue that process.

3. Access to genetic resources

The International Regime must first take into account the terms of Article 15 of the Convention and act as an instrument aimed at guiding the Parties and facilitating clear and transparent rules that can be developed in national legislation.

Seeing as access to derivatives is the most frequent way in which genetic resources are used, and given the principle of State sovereignty over the handling of such resources, they must be covered by national regulations. However, the International Regime must include measures to support national decisions with regard to access, and be subject to prior informed consent and the sharing of benefits arising from the use and marketing of genetic resources.

4. Compliance

Certificates of origin/source/legal provenance, which have also been called legal compliance certificates, must be an element of the International Regime. They must be an instrument to verify compliance with prior informed consent and mutually agreed terms. It is therefore of the utmost importance to make the necessary efforts to achieve international recognition of such certificates, so that they may be used as tools to control the legality of access.

It is of great importance to Costa Rica for certificates of origin/source/legal provenance or legal compliance certificates to be recognized internationally, seeing as they are a way of preventing undue and illegal access to genetic resources and traditional knowledge.

Costa Rica's national legislation on access to genetic resources and access to traditional knowledge defines and establishes the certificate of origin or legal provenance as: "*An official document issued by the National Commission for Biodiversity Management (CONAGEBio's) Technical Office, as the national authority, wherein it is certified that the access to genetic resources or traditional knowledge is legal and complies with the terms under which the corresponding access permit was granted to the interested party*."

Within the International Regime, the legal compliance certificate must be an instrument for control that provides proof of compliance with national access and benefit sharing regimes. This certificate can be an instrument for control required for intellectual property procedures, as well as for export, import, product registration and other procedures.

Costa Rica also shares and supports the outcome of the Meeting of the Technical Expert Group regarding an Internationally Recognized Certificate of Origin/Source/Legal Provenance, which met in Lima, Peru from January 22 to 25, 2007.

We also acknowledge the appropriateness of a simple, viable and low-cost certificate, and the need to establish a single identifier as an element of the certificate, to make it possible to track the various transformations that a genetic resource might undergo, with closer attention to their traceability throughout the process.

We furthermore recognized the need to establish mechanisms guaranteeing the international requirement of the "Legal Compliance Certificate", and the need for the Convention to take relevant steps with WIPO and the WTO to ensure that the "Certificate of Legal Compliance" and disclosure of the origin of genetic resources become control instruments required in procedures for acquiring intellectual property protection.

With regard to other compliance measures, the International Regime must guarantee Parties that measures will be established for: monitoring and control, access to justice, restrictions, the cancellation of access permits, and penalties or enforcement measures for unauthorized access or for noncompliance with the terms under which authorization was granted.

Although the components of the draft International Regime include access to justice and cooperative relations among authorities in the event of non-compliance, greater analysis is required to develop this aspect in a practical manner, given the differences in legal systems and in existing international instruments with regard to access to justice.

5. Traditional knowledge and genetic resources

The International Regime's measures must guide the parties so that their national legislation safeguards and provides international recognition of the knowledge, innovations and practices of men and women in indigenous and local communities linked to the use of components of biodiversity and associated knowledge.

The International Regime must also consider: measures to ensure compliance with prior informed consent, full and effective participation by men and women in indigenous and local communities in the maintenance and control of traditional knowledge, and mechanisms guaranteeing that traditional knowledge is not unduly appropriated.

The sharing of benefits arising from the use of traditional knowledge, by those using that knowledge, must be a mandatory aspect of prior informed consent, and of control over access to traditional knowledge, in accordance with national legislation.

The role of women in preserving and transmitting traditional knowledge and conserving biodiversity resources must also be recognized.

Finally, measures must be established to support financial mechanisms for the development of national and international action plans aimed at maintaining traditional knowledge.

6. . Capacity-building

The International Regime must promote national capacity building, and include measures to guarantee technical training for developing countries, as well as terms for technology transfer that explicitly mention non-monetary benefits.

To the extent possible, the Open-Ended Working Group must discuss the need for a financial instrument within the framework of the Convention, so that each Party may have the option to apply for economic means to implement its commitments under the International Regime, as appropriate.

7. Indicators:

We propose that the following indicators of access to genetic resources be included, particularly for the fair and equitable sharing of benefits arising from the use of genetic resources:

- Existence of a competent National Authority.
- Declaration of a focal point.
- Existence of a law or special regulation, already implemented or to be implemented, governing access (in situ, ex situ).
- Existence of a law or special regulation, already implemented or to be implemented, governing the protection of traditional knowledge, innovations, and associated practices of indigenous and local communities related to the use of components of biodiversity.
- Number of indigenous and local communities that apply the respective regulations for granting Prior Informed Consent in the context of access to genetic resources and traditional knowledge.
- Types of established ABS agreements.
- Type and quantity of benefits (monetary, non-monetary), negotiated as part of Prior Informed Consent.
- Number of direct and indirect beneficiaries of ABS contracts.
- Number of access permits granted.
- Number of applications presented, processed, and resolved (access permits granted and not granted).
- Number of State and private protected areas, as providers and beneficiaries of access to genetic resources.
- Types of users and providers.
- Number of national researchers participating in research processes.
- Type and quantity of samples obtained for access.
- Number of patents and other intellectual property rights granted in relation to the use of genetic resources and traditional knowledge, accessed according to national legislation, including disclosure of origin.
- Number of scientific publications related to the use of the genetic resources and/or traditional knowledge.

[ORIGINAL SUBMISSION]

COSTA RICA

OPCIONES CONCRETAS PARA LOS TEMAS SUSTANTIVOS DE LA AGENDA DE LA 5ª Y 6ª REUNION DEL WG/ABS

Negociación del Régimen Internacional de Acceso a recursos genéticos y distribución de beneficios.

1. Naturaleza, ámbito y objetivos del Régimen Internacional.

El Régimen Internacional deberá ser un instrumento jurídico internacional vinculante.

De conformidad con las disposiciones pertinentes en el Convenio sobre Diversidad Biológica, el ámbito del Régimen Internacional deberá incluir principios y medidas legales relacionadas con el acceso a recursos genéticos, participación justa y equitativa en los beneficios derivados y protección de conocimientos tradicionales, innovaciones, y prácticas asociadas de mujeres y hombres de las comunidades indígenas y locales, relacionadas con el empleo de elementos de la biodiversidad y el conocimiento asociado, que permitan cubrir los vacíos más importantes a nivel internacional.

Este instrumento debe contemplar medidas o elementos, que permitan a los países establecer y desarrollar sus propias normativas. Asimismo debe contemplar el establecimiento de medidas mínimas sancionatorias o de observancia, rescatar el establecimiento de medidas para garantizar la comunicación, información y sensibilización al público en el tema de acceso y distribución de beneficios y promover el apoyo recíproco del Convenio sobre Diversidad Biológica con otros marcos jurídicos internacionales, tales, como: la Organización Mundial para la Protección de la Propiedad Intelectual (OMPI), Tratado Internacional de Recursos Fitogenéticos para la Alimentación y la Agricultura de la FAO y la Unión Internacional para la Protección de las Variedades Vegetales (UPOV).

En caso de que los países determinen un Régimen Internacional con procedimientos mínimos de acceso apropiados para su situación, se requerirá también la construcción de capacidad para asegurar al menos, ciertas acciones para implementar y supervisar dichas medidas u obligaciones y para propiciar experiencias en el nivel internacional en una forma coherente.

Por lo tanto dentro de sus objetivos, deberán incluirse: cumplimiento de los de los tres objetivos del Convenio y la aplicación efectiva de sus Artículos 15 y 8j), facilitar el acceso a recursos genéticos y apoyar la aplicación y cumplimiento de la legislación nacional e internacional.

Es sumamente importante, promover el cumplimiento de los mecanismos participativos del consentimiento fundamentado previo (PIC, por sus siglas en inglés) y las condiciones mutuamente convenidas (MAT, por sus siglas en inglés) con perspectiva de género y asegurar la representatividad de las mujeres en los países proveedores, así como de las comunidades indígenas y locales.

Además se debería promover y salvaguardar la participación justa y equitativa en los beneficios; asegurar y reforzar los derechos y obligaciones de los usuarios de recursos genéticos y proteger los derechos de los hombres y mujeres de las comunidades indígenas y locales sobre sus conocimientos tradicionales relacionados con recursos genéticos. De esta manera se podrá garantizar que el Régimen Internacional de ABS actúe de conformidad con los marcos de derechos humanos y con los acuerdos internacionales y nacionales sobre equidad e igualdad de género, incluyendo la Convención sobre la Eliminación de todas las Formas de Descriminación de las Mujeres (CEDAW).

2. Participación justa y equitativa de los beneficios.

Durante el proceso de redacción del Convenio sobre la Diversidad Biológica la negociación del tema sobre distribución de beneficios derivados de la utilización de los recursos genéticos, fue concebida como una contraparte necesaria para la inclusión de los temas de conservación y uso sostenible de la biodiversidad.

A pesar de que el Convenio establece obligaciones destinadas a que las Partes tomen medidas para compartir en forma justa y equitativa los beneficios, el cumplimiento del tercer objetivo del

Convenio, todavía no se materializa, por lo que la distribución de beneficios no ha sido satisfactoria para todos los actores involucrados. En su mayoría han sido los países en desarrollo, proveedores de los recursos, quienes han emitido regulaciones sobre acceso y distribución de beneficios, de forma que los países desarrollados–usuarios, principalmente no han puesto en vigencia la normativa correspondiente, por lo que se motiva a establecer formas de control en cuanto al cumplimiento de las normativas nacionales y respaldar los procedimientos que garanticen eficazmente la distribución justa y equitativa de los beneficios.

En cumplimiento al párrafo 2 de la Decisión VIII/4B, Costa Rica envió a la Secretaría del Convenio su reporte sobre el tema:

" Experiencias en el desarrollo e implementación del Artículo 15 incluyendo los obstáculos y lecciones aprendidas", el cual se incluyó en el documento UNEP/CBD/WG-ABS/5/INF/2 ".

En este documento de la Secretaría, se refleja la necesidad de que el Régimen Internacional fomente acciones en países usuarios, para la distribución justa y equitativa de beneficios, con el fin de fortalecer en los regímenes de acceso, la capacidad de alcanzar y aplicar los objetivos del Convenio.

El Régimen internacional de acceso debe contemplar medidas funcionales y consistentes en el tema específico de distribución de beneficios, garantizando la distribución equitativa de los beneficios económicos, sociales, ambientales, científicos o espirituales, incluyendo posibles ganancias comerciales a corto, mediano y largo plazo, tanto para hombres como para mujeres.

Además deberá incentivar medidas de promoción de la investigación conjunta en recursos genéticos, pues facilitarán la aplicación de medidas de distribución de beneficios. Estas investigaciones deben ser desarrolladas en los países proveedores, garantizando el suministro de asistencia técnica y el acceso a tecnologías y a su transferencia, compatibles con la conservación y utilización sostenible de los componentes de la biodiversidad.

Finalmente, en aplicación del Régimen Internacional, los países usuarios deberán emitir leyes nacionales apropiadas, que incluyan los instrumentos de cumplimiento vinculantes establecidos en el Régimen. De esta forma, las legislaciones brindarán más certeza y flexibilidad, al existir medidas de países usuarios que permitan generar mayor confianza entre todos los actores involucrados.

Sin embargo el Régimen Internacional, no debe distraer las actividades nacionales o regionales realizadas, con el fin de mejorar la aplicación de los instrumentos existentes en materia de acceso y distribución de beneficios, e instamos a las Partes a continuar con este proceso.

3. Acceso a los recursos genéticos

El Régimen internacional de acceso deberá considerar en primer instancia los términos del Artículo 15 del Convenio y constituirse en un instrumento con un enfoque orientador hacia las Partes, el cual deberá facilitar reglas claras y transparentes, que podrán ser desarrolladas en las legislaciones nacionales.

Por ser el acceso a los derivados la forma más frecuente del uso de los recursos genéticos y atendiendo el principio de soberanía de los Estados sobre el manejo de los mismos, estos deben ser objeto de regulación nacional, sin embargo el Régimen internacional debe contemplar medidas para apoyar las decisiones nacionales, en cuanto a su acceso y estar sometido al consentimiento fundamentado previo y a la distribución de beneficios por su uso y comercialización.

4. Cumplimiento

El certificado de origen/fuente/legal procedencia y llamado también de legal cumplimiento, debe ser un elemento del Régimen internacional y un instrumento para verificar las medidas de cumplimiento del consentimiento fundamentado previo y los términos mutuamente acordados. Por lo tanto se considera de suma importancia realizar los esfuerzos necesarios, para que éstos sean reconocidos internacionalmente y sirvan como instrumentos de control para la legalidad del acceso.

Para Costa Rica es de gran importancia que el tema de los certificados de origen/fuente/legal procedencia o legal cumplimiento obtengan reconocimiento internacional, ya que es una forma de prevenir el uso indebido y el acceso ilegal a los recursos genéticos y al conocimiento tradicional.

De forma congruente en la normativa nacional de acceso a recursos genéticos y acceso al conocimiento tradicional, se define y se establece el Certificado de origen o legal procedencia como: "*Documento oficial emitido por la Oficina Técnica de la Comisión Nacional para la Gestión de la Biodiversidad como autoridad Nacional, donde se certifica la legalidad del acceso a los recursos genéticos o al conocimiento tradicional y el cumplimiento de los términos en los que fue otorgado al interesado, el permiso de acceso correspondiente*".

Dentro del Régimen Internacional, el Certificado de legal cumplimiento, deberá ser un instrumento de control, que proporcione prueba de cumplimiento de los regímenes nacionales de acceso y distribución de los beneficios. Este certificado puede ser un instrumento de control exigido tanto en procedimientos de derechos de propiedad intelectual como en procedimientos de importación, exportación, registro de productos, etc.

Asimismo, se comparte y se apoyan los resultados de la Reunión del Grupo de Expertos Técnicos sobre un certificado reconocido internacionalmente de origen/fuente/procedencia legal reunido en Lima, Perú, del 22 al 25 de enero del 2007.

Se coincide en la conveniencia de que el certificado sea sencillo, viable y de bajos costos., y la necesidad de establecer un identificador único, como elemento del certificado, que permita dar seguimiento a las diferentes transformaciones que puede tener el recurso genético, profundizando en el proceso sobre la trazabilidad de los mismos.

Adicionalmente se reconoce la necesidad de establecer mecanismos que aseguren la exigencia internacional del "Certificado de Legal Cumplimiento", y la necesidad de que el Convenio realice las gestiones de apoyo pertinentes ante la OMPI y la OMC, para que el "Certificado de legal cumplimiento" y la revelación de origen de los recursos genéticos se constituyan en instrumentos de control, exigidos en procedimientos para obtener protección de propiedad intelectual.

Sobre otras medidas de cumplimiento, el Régimen Internacional debe garantizar a las Partes establecer medidas: de monitoreo y control, de acceso a la justicia, de restricciones, cancelaciones de permisos de acceso, de sanciones o de observancia para el acceso no autorizado o por el no cumplimiento de los términos en los que fue otorgada una autorización.

Aunque el borrador del texto del Régimen Internacional contempla entre sus componentes, el acceso a la justicia y las relaciones colaborativas entre las autoridades en casos de no cumplimiento, se requiere un mayor análisis para desarrollar de manera práctica este aspecto, considerando las diferencias en los sistemas legales y los instrumentos internacionales existentes en materia de acceso a la justicia.

5. Conocimiento Tradicional y Recursos Genéticos.

Las medidas del Régimen internacional deben orientar a las Partes, para que bajo sus legislaciones, los Estados tutelen y reconozcan internacionalmente los conocimientos, las innovaciones y las prácticas de los hombres y las mujeres de las comunidades indígenas y locales relacionadas con el empleo de elementos de la biodiversidad y el conocimiento asociado.

El Régimen Internacional además debe considerar: medidas para garantizar el cumplimiento del consentimiento fundamentado previo, la participación plena y efectiva de los hombres y las mujeres de las comunidades indígenas y locales, en el mantenimiento y control sobre el conocimiento tradicional y mecanismos para garantizar que no se dé la apropiación indebida del conocimiento tradicional.

La distribución de beneficios por el uso de los conocimientos tradicionales debe ser una parte obligada a cumplir en el consentimiento fundamentado previo, por parte de quien hace uso de este conocimiento, así como la aplicación de mecanismos de control para el acceso de los conocimientos tradicionales, en concordancia con las legislaciones nacionales.

Además deberá reconocer el papel de las mujeres en la preservación y transmisión de los conocimientos tradicionales, la conservación de los recursos de la biodiversidad.

Finalmente deberá establecer las medidas para respaldar mecanismos de financiamiento para el desarrollo de planes de acción nacional e internacional para el mantenimiento del conocimiento tradicional. .

6. Creación de capacidad

El Régimen Internacional deberá promover la creación de capacidades nacionales, contemplando medidas para garantizar el suministro de capacitación técnica para países en desarrollo y términos para la transferencia de tecnología, en los cuales se incluya expresamente los beneficios no monetarios.

El Grupo de Trabajo de Composición Abierta en la medida de sus posibilidades debe discutir la necesidad de que exista en el Marco del Convenio, un instrumento financiero para que cada Parte Contratante tenga opciones de aplicar a medios económicos a fin de implementar eventualmente, los compromisos del Régimen internacional.

