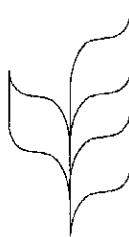




CBD



CONVENTION ON BIOLOGICAL DIVERSITY

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AD HOC OPEN-ENDED WORKING GROUP ON ACCESS AND BENEFIT-SHARING

Third meeting

Bangkok, 14 -18 February 2004

Items 3-8 of the provisional agenda**

COMPILED OF SUBMISSIONS PROVIDED BY PARTIES, GOVERNMENTS, INTERNATIONAL ORGANIZATIONS, INDIGENOUS AND LOCAL COMMUNITIES AND RELEVANT STAKEHOLDERS IN PREPARATION FOR THE THIRD MEETING OF THE AD HOC OPEN-ENDED WORKING GROUP ON ACCESS AND BENEFIT-SHARING

Note by the Executive Secretary

1. Following the seventh meeting of the Conference of the Parties, notifications were sent out respectively to Parties, relevant international and non-governmental organizations, indigenous and local communities and relevant stakeholders on 29 April 2004 (reminders were sent out on 29 September 2004), inviting them to contribute to the preparatory work for the third meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing and for the dissemination of information in accordance with decisions VII/19 A-F.

2. Submissions from Parties, non-Parties, relevant organizations and stakeholders received by the Secretariat pursuant to the above requests are compiled in the annex to the present note. They have been reproduced in the form and language in which they were provided. It should, however be noted that contributions relating to capacity-building projects as well as access and benefit-sharing measures are not included in this compilation. They are available in the databases on the Secretariat's web site at the following addresses: <http://www.biodiv.org/programmes/socio-eco/benefit/projects.aspx> and <http://www.biodiv.org/programmes/socio-eco/benefit/measures.aspx>.

* The contributions in the present compilation are reproduced in the language and form in which they were received by the Secretariat.

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Annex

**COMPILED OF SUBMISSIONS PROVIDED BY PARTIES, GOVERNMENTS,
INTERNATIONAL ORGANIZATIONS, INDIGENOUS AND LOCAL COMMUNITIES AND
RELEVANT STAKEHOLDERS IN PREPARATION FOR THE THIRD MEETING OF THE AD
HOC OPEN-ENDED WORKING GROUP ON ACCESS AND BENEFIT-SHARING**

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I. SUBMISSIONS FROM PARTIES

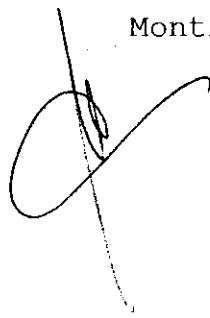
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N. 21 / 2004

The Consulate General of Brazil in Montreal presents its compliments to the Secretariat of the Convention on Biological Diversity and in reference to the Notification 034-2004 dated April 29th, has the honour to enclose herewith the information on access and benefit-sharing prepared by the Brazilian Government.

The Consulate General of Brazil avails itself of this opportunity to renew to the Secretariat of the Convention on Biological Diversity the assurances of its highest consideration.

Montreal, September 27th , 2004



"Ref: SCBD/SEL/VN/GD/43651 (Notification 2004-034)

The Brazilian Government would like to thank the Secretariat of the Convention on Biological Diversity for the opportunity to present its views on access and benefit-sharing as related to genetic resources. The Brazilian Government would also like to congratulate the Secretariat for inviting the Parties of the Convention to express their views on such an important issue.

However, despite the importance of all the issues concerning access and benefit-sharing related to genetic resources, priority must be given to the debate on the international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources (hereinafter "the international regime"). This priority is recognized by Decision VII/19 of the Seventh Meeting of the Conference of the Parties of the Convention that requests two meetings of the Ad Hoc Open-ended Working Group on Access and Benefit-Sharing before the Eighth Meeting of the Conference. It has to be considered that this decision on the number of meetings of the working group was adopted on an exceptional basis, due to the relevance and urgency of the negotiations of the international regime.

BONN GUIDELINES ON ACCESS TO GENETIC RESOURCES AND FAIR AND EQUITABLE SHARING OF BENEFITS ARISING OUT OF THEIR UTILIZATION

The implementation of the Bonn Guidelines could assist Parties of the CBD in the development of their national legal and administrative framework. However, it must be underlined that these Guidelines, as a non-binding document, will not avoid biopiracy or the general disrespect to these national legislations. The most appropriate mean to ensure compliance with the national legislations is through the creation of an international regime.

USE OF TERMS, DEFINITIONS AND/OR GLOSSARY

Definitions of terms eventually adopted should not be a substitute for the definitions of the national legislation of countries of origin of the genetic

resources. These legislations, in accordance with Article 15 (1) of the Convention, must always prevail. Brazil has a legal framework that defines some of the terms related to access to genetic resources, access to traditional knowledge associated to genetic resources and benefit-sharing and has been developing some others.

Some additional terms could be considered to the Secretariat such as "access to traditional knowledge associated to genetic resources", "bioprospecting" and "utilization of genetic resources".

ELEMENTS OF THE INTERNATIONAL REGIME TO PROMOTE AND SAFEGUARD THE FAIR AND EQUITABLE SHARING OF BENEFITS ARISING OUT OF THE UTILIZATION OF GENETIC RESOURCES

The negotiation of the international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources (hereinafter "the international regime") should have as its aim the adoption of a legally-binding instrument that effectively protects and guarantees the rights of countries of origin of genetic resources as well as the rights of indigenous and local communities in relation to their associated traditional knowledge.

The international regime on benefit-sharing could also address the issue of access to genetic resources. However, in accordance with Article 15 (1) of the Convention, provisions related to access to genetic resources should not be a substitute for the national legislation of countries of origin of those resources, but rather serve as a mean to reinforce the implementation of this legislation.

The international regime should also promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of traditional knowledge of indigenous and local communities relevant to biological diversity. The Conference of the Parties of the Convention has already recognized that CBD is the primary international instrument with the mandate to address issues regarding the respect, preservation and maintenance of that knowledge. Where traditional knowledge associated with genetic resources is being accessed, the rights of indigenous and local

communities over their traditional knowledge, including their right to fair and equitable sharing of benefits arising out of the utilization of that knowledge, should be respected and safeguarded.

Among the elements listed in Decision VII/19 of the Conference of the Parties, the Brazilian Government suggests that the discussions on the international regime should focus on the following ones:

- Measures to ensure compliance with national legislations on access and benefit-sharing, prior informed consent and mutually agreed terms, consistent with the Convention on Biological Diversity;
- Measures to ensure compliance with prior informed consent of indigenous and local communities holding traditional knowledge associated with genetic resources, in accordance with Article 8 (j);
- Measures to ensure compliance with the mutually agreed terms on which genetic resources were granted and to prevent the unauthorized access and use of genetic resources consistent with the Convention on Biological Diversity;
- Addressing the issue of derivatives;
- Internationally recognized certificate of origin/source/legal provenance of genetic resources and associated traditional knowledge;
- Disclosure of origin/source/legal provenance of genetic resources and associated traditional knowledge in applications for intellectual property rights;
- Recognition and protection of the rights of indigenous and local communities over their traditional knowledge associated to genetic resources subject to the national legislation of the countries where these communities are located;
- Monitoring, compliance and enforcement.

MEASURES, INCLUDING CONSIDERATION OF THEIR FEASIBILITY, PRACTICALITY AND COSTS, TO SUPPORT COMPLIANCE WITH PRIOR INFORMED CONSENT OF THE CONTRACTING PARTY PROVIDING GENETIC RESOURCES AND

MUTUALLY AGREED TERMS ON WHICH ACCESS WAS GRANTED IN CONTRACTING PARTIES WITH USERS OF SUCH RESOURCES UNDER THEIR JURISDICTION

Brazil has taken specific measures to support and ensure compliance with national legislation. The competent Brazilian authority - The Genetic Heritage Management Council (CGEN) - has been operative and several authorizations for access to genetic resources and for access to traditional knowledge associated to genetic resources were granted, always in accordance with prior informed consent requirements.

The competent authority has also clarified some terms in order to facilitate the adequate understanding of the process by the contracting parties and the national legislation has been largely informed to the interested parties.

STRATEGIC PLAN: FUTURE EVALUATION OF PROGRESS: NEED AND POSSIBLE OPTIONS FOR INDICATORS FOR ACCESS AND BENEFIT-SHARING

In accordance with Article 15 (1) of the Convention, Parties have the sovereign right to grant access to genetic resources based on their own national legislations. As decisions on access to those resources are strictly an internal matter, and Parties have the right to deny access, for example, in cases of non-compliance with the requirements contained in their legislations, there is no purpose on designing indicators for access to genetic resources.

Nevertheless, indicators for the fair and equitable sharing of benefits will be an important tool to assess the progress in the implementation of the Strategic Plan, in particular, in the focal area described in paragraph 1 (f) of Decision VII/30, namely "ensuring the fair and equitable sharing of benefits arising out of the use of genetic resources".