7. Indicadores:

Proponemos la inclusión de los siguientes indicadores de acceso a los recursos genéticos y en particular para la participación justa y equitativa en los beneficios provenientes de la utilización de los recursos genéticos:

- Existencia de una Autoridad Nacional competente.
- Declaración de un Punto Focal.
- Existencia de una Ley o normativa especial para regular el acceso (in situ, ex situ) implementada o en implementación.
- Existencia de una Ley o normativa especial para regular la protección de conocimientos tradicionales, innovaciones, y prácticas asociadas de las comunidades indígenas y locales relacionadas con el empleo de elementos de la biodiversidad y el conocimiento asociado implementada o en implementación.
- Número de comunidades indígenas y locales que aplican las respectivas regulaciones para otorgar el consentimiento previamente informado, en el acceso a los recursos genéticos y al conocimiento tradicional.
- Tipo de acuerdos de ABS establecidos.
- Tipo y cantidad de beneficios (monetarios, no monetarios) negociados en el Consentimiento Previamente Informado.
- Número de Beneficiarios directos e indirectos, derivados de los contratos de ABS.
- Número de permisos de acceso otorgados.
- Número de solicitudes presentadas, tramitadas y resueltas (permisos de acceso otorgados y no otorgados).
- Número de Áreas Protegidas Estatales y Privadas, como proveedoras y beneficiarias del acceso a los recursos genéticos.
- Tipo de usuarios y proveedores.
- Número de investigadores nacionales que participan en los procesos de investigación.
- Tipo y cantidad de muestra obtenida para el acceso.
- Número de patentes y otros derechos de propiedad intelectual otorgadas relacionadas con el uso de recursos genéticos y conocimiento tradicional, accesados de conformidad con las legislaciones nacionales, que incluyan la declaración de origen.
- Número de publicaciones científicas relacionadas con el uso de los recursos genéticos y/o conocimiento tradicional.

[ENGLISH TRANSLATION]

CUBA

INTRODUCTION

Biological diversity is one of the issues discussed in the Republic of Cuba's 2007-2010 National Environmental Strategy. Among the strategy objectives, 33 goals and more than 60 specific targets have been identified to ensure the implementation of the Convention on Biological Diversity's three fundamental objectives.1

The country's insular characteristics have fostered the evolution of a particular biodiversity with very high levels of endemism, resulting in turn in the fragility and vulnerability of some ecosystems. All this has made Cuba's biological diversity the focal point of evolution and speciation in the Caribbean, and one of the most important among the world's islands.2/

These conditions, combined with the country's scientific and technological development, enable us to state that the International Regime on Access and Benefit-Sharing is one of the top priority matters in Cuba's environmental policy.

In Cuba's view, the International Regime on Access and Benefit-Sharing must, above all, focus on the fair and equitable sharing of benefits arising out of the use of genetic resources, and must also create the necessary conditions so that national legislation in this field achieves international fulfillment.

Fair and equitable benefit-sharing

Benefit-sharing is the International Regime's cornerstone. The Regime should contain a set of measures guaranteeing fair and equitable access, including monetary and non-monetary benefits, technology transfer, and effective cooperation for the generation of social, economic and environmental benefits.

Among the measures to ensure the sharing of benefits arising from access to genetic resources and their derivatives, including research results and commercial use, are the following:

a) Transfer of research technology and know-how, by the party accessing the resource;
b) Development of scientific and technical capacities of national institutions;
c) Transfer of cutting-edge scientific equipment for the development of national capacities;
d) Phasing-out of royalties for the commercialization of resources;
e) Exemptions granted to the country by the traders in or processors of these resources;
f) Sharing in the royalties generated by intellectual property rights;
g) Financing of research and development programmes in national territory, related to the use of these resources;
h) Equipping or financing for the development of programmes for conservation of or research on species carrying genetic resources;
i) Financing for the strengthening of technical and human capacities of environmental agencies;
j) Financing of social and economic development of communities that provide genetic resources;
k) Other conditions agreed upon by the parties, in accordance with the principles laid down in the Convention on Biological Diversity.

Scientific research is one of the activities providing the greatest benefits, monetary as well as non-monetary, for countries of origin, providers and users.

1/ CITMA Resolution No. 40/2097, of March 21, 2007.
2/ 3rd Country Report to the CBD

Scientific research must be one of the themes and a substantive part of the International Regime, although we acknowledge that this activity requires special treatment in national legislation, aimed at establishing mechanisms or fast tracks for obtaining the necessary authorization and for negotiating Access Contracts, especially when the research is for taxonomic purposes.

In addition to those listed above, among the measures to ensure fair and equitable sharing of research benefits are the following:

a) Financing of projects in national territory for research and development related to the use of these resources;
b) Equipping and financing of programs for research or conservation of species carrying genetic resources;
c) Financing for the strengthening of the technical and human capacities of environmental agencies.

Participation of government authorities in negotiations of access contracts and for granting prior informed consent is a form of promotion and safeguarding of fair and equitable sharing of the benefits arising from the use of genetic resources.

Voluntary Disclosure and monitoring of the fulfillment of mutually agreed terms are measures that assure sharing of constant benefits arising from the commercial and other uses of genetic resources and their derivatives and products, in the context of mutually agreed conditions.

Access to Genetic Resources

States have sovereign rights over their genetic resources and the authority to determine access thereto, in accordance with national legislation.

Access procedures must be clear, simple and transparent, and offer legal security to the various types of users and providers of genetic resources, with the goal of properly applying Article 15 of the Convention on Biological Diversity, subject to prior informed consent.

Mutually agreed terms of access and specific uses of genetic resources and their derivatives could include conditions for transfers to third parties, in accordance with national legislation.

The states shall define the verification and control stations, the terms of access and benefit-sharing as well as the need to establish a single identifier to use as a certifying element which would facilitate follow-up of the various transformations that a genetic resource may have.

Implementation

The measures to ensure the implementation of national legislation relating to access and benefit-sharing, prior informed consent and mutually agreed conditions, in accordance with the Convention on Biological Diversity, must be aimed at:

a) participation of Government Authorities;
b) identification of the resources to be accessed, including specifications, limits, restrictions and mutual conditions under which said access shall be granted;
c) the appropriate environmental uses of such resources;
d) potential uses and the possible risks arising from said uses;
e) concrete conditions for the exercise of the right to share, in a fair and equitable manner, the results and benefits arising from commercial or any other utilization of biological diversity resources to which access is granted, including access to technologies and their transfer in

appropriate cases, or the forms of benefit-sharing that have been accepted as "mutually agreed terms";

f) terms of reference and transfer of accessed materials to third parties;
g) participation of the country's researchers in activities related to genetic resources, their derivative components and the associated intangible component;
h) the definition of terms and conditions related to intellectual property rights, including rights over undisclosed information corresponding to each user with access to genetic resources and their derivatives, and rights corresponding to both, in accordance with national legislation and the conditions and terms for specimen transfers;
i) the monitoring plan, if applicable;
j) any other measure which, in accordance with access characteristics, should be established between the parties.

Characteristics

The international regime could be made of a set of legally binding principles, standards, rules and decision-making procedures.

Scope

The International Regime shall be implemented in accordance with national legislation and other international obligations. It shall apply to all genetic resources and know-how, innovations and traditional practices; to the benefits arising from the use of such resources; to access to genetic resources, their derivatives and products; to the fair and equitable sharing of monetary and non-monetary benefits arising from the use of genetic resources and their derivatives and related traditional knowledge.

The regime shall also apply to the genetic resources of the species listed in *Annex I* of the International Treaty on Plant Genetic Resources for Food and Agriculture, when they are used for purposes other than food and agriculture.

Objectives of International Regime

For the International Regime on Access and Benefit-Sharing to be effective, its objectives must be:

a) To guarantee fair and equitable sharing of the monetary and non-monetary benefits arising from the use of genetic resources, their derivatives and associated traditional knowledge, taking into account the interlinkages between the Convention's three objectives.
b) To create conditions for the establishment of minimal homologous regulations reflecting national law regarding access to genetic resources and their derivatives.
c) To establish a mechanism for acknowledging or certifying the legal origin of genetic resources.
d) To protect the rights of indigenous and local communities over their traditional knowledge, innovations and traditional practices associated with genetic resources and derivatives, subject to national legislation.
e) To guarantee fulfillment with prior informed consent, within the framework of terms mutually agreed upon by the countries of origin and the indigenous and local communities.
f) To contribute to the effective application of the Convention's Article 15, 8(j), and Articles 16 through 19.
g) To contribute to the conservation and sustainable use of biological diversity.
h) To guarantee that fair and equitable benefit-sharing flows to the countries of origin of genetic resources.
i) To guarantee and achieve fulfillment of the rights and duties of the users of genetic resources.

j) To contribute to or promote the creation of capacity and guarantee technology transfers to developing countries, in particular to the least developed countries and small developing insular states.

Division of the Environment
November 2007

[ORIGINAL SUBMISSION]

CUBA

Introducción.

La diversidad biológica, es uno de los temas abordados en la Estrategia Ambiental Nacional de la República de Cuba 2007-2010, dentro de sus objetivos estratégicos se han establecido 33 metas y más de 60 acciones específicas para garantizar el cumplimiento de los tres objetivos del Convenio Sobre la Diversidad Biológica[1].

Las características insulares del país, han propiciado la evolución de una diversidad biológica particular y con valores muy altos de endemismo, lo que a su vez condiciona la fragilidad y vulnerabilidad de algunos de los ecosistemas y la convierte en el principal centro de evolución y especiación de las Antillas y uno de los más importantes entre las islas del mundo[2].

Estas condiciones unidas al desarrollo nacional de la ciencia y la tecnología, permiten afirmar, que el tema del Régimen Internacional sobre Acceso y Distribución de los Beneficios, es uno de los temas de mayor prioridad en la política ambiental cubana.

Para Cuba el Régimen Internacional sobre Acceso y Distribución de los Beneficios, tiene, ante todo, que enfocarse en la distribución justa y equitativa de los beneficios derivados de la utilización de los recursos genéticos, y crear las condiciones de cumplimiento internacional de las legislaciones nacionales en el tema.

Sobre la Participación justa y equitativa en los beneficios:

La distribución de los beneficios constituye la piedra angular del Régimen Internacional, el que debe incorporar un listado de medidas que garanticen su distribución justa y equitativa, comprendiendo entre otras, los beneficios monetarios y no monetarios, la transferencia de tecnología y la cooperación eficaz en apoyo a la generación de beneficios sociales, económicos y ambientales.

Entre las medidas que aseguran la distribución de los beneficios obtenidos por el acceso a los recursos genéticos y sus derivados, incluyendo de los resultados de la investigación y los beneficios que se derivan de la utilización comercial y otras, se encuentran:

a) La transferencia de tecnologías y conocimientos utilizados en la investigación, por parte del que accede al recurso.
b) El desarrollo de capacidades técnicas y científicas de instituciones nacionales.
c) La transferencia de equipamiento científico de punta para desarrollar las capacidades nacionales.
d) La cancelación de regalías por el aprovechamiento comercial de los recursos.
e) Las franquicias que los comercializadores o procesadores de estos recursos otorguen al país.
f) La participación en los royalties que se deriven de los derechos de propiedad intelectual.
g) El financiamiento para proyectos de investigación-desarrollo en el territorio nacional, relacionados con la utilización de estos recursos.

[1] Resolución No. 40/2007 del CITMA, de fecha 21 de marzo del 2007.
[2] III Reporte de País al CBD

h) El equipamiento o financiamiento para el desarrollo de programas de conservación o investigación d la especie portadora del recurso genético.
i) El financiamiento para el fortalecimiento de las capacidades técnicas y humanas de las autoridades ambientales.
j) El financiamiento para el desarrollo socio económico de las comunidades proveedoras del recurso genético.
k) Otras condiciones que pudieran acordar las partes conforme a los principios que establece el Convenio de Diversidad Biológica.

La investigación científica, es una de las actividades que mayores beneficios puede aportar para los países de origen, proveedores o usuarios; estos beneficios se expresan tanto en beneficios monetarios como en beneficios no monetarios.

La investigación científica debe ser un tema incorporado y parte sustantiva del Régimen Internacional, aún cuando reconocemos que como actividad requiere un tratamiento diferenciado en las legislaciones nacionales, dirigido a establecer mecanismos o vías expeditas para la tramitación de las autorizaciones correspondientes y las negociaciones de los Contratos de Acceso, sobre todo cuando la investigación se relaciona con fines taxonómicos.

Entre las medidas que aseguran la participación justa y equitativa en los beneficios de los resultados de la investigación, además de los listados anteriormente, se encuentran:

a) El financiamiento para proyectos de investigación-desarrollo en el territorio nacional, relacionados con la utilización de estos recursos.
b) El equipamiento o financiamiento para el desarrollo de programas de conservación o investigación de la especie portadora del recurso genético.
c) El financiamiento para el fortalecimiento de las capacidades técnicas y humanas de las autoridades ambientales.

La participación de las autoridades estatales en las negociaciones del Contrato de Acceso y para el otorgamiento del Consentimiento Fundamentado Previo, constituyen medidas de promoción y salvaguarda de la participación justa y equitativa en los beneficios provenientes de la utilización de los recursos genéticos.

Las Declaraciones Voluntarias y la fiscalización del cumplimiento de los términos mutuamente acordados son medidas que garantizan la participación en los beneficios provenientes de la utilización comercial y otras, de los recursos genéticos y sus derivados y productos, en el contexto de condiciones mutuamente convenidas.

Sobre el acceso a los recursos genéticos.

Los Estados tienen derechos soberanos sobre sus recursos genéticos y la autoridad para determinar el acceso conforme a la legislación nacional.

Los procedimientos de acceso deberán ser claros, simples y transparentes, y ofrecer seguridad legal a los diversos tipos de usuarios y proveedores de recursos genéticos, con vistas a la aplicación efectiva del Artículo 15, del Convenio sobre la Diversidad Biológica y estará sujeto al consentimiento fundamentado previo.

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Los términos mutuamente acordados para el acceso y los usos específicos de los recursos genéticos y sus derivados, podrían incluir condiciones para la transferencia a terceras partes, sujeto a la legislación nacional.

Los estados definirán los puntos de verificación y control, tanto para los términos del acceso como para los de la distribución de beneficios y la necesidad de establecer un identificador único como elemento del certificado, que permita dar seguimiento a las diferentes transformaciones que puede tener el recurso genético.

Sobre el Cumplimiento

Las medidas para garantizar el cumplimiento de las legislaciones nacionales sobre acceso y participación en los beneficios, el consentimiento fundamentado previo y condiciones mutuamente convenidas, de forma consecuente con el Convenio sobre Diversidad Biológica tienen que dirigirse a:

a) la participación de las Autoridades Estatales;
b) la identificación de los recursos objeto del acceso, incluyendo especificaciones, límites, restricciones y condiciones mutuas en que dicho acceso tendrá lugar;
c) los usos ambientalmente adecuados que se dará a esos recursos;
d) los usos potenciales y los riesgos eventuales derivados de dichos usos;
e) las condiciones concretas para el ejercicio del derecho a compartir, en forma justa y equitativa, los resultados y beneficios que se deriven de la utilización comercial o de cualquier índole de los recursos de la diversidad biológica a los que se les concede el acceso, incluyendo el acceso a las tecnologías y su transferencia en los casos procedentes o las modalidades de distribución de beneficios que se hayan acordado como "condiciones mutuamente convenidas";
f) los términos de referencia y transferencia del material accedido a terceros;
g) la participación de los investigadores nacionales en las actividades sobre los recursos genéticos, sus componentes derivados y el componente intangible asociado;
h) la definición de los términos y condiciones relativos a los derechos de propiedad intelectual, incluyendo los derechos sobre la información no divulgada que correspondiera a cada usuario del acceso a los recursos genéticos y sus derivados y los que corresponden conjuntamente a ambos de conformidad la legislación nacional y con las condiciones y términos para la transferencia de muestras;
i) el plan de monitoreo, si corresponde;
j) cualquiera otra que según la característica del acceso sea necesaria establecer entre las partes;

Sobre la Naturaleza

El régimen internacional podría estar compuesto por que un conjunto de principios, normas, reglas y procedimientos de toma de decisiones legalmente vinculantes.

Sobre el Ámbito

El régimen internacional se aplicará en correspondencia con la legislación nacional y otras obligaciones internacionales, se aplicará a todos los recursos genéticos y conocimientos, innovaciones y prácticas tradicionales, a los beneficios que surjan de la utilización de dichos recursos, al acceso a los recursos genéticos, sus derivados y productos, a la participación justa y equitativa en los beneficios monetarios y no monetarios provenientes de la utilización de los recursos genéticos y sus derivados y los conocimientos tradicionales asociados.

El régimen se aplicará además a los recursos genéticos de las especies que se hace referencia en el anexo I el Tratado Internacional sobre Recursos Fitogenéticos para la Alimentación y la Agricultura, cuando se utilicen para otros fines que no sean la alimentación y la agricultura.

Objetivos del régimen internacional.

Para lograr una eficacia del Régimen Internacional sobre Acceso y Distribución de Beneficios sus objetivos deben ser:

a) Garantizar la participación justa y equitativa, en los beneficios monetarios y no monetarios, provenientes de la utilización de los recursos genéticos, sus derivados y los conocimientos tradicionales asociados, tomando en cuenta que los tres objetivos del Convenio están entrelazados.

b) Crear las condiciones para establecer las regulaciones homólogas y de carácter mínimo que deben contener las leyes nacionales en materia de acceso a los recursos genéticos y sus derivados.

c) Establecer un mecanismo para conocer o certificar con seguridad la procedencia legal de los recursos genéticos.

d) Proteger los derechos de las comunidades indígenas y locales sobre sus conocimientos tradicionales, innovaciones y prácticas tradicionales asociados a los recursos genéticos y derivados, sujeto a la legislación nacional.

e) Garantizar el cumplimiento del consentimiento fundamentado previo en el contexto de términos mutuamente acordados de los países de origen y de las comunidades indígenas y locales.

f) Contribuir a la aplicación efectiva de los artículos 15, 8 j) y del 16 al 19 del Convenio.

g) Coadyuvar a la conservación y la utilización sostenible de la diversidad biológica.

h) Garantizar que una justa y equitativa participación en los beneficios fluya hacia los países de origen de los recursos genéticos.

i) Garantizar y hacer cumplir las obligaciones y los derechos de los usuarios de los recursos genéticos.

j) Contribuir o promover la creación de capacidad y garantizar la transferencia de tecnología a los países en desarrollo, en particular los menos desarrollados y los pequeños Estados insulares en desarrollo.