Convention on Biological Diversity**Ad Hoc Open-ended Working Group on Access and Benefit-sharing****Use of Terms, Definitions and/or Glossary, As Appropriate¹****Submission by Canada**

1. Canada is of the view that it is not essential at this time to address use of terms, definitions and/or a glossary, due to the early stage of negotiations on an international regime.
2. Previously, the issue of use of terms arose in the context of the Bonn Guidelines to ensure that they would be “user friendly”. ABS discussions have moved on from a narrow focus on the Guidelines, even though the Guidelines are an important part of the international ABS regime. Discussions in Thailand are expected to focus on the crucial conceptual level. Whether or when use of terms, definitions or a glossary will be required will necessarily depend on the outcome of those conceptual discussions.
3. Nevertheless, we support a full discussion of this issue at WG-ABS 3 under Sub-working Group 2 in order to come to a common understanding about when this type of discussion might become more appropriate. We do not support the creation of an expert group at WG-ABS 3, as set out in UNEP/CBD/WG-ABS/3/1/Add.1, para. 17, as this would divert attention from the important conceptual analysis which the ABS Working Group will be undertaking. Furthermore, if at any point terms were to be discussed, we would propose that it would be more appropriate in an open-ended context.
4. At this time, Canada is therefore not providing either existing national definitions or other relevant definitions of the terms cited in Decision VII/19B, nor are we suggesting additional terms that need to be addressed. We would also like to note that Canada recently embarked on a domestic ABS policy initiative which will address issues related to definitions in a Canadian legal and socio-economic context. As is the case for other countries, our perspective on definitions for the international regime will be guided in large measure by our domestic deliberations.
5. We are of the view that all of the terms previously proposed for discussion are:
(1) adequately defined by the ordinary meaning of the term (e.g. voluntary nature, “access” in “access to genetic resources”); (2) clear from their use in the Bonn Guidelines or would be made clear in any material transfer agreement (MTA) (e.g. benefit-sharing, commercialization, derivatives, provider, user, stakeholder); or (3) defined in the Biodiversity Convention itself (e.g. “genetic resources”, “ex situ”).

¹ As set out in Decision VII/19B.

Información relacionada con acceso a recursos genéticos

Respuesta de COLOMBIA a la solicitud enviada por la Secretaría del Convenio sobre Diversidad Biológica mediante notificación SCBD/SEL/VN/GD/43651

1) ¿Qué experiencias y lecciones aprendidas se tienen en Colombia en la implementación de los Lineamientos de Bonn sobre Acceso a Recursos Genéticos y Distribución Justa y Equitativa de Beneficios derivados de su utilización?

Colombia no tiene experiencia en la implementación de los Lineamientos de Bonn, ya que posee legislación regional y nacional específica sobre acceso a recursos genéticos y distribución de beneficios. Entre ellas están la Decisión Andina 391 de 1996, la Andina 486 de 2000 la Resolución 620 de 1997, el Decreto 730 de 1997 y el Decreto 309 de 2000.

2) Cuáles son las definiciones y términos utilizados en Colombia respecto a lo siguiente: (extraídas de la Decisión Andina 391)

- a) Acceso a recursos genéticos: "Obtención y utilización de los recursos genéticos conservados en condiciones ex situ e in situ, de sus productos derivados, o de ser el caso, de sus componentes intangibles, con fines de investigación, prospección biológica, conservación, aplicación industrial o aprovechamiento comercial, entre otros"
- b) Derivados: "Molécula, combinación o mezcla de moléculas naturales, incluyendo extractos crudos de organismos vivos o muertos de origen biológico, provenientes del metabolismo de seres vivos"
- c) Proveedores:
 - i) Proveedor del componente intangible: persona que a través del contrato de acceso y en el marco de la Decisión Andina 391 y de la legislación nacional complementaria, está facultada para proveer el componente intangible asociado al recurso genético o sus productos derivados.
 - ii) Proveedor del recurso biológico: persona facultada en el marco de la Decisión Andina 391 y de la legislación nacional complementaria, para proveer el recurso biológico que contiene el recurso genético o sus productos derivados.
- d) Otras definiciones que se consideren relevantes.

País de origen del recurso genético: país que posee los recursos genéticos en condiciones in situ, incluyendo aquellos que habiendo estado en dichas condiciones, se encuentran en condiciones ex situ.

3) Información sobre otros enfoques, incluyendo la consideración de un certificado Internacional de origen /fuente/ proveniencia legal, así como experiencias regionales, nacionales y locales sobre enfoques existentes, incluyendo códigos de ética.

De acuerdo con la Sentencia C-677 de la Corte Suprema de Justicia de Colombia, basada en la Decisión Andina 391 del Acuerdo de Cartagena sobre un régimen común de acceso a los recursos genéticos, los recursos genéticos son patrimonio de la nación, y por ello son de carácter inalienable, imprescriptible e inembargable. Esto significa que para cualquier recurso genético (ya sea fito o zoológico), y que se encuentre en colecciones ex situ o en condiciones in situ, se deberá entender que no puede haber apropiación de ninguna

naturaleza (como derechos de propiedad intelectual), y que su acceso debe regirse bajo las normas establecidas por la Decisión Andina 391, es decir, a través de un contrato con el Estado, y si es del caso, con los dueños del predio donde se haga la colecta y con las comunidades tradicionales en el caso de incluirse el componente intangible.

La Decisión Andina 391 se estableció en julio de 1996, con el objetivo de regular el acceso a los recursos genéticos, productos derivados y componentes intangibles asociados, que sean colectados en el territorio de cualquiera de los países Miembros (Bolivia, Colombia, Ecuador, Perú y Venezuela). Surgió por la necesidad de los Paises Miembros, de dar una protección a los recursos genéticos de la subregión que no tenían una regulación de acceso específica. Además, de acuerdo con el mandato del Convenio de Diversidad Biológica, los países debían regular el acceso a los recursos genéticos, de manera que éstos fueran con consentimiento fundamentado previo del país de origen, en términos mutuamente acordados, y con una repartición justa y equitativa de los beneficios derivados de ese acceso. Esta decisión cubre tanto a los recursos fitogenéticos como a los zoogenéticos, a las moléculas, combinaciones o mezclas de moléculas naturales, incluyendo extractos crudos de organismos vivos o muertos de origen biológico, provenientes del metabolismo de seres vivos, como a todo conocimiento, innovación o práctica individual o colectiva, con valor real o potencial, asociado al recurso genético, productos derivados o al recurso biológico que lo contiene, protegido o no por regímenes de propiedad intelectual.

La manera más apropiada que se consideró para regular el acceso, fue bajo la figura de un contrato. Este, que es un acuerdo de voluntad entre las partes, se celebra entre el Estado –como aquel que cumple unas funciones de vigilancia, regulación y control de los recursos genéticos–, y las personas naturales o jurídicas que quieren realizar la actividad de acceso. Adicionalmente, la Decisión Andina 391 prevé la suscripción de contratos accesorios, entre otros con los propietarios y administradores de los recursos biológicos y los predios donde éstos se encuentran, así como un anexo al contrato principal de acceso, cuando se quiere acceder también al componente intangible asociado a los recursos genéticos, referido a conocimiento tradicional o científico. Una vez se tiene definida cuál va a ser la actividad de acceso (para investigación, para comercialización, etc.) y dónde se va a realizar la bioprospección (localización geográfica), se debe presentar una solicitud ante el Ministerio de Ambiente, Vivienda y Desarrollo Territorial, quien ejerce las funciones de autoridad nacional competente en esta materia, que debe contener cierta información, además de la propuesta del proyecto para el cual se está realizando el acceso. Luego de que el Ministerio tiene toda esa información, antes de cinco días hábiles debe publicar un extracto de la solicitud, con el fin de que todo el público conozca que se está pidiendo acceso a un recurso genético, ubicado en un lugar determinado. Esto es muy importante especialmente cuando se incluye información sobre el componente intangible asociado, o si el recurso está en territorio de comunidades tradicionales. Si no hay ningún problema, luego de 30 días prorrogables, en los cuales el Ministerio hace un examen técnico y jurídico, se aprueba o no la solicitud de acceso. Posteriormente, se inicia la etapa de negociación y el caso en que se llegue a un acuerdo, se hará la suscripción del respectivo contrato de acceso.

Posteriormente a la Decisión 391, la Comunidad Andina de Naciones, expidió la Decisión 488 de 2000 sobre un Régimen Común en Propiedad Industrial, en donde se establece lo siguiente:

Artículo 3; "Los Países Miembros asegurarán que la protección conferida a elementos de la propiedad industrial se concederá salvaguardando y respetando su patrimonio biológico y genético, así como los conocimientos tradicionales de sus comunidades indígenas, afroamericanas o locales. En tal virtud, la concesión de patentes que versen sobre invenciones desarrolladas a partir de material obtenido de dicho patrimonio o dichos conocimientos estará supeditada a que ese material haya sido adquirido de conformidad con el ordenamiento jurídico internacional, comunitario y nacional."

Artículo 26: "La solicitud para obtener una patente de invención se presentará ante la oficina nacional competente y deberá contener lo siguiente:

h) de ser el caso, la copia del contrato de acceso, cuando los productos o procedimientos cuya patente se solicita han sido obtenidos o desarrollados a partir de recursos genéticos o de sus productos derivados de los que cualquiera de los Países Miembros es país de origen;

i) de ser el caso, la copia del documento que acredite la licencia o autorización de uso de los conocimientos tradicionales de las comunidades indígenas, afroamericanas o locales de los Países Miembros, cuando los productos o procedimientos cuya protección se solicita han sido obtenidos o desarrollados a partir de dichos conocimientos de los que cualquiera de los Países Miembros es país de origen, de acuerdo a lo establecido en la Decisión 391 y sus modificaciones y reglamentaciones vigentes."

Artículo 75: "La autoridad nacional competente decretará de oficio o a petición de cualquier persona y en cualquier momento, la nulidad absoluta de una patente cuando:

g) de ser el caso, no se hubiese presentado la copia del contrato de acceso, cuando los productos o procedimientos cuya patente se solicita han sido obtenidos o desarrollados a partir de recursos genéticos o de sus productos derivados de los que cualquiera de los Países Miembros es país de origen.

h) de ser el caso, no se hubiese presentado la copia del documento que acredite la licencia o autorización de uso de los conocimientos tradicionales de las comunidades indígenas, afroamericanas o locales de los Países Miembros, cuando los productos o procesos cuya protección se solicita han sido obtenidos o desarrollados a partir de dichos conocimientos de los que cualquiera de los Países Miembros es país de origen."

4) Puntos de vista, información y análisis sobre los elementos que contendría un régimen internacional en acceso a recursos genéticos y distribución de beneficios.

a) El régimen internacional de acceso a los recursos genéticos y distribución de beneficios debe partir del reconocimiento de la soberanía de los países para regular el acceso a sus recursos genéticos. Bajo ese entendido, un régimen internacional de acceso no tiene como fin entrar a negociar de manera detallada las condiciones para otorgar el acceso a los recursos genéticos (pues esto se considera es del ámbito nacional), sino acordar medios para garantizar que los regímenes nacionales de acceso a los recursos genéticos se cumplan en los países usuarios de esos recursos

genéticos, así como que se respeten los derechos de los países de origen de estos recursos.

- b) El régimen internacional de acceso no debe ser un régimen de acceso facilitado; sino un instrumento jurídico cuyo fin sea garantizar la distribución justa y equitativa de los beneficios que se derivan del acceso a los recursos genéticos.
- c) El régimen debe contemplar mecanismos de cumplimiento y observancia, entre las cuales se incluyen los instrumentos sancionatorios, para garantizar el respeto de los derechos de los países de origen de los recursos genéticos y la distribución justa y equitativa de los beneficios que se derivan del acceso.

5) Medidas para apoyar y asegurar el cumplimiento de la legislación nacional, el consentimiento informado previo de las Partes contratantes que proveen los recursos genéticos, incluyendo los países de origen y de las comunidades tradicionales que dan sus conocimientos.

Dentro de las normas que en Colombia desarrollan lo relativo al consentimiento informado de las comunidades se encuentran las siguientes:

- a) Decreto 1391 del 8 de Agosto de 1996 "Por el cual se crea la Comisión Nacional de Territorios Indígenas y la Mesa Permanente de Concertación con los pueblos indígenas y se dictan otras disposiciones", la cual tiene por objeto concertar entre estos y el Estado las decisiones administrativas y legislativas susceptibles de afectarlos y evaluar la ejecución de la política indígena del Estado. Las funciones de la Mesa Permanente de Concertación son las siguientes:
 - Adoptar principios, criterios y procedimientos en relación con la biodiversidad, recursos genéticos, propiedad intelectual colectiva y derechos culturales asociados a estos, en el marco de la legislación especial de los pueblos indígenas.
 - Concertar previamente con los pueblos y organizaciones indígenas las posiciones y propuestas oficiales para proteger los derechos de los indígenas en materia de acceso a recursos genéticos, biodiversidad y protección del conocimiento colectivo, innovaciones y prácticas tradicionales que presente el Gobierno Colombiano en instancias internacionales en el marco de acuerdos, convenios suscritos y ratificados por Colombia.
 - Concertar el desarrollo de los derechos constitucionales indígenas en relación biodiversidad, recursos genéticos, propiedad intelectual colectiva y derechos culturales asociados a estos y legislación.
- b) Decreto 2248 del 22 de Diciembre de 1995 por la cual se crea la Comisión Consultiva de alto nivel para las comunidades negras, adscrita al Ministerio del Interior y que está integrada por miembros del gobierno y de las comunidades negras, y cuya función es servir de instancia de diálogo entre comunidades negras y el gobierno nacional, y servir de espacio de debate de proyectos de decreto reglamentarios de la Ley 70 de 1993.

c) Decreto 1320 de 13 de Julio de 1998 "Por el cual se reglamenta la consulta previa con las comunidades indígenas y negras para la explotación de los recursos naturales renovables dentro de su territorio", la cual tiene por objeto analizar el impacto económico, ambiental, social y cultural que pueda ocaionarse a una comunidad indígena o negra por la explotación de recursos naturales dentro de su territorio, y las medidas para proteger su integridad.

d) Decisión Andina 486 sobre un régimen común en propiedad industrial:

Artículo 26: "La solicitud para obtener una patente de invención se presentará ante la oficina nacional competente y deberá contener lo siguiente:

h) de ser el caso, la copia del contrato de acceso, cuando los productos o procedimientos cuya patente se solicita han sido obtenidos o desarrollados a partir de recursos genéticos o de sus productos derivados de los que cualquiera de los Países Miembros es país de origen;

i) de ser el caso, la copia del documento que acredite la licencia o autorización de uso de los conocimientos tradicionales de las comunidades indígenas, afroamericanas o locales de los Países Miembros, cuando los productos o procedimientos cuya protección se solicita han sido obtenidos o desarrollados a partir de dichos conocimientos de los que cualquiera de los Países Miembros es país de origen, de acuerdo a lo establecido en la Decisión 391 y sus modificaciones y reglamentaciones vigentes."

Artículo 75: "La autoridad nacional competente decretará de oficio o a petición de cualquier persona y en cualquier momento, la nulidad absoluta de una patente cuando:

g) de ser el caso, no se hubiese presentado la copia del contrato de acceso, cuando los productos o procedimientos cuya patente se solicita han sido obtenidos o desarrollados a partir de recursos genéticos o de sus productos derivados de los que cualquiera de los Países Miembros es país de origen.

h) de ser el caso, no se hubiese presentado la copia del documento que acredite la licencia o autorización de uso de los conocimientos tradicionales de las comunidades indígenas, afroamericanas o locales de los Países Miembros, cuando los productos o procesos cuya protección se solicita han sido obtenidos o desarrollados a partir de dichos conocimientos de los que cualquiera de los Países Miembros es país de origen."

6) Acuerdos de acceso y distribución de beneficios que existan en sectores específicos.

NORMATIVIDAD EN MATERIA DE ACCESO A RECURSOS GENÉTICOS

a) En relación con los recursos genéticos la Constitución Política de Colombia de 1991 establece en el inciso 2 artículo 81º, que el Estado es el único ente facultado para regular la utilización, el ingreso o egreso de los recursos genéticos del país.

b) De igual forma, la Ley 99 de Diciembre de 1993 mediante en su artículo 2 dispone la creación del Ministerio de Ambiente, Vivienda y Desarrollo Territorial, como organismo rector de la gestión del medio ambiente y de los recursos naturales renovables, encargado entre otras cosas, de definir las regulaciones a las que se sujetarán la conservación, protección, manejo, uso y aprovechamiento de los recursos naturales

renovables y el medio ambiente de la Nación, a fin de asegurar el desarrollo sostenible.