Dirección de Medio Ambiente
Noviembre 2007

SUBMISSION BY THE EUROPEAN COMMUNITY AND ITS MEMBER STATES OF 28 NOVEMBER 2007 IN RESPONSE TO CBD NOTIFICATION 2007-132

CONCRETE OPTIONS FOR THE FURTHER NEGOTIATION OF SUBSTANTIVE ITEMS ON THE AGENDA OF THE FIFTH AND SIXTH MEETINGS OF THE AD HOC OPEN-ENDED WORKING GROUP ON ACCESS AND BENEFIT-SHARING

The European Community and its Member States are committed to completing the elaboration and negotiation of an international regime on Access and Benefit-sharing (ABS regime) at the earliest possible time before the tenth meeting of the Conference of the Parties as agreed at COP8 in Decision VIII/4.

The EU therefore regards it as essential that CBD COP9 in May 2008 will identify the main elements of the international ABS regime and determine the inter-sessional process between COP9 and COP10 for completing the negotiation of the international ABS regime.

The Ad Hoc Open-ended Working Group on Access and Benefit-sharing at its fifth meeting held in Montreal, from 8 to 12 October 2007 invited Parties, Governments, indigenous and local communities and stakeholders to submit to the Secretariat by 30 November 2007 concrete options on the substantive items on the agenda of the fifth and sixth meetings of the Working Group.

Responding to this invitation, the EU submits the following concrete options and elements on substantive items on the agenda of the fifth and sixth meetings of the Working Group, convinced that consideration and inclusion of these options and elements in the further negotiation of the international ABS regime will facilitate and expedite progress.

ADDRESSING THE LINK BETWEEN ACCESS TO GENETIC RESOURCES AND ADDITIONAL MEASURES TO SUPPORT COMPLIANCE

Explicitly addressing the link between national frameworks on access to genetic resources and additional measures to support compliance is essential for a successful conclusion of this negotiation.

In response to the demand for potentially binding international commitments to support compliance with ABS requirements through clearly specified measures, the EU has identified the need for developing international standards on national access law and practice as part of the ABS negotiations.

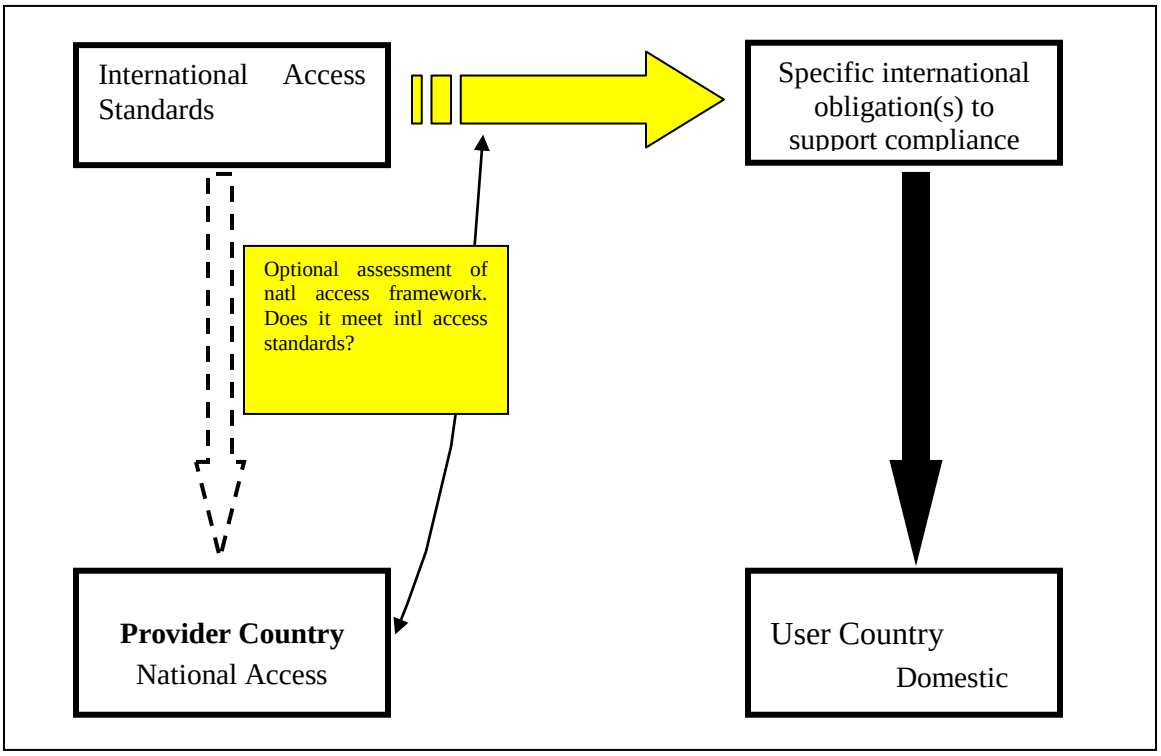
The EU believes that it is difficult to consider additional and more specific international commitments to support compliance with ABS requirements if there is uncertainty about and a broad variety of what exactly is to be enforced in countries with users under their jurisdiction.

Following from this argumentation the international ABS regime needs to include international standards on national access law and practice and an international mechanism/ process for assessing whether or not national access frameworks meet international standards.

In the EU's view, the international ABS regime could include international access standards as well as a commitment by all Parties to undertake additional enforcement activities vis a vis users of genetic resources which are provided by Parties whose national access framework meet international access standards. In this regard the EU envisages the following:

- Additional and more specific international obligations of all Parties to support compliance would be triggered vis a vis those Parties whose national access frameworks meet international access standards.
- To establish whether or not its national access framework meets international standards, each Party to the CBD could ask for an assessment of its national framework by an international mechanism/ process set-up under the ABS regime.
- Each Party to the CBD would decide whether or not to develop a national access framework that meets international access standards.
- Targeted capacity-building activities could support the development of national access frameworks that meet international access standards.

The following picture seeks to capture this description:



In addition, in the EU's view, all Parties could commit to further non-binding measures to support compliance with PIC and MAT without the need to develop international access standards.

Concrete options for the potential substance of international access standards and concrete options for additional and specific international obligations to support compliance are developed in the two subsequent sections of this submission.

DEVELOPING INTERNATIONAL STANDARDS ON NATIONAL ACCESS LAW AND PRACTICE

Article 15.1 CBD recognises the authority of national governments to determine access to genetic resources as part of the sovereign rights of states over their natural resources. Article 15.2 CBD obliges each Party to endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Parties and not to impose restrictions that run counter to the CBD objectives. – In the EU's view, an international ABS regime must enable, promote and facilitate national implementation of the access-related obligations under the CBD.

The EU suggests developing international standards on national access law and practice as a key component of the international ABS regime. These standards must also address the urgent need for simplified access procedures in case of research undertaken with non-commercial intent. As explained above, the establishment of international access standards is also important to respond to the demand for potentially binding international commitments to support compliance with ABS requirements through clearly specified measures. – In suggesting the development of international access standards, the EU is fully conscious of the capacity-building challenges involved.

International standards on national access law and practice should include:

- Guidance on national access legislation, for example in the form of model legislation or technical protocols guiding administrative decision-making;
- Essential procedural and substantive elements that need to be reflected in national access frameworks before national access frameworks can be regarded as meeting international standards. This should include
    1. specific rules on PIC requirements or the existence of other norms for obtaining PIC;
    2. clear legal status and rules on the acquisition of genetic resources found in situ and ex situ;
    3. availability and accessibility of information on how to obtain PIC;
    4. limitations on time and costs for obtaining PIC decisions;
    5. existence of a procedure for simplified access for non-commercial research.
- An international commitment of parties to notify up-to-date information on national provisions and administrative contacts relevant for access to genetic resources and, if relevant, associated TK to an international information sharing mechanism such as the CBD's Clearing House Mechanism.

An international commitment of parties to ensure that their national access rules apply in a non-discriminatory way.

ADDITIONAL MEASURES TO SUPPORT COMPLIANCE WITH PIC AND MAT

There are specific and very practical challenges for providers of genetic resources to be sufficiently certain that users of genetic resources comply with their agreed ABS obligations, including contractually agreed ones. Such challenges arise mostly from the difficulty to be informed about transactions and subsequent uses of genetic resources. Further challenges arise from the fact that often providers and users of genetic resources are located in different jurisdictions.

The EU has identified a range of concrete options for additional measures to support compliance with PIC and MAT. Each of these options by itself could substantively support compliance with ABS requirements.

CONCRETE OPTIONS TO SUPPORT COMPLIANCE WITH ACCESS RELATED OBLIGATIONS, IN PARTICULAR REGARDING PIC

- *Mandatory disclosure requirement in patent applications*. The EU recalls its proposal to the World Intellectual Property Organization (WIPO) of December 2004 that sets out a balanced and effective way to include in international patent law a binding requirement to disclose the origin or source of genetic resources and associated traditional knowledge in patent applications. The disclosure requirement as proposed by the EU would, if adopted by WIPO, allow States to keep track, at global level, of all patent applications with regard to genetic resources and thereby enhance transparency about uses of genetic resources that have left the providing country.
- *International definition of misappropriation of genetic resources*. The EU suggests developing an international definition of what constitutes "misappropriation" of genetic resources. The outcome of this work could then be linked to an international obligation for all Parties to the Convention, to prohibit the use of misappropriated genetic resources.
- *Unilateral declarations by users*: The EU suggests discussing the potential role of unilateral declarations by users that genetic resources have been legally obtained in supporting compliance particularly with PIC.

Internationally recognised certificate of compliance. The EU is ready to consider an internationally recognised "certificate of compliance" with national access rules. However, more detailed considerations on the scope, nature, content and governance of such certificate are needed, particularly, how it would relate to and interact with other potential elements of the international ABS regime.

- *Promoting and building on ABS-related codes of conduct*. The EU regards it as important to explore how the international ABS regime can promote ABS-related codes of conducts for important groups of users and identify codes of conduct that are regarded as best practice.
- *Engaging with public research funding agencies*. Many *in situ* bioprospecting activities are supported with public research funds. Public research funding agencies therefore have a possible role in obliging users of genetic resources receiving research funds to comply with specific ABS requirements. The EU suggests engaging with public research funding agencies and exploring how these can support compliance with PIC and MAT.

CONCRETE OPTIONS TO SUPPORT COMPLIANCE WITH MAT

Mutually agreed terms (MAT) are typically set out in contracts between providers and users of genetic resources; so called "Material Transfer Agreements" (MTAs).

Specific compliance challenges that result from the fact that parties to an ABS-contract reside in different jurisdictions are addressed in private international law relating to contracts. It is therefore essential that the ABS negotiations build upon existing rules of private international law relating to contracts in supporting compliance with MTAs to avoid duplication of efforts.

Significant support to compliance with MAT would also result

- from *work to improve the information base for ABS-related transactions*, and
- by offering providers and users of genetic resources *menus of model clauses for potential inclusion in Material Transfer Agreements*.

Both of these concrete options are further explained in the following sections of this submission.

DEVELOPING MENUS OF MODEL CLAUSES FOR POTENTIAL INCLUSION IN MATERIAL TRANSFER AGREEMENTS

A concrete and practical option relevant to the fair and equitable sharing of benefits as well as to supporting compliance with ABS requirements is the development of menus of model clauses for potential inclusion in Material Transfer Agreements.3/

It would enhance legal certainty and compliance with ABS requirements and add to a supportive environment for the fair and equitable sharing of benefits if providers and users of genetic resources could turn to such menus of model clauses when negotiating "their" Material Transfer Agreement (MTA).

The availability of model MTA-clauses for specified uses of genetic resources would protect the weaker party in negotiations of mutually agreed terms by creating a level playing field. It also has significant potential for lowering transaction costs and for achieving legal certainty that obligations agreed between provider and users are enforceable in practice.

Such menus of model clauses should primarily be developed through sectoral processes in a bottom-up way with the involvement of stakeholders. Governments cooperating in the framework of the CBD should identify suitable sectors, spell out minimum process requirements and provide support as appropriate.

The international ABS negotiations need to address how the development of menus of model clauses for inclusion in MTAs would fit into and contribute to the international ABS regime. To facilitate a concrete and outcome-oriented discussion, the EU has made a submission on this specific issue in June 2007 (see pp. 49 ff. of Document UNEP/CBD/WG-ABS/5/INF/1).

MAXIMISING THE UTILITY OF MODERN IT-TOOLS TO IMPROVE THE INFORMATION BASE OF ABS-RELATED TRANSACTIONS

One of the greatest challenges to the effective implementation of access and benefit-sharing obligations are difficulties for both providers and users of genetic resources to be informed about transactions of genetic resources, changes in uses of genetic resources and ABS-related rights and obligations, including those from traditional knowledge associated with genetic resources.

It is therefore essential that the international ABS regime improves the information-base of ABS governance and thereby adds to enhanced transparency of and legal certainty in transactions of genetic resources. Practical and meaningful steps in this regard will also contribute to the ability of governments and stakeholders to take on further commitments to support compliance with PIC and MAT.

There is room for achieving significant improvements in the availability of ABS-related information at very low cost, if the advanced communication capacities of modern electronic networks were employed to support providers and users in obtaining a record of transactions of "their" GR and associated rights and obligations.

It is therefore essential that the ABS negotiations reflect and build on existing technological possibilities to ensure that rules and instruments of the international ABS regime are crafted in a way that maximises the utility of modern IT-tools to ABS governance.

CONSIDERING AND RESPONDING TO CAPACITY-BUILDING NEEDS

The EU regards capacity-building as a cross-cutting issue and relevant considerations as integral to the ABS negotiations and the international ABS regime.

However, specific capacity-building needs resulting from the international ABS regime and specific responses can only be discussed with negotiations further advanced. Nevertheless, the EU

3/ Responding to discussions on its proposal to initiate work on "standardising choices in MTAs", the EU will in the future refer to "the development of menus of model clauses" to express more clearly the overall thrust and potential contents of such work.

stresses its willingness to support capacity-building, as appropriate, to help eligible countries meet emerging requirements under the international ABS regime.

The EU also holds that GEF should play a major role in ABS-related capacity building over the coming years.

INTEGRATING TRADITIONAL KNOWLEDGE INTO THE ABS REGIME

The EU works to ensure that the international ABS regime contributes to the respect for and the preservation and maintenance of traditional knowledge associated with genetic resources as well as to the equitable sharing of benefits arising from the use of such knowledge in accordance with Article 8j CBD.

The EU is convinced that indigenous and local communities and their representatives could make important contributions to the ABS negotiations by providing well reflected, focused views on issues linked to traditional knowledge.

The EU has identified the following list of issues where work on the ABS regime could benefit from targeted, technical reflections by experts from indigenous and local communities.

- Internationally Recognised Certificate of Compliance: How could the scope of such certificate also include traditional knowledge associated with GR?
- Ethical code of conduct: How could the draft code contribute to the effective implementation of the CBD's ABS-related obligations?
- TK and ABS-related research: best practices to ensure that ABS-related research respects existing TK? (e.g. publication policies, TK registries)
- TK and PIC: ways to incorporate TK in PIC decisions. Options to address the balance between domestic flexibility and international minimum requirements on access. How to ensure that national PIC decisions respect transboundary indigenous communities?
- TK and MAT: Options and examples for incorporating TK in efforts to standardise choices for MAT.
- TK and Capacity-Building: Identification of current capacity-building needs, as well as potential capacity-building implications in the proposed international ABS regime context.

INDIA'S SUBMISSION ON CONCRETE OPTIONS ON SUBSTANTIVE ITEMS ON AGENDA OF ABSWG-5 AND ABSWG-6

1. Items on Agenda of ABSWG-5

3.1 Fair and Equitable Sharing of Benefits

Minimum conditions and standards for the fair and equitable sharing of the benefits arising out of the use of genetic resources, derivatives and/or associated traditional knowledge shall be stipulated in national legislations and shall be based on mutually agreed terms and on prior informed consent.

The conditions for the equitable sharing of the benefits arising out of the use of traditional knowledge, innovations and practices associated with genetic resources and derivatives shall be stipulated in mutually agreed terms, in accordance with national legislations: a) between the indigenous or local communities and the users; or b) between users and the national authority of the provider country, with active involvement of concerned indigenous and local communities.

Parties shall establish, taking into account Article 16, paragraph 3 and 4, Article 19, paragraph 1 and 2, and Article 20, paragraph 4 of the Convention, measures to ensure the fair and equitable sharing of benefits from the results of research and development, including through facilitating access to the results of such research and development and through access to and technology transfer, and other utilization of genetic resources, derivatives and/ or associated traditional knowledge, including technology protected by patents and other intellectual property rights on concessional and preferential terms to developing countries, taking into account prior informed consent and mutually agreed terms and respecting national legislations of the country of origin of such resources or the parties that have acquired the resources in accordance with the Convention.

Parties that develop technologies making use of genetic resources, derivatives and/or associated traditional knowledge shall establish national legislation to facilitate access to, joint development and transfer of those technologies to developing countries that are the origin of such resources, derivatives and/or associated traditional knowledge under mutually agreed terms.

3.2 Access to Genetic Resources

States have sovereign rights over their own genetic resources and derivatives and the authority to determine access rests with national Governments and is subject to national legislation.