- c) Respondiendo al mandato consagrado en el inciso 2 del artículo 81 de la Constitución Política, la Ley 99 de 1993 en el numeral 21 del artículo 5 le asignó al Ministerio Ambiente, Vivienda y Desarrollo Territorial la función de "Regular, conforme a la Ley, la obtención, uso, manejo, investigación, importación, exportación, así como la distribución y el comercio de especies y estirpes genéticas de fauna y flora silvestres; regular la importación, exportación y comercio de dicho material genético, establecer los mecanismos y procedimientos de control y vigilancia, y disponer lo necesario para reclamar el pago o reconocimiento de los derechos o regalías que se causen a favor de la nación por el uso de material genético". Aspectos estos que ha venido cumpliendo éste Ministerio.
- d) En consonancia con lo anterior, la Decisión 391 de la Comisión del Acuerdo de Cartagena relativa al Régimen Común sobre Acceso a los Recursos Genéticos, entró en vigencia el 17 de julio de 1996, fecha de su publicación en la gaceta oficial del Acuerdo. La Decisión Andina 391 es el primer marco jurídico regional que regula el acceso a los recursos genéticos y sus productos derivados, de tal forma que además de establecer el procedimiento que se debe surtir para lograr el acceso a dichos recursos, se destaca que sus postulados respetan lo previsto en el Convenio de Diversidad Biológica; y obviamente dentro de ese marco, reconociendo y valorando los derechos y la facultad de decidir de las comunidades sobre sus conocimientos, innovaciones y prácticas tradicionales asociados a los recursos genéticos y sus productos derivados
- e) En desarrollo de la Decisión Andina 391 de 1996, el gobierno colombiano expidió el Decreto 730 del 14 de marzo de 1997, mediante el cual se designó al Ministerio de Ambiente, Vivienda y Desarrollo Territorial como la Autoridad Nacional Competente, en los términos y para los efectos establecidos en la decisión 391 de la Comisión del Acuerdo de Cartagena relativa al Régimen Común sobre Acceso a los Recursos Genéticos. Conforme al citado decreto al Ministerio le compete expedir las regulaciones administrativas internas necesarias para el cumplimiento de dicha decisión; recibir, tramitar y autorizar o no las solicitudes de acceso a recursos genéticos y negociar y suscribir en consecuencia los respectivos contratos de acceso; supervisar y controlar el cumplimiento de las condiciones de los contratos de acceso y establecer en consecuencia los mecanismos de seguimiento y evaluación a que haya lugar; entre otras cosas.
- f) El Ministerio de Ambiente, Vivienda y Desarrollo Territorial expidió la Resolución No. 0620 del 7 de julio de 1997, a través de la resolución citada, se delegaron una serie de funciones al interior de éste Ministerio en lo relacionado con esta materia, y se estableció el procedimiento interno para tramitar las solicitudes de acceso a los recursos genéticos y sus productos derivados, de tal forma que se estipuló con claridad la competencia de cada una de las dependencias de este Ministerio que deben adelantar algún procedimiento en esta materia ante una eventual solicitud.

- g) Con el objeto de tener mayor claridad sobre el régimen jurídico del dominio aplicable a los recursos genéticos, el Ministerio de Ambiente, Vivienda y Desarrollo Territorial elevó una consulta la Sala de Consulta y Servicio Civil del Consejo de Estado, la cual fue resuelta mediante Concepto de fecha agosto de 1997. Rad. No. 977. Consejero Ponente: Cesar Hoyos Salazar, en la cual concluyó:

"El régimen jurídico de propiedad aplicable a los recursos genéticos, de utilidad real o potencial, es el establecido para los bienes de dominio público, en forma general en la Constitución Política, y de manera particular, en la decisión 391 de la Comisión del Acuerdo de Cartagena, en el decreto ley 2811 de 1.974, la ley 165 de 1.994 y las disposiciones legales que en el futuro se expidan sobre la materia.

El tratamiento jurídico de los recursos genéticos no es el mismo que le da la legislación colombiana a los recursos naturales no renovables, porque estos tienen un régimen legal especial, el cual no dispone que sus normas se apliquen también a los recursos naturales renovables. Por el contrario, existe un Código Nacional de Recursos Naturales Renovables y disposiciones que lo adicionan y complementan.

Al recurso genético puede dársele un tratamiento jurídico de propiedad independiente al previsto para el recurso biológico. Aunque este contiene al primero, mientras formen unidad o estén integrados, la función ecológica impuesta a la propiedad privada y el interés nacional garantizan la propiedad pública de la nación y una vez separados cada uno se sujeta al régimen jurídico que le es propio".

7) Medidas administrativas y judiciales existentes en los países con usuarios bajo su jurisdicción.

El Código Penal (Ley 599 de 2000), en su artículo 328 dispone que: "El que con incumplimiento de la normatividad existente introduzca, explote, transporte, tráfique, comercie, aproveche o se beneficie de los especímenes, productos o partes de los recursos faunísticos, forestales, florísticos, hidrobiológicos de especie amenazada o en vía de extinción o de los recursos genéticos, incurirá en prisión de dos (2) a cinco (5) años y multa hasta de diez mil (10.000) salarios mínimos legales mensuales vigentes."

8) Prácticas y tendencias existentes relacionadas con la comercialización y utilización de recursos genéticos y generación de beneficios.

Compensaciones Monetarias.

La literatura internacional reseña la creciente conciencia de las compañías farmacéuticas y de biotecnología concerniente a que los países dueños de los recursos genéticos, que los

han conservado, y las comunidades involucradas deben recibir una contraprestación monetaria de las actividades de prospección de estos recursos¹

La contraprestación monetaria se deriva de la propiedad del Estado sobre los recursos genéticos y productos derivados y del esfuerzo que ha hecho para conservarlos. Este debe entenderse como un reconocimiento al Estado por utilizar recursos de su propiedad, a los costos en que han incurrido el Estado y las comunidades para conservar estos recursos y al valor de la información contenida en ellos.

En el caso de acceso a recursos genéticos para bioprospección la literatura reseña dos tipos de contraprestaciones monetarias que se causan en diferentes momentos del tiempo: el precio de acceso a los recursos y las "regalías"²

Por lo tanto, el análisis económico de las solicitudes de acceso con fines comerciales se basa en estos dos puntos fundamentales:

- i. Precio de Acceso.
- ii. Regalías

La literatura también reseña un aporte adicional como contribución a la conservación de los recursos, que puede ser asimilado a un precio de acceso.

Relaciones y Roles en los Acuerdos de Bioprospección

En primer lugar es necesario aclarar los papeles que juegan cada uno de los actores involucrados en el proceso. La tendencia mundial de las compañías farmacéuticas es establecer un contrato con un agente llamado recolector quien le proporcionará las muestras para su posterior investigación y desarrollo.

El recolector es quien realiza las actividades de prospección en los países fuente de los recursos genéticos, y dependiendo de su capacidad tecnológica y del acuerdo al que ha llegado con la compañía, puede proporcionar muestras recolectadas, bioensayadas o compuestos *in vitro* que muestran algún tipo de actividad posiblemente útil para el objetivo final de la compañía.

Es recomendable que en el espacio de una negociación, se negocie un porcentaje sobre los ingresos o sobre la venta de compuestos de manera que la Nación no asuma los costos de desarrollo, los gastos generales de operación ni los gastos financieros de la empresa. El porcentaje de regalías sobre la venta del producto final, apoyo técnico y de laboratorios, *advanced payments*, capacitación, exclusividad, etc. son negociados entre el recolector y la compañía.

¹ Laird, Sara. "Contracts for Biodiversity Prospecting" en "Biodiversity Prospecting". World Resources Institute, 1993

² Según la legislación colombiana sólo es posible obtener regalías por el acceso a recursos naturales no renovables. No obstante, la ley contempla el concepto de pago de una contraprestación por el uso de recursos naturales renovables propiedad de la nación, ejemplo de ello son las tasas de aprovechamiento forestal y las concesiones por utilización del agua, vigentes en la actual legislación.

El recolector es quien tramita ante las autoridades del país origen los permisos y contratos necesarios para obtener acceso a los recursos genéticos y productos derivados con fines de bioprospección, y las contraprestaciones monetarias y no monetarias tanto para la nación como para las comunidades involucradas.

En conclusión, el análisis económico de las solicitudes de acceso a recursos genéticos con fines comerciales debe incluir beneficios monetarios (entendidos como precio de acceso y regalías) y no monetarios. En el caso de solicitudes de investigación se trata en la mayoría de los casos de beneficios no monetarios como copias (y muestras) de los análisis y estudios desarrollados a los jardines botánicos, herbarios nacionales y/o regionales y otros institutos encargados del tema. Pero además, el acceso a recursos genéticos para investigación sin fines comerciales, no solo puede derivar beneficios no monetarios, sino también monetarios, tales como pagos por el ingreso al predio, pagos por la colección del material, etc.

Por otra parte, de conformidad con el estudio realizado por el Instituto Humboldt, como parte del proyecto de investigación "Diseño de una Política de Acceso y Aprovechamiento de los Recursos Genéticos y Productos Derivados para Colombia", la capacidad de la bioindustria nacional es muy limitada, ya que su demanda por insumos intermedios o materias primas de origen local es muy baja, así como su interés en la innovación a través de la búsqueda de nuevos recursos genéticos y el desarrollo de nuevos productos. De manera general, podríamos afirmar que la bioindustria nacional cuenta con muy escasa capacidad para hacer bioprospección y para innovar sus procesos o desarrollar bienes y servicios derivados de los recursos genéticos y productos derivados. Esto se manifiesta también en su débil capacidad de articulación con los centros de investigación en recursos genéticos. Por otra parte, el estudio demostró que la satisfacción de la demanda de la bioindustria nacional por estos insumos es altamente dependiente de las importaciones de recursos genéticos.

Al mismo tiempo, la oferta internacional en este mercado de información genética es cada vez mayor, en la medida que más países entran al proceso. En consecuencia, a mayor competencia los precios ofrecidos por las entidades demandantes tienden a la baja. Es conveniente buscar una forma sencilla de manejar los beneficios económicos que minimice el riesgo para el inversionista y para el país, promoviendo la inversión y desarrollo del proyecto a corto plazo. Por un lado, se deben pactar cautelosamente las condiciones de los beneficios no-monetarios asociados (manejo de información taxonómica, capacitación, transferencia de conocimiento, etc.) y la forma de monitoreo.

En síntesis, existe una gran incertidumbre sobre la disponibilidad a pagar por parte de las entidades que solicitan acceso a recursos genéticos, por ser este un mercado nuevo y desconocido, sin suficientes transacciones a la luz pública. Por otro lado, puede existir gran incertidumbre por parte de las compañías que hacen investigación y/o explotación: hacer una inversión significativa sin tener certidumbre sobre la posibilidad de encontrar sustancias activas que puedan ser vendidas o que tengan una utilidad real en la industria. Esta incertidumbre económica existe para las dos partes en cada etapa de la cadena de investigación y desarrollo de los productos asociados con el acceso a los recursos

genéticos. En una relación con tanta incertidumbre, la solución puede ser un adecuado apoyo legal: negociar un porcentaje significativo de los ingresos por ventas, mas los beneficios no monetarios pactados: (identificación de todas las especies evaluadas, consolidación del inventario del recurso taxonómico nacional, transferencia de tecnología y capacitación de profesionales, etc.).

9) Medidas para preservar y promover la certeza legal para los usuarios sobre los términos y condiciones de acceso y uso.

La Decisión 391 de 1996 establece en su artículo 26 la información que deberá aportar el solicitante del acceso a los recursos genéticos. Según la legislación nacional, esta información es la siguiente:

- a) Identificación del solicitante
- b) Documentos que acrediten la capacidad jurídica de contratar del solicitante
- c) Identificación del proveedor que dará el acceso (al recurso genético, biológico y conocimiento asociado con el recurso genético)
- d) Identificación de la persona o institución nacional de apoyo
- e) Identificación y currículo vital del responsable del proyecto y de su grupo de trabajo
- f) La actividad de acceso que se solicita
- g) La localidad o área en que se realizará el acceso, señalando sus coordenadas geográficas

La Resolución 620 de 1997 señala la información deberá presentar el solicitante, en su artículo 15, adicional a la consignada en la Decisión 391.

Igualmente, la Resolución 414 de la Comunidad Andina adopta un modelo referencial de solicitud de acceso a los recursos genéticos; y la Resolución 415 un modelo de contrato de acceso a los recursos genéticos.



2004

Brussels, 15 October 2004

Subject: Decision VII/19 on Access and Benefit-sharing as related to genetic resources

Dear Mr Zedan,

The Netherlands and the European Commission, on behalf of the European Community and its Member States, would like to transmit the enclosed EU submission in accordance with the decision above.

Rebecca Parzer
Directorate for Nature
Netherlands Ministry of Agriculture, Nature
and Food Quality

Your sincerely,

Julio Garcia Burgues
European Commission

UNEP/CBD 45478

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Decision VII/19 on Access and Benefit-sharing as related to genetic resources – Request by the CBD Secretariat for submission of views and information (notification 29/04/04) –

EU submission

The present paper aims at responding to the above notification by the CBD Secretariat. Each request is dealt with in the order in which it was presented in the secretariat's notification. Additional information on EU Member States national experience is included in the Annex.

1) Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of their Utilization

Parties are invited to submit information on relevant experience and lessons learned in the implementation of the Guidelines to the Executive Secretary as soon as it becomes available.

With a view to implementing the Bonn Guidelines in the EC, the European Commission adopted, on 23 December 2003, a Communication (COM 2003 (821) final)¹ that identified possible actions at EC level for the implementation of the Guidelines.

Among these actions, the Communication mentions:

- The establishment of a European network of access and benefit-sharing focal points and/or Competent National Authorities - building on existing networks - which could be connected, *inter alia*, through the EC Biodiversity Clearing House Mechanism (EC-CHM).
- The creation of a specific section of the EC-CHM devoted to the issue of access and benefit-sharing. Such a section could contain the text of the Bonn Guidelines together with an explanation of their relevance to different European stakeholders' profiles. The EC-CHM could become an important channel to inform stakeholders on their rights and obligations internationally, including in relation to other international instruments such as the International Treaty on Plant Genetic Resources on Food and Agriculture; in the EC, and in the Member States (MS). To this end, appropriate links with, *inter alia*, the CBD and Member States' Biodiversity Clearing Houses could be provided.
- Publicising the EC-CHM website widely and writing to all relevant stakeholder groups encouraging them to register with the EC-CHM and to provide copies of their own policies, codes of conduct, guidelines, principles, case studies, material transfer agreement examples, etc., related to access and benefit-sharing.

¹ See Annex

In view of the above, the European Commission placed a contract to identify the most cost-effective way of establishing a European network of access and benefit-sharing focal points; to collect all relevant information to be fed into a specific section of the EC-CHM devoted to the issue of access and benefit-sharing; and to widely publicise the EC-CHM website with all relevant stakeholder groups encouraging them to register with the EC-CHM.

The Commission is currently in the process of evaluating the proposals submitted to it by potential contractors. It is expected that the selected contractor will start working at the end of October and will conclude its work by April 2005.

The above-mentioned Communication also launched a debate in the EU on the issue of "disclosure of origin" of genetic resources and traditional knowledge (TK) in patent applications. Several meetings have been convened gathering EU intellectual property and biodiversity experts. As a result, the EU is working on different options and will be ready to further discuss them in the next meeting of the WIPO Inter-governmental Committee dealing with this matter (1-5 November 2004).

As a follow-up to the Communication, the Commission has also created an inter-departmental working group on indigenous issues which aims at promoting EC action in this field and ensuring its coherence throughout the wide array of policies relevant to indigenous peoples, including environment, development co-operation, human rights, trade and intellectual property. The group is in the process of defining its own work plan.

Also as a follow-up to the Communication, the Commission continues to lend support to the implementation of institutional policies and codes of conduct on ABS by stakeholder groups, including for *ex situ* collections. The Commission has supported in the past the development of the Micro-organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC)² by the Belgian Co-ordinated Collections of Micro-organisms (BCCM), together with 16 other organisations from around the world. At present, the Commission is financing a follow-up of the MOSAICC project aimed at providing validated reliable methods for the value assessment of microbial resources. Such methods are necessary to put a socially, economically and environmentally sound 'price' on genetic resources and therefore facilitate benefit-sharing. The project also aims to develop validated model documents to enable traceability of microbial resources (origin, transfer and transport).

The Commission will provide an update on these and other actions undertaken for the implementation of the Bonn Guidelines in the EC at the next meeting of the CBD ABS Working Group (February 2005, Thailand).

Please refer to the Annex for national input from EU Member States on the implementation of the Guidelines.

² <http://www.belspo.be/bccm/mosaicc>

2) Use of terms, definitions and/or glossary, as appropriate

(a) Information on existing national definitions or other relevant definitions of the following terms: access to genetic resources, benefit sharing, commercialization, derivatives, provider, user, stakeholder, ex situ collection, and voluntary nature (as contained in annex II of document UNEP/CBD/COP/6/INF/4);

(b) Views on whether additional terms need to be considered, such as arbitrary restrictions;

Parties are invited to submit information on existing national definitions and other relevant definitions of the terms referred to above and to provide their views on whether additional terms need to be considered to the Secretariat by 15 October 2004, using the format provided in Annex 1.

The above mentioned terms are not the subject of specific definitions in the context of biodiversity/genetic resources under EC legislation with one exception: Council Regulation (EC) No 870/2004 of 24 April 2004 establishing a Community programme on the conservation, characterisation, collection and utilisation of genetic resources in agriculture and repealing Regulation (EC) No 1467/94 defines, in its Article 3 h), an ‘ex situ collection’ as “a collection of genetic material for agriculture maintained outside their natural habitat”. This definition is relevant for the purpose of that Regulation. The latter, in several places, also refers to ex situ collections as ‘gene banks’.

European stakeholders including research institutions and networks in the framework of institutional policies and codes of conducts have developed operational definitions of some of the above terms. This is the case, for instance, of European botanical gardens. More information on this is available in the EC Thematic Report on Access and Benefit-sharing, section 5, posted on the CBD website.

Please refer to the Annex for MS input on national definitions.

The EU does not support the development of further definitions for additional terms, including ‘arbitrary restrictions’ which are normally defined under trade law. The EU believes that the compilation of a Glossary containing definitions already used in Multilateral Environmental Agreements and other relevant Multilateral Agreements, Codes of Conduct, Guidelines, Guiding Principles, etc. would be helpful. Such Glossary would usefully encourage stakeholders’ endorsement and use of the Bonn Guidelines throughout a wide range of sectors.

3) Other approaches, as set out in decision VI/24B

Parties are invited to submit to the Secretariat, by 15 October 2004, their views and relevant information on additional approaches, including the consideration of an international certificate of origin/source/legal provenance, as well as regional, national and local experiences on existing approaches, including on codes of ethics.

The EU believes that the 'other approaches' identified by the Secretariat in its paper ABS/WG2/2 prepared last year could provide an important contribution to the achievement of the ABS objective of the CBD and should therefore be encouraged taking as a reference point the Bonn Guidelines.