3.3(a) Measures to support compliance with PIC and MAT

Disclosure of Origin of Genetic Resources, Derivatives and/or Associated Traditional Knowledge

Intellectual property rights applications whose subject matter concerns or makes use of genetic resources, derivatives and/or associated traditional knowledge shall disclose the country of origin or source of such genetic resources, derivatives and /or associated traditional knowledge, as well as evidence that provisions regarding prior informed consent and benefit sharing have been complied with, in accordance with the national legislation of the country providing the resources.

National legislation shall provide for remedies to sanction lack of compliance with the requirements set out in the above paragraph which must include inter alia revocation of the intellectual property rights in question, as well as co-ownership of the IPR and its transfer.

3.3(b) Internationally Recognized Certificate of Origin/Source/Legal Provenance

The certificate should be an integral part of the international regime.

Elements of the certificate are:

- Compliance with national law (including exemptions)
- International recognition

- Mandatory
- Effective supporting mechanisms in user countries to prevent misappropriation or abuse (effective checkpoints, such as registration for commercial application; IPRs offices; entities funding research) to provide evidence of PIC
- To provide for consequences of infringement – sanctions

(Comment: Nature and scope of the certificate could be based on paragraphs 15 and 16 of the Report of the meeting of the Group of Technical Experts on an Internationally Recognized Certificate of Origin/Legal Provenance; certificate could be referred to as a certificate of compliance with national law, in accordance with the Convention, and its basic role should be to provide evidence of compliance with national access and benefit-sharing regimes, as mentioned in paragraph 7 of the Report.)

3.3(c) Monitoring, Enforcement and Dispute Settlement

Access to justice

Measures to ensure access to justice and redress.

Measures to guarantee and facilitate expeditious, effective and at a low transaction cost access to justice and redress, tailored to the subject of this regime, including administrative and judicial remedies, as well as alternative dispute resolution mechanisms by providers and users.

Measures to ensure cooperation, including procedures and institutional mechanisms, between contracting parties to address infringements of national legislation and of agreements on access and benefit-sharing.

Compliance and enforcement

Parties shall develop national legislation for the implementation of the international regime.

Each Party shall comply with national legislation of the countries of origin of such resources or of the Parties that have acquired the genetic resources in accordance with the Convention, regarding access and benefit-sharing when accessing and/or using genetic resources, derivatives and/or associated traditional knowledge.

Parties shall take measures to ensure that the use of genetic resources accessed within their jurisdiction comply with the Convention on Biological Diversity and with the conditions under which access was granted.

Parties shall establish mechanisms to facilitate collaboration among relevant enforcement agencies in both provider and user countries.

Without prejudice to specific remedies concerning IPR applications, national legislations shall provide for sanctions to prevent the use of genetic resources, derivatives and/or associated traditional knowledge without compliance with provisions of the international regime, in particular those related to access and benefit-sharing legislations from countries of origin of such resources or from the Parties that have acquired the genetic resources in accordance with the Convention.

Parties shall take all appropriate measures to prevent and combat misappropriation of genetic resources, their derivatives and/or associated traditional knowledge.

(Comment: examples mentioned in paragraph 12 of the Annex to Dec. COP/8 could be considered as inputs for the consideration of the issue of misappropriation in the context of the elaboration and negotiation of the international regime)

Dispute settlement mechanism

Parties shall establish a dispute settlement mechanism for the international regime.

Financial mechanism

Parties shall establish a financial mechanism for the international regime including for benefit-sharing arrangements.

4. Traditional Knowledge and Genetic Resources

Recognition and protection of traditional knowledge associated with genetic resources and derivatives

(Comment: sui generis systems for the protection of the knowledge, innovations and practices of indigenous and local communities should be developed; sui generis systems should be complementary to the international regime; classical instruments of intellectual property rights have revealed themselves insufficient to ensure respect for the rights of the holders of traditional knowledge.)

The elements of the international regime shall be developed and implemented in accordance with Article 8(j) of the Convention on Biological Diversity:

(a) Parties may consider developing, adopting and/or recognizing, as appropriate, sui generis systems for the protection of traditional knowledge, innovations and practices associated to genetic resources and derivatives;

(b) Parties shall recognize and protect the rights of indigenous and local communities to their knowledge, innovations and practices and ensure the equitable sharing of benefits arising from the utilization of the knowledge, innovations and practices associated with genetic resources and derivatives, subject to the national legislation of the countries where these communities are located;

(c) Users shall obtain the prior informed consent of indigenous and local communities holding traditional knowledge associated with genetic resources and derivatives, in accordance with Article 8(j) of the Convention on Biological Diversity, subject to national legislation of the country where these communities are located.

5. Capacity Building

The international regime shall include provisions for the building and enhancement of capacity in developing countries, least developed countries and small-island developing States, as well as countries with economies in transition, for the implementation of the international regime at national, regional and international levels.

Measures for effective technology transfer and cooperation so as to support the generation of social, economic and environmental benefits.

Building of human, institutional and scientific capacities including for putting in place a legal mechanism, taking into account Articles 18, 19 and 20.4 of the Convention.

2. New Items on Agenda of ABSWG-6

3.4 Nature, Scope and Objectives of the International Regime

Nature

The international regime could be composed of one or more instruments within a set of principles, norms, rules and decision-making procedures legally-binding and/or non-binding.

Objectives

To endeavour to create conditions to regulate access to genetic resources for environmentally sound uses by other Parties and not to impose restrictions that run counter to the objectives of this Convention.

To ensure the fair and equitable sharing of the monetary and non-monetary benefits arising from the use of genetic resources and associated traditional knowledge, taking into account that the three objectives of the Convention are interlinked.

Subject to national legislation, to protect the rights of indigenous and local communities to their traditional knowledge, innovations and practices associated to genetic resources and derivatives and to ensure the fair and equitable sharing of the monetary and non-monetary benefits arising from the utilization of their knowledge, subject to national legislation of the countries where these communities are located and applicable international law.

To ensure compliance with PIC in the context of MAT of countries of origin and of indigenous and local communities.

To contribute to the effective implementation of articles 15, 8(j) and 16 to 19 and the three objectives of the convention.

The conservation and sustainable use of biological diversity.

To prevent the misappropriation and misuse of genetic resources, their derivatives and associated traditional knowledge.

To ensure that fair and equitable sharing of benefits flow to the countries of origin of the genetic resources.

Ensure compliance with prior informed consent of the providing countries and of indigenous and local communities and mutually agreed terms;

Ensure and enforce the rights and obligations of users of genetic resources;

Ensure mutual supportiveness with relevant existing international instruments and processes and that they are supportive of and do not run counter to the objectives of the convention.

Contribute or promote capacity-building and to ensure technology transfer to developing countries, in particular least developed countries and small island developing States

Scope

1. The international regime applies to, in accordance with national legislation and other international obligations:

(a) Access to genetic resources and derivatives and products subject to the national legislation of the country of origin;

(b) Conditions to facilitate access to and transboundary utilization of genetic resources and derivatives and products and/or traditional knowledge;

(c) Fair and equitable sharing of the monetary and non-monetary benefits arising out the utilization of genetic resources and their derivatives and/or associated traditional knowledge and, where appropriate, their derivatives and products, in the context of mutually agreed terms based on prior informed consent in accordance with the national legislation of the country of origin;

(d) Protection of traditional knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biodiversity associated to genetic resources and their derivatives and products in accordance with national legislation.

2. The international regime applies to all genetic resources and associated traditional knowledge, innovations and practices and benefits arising from the utilization of such resources.

3. The international regime will not apply to the plant genetic resources of those plant species that are considered by under annex 1 of the International Treaty on Plant Genetic Resources for Food and Agriculture

4. The international regime is without prejudice to the FAO International Treaty on Plant Genetic Resources for Food and Agriculture and will take into account the work of the WIPO/IGC on the

intellectual property aspects of *sui generis* systems for the protection of traditional knowledge and folklore against misappropriation and misuse.

5. The international regime ensures mutual supportiveness and complementarity with relevant existing international instruments and processes and that they are supportive of and do not run counter to the objectives of the Convention.

6. The international regime will not apply to human genetic resources.

7. The scope of the regime would be in compliance with national access and benefit-sharing regimes relating to the genetic resources within national jurisdictions.

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II. SUBMISSIONS FROM INDIGENOUS AND LOCAL COMMUNITIES AND STAKEHOLDERS

COMMENTS OF THE INDIGENOUS PEOPLES COUNCIL ON BIOCOLONIALISM

Submitted to the Convention on Biological Diversity in Preparation for the Sixth Meeting of the Working Group on Access and Benefit Sharing

Introductory Note

The Indigenous Peoples Council on Biocolonialism 4/ (IPCB) actively participated at the WGABS-5 as well as the WG8j-5 agenda item on ABS in Montreal and similarly expects to be actively engaged in the WGABS-6 upcoming in Geneva. Therefore, in response to the Executive Secretary's Notifications SCBD/SEL/VN/GD/60541 and SCBD/SEL/VN/GD/60723, inviting Parties, Governments, indigenous and local communities and stakeholders to submit to the Secretariat, by 30 November 2007 concrete options on the substantive items on the agenda of the fifth and sixth meetings of the Working Group, the IPCB respectfully submits the comments below. Our comments are organized according to the same headings used by the Co-Chairs and following the agenda items of the meeting, however, not all issues or agenda items are addressed.

As an introductory remark, in reviewing these documents, IPCB notices a general lack of attention to the rights of Indigenous peoples. Perhaps that is because the focus of the Co-Chair's document is on points of convergence, rather than divergence. The lack of substantive elements related to recognizing and protecting Indigenous peoples' rights within the context of ABS leads our organization to the reasonable assumption that there is a divergence amongst the Parties about the content of such rights and how these rights might be addressed in the international regime. We realize that Indigenous rights have in the past, and undoubtedly, will remain a contentious issue.

Many of these issues could be fleshed out in an international consultation process that involved indigenous experts, states, and others, where meaningful dialogue could take place. Such a process was proposed at WGABS-5 and WG8(j)-5 by the IIFB and other Indigenous organizations. Such a process could serve to bridge the work of WGABS and WG8(j) and could be a contribution to much needed collaboration between the two bodies.

Potential Areas of Convergence

Within this list of potential areas of convergence, the IPCB does not see any note of a commitment by Parties to recognize the rights of Indigenous peoples and ensure that these rights will be protected within any future international regime. The only item listed that begins to approach that necessary point is "Linkage between genetic resources and traditional knowledge need to be addressed."

Benefit Sharing

Within this list of points of convergence, we certainly agree that benefit sharing must be mandatory and that benefit sharing and related negotiations must include Indigenous peoples. The more difficult question is how will that involvement play out? We contend that Indigenous peoples have the right of self-determination, therefore, if through their own decision making processes agree to enter into a benefit sharing arrangement, they must be principal parties, fully involved in all aspects and stages of the negotiations leading to the final contract. They must be principal parties to the contract, not merely third-party beneficiaries.

Benefit sharing must relate to those benefits generated from derivatives of genetic resources. Certainly we agree that a definition of derivatives must be developed, and such a definition must include

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4/ The Indigenous Peoples Council on Biocolonialism is an Indigenous non-profit organization based on the Pyramid Lake Paiute Tribe Reservation in Nixon, Nevada (USA). IPCB was created to assist Indigenous peoples in the protection of their genetic resources, Indigenous knowledge, and cultural and human rights from the negative effects of biotechnology. See www.ipcb.org. For more information, please contact Le`a Malia Kanehe, Esq., Legal Analyst at lkanehe@ipcb.org.

all so-called "inventions" that are based on non-human genetic material, including *inter alia* isolated genes, copies of genes (cDNA), cell lines and synthetic genes, as well as all information and data derived from such genetic material. If the item or information can be patented, it should be considered a derivative, and subject to benefit sharing.

Access

We are pleased to see that there is a point of convergence that access to genetic resources must involve the PIC of Indigenous peoples. What does that right to PIC mean in this context for Indigenous peoples? How will that right be recognized and protected in the regime? Although we realize that PIC is a specific term of art within the CBD, we encourage that the understanding should be informed by other processes outside the CBD, including the United Nations Declaration on the Rights of Indigenous Peoples' relevant provisions on free prior informed consent (FPIC). These provisions represent the appropriate international standard that should be strived for in the CBD.

Regarding access for non-commercial or commercial use, IPCB maintains that the international regime should respect the right of states to adopt national laws to regulate both. What may begin as non-commercial research always has the potential to be used in a commercial context. The reality is that the same genetic material can be applied for a range of uses conservation to genetic engineering, from food and agriculture to pharmaceutical or chemical. Some uses may lend more towards non-commercial use, while others have definite commercial potential. But with the ability of researchers to copy genes and make synthetic genes, this means that the research institution may never have to return to the in situ or ex situ collection again. They will have all they need in their laboratory to apply for any use. Thus the initial access must be regulated, whether it comes from an academic research intending to "pure science" or whether it comes from a corporation with clear commercial intent.

There are two primary issues that are not reflected in the Co-Chairs' document. Both of these were presented on the floor by both the Pacific Indigenous Caucus as well as the Pacific Small Island Developing States.

1. Special measures to address access to marine genetic resources, which is a primary biodiversity resource of Pacific Island Countries, and at the same time of great interest to the biotechnology industry. Unlike *in-situ* terrestrial species, the country of origin of *in-situ* marine species maybe more difficult to ascertain. Marine species, move quite freely across national boundaries (Exclusive Economic Zones), thus their transboundary nature must be taken into account regarding PIC, MAT and benefit-sharing. Discussions regarding access to marine genetic resources also need to take into account collection that occurs outside areas of national jurisdiction, i.e, on the high seas or deep sea floor, but where species have originated within the national boundaries of a country and have migrated into areas where there is no national jurisdiction.
2. How will an international regime respect national laws that recognize collective land ownership by Indigenous peoples and related rights to control access and use of genetic resources within those areas?

Certificate of Origin

Many Indigenous peoples are uncomfortable with the proposals surrounding Certificate of Origin/Source/Legal Provenance/Compliance with National Law. This partly due to the fact that Indigenous peoples only had one representative at the Group of Technical Experts, there most Indigenous peoples have not had the opportunity to learn about the proposals and engage in a dialogue about how Indigenous peoples' rights may or may not be protected within such a certificate system, both at the international and national level. Particular attention needs to be paid to the concept of applying a certificate system to TK. Unlike a tangible biological samples (containing genetic material) or a genetic sample (no matter how small that is), it is not clear how intangible knowledge could be stamped with a

unique identifier code. One of the central questions that must be addressed is would documenting the knowledge be a requirement to having a certification issued? Certainly a document containing information about the knowledge could be stamped, but the implications of that documentation is far reaching and poses great threat to Indigenous knowledge, and the rights of the holders of that knowledge.

Monitoring, Enforcement and Dispute Settlement

Although each of these areas are important, one central question that IPCB would like to highlight is what rights will Indigenous peoples have in whatever enforcement and dispute settlement system is created. Most international systems of enforcement and dispute settlement are not forums where Indigenous peoples can be claimants on our own behalf. What would be the point of having rights, if they cannot be enforced? Such a system must provide Indigenous peoples with a mechanism to hold states accountable for their obligations to protect our rights as well hold non-state actors, namely individual researchers, research institutions, and corporations as the case may be, accountable for violating our rights, including those rights conferred through contract.

Traditional Knowledge and Genetic Resources

There are many problematic points raised in this section of the Co-Chair's Reflections. If there was a point of convergence that the UNDecRIPs Article 31 formed a foundation for any elements related to IK, the points listed under this section would be a lot less problematic.

Some of the problems could be addressed if Indigenous knowledge was simply dealt with as a special subcategory of traditional knowledge. When IK is subsumed by TK, the unique rights of Indigenous peoples to and over our IK are ignored.

Surely, the objectives of Article 8(j) should be met, but it is time for the CBD to evolve to incorporate the current status of Indigenous peoples in international law within the context of Article 8(j) and 15 that has developed over the last 15+ years since the adoption of the Convention. An accurate and honest assessment of the status of our rights under international law requires will require going beyond the limited text of Article 8(j). It is incumbent upon the COP to adopt decisions that interpret the text of the Article in accordance with existing international law in a language that recognizes and protects the rights of Indigenous peoples. This means Article 8(j) must be interpreted and implemented in a manner consistent with the rights under the DecRIPs, but also those accepted under the UN Charter, the Universal Declaration on Human Rights, the ICCPR, ICESCR, CERD and other human rights instruments. Many of these were listed in the annex to the COP7 decision as processes that should be considered in the development of elements, but no attention has been paid to their specific provisions and legal interpretations that have been attributed to them by the relevant human rights bodies.

The adoption of an international regime provides an opportunity for the CBD to expand its terminology, including related to Indigenous peoples and traditional knowledge. This presents an opportunity to deal directly with "indigenous peoples" per se rather than just lumping us into a category of "indigenous and local communities." This also presents an opportunity to deal directly with the unique category of TK that belongs to Indigenous peoples, namely "indigenous knowledge."

The point of convergence stated in the Co-Chairs' Reflections seems to imply that the right that states have to PIC for genetic resources would be the same for traditional knowledge. Indigenous knowledge belongs to Indigenous peoples, therefore, the only appropriate authority to consent to any use of that knowledge is the Indigenous peoples themselves. States have no rights in the knowledge. Indigenous peoples need a commitment from Parties that the international regime will set a standard for national law in relation to the minimum standards that must be met to recognize Indigenous peoples' rights to their knowledge. The role of national law is to protect the minimum standard of rights. States do not have carte blanche to pass laws that will derogate or diminish international minimum standards.

It is a dangerous proposition to propose to develop a *sui generis* system for TK only after an international regime. A *sui generis* system of protection for Indigenous knowledge at the international level is urgently needed and should be a precondition to and binding element of any international regime on ABS. The international regime must be one that protects TK. The existing system is insufficient and

must be brought up to standard before moving forward with adopting an international regime that purports to cover TK within its scope. There have been some proposals made in the CBD that WIPO is the appropriate forum for this discussion; We maintain that although WIPO may have some contributions to make, it does not that the discussion and decisionmaking can just be left to WIPO. This is a CBD issue, and CBD must deal with it.