Also some sectoral instruments such as the FAO International Treaty on Plant Genetic Resources for Food and Agriculture, and regional instruments have been elaborated with a view to contributing to the implementation of Article 15, and where appropriate, Article 8j) of the CBD, in specific contexts.

Similarly, Codes of conduct, Guidelines and corporate policies developed by specific users' groups contribute to raising users' awareness of their responsibilities and to increasing their sense of ownership with regard to the CBD objectives. In this context, the positive experience of the European botanical gardens and culture collections is worth mentioning. More information on this is available in the EC Thematic Report on Access and Benefit-sharing, section 5, available from the CBD website.

Moreover, the EU recalls in this context that the European Commission continues to lend support to the implementation of institutional policies and codes of conduct on ABS by stakeholder groups, as it is the case for the above-mentioned MOSAIC project.

With regard to a certificate of origin, this is relevant in relation to the whole chain of the ABS process: it could accompany the genetic resources from the collection phase until the marketing of the product which makes use of them and therefore increase transparency and traceability. Some have also argued that it could be related to the patent application process.

However, national access laws in the different countries Parties to the CBD vary widely where they exist at all. The same applies to the requirements that access applicants have to fulfil. Therefore, at present, there is no single document which could be used in all Parties to the CBD in order to provide evidence of PIC. In some cases, such document would be a Material Transfer Agreement (MTA), in some others an authorisation provided by a public authority or a concession or a licence, etc.

Any requirement to submit documentary evidence of PIC would be facilitated by a clear, simple and harmonised system for certifying access such as a standard MTA. However, genetic resources and their uses can be very diverse, and it is not realistic to develop a 'one fits all' MTA. It will be necessary to let stakeholders enjoy sufficient flexibility in order to adjust an MTA on a case by case basis.

Therefore, the EU is open to further discuss in the CBD framework the development of a certificate of origin. It will be necessary to analyse how such certificate of origin could be accommodated within the existing body of international intellectual property law.

The EC and its Member States are also open to discuss both within WIPO and in other international fora, in particular the CBD, means to harmonise private law provisions also regarding an international certificate for genetic resources.

An opportunity for further discussion on the Certificate of Origin will be the Expert Meeting on the “Practicality, Feasibility and Cost of Certificates of Origin” in Paris, November 9-13 2004, which is organised by the UNU (United Nations University), IDDRI and UCL-CPDR.

The EU stresses the importance of acting coherently in different international fora which deal with ABS-related issues (CBD, FAO-IT, WIPO, WTO/TRIPS and UPOV). Similarly, the EU wishes to see environmental, patent, and other relevant authorities and stakeholders working together to discuss and analyse the different options.

4) International regime on access to genetic resources and benefit-sharing

Parties are invited to submit to the Executive Secretary their views, information and analysis on the elements of the international regime by 15 October 2004.

CBD COP Decision VII/19 contains the terms of reference that Parties have agreed for the Ad Hoc Open-ended Working Group on Access and Benefit-sharing that will deal with the ‘international regime’. The process for negotiations is described as follows:

“a) Process:

(i) To elaborate and negotiate the nature, scope and elements of an international regime on access and benefit-sharing within the framework of the Convention on Biological Diversity, as contained in paragraphs (b), (c) and (d) below, drawing on inter alia an analysis of existing legal and other instruments at national, regional and international levels relating to access and benefit-sharing, including: access contracts; experiences with their implementation; compliance and enforcement mechanisms; and any other options.

(ii) As part of the work, the Ad Hoc Open-ended Working Group on Access and Benefit-sharing will examine whether and to what extent possible elements as contained in paragraph (d) below are part of these instruments and determine how to address the gaps.”

In conformity with this process, the EU is of the view that an exhaustive analysis of existing legal and other instruments at national, regional and international levels relating to access and benefit-sharing needs to be conducted to enable the Working Group to identify gaps and ways to address them. Decision VII/19 does not clarify who should do this analysis. Therefore, the ABS Working Group should, in its next meeting, clarify who should be asked to accomplish this task. This should preferably be an independent/neutral body with specific competence/expertise in this field.

At this stage, the EU will set out its preliminary views on the above request from COP concerning the elements for the international regime as agreed at COP7. As some of these elements are part of “existing legal and other instruments at national, regional and international levels relating to access and benefit-sharing”, this will be our first contribution to the above-mentioned analysis.

The Annex to Decision VII/19, section D, contains under d) a long list of elements to be considered by the Working Group. This list also contains some redundancies. The EU will only focus on a selected number of elements to which it attaches particular importance.

- (i) *Measures to promote and encourage collaborative scientific research, as well as research for commercial purposes and commercialisation, consistent with Articles 8(j), 10, 15, paragraph 6, paragraph 7 and Articles 16 18 and 19 of the Convention;*

Element (i) comprises two important elements:

First, that of differentiation between scientific research and research for commercial purposes. In some instances it may be desirable to encourage collaborative scientific research through a range of measures including, for example, differentiated and simpler procedures such as non-commercial MTA's.

Second, among the measures to promote research consistent with the CBD, there is a need to highlight the importance of identifying best practice and its dissemination among sectors and across sectors. In this context, Action Plan for Capacity Building in decision VII/19, calls repeatedly for the identification of practices, in particular best practice and its dissemination along with case studies (see paragraph 9 (e) of the Action Plan on actions at the regional and sub-regional levels and at the international level.)

In our view, elements ii), iv), xiii) and xiv) of paragraph d) of the terms of reference, as reported below, deserve particular attention. They express the two sides of the ABS debate by highlighting the need to facilitate access to genetic resources for environmentally sound uses and the need to ensure that the fair and equitable sharing of the benefits arising from the use of these resources takes place:

- (ii) *Measures to ensure the fair and equitable sharing of benefits from the results of research and development and the benefits arising from the commercial and other utilization of genetic resources in accordance with Articles 15.7, 16, 19.1, 19.2 of the Convention;*
- (iv) *Measures to promote facilitated access to genetic resources for environmentally sound uses according to Article 15.2 of the Convention on Biological Diversity;*
- (xiii) *Internationally recognized certificate of origin/source/legal provenance of genetic resources and associated traditional knowledge;*
- (xiv) *Disclosure of origin/source/legal provenance of genetic resources and associated traditional knowledge in applications for intellectual property rights;*

The EU views on these two types of measures are largely expressed in sections 3) and 5) of this paper that contains a number of examples of how the EU contributes to the development of such measures at national, regional and international level.

The EU also attaches great importance to three other elements outlined in paragraph d):

- (xv) *Recognition and protection of the rights of indigenous and local communities over their traditional knowledge associated to genetic resources subject to the national legislation of the countries where these communities are located;*
- (xvi) *Customary law and traditional cultural practices of indigenous and local communities;*
- (xvii) *Capacity-building measures based on country needs.*

In the further development of the international regime on ABS, it will be essential to protect the rights of indigenous and local communities over their traditional knowledge. The EU is supportive of the development of an international *sui generis* model for the legal protection of traditional knowledge and is hopeful that progress will be made on this in the framework of WIPO's Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore and in the CBD Working Group on Article 8j). Any such system shall be compatible with the customary law and traditional cultural practices of indigenous and local communities and be developed with their approval and involvement.

The EC also considers it essential for a functioning international regime to address capacity building needs. The Annex to section F of COP Decision VII/19 contains an Action Plan on Capacity Building for ABS which provides a framework for identifying country, indigenous and local community and all relevant stakeholder needs, priorities, mechanisms of implementation and sources of funding. The implementation of this Action Plan will greatly contribute to build the capacities of Parties to manage and develop their genetic resources and should contribute to the conservation and sustainable use of biological diversity.

With regard to paragraph (xxiii) of the terms of reference, on 'Relevant elements of existing instruments and processes', the EU is pleased to note that the terms of reference reflect the EU view that a number of elements of an international regime on ABS already exist, including measures taken in application of Article 15 of the CBD, and should be the starting point for any discussion on further developments. Among them we recall the following to which we attach particular importance:

- The Bonn Guidelines represent a central element of the international regime on ABS under the CBD. In this respect, present and future reports by Parties on the use they have made of the Bonn Guidelines at national and regional level provide essential information in order to review and revise the Guidelines if necessary.
- In addition, the developments of 'other approaches' also provide further elements for the international regime.
- Similarly, possible outcomes of the work of the CBD 8j) Working Group and of the UN Permanent Forum on Indigenous Issues could provide valuable inputs, in particular in relation to traditional knowledge.

- The EU also recognises the fundamental importance of the International Treaty on Plant Genetic Resources for Food and Agriculture. The recent entry into force and the implementation of this Treaty, in particular through its standard material transfer agreement, will make it an important element of the international regime on ABS.
- Other existing elements include relevant provisions of the TRIPs Agreement; different intellectual property instruments administered by WIPO, and relevant provisions of the UPOV Conventions. Further developments in these fora may be of great importance for the international regime on ABS and the EU is committed to playing a constructive and coordinated role in them. This is true for instance for the issue of 'disclosure of origin' in intellectual property rights applications.