IPCB sees an international *sui generis* system as one that sets minimum standards for protection, which must be actualized at the national level. Once at the national level, States must recognize the *sui generis* systems of protection already existing within Indigenous law as the appropriate body of law to deal with all aspects of ABS, including access to and utilization of GR and IK.

The fact that so many issues within the proposed international regime relate to TK, it only seems logical that it must be dealt with as a cross-cutting issue, not just as an isolated element. The true linkage between genetic resources and traditional knowledge and/or Indigenous knowledge needs to be addressed. IK is inseparable from GR and therefore can be isolated in one or even a few elements of the regime. Furthermore, protection of IK cannot be voluntary, therefore adoption of mere guidelines will not be sufficient.

One issue that has not been reflected in the Reflections is the need for any international regime to address the transboundary nature of traditional knowledge. For example, their may be similar TK in different countries about plants indigenous to the Pacific, such as kava, noni, and taro, among others, which needs to be addressed in elements of an international regime, including for the international regime to respect regional agreements.

INDIGENOUS WOMEN'S BIODIVERSITY NETWORK (IWBN)

Re: Concrete Options on the Substantive Items on the Agenda of the Fifth and Sixth Meetings of the Working Group on Access and Benefit-sharing

Submitted by the Netherlands Centre for Indigenous Peoples

I. Who We Are

The Indigenous Women's Biodiversity Network (IWBN) is a network of Indigenous women working on environmental issues. The goal of the network is to promote, and to ensure, the active participation of Indigenous women in all relevant international environmental fora, especially as Indigenous women continue to be under-represented. Specifically, it seeks to promote the vital, important role that Indigenous women have in the conservation and sustainable use of biological diversity, and in regards to maintaining Indigenous Peoples' traditional knowledge, cultures and languages, which are passed on from generation to generation. Further, as Indigenous women have less access to the money economy, but greater responsibilities in child-rearing and community health, Indigenous women thus often have a far greater dependence on natural resources and biodiversity.

The IWBN is a part of the International Indigenous Forum on Biodiversity (IIFB), the formal Indigenous Peoples' Caucus and advisory body to the Conference of the Parties that is active at the international level environmental meetings. The IWBN's meetings are held separately, but its members also fully and actively participate in the IIFB, contribute the gender perspective, and regularly report to this body on its activities.

Indigenous women are the guardians of Indigenous knowledge and their main responsibility is to protect and perpetuate this knowledge. Their weavings, music, songs, costumes, and their knowledge of agriculture, hunting or fishing are all examples of some of their contributions to the world. They are daughters of Mother Earth and to her they are obliged. Their ceremonies recognize her and they return to her the placentas of their children. She also safeguards the remains of their ancestors.

II. Concrete Options on the Substantive Items on the Agenda

International Regime on Access and Benefit-sharing

The IWBN reaffirms the existence of universal human rights' standards for the protection of the collective rights of Indigenous Peoples as adopted in the United Nations Declaration on the Rights of Indigenous Peoples. The Declaration on the Rights of Indigenous Peoples shall be used as a standard in any potential international regime on Access and Benefit Sharing. Any potential regime must be implemented in the context of the recognition and protection of Indigenous Peoples' rights, including their rights to lands, territories and natural resources, and identity.

Without the recognition of the rights of Indigenous Peoples, especially the right to free, prior and informed consent of Indigenous Peoples, there can be no access to their genetic resources or their traditional knowledge. The IWBN would like to remind Parties of the Provisions of Article 31 of the Declaration on the Rights of Indigenous Peoples, which should be used as the guiding principles:

Article 31

1. *Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions.*

2. *In conjunction with indigenous peoples, States shall take effective measures to recognize and protect the exercise of these rights.*

Access to Genetic Resources and Fair and Equitable Sharing of Benefits

The IWBN strongly feels that Indigenous Peoples must be involved at all stages of the development of any potential International Regime and determine the form of benefit-sharing. This should include in particular, strong participatory rights in any national, regional or sub-regional bodies established for the implementation of any access and benefit-sharing regimes. Alternatively, Indigenous institutions could be established or, where they exist, strengthened, for the same purposes. Consultation processes should, in particular, serve to identify Indigenous priorities with regard to benefit-sharing.

The IWBN would like to also reiterate that there can be no benefit-sharing without effective implementation of the concept of free, prior and informed consent (FPIC) of Indigenous Peoples. Any agreed terms for benefit-sharing can only be developed through a functioning FPIC process. In the same vein, any benefit-sharing arrangement must respect Indigenous Peoples' rights to lands, territories, and natural resources, and traditional knowledge.

The traditional knowledge, innovation and practices of Indigenous women are vast. Their specialized experience has made them midwives, spiritual leaders, healers, herbalists and botanists within their peoples, and beyond. Their knowledge, use and control of medicinal plants must be protected from misuse and misappropriation, including studies, research and commercialization efforts.

Indigenous Peoples may in some cases be confronted with a situation where they may be unable to afford access to medicines, agricultural products or other innovations developed from their genetic resources and traditional knowledge. Access and benefit-sharing arrangements should also address the ability of Indigenous Peoples to access products based on the use of their genetic resources and traditional knowledge. Access and benefit-sharing regimes should contain elements that allow for the preferential access and the ability of national governments to apply compulsory licensing that increase Indigenous access to products and technology that derive from their cultural heritage.

Traditional Knowledge and Genetic Resources

The IWBN reaffirms that both traditional knowledge and genetic resources are closely interrelated and cannot be separated. The customary laws of Indigenous Peoples must be respected and recognized in the regulation of the access and use of our genetic resources and associated traditional knowledge. Without recognition of our rights, there can be no access.

Capacity-building

The full and effective participation of Indigenous women is critical, so that we are active participants and decision-makers at every stage in the development and implementation of the programs of work and decisions of the Convention on Biological Diversity (CBD), in accordance with COP Decision VI/10. In this regard, the IWBN calls for capacity-building, especially on communication and awareness-raising on the CBD processes and relevant international instruments.

Capacity-building needs to be on the terms defined by Indigenous Peoples, and be sensitive to their cultures, laws and aspirations. Training must be neutral and not designed to bias Indigenous Peoples towards a regime on access and benefit-sharing or certain aspects of it.

The IWBN notes the relationship between capacity-building and access to financial resources. More resources are needed for capacity-building and for adequate participation of Indigenous women in the elaboration of any potential regime on access and benefit-sharing. The right to control and form capacity-building efforts should, to the largest extent possible, be brought down to the community level and to their institutions.

RED DE MUJERES INDÍGENAS SOBRE LA BIODIVERSIDAD (EMIB)

Re: Opciones Concretas sobre Temas Sustantivos de la Agenda de la 5ª y 6ª reuniones del Grupo de Trabajo sobre Acceso y Distribución de Beneficios

Presentado por el Centro Holandés para los Pueblos Indígenas

I. Quiénes somos

La Red de Mujeres Indígenas sobre la Biodiversidad (EMIB) es una red de mujeres indígenas que trabajan sobre temas del medio ambiente. El objetivo de la red es promover y asegurar la participación activa de las mujeres indígenas en todos los foros internacionales pertinentes sobre medio ambiente, en especial porque como mujeres indígenas continuamos estando representadas de manera insuficiente. Específicamente, busca promover que la mujer indígena desempeñe un papel primordial, importante en la conservación y uso sostenible de la diversidad biológica y, en cuanto a mantener el conocimiento tradicional de los pueblos indígenas, culturas y lenguas, que se han transmitido de generación en generación. Además, en tanto mujeres indígenas tenemos menor acceso a la economía monetaria, pero mayores responsabilidades en la crianza de los hijos y la salud de la comunidad, de ahí que, las mujeres indígenas a menudo tenemos mayor dependencia de los recursos naturales y biodiversidad.

La EMIB es parte del Foro Indígena Internacional sobre Biodiversidad (FIIB), el *Caucus* oficial de los pueblos indígenas y órgano asesor de la Conferencia de las Partes que es activa en el ámbito internacional en las reuniones de medio ambiente. Las reuniones de la EMIB se celebran separadamente, pero sus miembros también participan plena y activamente en el FIIB, contribuye a la perspectiva de género y de manera regular informa a este órgano sobre sus actividades.

Las mujeres indígenas son las guardianas del conocimiento indígena y su principal responsabilidad es proteger y perpetuar este conocimiento. Sus tejidos, música, canciones, trajes, y sus conocimientos sobre agricultura, caza o pesca son ejemplos de algunas de sus contribuciones al mundo. Ellas son hijas de la Madre Tierra y a ella dan gracias. Sus ceremonias la reconocen como tal y a ella devuelven las placentas de sus hijos. Ella también salvaguarda los restos de sus ancestros.

II. Opciones concretas sobre los puntos sustantivos de la Agenda

Régimen Internacional sobre Acceso y Distribución de Beneficios

La EMIB reafirma la existencia de normas universales de derechos humanos para la protección de los derechos colectivos de los pueblos indígenas tal como fueron adoptados en la Declaración de las Naciones Unidas sobre los Derechos de los Pueblos Indígenas. La Declaración sobre los Derechos de los Pueblos Indígenas debe ser utilizada como una norma en todo posible régimen internacional sobre acceso y distribución de beneficios. Todo posible régimen debe ser implementado en el contexto del reconocimiento y protección de los derechos de los pueblos indígenas, incluyendo el derecho a la tierra, territorios y recursos naturales, así como a la identidad.

Sin el reconocimiento de los derechos de los pueblos indígenas, especialmente el derecho al consentimiento libre, previo e informado de los pueblos indígenas, no puede haber acceso a sus recursos genéticos o a sus conocimientos tradicionales. La EMIB quisiera recordar a las Partes las disposiciones del Artículo 31 de la Declaración sobre los Derechos de los Pueblos Indígenas, que deben ser utilizados a manera de principios rectores:

Artículo 31

1. *Los pueblos indígenas tienen derecho a mantener, controlar, proteger y desarrollar su patrimonio cultural, sus conocimientos tradicionales, sus expresiones culturales tradicionales y las manifestaciones de sus ciencias, tecnologías y culturas, comprendidos los recursos humanos y genéticos, las semillas, las medicinas, el conocimiento de las propiedades de la fauna y la flora, las tradiciones orales, las literaturas, los diseños, los deportes y juegos tradicionales, y las artes visuales e interpretativas. También tienen derecho a mantener,*

controlar, proteger y desarrollar su propiedad intelectual de dicho patrimonio cultural, sus conocimientos tradicionales y sus expresiones culturales tradicionales.

2. *Conjuntamente con los pueblos indígenas, los Estados adoptarán medidas eficaces ara reconocer y proteger el ejercicio de estos derechos.*

Acceso a Recursos Genéticos y Distribución Justa y Equitativa de Beneficios

La EMIB está profundamente convencida que los pueblos indígenas deben participar en todas las etapas del desarrollo de todo posible Régimen Internacional y determinar la forma de distribución de beneficios. Esto puede incluir en particular, derechos de importante participación en todos los órganos nacionales, regionales o sub-regionales establecidos para la aplicación de todo tipo de regímenes de acceso y distribución de beneficios. Alternativamente, las instituciones indígenas pueden ser establecidas o, donde ya existan, reforzarlas para los mismos propósitos. Los procesos de consulta deben, en particular, servir para identificar las prioridades indígenas en relación a la distribución de beneficios.

La EMIB desearía también reiterar que no puede haber distribución de beneficios sin la efectiva implementación del concepto de consentimiento libre, previo e informado (FPIC) de los pueblos indígenas. Todas las condiciones acordadas de distribución de beneficios sólo pueden ser desarrolladas a través un proceso de funcionamiento FPIC. En el mismo sentido, todo acuerdo de distribución de beneficios debe respetar los derechos de los pueblos indígenas a sus tierras, territorios, recursos naturales y conocimientos tradicionales.

Los conocimientos tradicionales, innovación y prácticas de mujeres indígenas son muy vastos. Sus experiencias especializadas las hizo comadronas, líderes espirituales, curanderas, herbolarias y botanistas en el seno de sus pueblos, y fuera de ellos. Sus conocimientos, utilización y control de plantas medicinales debes protegerse del empleo erróneo y apropiación ilícita, incluyendo estudios, investigación y esfuerzos de comercialización.

Los pueblos indígenas deben, en algunos casos, confrontarse con una situación donde pueden ser incapaces de permitir acceso a medicinas, productos agrícolas u otras innovaciones desarrollas de sus recursos genéticos y conocimientos tradicionales. Los acuerdos de acceso y distribución de beneficios pueden también estudiar la habilitad de los pueblos indígenas para acceder a productos basados en el uso de sus recursos genéticos y conocimientos tradicionales. Los regímenes de acceso y distribución de beneficios pueden contener elementos que permitan el acceso preferencial y la capacidad de los gobiernos nacionales a aplicar la licencia obligatoria que aumente el acceso de los indígenas a los productos y la tecnología que se deriven de su patrimonio cultural.

Conocimientos Tradicionales y Recursos Genéticos

La EMIB reafirma que tanto los conocimientos tradicionales como los recursos genéticos están estrechamente vinculados y no pueden ser separados. Las leyes consuetudinarias de los pueblos indígenas deben ser respetadas y reconocidas en la reglamentación del acceso y utilización de nuestros recursos genéticos y conocimientos tradicionales relacionados. Sin reconocimiento de nuestros derechos, no puede haber acceso.

Desarrollar las competencias

La plena y efectiva participación de la mujer indígena es esencial, ya que somos participantes activas y responsables en cada etapa del desarrollo e implementación de los programas de trabajo y decisiones de la Convención sobre Diversidad Biológica (CBD), de acuerdo con la Decisión VI/10 COP. Con respecto a esto, la EMIB pide desarrollar las competencias, especialmente en lo que se refiere a comunicación y sensibilización de la opinión pública sobre el proceso de la CBD e instrumentos internacionales pertinentes.

El desarrollo las competencias necesita ser en los términos definidos por los pueblos indígenas, sensibles a sus culturas, leyes y aspiraciones. La capacitación debe ser neutra y no diseñada para influenciar a los pueblos indígenas hacia un régimen de acceso y distribución de beneficios o ciertos aspectos de ello.

La EMIB observa la relación existente entre desarrollar las competencias y acceso a los recursos financieros. Se necesitan más recursos para desarrollar las competencias y para la participación adecuada de mujeres indígenas en la elaboración de cualquier posible régimen sobre acceso y distribución de beneficios. El derecho a controlar y formar parte de los esfuerzos para desarrollar las competencias deben ser lo más amplios posibles, revertido al nivel de la comunidad y de sus instituciones.

VIEWS OF THE AMERICAN BIOINDUSTRY ALLIANCE (ABIA) IN RESPONSE TO CBD NOTIFICATION SCBD/SEL/VN/GD/60541 TO PROVIDE CONCRETE OPTIONS ON THE SUBSTANTIVE ITEMS ON THE AGENDA OF THE FIFTH AND SIXTH MEETINGS OF THE AD HOC OPEN-ENDED WORKING GROUP ON ACCESS AND BENEFIT-SHARING.

American BioIndustry Alliance (ABIA) Members are pleased to submit this information document in response to Convention on Biological Diversity (CBD) Notification SCBD/SEL/VN/GD/60541 of 26 October 2007 issued to Parties, Governments, indigenous and local communities, and stakeholders to provide concrete options on the substantive items on the agenda of the fifth and sixth meetings of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing (ABSWG 5/6).

The ABIA welcomes this opportunity to provide its views on the principal substantive items on the agenda of ABSWG-5/6 for the further elaboration and negotiation of goals, objectives, and methodologies relating to an Access and Benefit Sharing International Regime (ABS IR). As discussed in Montreal, the focus of ABS-WG6 discussions should be on the practical impact that proposed ABS IR elements would have in the encouragement of access to genetic resources and the equitable sharing of the benefits relating to their commercialization.

Following the lead of the ABS Working Group Co-Chairs, this information document provides a compendium of ABIA Member views on key criteria and elements for success in the ongoing ABS negotiating process. Chief among these criteria and elements for success are the need for experience-based ABS practices and procedures; full intellectual property protection that takes into account the interests and concerns of all stakeholders; and a focus on positive incentives, front-loaded benefits to stakeholders, capacity building, technical cooperation, and other cooperative measures designed to improve the enabling environment for improved ABS outcomes on the ground.

If the ABS IR is to promote increased livelihood opportunities and social and economic benefits through the sustainable use of genetic resources (GR) and/or related traditional knowledge (TK), it is important to engage in an open and free discussion of how ABS provisions already in place have at times had a perverse effect on the ABS process. The work of the ABSWG has reached a critical stage where stakeholders can no longer afford to avoid the on-the-ground realities and real-world experiences of CBD Members, indigenous and local communities, research institutions and companies. At the same time, ABIA Members have identified positive alternatives developed by Australia, China, Costa Rica, India, and other CBD members to promote effective ABS regimes and to provide meaningful benefits to stakeholders on a transparent, predictable and sustainable basis. This information document also attempts to review those efforts and identify non-patent alternatives for effective ABS regimes.

Introduction and Summary

The ABIA was founded in September 2005 by large and small companies across the broad spectrum of the biotechnology industry and is the sole industry advocacy organization exclusively focused on Access and Benefit Sharing. Since that time, ABIA Members have engaged consistently in the deliberations of the ABS Working Group process and intend to continue to play an active role at ABSWG-6 in Geneva, at COP-IX and through the 2010 deadline and beyond. ABIA Members seek to provide timely and practical input and feedback to CBD Members and other stakeholders in support of an international ABS regime that stands the best chance of actually generating benefits that can be shared equitably among providers and users, including:

1. Emphasis on actual experiences of CBD Stakeholders

ABS Working Group outcomes should be fully consistent with on-the-ground realities facing ABS stakeholders, including those realities facing research institutes, universities and biotechnology companies (small, medium and larger enterprises). The outcomes should include appropriate positive incentives to balance the expected user measures and enforcement provisions that will be needed to ensure compliance by all Parties. Such a balanced approach will ensure that the regime will benefit all stakeholders.

Accordingly, the ABIA believes that the regime should include measures that demonstrably generate benefits, on a sustainable basis, and the equitable sharing of benefits relating to their commercialization. The regime should be based on the actual experiences of stakeholders either at the local, regional or state level, including the actual experiences of countries, indigenous communities, NGOs, and industry. In other words, the regime should be based on reality and experience. The national experiences of those countries that have adopted patent disclosure obligations in their national patent laws demonstrate that patent disclosure does not produce practical ABS benefits.

- Provision of positive incentives to encourage ABS activities

CBD stakeholders have acknowledged publicly and privately that current negative measures implemented at the national level, including mandatory disclosure of source and origin of genetic resources and/or related traditional knowledge, have failed to provide positive incentives for stakeholders to engage in the ABS process. In fact, patent-centric and other defensive measures have actually undermined efforts to encourage sustainable use of genetic resources (GR) and traditional knowledge (TK) to promote livelihood opportunities and other social and economic benefits from the commercialization of biodiversity-related innovations. While ABIA Members recognize the need for enforcement provisions in an ABS IR, these should be balanced by positive incentives to encourage engagement by all stakeholders in the ABS process.

- Avoidance of patent disclosure requirements

Elements of an international ABS regime should reflect individual needs and experiences of CBD Members at various stages of economic development. This suggests a bottom-up "cafeteria style" approach rather than a top-down "one-size -fits-all" mandatory patent disclosure regime.

- Inclusion of front-loaded benefits

International ABS experts increasingly caution against reliance upon the patent system as a mechanism for enforcing ABS benefits at the point of commercial success, pointing instead to the importance of front-loaded ABS benefits, so-called as they provide for early-stage guaranteed returns to providers of genetic resources.

> Groups with the most experience in benefit-sharing generally emphasize the importance of non-monetary benefits and "front-loading" benefit-sharing packages. "Front-loading" benefit-sharing packages ensure that provider countries receive a stream of benefits through the discovery and development phases, given the small odds of any one partnership yielding a commercial product and the fact that all products will not necessarily be billion-dollar "blockbusters," generating large royalties, or that in most industries products rarely, if ever, achieve this status.5

Even after the issuance of a patent, product development is a slow, uncertain process. Few life sciences products in the R&D cycle reach the commercial stage, let alone provide a return on investment. For example, the Merck/ INBIO Costa Rica Agreements did not result in new Merck products. However, Costa Rica used the Merck and other GR R&D agreements to build their science base.6

- Capacity building to enable technology transfer

5/ "Commercial Uses of Biodiversity: An Update on Current Trends in Demand for Access to Genetic Resources and Benefit-Sharing, and Industry Perspectives on ABS Policy and Implementation," Sarah A. Laird and Rachel Wynberg, distributed at CBD/ABS 4 as UNEP/CBD/WG-ABS/4/INF/5, 22 December 2005, p. 26.

6/ At the ABIA Curitiba COP-8 Side Event, Mr. Jorge Alberto Cabrera Medaglia, Legal Adviser to the Instituto Nacional de Biodiversidad (INBio), and Adviser to the Costa Rican Ministry of the Environment on Technology Transfer related benefits to Costa Rica through ABS Agreements over the past 15 years. See http"//www.abialiance.com/html/news.html for a summary of his presentation and tabular data on benefits to Costa Rica from front-loaded ABS Agreements which provided legal certainty, i.e., IP rights, to Merck and other companies

ABS experts have identified capacity building as a critical front-loaded ABS benefit that promotes enabling environments for technology transfer. In the often-cited case of P57 (Hoodia), for example, no innovative product has yet reached the market through the South African Council for Scientific and Industrial Research (CSIR) / Phytopharm / Unilever Agreement, and the San Tribe would have benefited from non-monetary capacity building:

> [I]n practice bioprospecting delivers limited financial benefits to provider countries. There are various reasons for this, including the high costs of research and development, the substantial risks involved, and the slim chances of success. Only one in every ten thousand compounds screened scores a "hit," which then takes five to ten years to be developed into a marketable product. In Southern Africa, for example, it has taken more than ten years to develop the succulent plant Hoodia as a potential appetite suppressant drug and/or food supplement and still the product is not fully commercialized."7/

Front-loaded non-monetary or monetary alternatives improve outcomes, including "strengthen[ed] scientific institutions and research capacities. Other non-monetary, benefits can also be significant. Biodiversity information can be collected to assist conservation managers. Community-based projects such as medicinal plant nurseries or environmental education facilities can also be supported by bioprospecting."8/

Discussion: Real-World Experience with Patent Disclosure at the National Level

As documented by international ABS experts, national experiences on the ground amply demonstrate the disutility of mandatory patent disclosure. Mandatory patent disclosure as part of an ABS IR would be self-defeating and only extend failed national policies across borders.

The following reflects recent experience of Brazil, the Philippines and India, three countries whose regimes have led to reduced ethnographic work, conservation and other commercial and non-commercial activities relating to genetic resources and traditional knowledge. Because the patent disclosure schemes resulted in reduced commercial activity, expected generation of benefits from the increased commercial activities failed to materialize. Most significantly, these countries experienced a breakdown of trust and dialogue among stakeholders. Instead of providing certainty to all parties, the adoption of negative incentives has resulted in frustration and driven parties further apart.

- Brazil

Since the implementation of mandatory patent disclosure, Brazil has experienced a well-documented reduction in conservation, bioprospecting and both academic and commercial R&D efforts relating to natural products. "Brazilian scientists claimed the 2001 rules hindered research on biodiversity by creating complex and time consuming procedures for those applying for research permits," affecting both domestic research and international collaboration.9/

The Government of Brazil's undocumented assertions of biopiracy have created a climate of fear and intimidation, with critics of Brazil's policy noting that: "the reality is that the search for the next miracle drug is being hampered by a deep Brazilian suspicion of 'biopiracy.'"10/ This has all but shut down both academic and commercial research in Brazil in favor of better operating environments in neighboring states: "[S]cientists say the rules are so stringent and overzealously enforced that it has become impossible to ship samples abroad for analysis, *reducing research to a crawl and driving many scientists to move their research to Ecuador, Bolivia and Peru.*"11/ (Emphasis added) This

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7/ Rachel Wynberg, "Biodiversity Prospecting: Access and Benefit Sharing," Southern African Trade Director of Indigenous Natural Product, http://cpwild.co.za/docTrade.htm.

8/ Ibid.

9/ "Brazil seeks public views on biodiversity research rules," Wagner de Oliveira, 22 March 2005, http://www.scidev.net/News/index.cfm?fuseaction=readNews&itemid=2005&language=1

9/ See "Biopiracy fears hampering research in Brazilian Amazon," Michael Astor, Associated Press October 30, 2005, http://news.mongabay.com/2005/1030-ap.html

10/ Ibid.

11/ http://www.scidev.net/News/index.cfm?fuseaction=readNews&itemid=2005&language=1

goes beyond commercial collaboration and has also shut down international cooperation between academic institutions and museums: "'One of our masters students has been waiting for nearly two years for government permission to collect samples of plants that she is studying,' says Ruy José Válka, curator of the herbarium of the National Museum, based at the Federal University of Rio de Janeiro . . . the herbarium, which houses more than half a million specimens of Brazilian plants, has had to virtually cease research collaborations with foreign institutions because of the current laws."12/

- The Philippines

Along with the Andean States, the Republic of the Philippines was the first to adopt stringent ABS obligations, which, according to UNEP, have "acted as deterrents to biodiversity research and bioprospecting."13/ Filipino officials acknowledge that the ABS system implemented in 1995 through Executive Order No. 247, and later implemented under the Wildlife Resources Conservation and Protection Act of July 30, 2001,14/ has failed to have any positive impact. According to Paz J. Venavidez II, Philippine Government official and ABS negotiator, the ABS process developed by the Philippines Government under EO 247 was "considered a deterrent to research growth and development."15/ The Prior Informed Consent (PIC) requirements have also been viewed as bureaucratically burdensome for applicants; the required interagency approval as unworkable; and the benefit-sharing obligations as being problematic.

Taken together, the Philippine ABS regime has all but eliminated bioprospecting in the Philippines, as Philippine Government officials report: "Since 1995 we have had only one Commercial Research Agreement (CRA) and one Academic Research Agreement (ARA) that has been processed under EO 247."16 Although the 2001 Wildlife Act was intended to mitigate the major problems encountered under EO 247 (and does exempt non-commercial research from its scope), the bottom line is that, since 1995, bioprospecting and natural products R&D in the Philippines have all but dried up.17

- India

The Government of India adopted mandatory disclosure of the source of genetic resources and related traditional knowledge in 2002 as part of the Second Patent Amendments. The Biological Diversity Act of 2002 and Biological Diversity Rules, 2004 also play a significant role in India's patent disclosure regime.18/ Since the entry into force of the regime, India has made little to no progress in the approval of bioprospecting applications by the National Biodiversity Authority (NBA), which was established in 2004 to administer the approval process.

Biotechnology experts within India have noted that the mandatory patent disclosure and other elements of the domestic regime have created uncertainty and harm India's interests in the area of natural products development.19/ While the 2004/2005 Report of the NBA documents a number of interesting biodiversity educational and awareness programs, it fails to record any actual approvals of commercial bioprospecting applications.20/ The NBA website further reports that approval has been

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12/ UNEP, quin.unep-wcmc.org/resources/publications/pa_biodiv/key_issues.pdf, p. 46

13/ The Challenges in the Implementation of the Philippine ABS Regulations: Monitoring and Enforcement of Bioprospecting Activities in the Philippines," Paz J. Benavidez II. Legal Research Consultant, Committee on Ecology, House of Representatives, Republic of the Philippines. See "www.canmexworkshop.com/documents/papers/I.2.1.pdf

13/ Ibid.

14/ Ibid.

15/ Ibid.

16/ Additional inconsistencies have been raised between the Biological Diversity Act and Rules and the earlier Plant Variety Protection and Farmers Rights (PVPFR) Act of 2001. See http://www.ias.ac.in/currsci/jan102006/15.pdf

16/ Presentation and comments by Dr. M. K. Nair, Hi-Tech Pune: Where IT Meets BT, October 27, 2006, Pune, India

17/ http://www.nbaindia.org/docs/annual_report(04-05).pdf

18/ http://www.nbaindia.org/approvals/approvals_withheld.htm

19/ http://www.nbaindia.org/approvals/patent.htm

20/ http://www.atimes.com/atimes/South_Asia/FJ26Df02.html

withheld from at least ten bioprospecting applications.21/ The patent disclosure regime has also created disincentives for IP protection of GR inventions in India: according to the NBA website, only four applications have been received for advanced approval of patent rights associated with GR/TK.22/

As in Brazil and the Philippines, the political environment for industry in India has not improved with the advent of the patent disclosure regime. Critics of the Government claim that biopiracy in India is rampant, and "that plant and soil samples are being regularly flown out of India under the pretext of joint research collaboration."23/ Despite the lack of documentation, activists further demonize industry, asserting that "the herbal drug industry in India is mostly a flourishing biopiracy business. Companies collecting medicinal plants from forests and using the knowledge of communities to make products worth millions of dollars are accused of not paying anything to the communities from whom they got that knowledge," and Devendra Sharma of the Forum for Biotechnology and Food Security in New Delhi accuses the Government of India of selling India's "green gold for peanuts."24/

The problem, as stated by Tomme Young [then-Senior Legal Officer, International Union for the Conservation of nature and Natural Resources (IUCN)) at the ABIA Side event in Curitiba, Brazil, is that ABS mandatory disclosure regimes frequently provide negative incentives that do not lead to the generation or sharing of social benefits.25/ Among the adverse factors that act as disincentives are:

1. Cumbersome and complex regulatory processes -- The cost and time required to develop partnerships within complex and evolving regulatory frameworks are significant barriers to bioprospecting, where delay equals foregone opportunities: "Countries like Brazil and India, for example, are regularly avoided; it takes 1-3 years to get a permit, and researchers fear both the hostility they find to any research on genetic resources, and what one observer called the 'national regulatory labyrinths'."26/

2. Regimes that do not encourage the generation of benefits -- Patent disclosure obligations have been ineffective as a mechanism to encourage the generation of benefits from genetic resource inventions. Without academic or commercial bioprospecting, there can be no generation of benefits for either the country or its indigenous people.

3. A worsened climate for ABS discussions -- despite the growing number of states that have implemented mandatory patent disclosure regimes and other ABS obligations.27 Companies are tried and found guilty in the media, regardless of the merits of the situation, and are further alienated from participation in ABS regimes.28/

4. *Cutbacks in GR investment by multinational corporations* -- In addition to the scientific reasons given for the sharp fall-off in natural products development, the legal and public relations uncertainties associated with gaining access to genetic resources as a result of the Convention on Biological Diversity have also been cited. Companies that have reduced or eliminated natural products development include Lilly, Merck and Pfizer.29/

21/ Ibid.

22/ "Incentive and Motivation in the ABS Regime," Tomme Rosanne Young, Senior Legal Officer, IUCN, PowerPoint Presentation, Curitiba, Brazil, accessed at http://www.abialliance.com/html/news.html

23/ Laird and Wynberg, p. 37, also citing extensive delay and difficulty of natural products R&D in the Philippines.

24/ The CBD "has done little to quell poor nation's fears of exploitation," Dalton, Rex. "Bioprospects less than golden." Nature V. 429 (2004): 598-600, and instead has actively precluded "the anticipated bioprospecting bonanza."

25/ Ibid.

26/ Rouhi, A. Maureen. "Betting on Natural Products for Cures." CENEAR 81 41 (2003): 93-103. See http://pubs.acs.org/cen/coverstory/8141/8141pharmaceuticals3.html See also Laird and Wynberg, p. 9.

27/ Laird and Wynberg. p. 30.

28/ For more discussion of China's successful technology transfer, see "Enabling Environments for Technology Transfer," by Susan K. Finston, Business 2010: A newsletter on business and biodiversity by the Secretariat of the Convention on Biological Diversity, Vol. 2, Issue 3, September 2007, pp. 24 - 27.

29/ In the biotech sector, the overall value of China's biotech market was estimated in 2004 at approximately $4.5billion on the strength of strong FDI, or more than twice that of India, having passed the billion dollar mark in1997. See "China's Biotechnology Bloom: Life Sciences in the World's Fastest Growing Economy," Nancy Chen, Gene Watch, Volume

In December 2005, long-time ABS experts Laird and Wynberg drew the following negative conclusions on the efficacy of mandatory patent disclosure and other related ABS regulations:

> In 1999, ten Kate and Laird reported that over the course of the previous two years of their study many of the companies they interviewed had come to believe that implementation of the CBD had gone badly wrong. They cited lack of clarity in the regulatory framework; bureaucracy and delays in receiving permits; lack of understanding of business; confusion about national focal points; unrealistic expectations and transaction costs; restriction of scientific traditions of collaboration and exchange; and the pressures these new regulatory frameworks place on already taxed natural product research programs (ten Kate and Laird, 1999, p296). These concerns continue today, but are also increasingly accompanied by an underlying unease with what are characterized as "dangerous" and "political" minefields of fickle regulatory processes, and an absence of goodwill.30/

Where a potential patent holder is unsure about the possible adverse impact of a disclosure obligation, the individual investor or company will much less likely try to develop new products out of genetic resources, whether or not it is certain of the source of the materials. This uncertainty may reduce access to foreign venture capital by local biotech entrepreneurs.

In contrast to the self-defeating nature of a mandatory patent disclosure regime, there is a growing consensus on the practical benefit of positive front-loaded incentives for access and benefit sharing. For example, there is agreement on the critical need for ABS-related scientific and technical assistance and capacity building programs. Scientific research, science exchange and other capacity building programs have a proven positive track-record at the national level--in countries as varied as Australia, China, Costa Rica, and Thailand.

Using ABS to Promote Livelihood Opportunities: The Example of China

China's current ABS policies, for example, follow a proven model for successful technology transfer and the generation of meaningful benefits to its GR and TK providers. Core elements of China's successful strategy include:

Reliance on market forces for R&D;

Strong rule of law protections, including IP Rights and, especially, continued patent protection; and

A durable government commitment to science education and research.31/

China's commitment to patent protection has resulted in much early foreign direct investment in biotechnology32/ and facilitated China's own substantial investment in the systematic study of Traditional Chinese Medicines (TCM).

The increased certainty provided by patent protection has permitted China to undertake its own initiatives to promote the commercialization of TCM. These have included the study and sustainable cultivation of at-risk plants and the publication of monographs and other long term research on the properties of these herbs by the China Institute of Medicinal Plant Development (IMPLAD) as well as encouragement of international research partnerships and direct government support for TCM R&D.33/

17, No. 1. India's biotech sector first broke the billion dollar mark in mid-2005, and remains second to China overall in FDI attractiveness. http://www.sunmediaonline.com/ indiachronicleapril/investmentupdate.html

30/ Ibid.

31/ See "Ancient and Modern Medicinal Herbs: China," Shilling Yang, Institute of Medicinal Plant Development (IMPLAD), Beijing China, http://tcdc.undp.org/sie/experiences/vol7/Ancient%20and%20Modern%20Medicinal_China.pdf

31/ "China sets traditional Chinese medicine as strategic industry," People's Daily Online, 26 September 2005, http://english.peopledaily.com.cn/200509/26.