The EU believes that the analysis of the effectiveness of the instruments we have mentioned and of their on-going development as well as the enhancement of synergies among them should be the basis for further work on ABS under the CBD.

5) Measures, including consideration of their feasibility, practicality and costs, to support compliance with prior informed consent of the Contracting Party providing genetic resources and mutually agreed terms on which access was granted in Contracting Parties with users of such resources under their jurisdiction.

Parties are invited to provide information relating to sub-paragraphs (a) to (g) to the Secretariat by 15 October 2004.

a) Specific measures to support and ensure compliance with national legislation, prior informed consent of the Contracting Parties providing such resources, including countries of origin, in accordance with Article 2 and Article 15, paragraph 3, of the Convention, and of the indigenous and local communities providing associated traditional knowledge, and with mutually agreed terms on which access was granted;

b) Existing measures to support compliance with national, regional, and international legal instruments;

The European Commission has addressed in some detail the issue of specific measures to support compliance with prior informed consent of provider countries as well as with regional and international instruments in its Communication on the implementation of the Bonn Guidelines in the EC whose follow-up was covered in section 1 of this paper.

Key to ensure the respect of PIC and support compliance is stakeholders' awareness of their responsibilities. Therefore, the above-mentioned Communication highlights the usefulness of actions at stakeholders' level such as the development of institutional policies, codes of conduct and corporate policies.

As said before, the EC is fostering users' measures which are in harmony with the Bonn Guidelines such as Material Transfer Agreements and stakeholders' codes of conduct that are key instruments for stakeholders to live up to their responsibilities as identified by the Bonn Guidelines. The European Commission has also undertaken a number of actions aimed at raising users' awareness of their obligations under the CBD, including: the creation of a European network of ABS focal points; the establishment of a specific section on ABS on the EC

Biodiversity Clearing House Mechanism, and the setting up of a register of stakeholders' groups on this clearing house. In addition, the integration of the ABS issue into the EC process on Corporate Social Responsibility is also envisaged.

The Commission Communication also recalls existing requirements that can entail the disclosure of the origin of genetic resources and related traditional knowledge under EC law and European intellectual property law and recognises the possible role of such requirements in providing incentives for the respect of prior informed consent by the providers of genetic resources.

As mentioned above, the Communication also launched a debate in the EU on the issue of "disclosure of origin" of genetic resources and traditional knowledge in patent applications. Several meetings have been convened gathering EU intellectual property and biodiversity experts. As a result, the EU is working on different options and will be ready to further discuss them in the next meeting of the WIPO Inter-governmental Committee dealing with this matter (1-5 November 2004).

Also relevant in this context is the development, in the CBD framework, of a certificate of origin for genetic resources as evidence of prior informed consent. The EU view on this issue has already been expressed in section 3 above.

Finally, the potential role of the EC Eco-Management and Audit Scheme as a voluntary certification scheme for organisations that comply with the Bonn Guidelines also need to be mentioned.

c) The extent and level of unauthorized access and misappropriation of genetic resources and associated traditional knowledge;

The EU would welcome the availability of fuller and reliable information on this issue. On the basis of the scarce information available at present to us, it is difficult to have any idea of the extent and level of misappropriation. The EU attaches great importance to getting more information on misappropriation of genetic resources. We look forward to seeing the information that other countries/organisations may provide and will look into means of improving the availability of such information in the future.

d) Access and benefit-sharing arrangements existing in specific sectors;

See section 3 above on 'other approaches'.

e) Administrative and judicial remedies available in countries with users under their jurisdiction and in international agreements regarding non-compliance with the prior informed consent requirements and mutually agreed terms;

Enforcement problems in relation to ABS national laws and agreements can arise. Possibilities to prevent these situations need to be further studied on the basis of experience gained under international law in the enforcement of foreign judgements. Experiences in the field of intellectual property, in relation to the issue of entitlement to apply for or be granted a patent, could also provide inputs to solve enforcement problems.

One alternative dispute resolution system that could help addressing these problems is arbitration. For instance, it could prove helpful, under the terms of a MTA, for parties to agree to submit their disputes to a specific arbitration system available under international law whose decisions would be enforceable in a great number of States. Arbitration procedures are normally faster and less expensive than court proceedings and could therefore prove more attractive than court proceedings. Another problem that could arise in relation to ABS disputes concerns the possibility for providers to obtain information and access to justice in the countries where the users are located. In this respect, countries' ABS focal point could play a facilitator role by providing information, including on the legal system of their country. Moreover, controversies between providers and users located in different countries could be presented to the CBD Conference of the Parties and mediated by national authorities.

f) Existing practices and trends with regard to commercial and other utilization of genetic resources and the generation of benefits;

The Commission has supported the leading publication on the issue of the commercial demand for access to genetic resources: ten Kate, K. and Laird S.; *The Commercial Use of Biodiversity* (1999) Earthscan, London. The trends and practices identified in that book are overall still relevant today.

g) Measures that preserve and promote legal certainty for users over the terms and conditions of access and use;

Compliance with national, regional and international instruments will always be facilitated when these instruments are clear, transparent and non-discriminatory so that they encourage rather than discourage sustainable access and use of genetic resources. The implementation of the Bonn Guidelines can facilitate the development of instruments that present these characteristics. The appointment of National Focal Points and/or Competent National Authorities is particularly important in this respect.

Please refer to the Annex for MS input on national user measures.

6) Capacity-building for access and benefit-sharing

Parties are invited to make any new information regarding capacity-building measures available to the Secretariat on an ongoing basis and to fill out the data entry form in Annex 2.

The Commission has no new information to make available at this stage.

Please refer to the Annex for MS input on available information at national level.

7) Information on access and benefit-sharing measures

In order for the database to provide an accurate overview of existing access and benefit-sharing measures worldwide, Parties and relevant organizations are invited to provide information to

the Secretariat on these measures, as they become available, by filling out the data entry form in Annex 3.

The EC has no new information to make available at this stage.

Please refer to the Annex for MS input on available information at national level.

8) Strategic Plan: future evaluation of progress

Parties are invited to provide their views to the Secretariat on the need and possible options for indicators for access and benefit-sharing, by 15 October 2004.

The EU supports the development of indicator/s related to ABS as for other areas covered by the CBD but is also conscious of the difficulty of finding meaningful indicators in this field which would provide an objective view of the situation. Possible indicators could be:

“Number of countries that have enacted legislation/taken measures on access and benefit-sharing implementing CBD Article 15 and the Bonn Guidelines”;

“Number of countries that have nominated National Focal Points and/or competent national authorities;

“Number of “foreign” users who contacted National Competent Authorities in order to obtain consent for access”;

“Number of successful applications”;

“Percentage of applications for intellectual property rights on inventions based on genetic resources and/or traditional knowledge that disclose the country of origin/source of these resources and knowledge” (on a voluntary basis, as this is not a requirement under international intellectual property law at this stage);

“Number of countries that make use of an internationally recognised certificate of origin for genetic resources and related traditional knowledge”; (should such a certificate be developed in the framework of the CBD).

ANNEX: Member States' experiences with ABS issues

1) Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of their Utilization

Belgium

Between 1997 and 1999 a research project called MOSAICC has examined how to comply with the requirements on Access and Benefit sharing in the special case of microbial resources. This project was launched by the Belgian Coordinated Collections of Micro-organisms (BCCM), which led a consortium of 16 organizations involved in microbiology and the use of microorganisms from around the world, with the support of the Directorate General Research of European Commission.

MOSAICC is a voluntary code of conduct (Micro-organisms Sustainable use and Access Regulation International Code of Conduct - MOSAICC³) which aim to:

- *Facilitate access to microbial genetic resources in line with the CBD and other applicable national and international laws;*
- *Help partners to make appropriate arrangements when transferring microbial resources.*

MOSAICC assists countries by suggesting simple operating procedures when collecting microbial resources (registration of the in situ origin of the material) and when transferring the microbial resources (mention of the in situ origin, the provider and the recipient to ensure traceability + stipulation of the conditions and general terms of the transfer in MTA).

A new project will soon be started which will examine methods to evaluate the economic value of microbial resources, as this value is important to know when starting negotiation on benefit sharing. The project will also propose standard documents that can be used when transferring microbial resources, such as accession documents and Material Transfer Agreements.

Belgium would also like to mention the University research network on ABS at the UCL (catholic University of Louvain, Belgium) which launched the research of the "global common goods unit" of the Integrated Program "Reflexive Governance in the Public Interest" coordinated by the CPDR (Center for Philosophy of Law - UCL) and financed by the 6th framework program. The University research network continues the work accomplished within the sub-network "Biodiversity and reflexive governance" of the research project "The collective training as a contribution to democratic governance" coordinated by the CPDR and financed by the 5th European Framework Program. This sub network has already organized two international workshops devoted to ABS (overview of these two workshops cf. <http://www.cpdr.ucl.ac.be/biodiversity.php> and <http://www.cpdr.ucl.ac.be/ipr/>).