31/ Ibid.

32/ See www.piipa.org/survey.asp to download data relating to the 2005 PIIPA survey.

33/ See, *inter alia*, the Report of the New Mexico Chile Task Force on Regional Branding in a Global Market Place (November 2005), which discusses the use in the United States of certification marks as a means of identifying the origin of

IMPLAD activities since 1996 have included ethnography to rescue plants from the threat of extinction, cultivation of medicinal plants to establish germplasm- and gene-pool for development of medicines, R&D, patenting, and commercial development and production of drugs along the Western model. To date, IMPLAD has entered into joint ventures with three commercial companies in China, established three branch institutes in sub-tropical southern China, and published more than 1,000 papers and thirty monographs.34/

China has also established research partnerships at the official level with foreign institutions and governments. These include the World Health Organization, the United States, France, Germany, Japan, and Singapore, while private R&D Agreements include Merck KGaA, Merck (US), Novartis, P&G, and Pfizer, among others.

The Chinese Government has also designated TCM set as a strategic industry, of primary importance in China's science and technology agenda. In 2005, at the Second International Technology Conference on the Modernization of Chinese Traditional Medicines, the Vice Minister of Science and Technology Lui Yanhua noted the growing international demand for TCM, with production up more than 18% from 2003 to 2004, reaching 95.8 billion yuan, or approximately $12 billion.35/ Liu added that cultivation of 500 varieties of medicinal herbs were being grown in plantations as a new source of rural Chinese farmers in provinces, and a "Pillar industry" in Sichuan, Hebel, Guizou, Shaanxi, and Shanxi Provinces.36/

China's current system for the study and commercialization of TCM already provides practical ABS benefits to rural farmers and others in the GR value chain and should serve as a model for front-loaded ABS systems.

Positive Alternatives for the Establishment of Effective ABS Regimes

As noted above, ABIA Members believe that the ABSWG should seek to promote a number of alternatives that CBD Members would adopt on the basis of their individual levels of economic development and ABS needs. Among the positive alternatives to patent disclosure that generate benefits are Material Transfer Agreements (MTA) and Traditional Knowledge Data Libraries or Bases (TKDL).

- Improved Intellectual Property Protection and Related Capacity Building

ABIA Members believe that the ABSWG has for too-long focused exclusively on a very narrow band of Intellectual Property Protection (IPP), namely the issue of patent disclosure, in the process ignoring the real needs of ABS Stakeholders for IPP capacity building in the areas of trademarks and regional certification systems that have been adopted in countries like Ethiopia and others to promote a return from genetic resources to local communities. In fact, the 2005 Public Interest Intellectual Property Advocates (PIIPA) Survey identified trademarks and other doing-business IPP issues as leading areas where developing country entrepreneurs and local communities seek increased information and capacity building.37/

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a particular product or product characteristic. See discussion on pages 21-23 at http://www.cahe.nmsu.edu/pubs/research/horticulture/CTF21.pdf "

34/ The *Guidelines* and a recommended MMTA are available at http://bio.org/ip/international/200507guide.asp.

35/ "Intellectual Property Rights and the Third World," Current Science, vol. 81, No. 8, 25 October 2001.

36/ Some remain concerned that a public system of TK databases or digital libraries would provide a "license to steal" by cataloging GR and associated TK in a way that would be accessible to commercial researchers and scientists. The argument that the mere availability of TKDLs will lead to increased biopiracy is misleading, as it is based on the incorrect assumption that the mere knowledge of the GR and/or TK is itself patentable. In fact, any TK that is known to a community and/or included in a TKDL would constitute prior art, and would thus not be patentable. This important and basic point is often overlooked in the TKDL debate.

37/ See www.abialliance.com/html/issue.html for more details on TKDLs and other ABIA Issue Briefs.

38/ See, *inter alia*, the Report of the New Mexico Chile Task Force on *Regional Branding in a Global Market Place* (November 2005), which discusses the use in the United States of certification marks as a means of identifying the origin of a particular product or product characteristic. See discussion on pages 21-23 at http://www.cahe.nmsu.edu/pubs/research/horticulture/CTF21.pdf 39/ The *Guidelines* and a recommended MMTA are available at http://bio.org/ip/international/200507guide.asp.

In the United States, a wide variety of indigenous communities and regional cooperatives have effectively implemented certification and related trademark programs to prevent mis-appropriation and consumer confusion over the origin of unique agricultural products.38/ These measures would go much further to address concerns over basmati, maca, and other indigenous products and resources than mis-placed patent disclosure requirements. Regional certification and trademarks, accompanied by appropriate capacity building programs, could provide immediate benefits, and, would require no further international action for immediate implementation even before the conclusion of the ABS IR.

- Material Transfer Agreements (MTAs)

Model Material Transfer Agreements (MTAs) may provide legally-binding instruments to define the access and benefit sharing terms and conditions up-front and establish milestone events triggering either compensation or additional negotiations. In this regard, the ABIA has supported from the outset the Model Material Transfer Agreement for ABS (MMTA), developed by its sister organization, the Biotechnology Industry Organization (BIO), as an institutional structure that facilitates compliance with the CBD but allows all parties the flexibility to customize the benefits for each situation through mutual agreement. The MMTA comports with the long-standing position of both the ABIA and BIO that mutually agreed terms or contracts provide the most effective means for fulfilling the objectives of the CBD, because they allow the parties the most flexibility in structuring the successful conditions for transfer, allocating benefits arising from the transfer, and administering the transfer.

It is important to note that the MMTA is not a standard or one-size-fits-all contract such as the Standard Material Transfer Agreement developed under the International Treaty on Plant Genetic Resources, which was developed for a very specific type of low-cost, limited purpose and administratively simple transfer. Also, the MMTA can be a "stand-alone" agreement for use in the transfer of a small number of samples of a single genetic resource from an *ex situ* collection. The Model is also designed to be used as part of a bioprospecting agreement or could be supplemented to cover the transfer of associated technological information such as traditional knowledge. At the same time, development of the MMTA can be used in capacity building efforts to assist resource providers in understanding the full range of front-loaded options available to them.

On a closely related matter, the ABIA notes that ABIA and BIO Members and other leading biotechnology companies representing more than 95% of the global industry are committed to meeting existing CBD ABS obligations, including meaningful Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) for commercialization. ABIA and BIO Members have a proven record of compliance with the Bonn Guidelines. The ABIA supports BIO's work on a Code of Conduct for bioprospecting and related activities. The *Guidelines for BIO Members Engaging in Bioprospecting*, which BIO has developed, seek to assist its members to meet the Bonn Guidelines.39/ Notwithstanding that, in general, BIO Members work with materials obtained from *ex-situ* sources (e.g., gene banks, depositories, internal sources), BIO Members developed the *Guidelines* to educate BIO Members on the relevant issues that can arise in the conduct of bioprospecting activities. In doing so, the *Guidelines* identify certain "best practices" that can be followed by companies that elect to engage in these activities.

Finally, Dr. Shakeel Bhatti, Secretary of the International Treaty for Plant Genetic Resources (ITPGR) reported to ABSWG-5 on the extensive use of MTAs under the ITGPR. His report further demonstrated the practicality, transparency and effectiveness of this mechanism as a means to promote increased participation in any future ABS IR.

- Traditional Knowledge Digital Libraries (TKDLs)

ABIA Members recognize the leadership of the Government of India in designing and implementing its Traditional Knowledge Digital Library (TKDL). TKDLs provide for efficient prior art searches

39/ The *Guidelines* and a recommended MMTA are available at http://bio.org/ip/international/200507guide.asp.
39/ The *Guidelines* and a recommended MMTA are available at http://bio.org/ip/international/200507guide.asp.

and prevent the issuance of patents for inventions based on prior art, i.e., lacking novelty or an inventive step, and have a proven track record in providing positive incentives for research and investment in the commercialization of genetic resources. CBD Parties at varied stages of development, including India, Malaysia, Venezuela, China and others, have already implemented such on-line databases of genetic resources and/or traditional knowledge. These data bases have the added advantage of providing incentives for commercialization by providing transparency about the origin of genetic resources, the related traditional knowledge and any indigenous groups from whom prior consent should be obtained.

The dual purpose of the TKDL has been recognized by Dr. R A. Mashelkar, Director General of India's premier independent research institute the Council of Scientific and Industrial Research (CSIR):

> To mitigate this problem [of non-original inventions], the creation of TKDL in the developing world would serve a bigger purpose in providing and enhancing its innovation capacity… It could act as a bridge between the traditional and modern knowledge systems. Availability of this knowledge in a retrievable form in many languages will give a major impetus to modern research in the developing world, as it itself can then get involved in innovative research in adding further value to this traditional knowledge."40/

The role of TK data bases and digital libraries in generating meaningful benefits to stakeholders from genetic resources and related traditional knowledge was the subject of a side event that the ABIA sponsored at ABSWG-4 in Granada, Spain in February 2005. Presentations made by Dr. Shakeel Bhatti (then) of the World Intellectual Property Organization (WIPO) and Dr. K. Gupta of the Council on Scientific and Industry Research (CSIR) of India, focused on the role of traditional knowledge databases, registries and digital libraries in providing positive benefits to stakeholders and in preventing issuance of patents lacking novelty or an inventive step by ensuring access to prior art. Their findings were instructive.

As Dr. Gupta explained, the TKDL database acts as a bridge between ancient verses in different local languages and patent examiners in other countries, since it provides information on modern as well as local names in a language and format understandable to patent examiners. He concluded that the TKDL is an important tool both to prevent issuance of patents based primarily on prior art, as well as to promote new research. The results of independent research contracted by the ABIA underscores the role of the Indian TK Digital Library in encouraging innovative research by CSIR institutions on Ayurvedic and other traditional knowledge and/or medicinal plants. Between 1980 and 2005, TK-related innovation by CSIR scientists resulted in 725 granted or published United States (US) patents. Of the 161 non-biotechnological patents that were directly related to TK and GR, 123 were herbal/medicinal applications; 24 involved plants and 14 involved microorganisms related to bioremediation. CSIR's US patents were informed by the TDKL, which provided both a road map to CSIR scientists as well as information on prior art to US patent examiners.

Dr. Bhatti confirmed that, beyond India, there are a number of other developing countries in all regions that have adopted databases and registries for traditional knowledge and genetic resources, both individually and through regional initiatives. Among the databases that he cited were the Traditional Chinese Medicine (TCM) Patent Database of China; the system of national and local registers established under Peruvian Law 27811; and the Biozulua Data Base in Venezuela, which covers native medicines, ancestral technology and traditional agricultural knowledge.41/ The ABIA

40/ "Intellectual Property Rights and the Third World," Current Science, vol. 81, No. 8, 25 October 2001.

41/ Some remain concerned that a public system of TK databases or digital libraries would provide a "license to steal" by cataloging GR and associated TK in a way that would be accessible to commercial researchers and scientists. The argument that the mere availability of TKDLs will lead to increased biopiracy is misleading, as it is based on the incorrect assumption that the mere knowledge of the GR and/or TK is itself patentable. In fact, any TK that is known to a community and/or included in a TKDL would constitute prior art, and would thus not be patentable. This important and basic point is often overlooked in the TKDL debate.

supports the proposal of Japan in the World Intellectual Property Organization (WIPO) for development of an inter-operable, integrated and comprehensive system of national TKDLs as the logical next step towards a functioning international TDKL system. 42/ Such an internationally-integrated system, which, to some degree, would be publicly available, would make it easier for patent offices to prevent issuance of invalid patent claims.

International Certificates of Source / Origin / Legal Provenance

The ABIA remains concerned about proposals that some stakeholders have put forward for the development of an international certificate of source, origin, and/or legal provenance to serve as an additional formality for either patent protection or certification of conformity with ABS requirements. The ABIA does not support the establishment of a certificate system on this basis and is concerned about the feasibility, practicality, complexity and cost of a certificate system.

Like the International Chamber of Commerce (ICC), the ABIA does not view the CBD Technical Experts Committee on an internationally recognized certificate of origin/ source/legal provenance ("Experts Group") as being fully representative of the broad spectrum of views found in the biotechnology sector ((seed, other agro-chemical, bio-pharmaceuticals, industrial enzymes, and environmental remediation, among others). The Experts Group should be broadened to reflect the diverse needs and real-world experiences of industry. The CBD Experts Group on Technology Transfer, which allows for representation from different segments of the biotechnology sector, may provide a model for inclusion of more than one industry representative. The appointment of a second industry observer would also recognize the essential role that the biotechnology industry will play in generating the expected benefits from any ABS regime.

Remaining Areas of Contention

Currently, there is a lack of clarity over key definitions, jurisdiction, and overall boundaries for a future ABS IR. Without a precise understanding of such important terms as "genetic resources, products, derivatives" and/or "Traditional Knowledge," it is impossible for any private company to enter into an agreement with indigenous communities or other holders of TK. Businesses can only make rational commercial decisions about any commitment if they can understand the nature and scope of the contemplated obligations.

Moreover, if more than one indigenous community (either within a country or otherwise) states a claim to the same GR and/or associated TK, there needs to be a clear approach to TK rights that does not threaten a private company that has acted in good faith and is working on the basis of prior informed consent (PIC) and mutually-agreed terms (MAT) with one of these communities or with a focal point in a CBD member country that has entered into a good faith PIC and with a community.

Other difficult issues for the ABIA include suggestions from some CBD Members of coverage of both *in situ* and *ex situ* resources; pre-CBD vs. post 1994 genetic resource bioprospecting; human vs. plant and animal genetic resources; and products vs. derivatives of genetic resources. There have to be clear and fair boundaries on the ABS IR; lines should be drawn consistent with the obligations and explicit legal boundaries of the CBD Treaty.

42/ See www.abialliance.com/html/issue.html for more details on TKDLs and other ABIA Issue Briefs.

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ANNEX

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Options on the Substantive Agenda Items for the Sixth Meeting of the Working Group on Access and Benefit-sharing

Agenda Item 3. International regime on access and benefit-sharing

3.1(a) Compliance – Measures to support compliance with prior informed consent and mutually agreed terms.

BIO believes that the most appropriate and effective measure for supporting compliance with the provisions in the Convention on Biological Diversity (Convention) on prior informed consent (PIC) and mutually agreed terms (MATs) is a reasonable national regime. Such a regime should provide a transparent and equitable legal framework governing transfers of genetic resources (GR) through voluntary contracts. Both the provider and the user of the GR must be well informed when evaluating the possible terms and attendant obligations.

BIO also believes that guidelines and model instruments developed by stakeholders, such as the BIO *Guidelines for Members Engaging in Bioprospecting* and its *Model Material Transfer Agreement* have utility in such national regimes. These instruments, based on real-world experience and a mindset of win-win or mutual success, offer a practical tool which provides the flexibility to optimally structure the given bargain for accessing and transferring GR in compliance with the requirements for PIC and MATs.

BIO opposes inclusion of special patent disclosure requirements as additional formalities for patentability, because such requirements create burdens on applicants, create unpredictability in patent rights, and discourage use of GR without significantly encouraging compliance with the requirements for PIC and MATs.

> *BIO suggests encouraging countries to establish their own national regimes; and further encourages the development of guidelines and models by stakeholders. In addition, BIO suggests capacity building to enable technology transfer as a significant element of any national regime. (Capacity building will be considered in Item 3.3.)*

3.1(b) Compliance – Internationally recognized certificate of origin/source/legal provenance.

BIO is hesitant to discuss the merits or drawbacks of a certificate system because there is no common understanding of the details of such a system. BIO believes that before there could be a meaningful discussion on a certificate system certain questions must be answered. For example: (a) what would the system certify (*e.g.,* compliance with national law, compliance with the Convention) and why? (b) who would certify (*e.g.,* national officials, international officials, private entities)? (c) who would use the certification and why? (d) What would be the effect of having or not having a certificate? In addition, there must be a cost-effectiveness analysis of such

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a system as well as possible permutations that would enhance benefits and reduce costs. Moreover, there would need to be protections for a good faith user who met the diligence requirements in the event that compliance be challenged at a later point.

3.1(c) Compliance – Monitoring, enforcement and dispute settlement

BIO does not believe that discussing monitoring, enforcement and dispute settlement in the absence of specific national measures to enforce requirements for PIC and MATS is particularly useful. That said, we noted in the discussion of Item 3.1(a) that in our view the most useful measure to obtain compliance is a reasonable national regime that provides a transparent and equitable legal framework governing transfers of GR through voluntary contracts.

> *In our view, it would also be useful to explore ways in which national regimes may be improved to enable enforcement of contracts for the transfer of genetic resources As previously mentioned, capacity building may be a significant element of any solution.*

3.2. Traditional knowledge and genetic resources

BIO believes that resolution of the issues related to the protection of traditional knowledge are extremely difficult given the extremely wide range of subject matter that could constitute traditional knowledge; the lack of a common definition of traditional knowledge; and the large variation in the goals of the custodians of traditional knowledge (*e.g.*, some want a regime that guarantees confidentiality while others want a regime that promotes commercialization).

We note that Article 8(j) of the Convention relates only to a subset (albeit an important subset) of subject matter that is commonly classified as traditional knowledge. That is, the Convention only applies to certain "knowledge, innovations and practices … embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity" whereas most contend that traditional knowledge extends to knowledge unrelated to biological diversity. [Emphasis added.]

We also note that the extensive discussions have taken place within the framework of the World Intellectual Property Organization (WIPO) on the protection of traditional knowledge. These discussions appear to embrace the broader understanding of traditional knowledge. Furthermore, we believe that the WIPO is best suited to establish a workable regime for protecting traditional knowledge given its experience with, and expertise in other regimes for protecting intellectual achievements.

> *In our view, one useful option would be to delay discussion of protection of the specific type of traditional knowledge covered the Convention until there is a clear idea of the direction being taken for the protection of traditional knowledge generally in WIPO. Once there is a resolution of issues on the general level of protection, discussion could resume on what specific protection would be necessary for the subset of traditional*

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knowledge covered by Article 8(j) and that is not covered by the general regime. This option would reduce duplicative and/or counterproductive efforts as well as allow additional time to be spent on Items 3.1(a) and 3.1(b).

3.3. Capacity building.

It is BIO's position that the most effective measure for ensuring compliance with PIC and MATs is a reasonable national regime that provides a transparent and equitable legal framework governing transfers of GR through voluntary contracts. Transferors and transferees must be able to understand and work within the framework as well as be able to understand the obligations and to enforce the rights acquired under the framework for it to be workable and effective.

One useful option would be to establish a concrete plan for capacity building in this area as mentioned in Items 3.1(a) and 3.1(c). Implementation of such a plan could bring about significant benefits in the near future. See also Benefit sharing.

3.4. Nature, scope and objectives of the international regime.

BIO notes the statement in Decision VII/19 that "The international regime could be composed of one or more international instruments within a set of principles, norms, rules and decision-making procedures, legally binding and/or not binding."

BIO also notes:

- the work on the protection of traditional knowledge and the capacity building in the area transfer of GR within the framework of the World Intellectual Property Organization;

- the work on facilitated access and model transfers agreements of certain GR under the Food and Agriculture Organization;

- the adoption of the Bonn Guidelines by the Conference of the Parties of the Convention;

- the work on management tools and capacity building by the International Institute for Sustainable Development that was funded by the Swiss State Secretariat for Economic Affairs; and
- the work done by stakeholders including BIO on developing guidelines and model material transfer agreements.

BIO does not believe that a new international instrument is necessary at this time. As mentioned in connection with Item 3.1(a), it is our view that a network of reasonable national regimes would be a more effective than an international regime. Further, we believe that such a network is more likely to be achieved successfully in the shorter term than the negotiation and

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implementation of a new international instrument. Such lengthy time-frames particularly disadvantage developing countries. It is BIO's position that transparent, equitable and predictable national laws in conjunction with guidelines and material transfer agreements, provide for the effective implementation of the Convention, without the need for a new instrument at this time.

BIO Members believe that any element of the international regime developed under the Convention should be limited to implementing the Convention. That is the regime should not regulate access and benefit-sharing related to human GR, derivatives, *etc.*, and should not regulate resources acquired before the entry into force of the Convention or otherwise outside of the regulation of the Convention.

Benefit-sharing

BIO believes that the suitable mixture of benefits to be shared will vary widely from one transfer of GR to another depending on the needs of the transferors, the needs of designated beneficiaries such as indigenous or local communities, the commercial value of the transferred physical samples, the intended use of the samples, the likelihood of using the samples to create a commercially viable product, and other factors. As a consequence, it is not appropriate to suggest a model formulation for the nature of benefits, or the manner in which benefits should be shared, as no single definition will be appropriate in all circumstances. Rather, a different set of benefits should be negotiated in each transfer contract that will maximize the value to each party to the transfer and that are consistent with national framework. Standardized or mandatory benefit rules would be counterproductive whether part of an international instrument or a national regime.

BIO notes that the Bonn Guidelines provide an extensive list of the available types of benefits and note other reference material such as the *ABS Management Tool* that discuss the types of benefits available to parties to a transfer as well as some of their merits and drawbacks of each benefit. Consequently, it should not be difficult for parties to identify the types of benefits available to them. Rather, it appears that the most significant problem in the area of benefit sharing is that some parties may have difficulties in identifying which available benefits will be the most useful to them in a particular transfer, and in assessing the realistic commercial value of the resources transferred.

> *Improving the negotiation capacity of parties to transfer contracts or encouraging mechanisms for assisting parties in the negotiation of specific transfers would go a long way to addressing this issue.*

Access

BIO believes access to GR should be encouraged, rather than discouraged, given the potential of these resources to promote the health and welfare around the world. However, we believe, that

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measures that regulate access should be part of the national regime that also regulates PIC and MATs given the greatly varied nature of the resources and conditions in a given territory. No new instrument or standardized regulation is needed at this time.

BIO members believe that the national regime should be transparent. For example, governments should clearly define which acts constitute access and should clearly designate officials responsible for aspects of the regime. Furthermore, conditions and procedures for access should not be overly complex or burdensome.

In our view, one useful option would be for the Working Group to discuss recent national experiences related to "access". For example, how is the term "access" defined? Is obtaining detailed information about a resource access? Is access limited to physical samples? What experiences have Parties or stakeholders had with focal points? Are these focal points facilitating access? Are they a barrier to access?

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Intellectual Property Owners Association

November 27, 2007

Dr. Ahmed Djoghlaf, Executive Secretary
Secretariat of the Convention on Biological Diversity
413, Saint-Jacques Street, Suite 800
Montreal QC H2Y 1N9
Canada

RE: Notification SCBD/SEL/VN/GD/60541
Preparations for the sixth meeting of the Ad hoc Open-ended Working Group on Access and Benefit-sharing (ABSWG-6), 21-25 January 2008, Geneva

Dear Secretary Djoghlaf:

Submission by Intellectual Property Owners Association

Intellectual Property Owners Association (IPO) appreciates the opportunity to submit concrete options on the substantive agenda items of the fifth and sixth working groups in advance of the sixth working group. We make the following brief points below with regard to the agenda items of both the fifth and sixth working groups.

Benefit-sharing

- IPO is of the firm view that mutually agreed terms between users and providers of genetic resources through the use of an agreement is the best means for ensuring fair and equitable benefit-sharing. Often, the use of genetic resources for research fails to lead to successful commercialization of a product. Therefore, any benefit-sharing system that is linked solely to commercialization would significantly diminish the range of benefits to be shared. In contrast, when parties enter into a contract with mutually agreed terms, up-front benefits can be an important part of that agreement, particularly for providers. Options for up-front benefits could include license fees, transfer of technology, or the promise of payments when milestones are achieved in the research and development process.
- The Bonn Guidelines generally provide a useful tool to users and providers for how to reach mutually agreed terms. IPO believes the importance of the Bonn Guidelines has been overlooked by the parties.

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- National laws are an important means to promote and safeguard fair and equitable benefit-sharing. National laws are useful to identify the party with authority to negotiate on behalf of the provider, and such laws provide certainty to users. National laws can ensure consistent approaches to access and benefit-sharing, and provide stability over the term of the agreement.
- IPO believes that the primary benefit of using agreements is that they provide flexibility to the user and provider to set terms for access and benefit-sharing that are appropriate for that particular use.

Access

- Regulation of access to genetic resources is best left to the provider country. Access is a necessary prerequisite for fair and equitable benefit-sharing, but how that access is regulated is best determined by the provider country, as envisioned in the CBD. National laws can be customized to the needs of the country and can give users a means to gain prior informed consent and access to genetic resources. To that end, designation of a focal point increases legal certainty for users that the access has been in compliance with the laws of the provider country.

Measures to Support Compliance with Prior Informed Consent and Mutually Agreed Terms

- IPO supports the implementation of national laws to govern the means by which users can obtain prior informed consent.
- Codes of conduct can also play an important role in ensuring compliance with the laws of the provider country.
- The Bonn Guidelines are generally a useful tool for parties to come to mutually agreed terms. Other tools available to users and providers include model material transfer agreements.
- IPO does not believe that patent disclosure proposals are an effective means for monitoring compliance with prior informed consent or mutually agreed terms. Many of the examples of purported misappropriation involving patents already include information about the source of the resource in question. In these instances, disclosure of such information did nothing to promote fair and equitable benefit-sharing, and it did not change the need for or outcome of litigation.
- In view of ongoing discussions at the World Intellectual Property Organization (WIPO) relating to patent disclosure of GR/TK, we believe such discussions in the ABS working groups would be duplicative and therefore unnecessary.

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Internationally Recognized Certificate of Compliance

- IPO believes that much greater analysis is still required before the parties can further develop the idea of a Certificate of Compliance. The parties have not addressed important issues, such as the cost or feasibility of a Certificate. We seek further clarification as to what items would require a Certificate. Would Certificates be required for all items in trade? If items in trade are excluded from a Certificate system, on what basis would such a discriminatory approach be justified? IPO is concerned that the proposals for a Certificate are limited to instances where access is sought for research. Such proposals are a negative incentive to innovation and could undermine the conservation and sustainable use goals of the Convention.

Monitoring, Enforcement and Dispute Settlement

- IPO believes that the best means for dispute management is through mutually agreed terms in an agreement between users and providers. Contracts include terms for dispute settlement, and allow the parties to determine the best means for resolving conflicts. Conventional approaches, including choice of governing law, as well as alternative mechanisms, such as mediation or arbitration, can be specified in a contract. Many research contracts also include provisions for a steering committee, composed of members of both parties to a contract, which is established for the sole purpose of resolving contractual issues. The establishment of such a committee can be helpful to avoid more formal dispute resolution mechanisms, such as arbitration or litigation.

Traditional Knowledge and Genetic Resources

- The parties must be careful not to incorporate traditional knowledge into an International Regime focused on genetic resources without careful deliberation, especially as there is no agreement on the meaning of the term "traditional knowledge."
- IPO recognizes that a great deal of work has been done in WIPO on the intersection of traditional knowledge with intellectual property, and believes that WIPO is the most appropriate body for continuing such discussions. It is a fundamental principle that knowledge that has been made publicly available cannot later be re-captured and accorded any form of intellectual property protection. The public has legitimate rights and expectations that such knowledge is freely accessible and that it will remain so.

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Capacity Building

- IPO notes favorably the work done thus far on an ABS-Management Tool (ABS-MT), with support of the Swiss Confederation. The ABS-MT is a voluntary measure that provides best practice standards, as well as guidelines to ensure implementation of those standards. It is designed to ensure compliance with the CBD and the Bonn Guidelines, and it could prove to be quite a successful capacity building measure for both users and providers of genetic resources.

Nature, Scope and Objectives of an International Regime

- IPO believes an effective International Regime will provide a framework or guidelines for implementation of national laws regulating access and benefit-sharing. We are not convinced of the need for a separate legally-binding instrument to achieve the goals of fair and equitable access and benefit-sharing. In fact, the International Regime may be more effective if it serves as a guideline of best practices in national access and benefit-sharing legislation. Such an approach would be consistent with obligations under the CBD itself. Overly prescriptive or burdensome approaches to creation and implementation of the International Regime could severely undercut the very goals of the CBD.
- The scope of an International Regime must not extend beyond the scope of the CBD itself, and must be implemented and applied prospectively. We also note that any regime created under the CBD will not apply to those plant genetic resources for food and agriculture that are already the subject of the IT-PGRFA.
- The International Regime should not focus solely on the goal of fair and equitable access and benefit-sharing, to the exclusion of the other goals of the CBD – namely, conservation and sustainable use. To disregard the role of conservation and sustainable use in the implementation of an International Regime will undermine the very purpose of the CBD. As scientific research often requires very little genetic material, an International Regime that is focused solely on research uses of genetic resources may leave more damaging and unsustainable uses of materials unchecked.

Sincerely,

Herbert C. Wamsley

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ACCESS AND BENEFIT SHARING, A MAIN PREOCCUPATION

OF THE WORLD FEDERATION FOR CULTURE COLLECTIONS (WFCC)

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Most culture collections were started by scientific institutions or individual scientists, some of them more than 100 years ago, when stable long-term *ex situ* conservation of microbes was almost fiction. Today 525 culture collections in 67 countries are registered with the World Federation for Culture Collections (WFCC[1]), World Data Centre for Micro-organisms (WDCM43). One of the aims of the WDCM is optimal transparent dissemination of information. WFCC members contribute daily to the study, exploration and *ex situ* conservation of microbiological resources vital for humankind. WFCC is organized in a cooperative spirit, best illustrated by its program of "endangered collections" that tries to secure stock of microbial specimens doomed to be lost by lack of funding.

Two years before the Bonn guidelines were drafted, the WFCC became a partner in a European funded project that conceived and developed the MOSAICC44 code of conduct for micro-organisms sustainable use and access management. The purpose of this work was to secure transparent access to microbiological diversity for *bona fide* and sustainable use by either public or private entrepreneurs in a fair win-win scheme.

For sustainable balanced socio-economic use of biodiversity, including scientific research, it is necessary to secure sound and easy access to biological material and related information. To achieve a balanced implementation of the Access and Benefit Sharing concept, from a practical perspective, taking into consideration the technical developments, **the World Federation for Culture Collections seeks to develop a simple, cost effective and efficient multi-purpose conveyance system that integrates tracking biological material as well as collecting, managing, and exploiting related information.**

The WFCC works towards the development of a balanced system through the following elements:

Standard microbiological resources transfer and use framework

Material Transfer Agreements (MTA) already exist and have been used for more than a decade but the issue is to get more uniformity in the general conditions of transfer, to ease the distribution of biological material in a coherent contractual framework. Uniformity should be sought preferably at the level of model provisions forming a tailored MTA. WFCC supports the initiative of the European Culture Collections Organisation (ECCO) that is working on a standard MTA for all its members.

Beside facilitating access to microbiological resources through uniform access and distribution rules, it is also necessary to ease their sound exploitation. Well defined property rights play a key role in enhancing economic innovation and the provision of services of general interest. Their most important contribution is to stimulate long term investment by adjusting the institutional rules to new technologies and evolving societal expectations.

43/ See www.wfcc.info
44/ See www.belspo.be/bccm/mosaicc

The mere static concept of ownership must be adapted to the requirements of the newly emerging, moving knowledge based bio-economy.

Full private ownership implies exclusive property and the right to sell or lease this exclusive property and all the other rights. However, this concept applies poorly to biological resources when the same material is 'owned' by different stakeholders (collectors, isolators, institutes, research groups, etc). In general, innovation in life sciences is characterized by a diffuse process of "exploration" of microbiological resources. Forms of non exclusive property, such as the sharing of resources among public and private research institutions or collaborative databases are thus common in the intermediary stages of the innovation process.

There is thus a need for flexible property rights management tools. Instead of having just the two options of full or no ownership, ownership can constitute a "bundle" of use and decision rights that are attributed to a number of stakeholders / economic agents. It is a scheme allowing multi-ownership of gradual level of use and decision rights. Several rights-owners determine use and access to resources. These rights range from basic access rights to alienation rights.

The concept of "**bundle of rights**" is rooted in intellectual property rights but scales the implementation of IPR according to the stakeholders' socio-economic needs and goals. It could also take into consideration the role of traditional knowledge.

Practical integrated conveyance system: the use of Globally Unique Identifiers (GUIDs)

By registering its members through a unique acronym and numerical identifier in its official list and urging them to catalogue their microbiological resources, WFCC has developed a pioneering database system in the World Data Centre for Micro-organisms. This feature was originally developed to manage and secure the *ex situ* conservation of microbiological resources. This system allows the tracking of microbiological items. But it also allows the implementation of the CBD "Access and Benefit Sharing" principle since it can potentially retrieve all kinds of information about microbiological resources, including information related to the location and movements of the resource.

Although the labeling within the culture collections world is fairly efficient for its initial purpose, there is a need for complementary ways to detect multiple digital resources: for example, a way to know whether others than the WDCM have data on the same biological source. An initiative in this context, Straininfo.net45 operates through an Integrated Strain Database, which is a central repository that provides a complete and correct view on the synonymous labels assigned to biological specimens during their lifetime. The Straininfo.net portal adds to the commonly used strain numbers a more persistent identifier, a larger identifier that provides extended uniqueness.

Taking advantage of the Straininfo.net project, a model was built for assigning Globally Unique Identifiers (GUIDs) to biological resources. WFCC proposes the development of persistent unique identifiers for global use, combining both the strain label and a persistent location where to retrieve information on microbiological resources. Such GUIDs would be assigned to (micro)biological resources and stored in integrated strain databases. For microbiological resources, an integrated database could be located at the World Data Centre for Micro-organisms (WDCM), which already retains an ID system for WFCC registered culture collections and institutions. Unique identifiers do not intend to replace traditional labeling of strains, genes or other data elements, but allow incorporating them in a larger namespace that provides an extended uniqueness and interoperability. This is a multi-purpose system that can retrieve all kind of data: scientific, technical, administrative, etc., for any kind of use: research, conveyance, resources conservation, etc.

45/ www.straininfo.net

Valuation of microbiological resources

Having organized the legal framework and the technical issues paves the way to benefit sharing but ultimately, to reach a fair deal requires reliable figures. One cannot reach a quantitative deal without having a good estimation of the socio-economic, ecological and scientific value of the microbiological resource that is "traded". The WFCC has participated in the MOSAICS project which advises further work on appropriate methods to appraise the multiple values of microbiological resources, in such a way that these can be translated in economic terms.

Methods to value ecological items such as ecosystems exist but at present there is no reliable way to value biological items as such. In the case of micro-organisms, the inherent value is not easily defined. In many cases, there is no identifiable inherent value in the microbe until a lot of scientific work has been done to investigate the metabolic pathways of the organism and determine if it has any unique feature.

More specific economic studies on test cases are necessary to adapt existing methods or develop new ones to appraise the value of microbiological items and express it in monetary terms. Such studies could conciliate the economic and the ecological aspects.

Conclusion

The implementation of the concept of "bundle of rights" to allot the right and duties to entitled stakeholders, the use of Global Unique Identifiers to convey transfers of microbiological items combined with an appropriate valuation of the microbiological items make it possible for fair and equitable transaction between provider and users of microbiological items. Building on decades of WFCC efforts in cooperative networking and pioneer work in IT, these new tools are the latest contribution of the culture collections to facilitate access to genetic resources.

However, it remains the responsibility of all stakeholders, including lawmakers, to make the system work and secure access to genetic resources enabling fair benefit-sharing whist facilitating the objectives of the CBD.