³ www.belspo.be/bccm/mosaicc

Denmark

Denmark has no legal provisions regulating access to genetic resources. In relation the project in the Nordic Council of Ministers on ABS this was reconsidered and there is no plan to restrict access for the time being. The home rule authorities of Greenland are considering regulating access to the resources in Greenland, but no decision has been made yet.

Denmark has revised its Patent law with a provision demanding patent applicants to give information of the origin of genetic resources used in the invention for which patent is applied. This provision does not seem to cause problems to applicants or to the patent authorities. The provision is not sanctioned within the patent system but can be sanctioned under criminal law under the provision on providing false information to public authorities.

On a number of occasions potential users of genetic resources have been prompted to seek information on the Bonn Guidelines and we have been informed that the leading Danish medical developer, Novo Nordic, follows the guidelines.

This fall a meeting is arranged with potential users of genetic resources to further promote the guidelines. At the meeting information on professional codes of ethics within academic society or institutions will also be gathered in order to promote the application of the Bonn Guidelines part of such codes.

As a supplement to the meeting providers of funding of research and development projects will be contacted to include the application of the Bonn Guidelines part of the condition for funding.

As mentioned above the promotion of the Bonn Guidelines is carried with a number of activities and builds on several incentives and awareness raising campaigns. Some of the activities could be listed as "Other approaches".

Finland

Finland's Ministry of the Environment has translated the Bonn Guidelines into Finnish to facilitate the implementation of the ABS, including the use of the Bonn Guidelines, at national level. An ABS National Working Group will be established in autumn 2004, and it will gather together different Ministries and stakeholders. The national discussion has emphasised the need to disseminate more information on the CBD, the Bonn Guidelines and the ABS issues nationally, regionally and internationally. There is also a clear need to further analyse the different ways and means by which the Guidelines can be put into practice.

Finland wants to reiterate its full support of the Bonn Guidelines. We believe that the exchange of practical experiences on the different types of implementation systems is crucial and can provide valuable background information for governments and other stakeholders when different options for an international system and/or national activities are considered.

Germany

The German Environment Ministry has commissioned a study that aims at exploring "German users" of genetic resources originating from outside the country and their knowledge of ABS regulations. The study focuses in particular on the knowledge of and the use of the Bonn Guidelines by "users" and "stakeholders" and will be finalized by the end of September 2004. Any news?

Hungary

Act No. LII of 2003 on the state registration of plant varieties and the production and marketing of reproductive material (with its implementing regulations) and the Decree of Hungary (No. 92/1997) on the conservation and utilization of plant genetic materials state the importance of genetic materials. The Decree states as well that the genetic variability of cultivated plants must be explored and conserved. All actions directed towards the conservation of genetic resources shall be executed in accordance with the contents of the Convention on Biological Diversity and of the Agreement on Plant Genetic Resources and these steps need to be taken in accordance with the internationally agreed and standardized methodological recommendations and prescriptions of the International Plant Genetic Resource Institute.

A Plant Gene Bank Council has been established in Hungary to fulfil the tasks related to the standardization of methods used in gene banks; identification of the genetic resources to be conserved; decision on special scientific issues concerning the collections. It generally gathers once a year.

Within the framework of the Plant Gene Bank Council, specific committees were created with the participation of experts from the following fields: agricultural plants, vegetables, medicinal plants, spice and volatile oil plants, fruit plants, grapes, ornamental plants, forest trees and micro-organisms.

Gene banks registered and approved by the Gene Bank Council are owned by the State. Collections in state owned gene banks can be accessed by the domestic users without any restriction. Material of gene banks can be obtained by foreign users in accordance with the international specifications of the Food and Agriculture Organization (FAO). Users of obtained genetic resources must not directly patent and must not restrict the further utilization of the received items. Users must indicate the origin of the material during utilization and must inform the gene bank maintaining the item about the experiences and observations of the utilization.

In Hungary there is a national base institution for genetic resources of cultivated plants, which operates the national base collection of generatively propagated plants and the computerized nation-wide gene bank database serving the registration of information concerning the genetic resource collections in the country. The national base institution for genetic resources of cultivated plants ensures for the continuous updating of the national gene bank database and the co-ordination between the databases of natural persons or organizations maintaining domestic base collections (a collection that provides the long-term unaltered conservation of genetic resources) or active collections (a collection that serves for the propagation, evaluation, distribution and utilization of plant genetic materials) and the international gene bank

information systems. These databases hold provenance data (passport and collection data), as well as additional data of properties.

Netherlands

In the Netherlands, much effort is placed in finding structural solutions to the loss of biodiversity and ways of achieving sustainable use of genetic resources. The Dutch government has fostered strong links with both the business world and NGO's.

On EU level the Netherlands and the European Patent Office (EPO) are planning a congress in The Hague (Spring 2005) on the relationship between the EPO and developing countries.

Developing Codes of Conduct on ABS is another priority for the Netherlands. Last year (2003) a Code of Conduct was agreed upon by the Botanical Gardens in The Netherlands and presented to our Minister of Agriculture, Nature and Food Quality. With this Code, the Botanical Gardens commit themselves to the exchange of material in accordance with the principles laid down in the CBD.

We think more needs to be done to encourage constructive dialogue between all the actors involved and improve instruments like Codes of Conduct.

Spain

Concerning the Spanish report on the implementation of the Bonn Guidelines, the Spanish focal point has contacted most of the Spanish public and private sector stakeholders (among others through ASEBIO the association that represents the private biotech sector) and will be organizing a first workshop in the following months.

Spain is preparing a workshop to inform all different actors involved in processes of ABS (both users and providers) to be held at the beginning of next year (and focusing mainly in the Bonn Guidelines). Prior to this meeting the companies and actors will have received and returned a questionnaire and a set of documentation for the meeting.

On the other hand, although there is no national legislation on ABS at this moment, the Ministry of Environment has been acting as the national focal point and there is some experience in few cases of genetic material requests. For every case, the Ministry of Environment has been acting as a mediator between the applicant, the regional administrations responsible and the donors, trying to develop specific agreed terms in each case. For example, because of extractive activities that have been carried out within protected areas in Spain, there exists a preliminary draft of MTA between the Spanish National Park Service and a private company.

Sweden

Several steps toward the implementation of the Guidelines have been taken by the Swedish government and its competent authorities:

As user of genetic resources:

- A new provision on disclosure of origin of biological material of plant or animal origin in patent applications came into force in Sweden on the 1st of May 2004 - Article 5 a of the Patents Regulations (SFS 2004:162) under the Patents Act). The Article reads as follows:

"5 a § If an invention concerns biological material of plant or animal origin, or if it uses such material, the patent application shall include information on the geographical origin of such material, if known. If the origin is unknown, this shall be said.

Lack of information on the geographical origin or on the knowledge of the applicant regarding the origin is without prejudice to the processing of the patent application or the validity of rights arising from a granted patent."

- The Swedish International Development Cooperation Agency has adopted a policy that requires the establishment of a material transfer agreement between the provider and receiver of genetic material in research cooperation activities financed by the Agency that involves genetic material.

- In 2003, the Swedish Scientific Council on Biological Diversity made an inquiry to all Swedish universities to gather experiences and lessons learned in relation to issues of access and benefit sharing, and to investigate the awareness of the Bonn Guidelines among Swedish universities. The result showed that awareness of the Guidelines needs to be increased significantly, especially in central university administration bodies. Researchers expressed frustration over difficulties to find reliable information on national access legislation, and they sometimes felt that the international regulations needed to be clearer. There was a clear demand among researchers for more practical guidance. As a response to this demand, the Swedish Scientific Council on Biological Diversity, in cooperation with the Swedish International Development Cooperation Agency, is preparing a handbook for researchers interested in obtaining genetic material from other countries, in order to facilitate research, which is essential for the conservation of biological diversity and to enhance compliance with the Guidelines and national legislation. There is also in Sweden a discussion on who is responsible for compliance with the regulations – whether it is the researchers themselves or their employers or the financing bodies. This issue is as yet unresolved, but awareness of the issue appears to be steadily increasing among scientists and financing institutions.

As provider of genetic resources

- The Swedish position with regard to access to its national genetic resources is presented in the study "A Nordic approach to access and rights to genetic resources" published by the Nordic Council of Ministers in 2003. In summary, Sweden aims to make genetic resources available with a minimum of restrictions, for the benefit of scientific and societal progress. Genetic material held in public institutions is freely available, while material held in private collections is regarded as private property. There are no regulations regarding access to wild genetic resources.

Sweden has also undertaken a study on how article 8(j) has been implemented in Sweden.

United Kingdom

Over the last year the United Kingdom has undertaken a review into the practical implementation of ABS, including the use of the Bonn Guidelines, by UK based stakeholders. Whilst the final analysis and writing of the report is not yet complete, some facts have emerged which we believe would be helpful to share with colleagues at this stage, along with initial thoughts on remedial action we believe it would be useful to undertake:

General awareness of the CBD is high (80% of 127 respondents), although fewer respondents indicated an awareness of the specific provisions in the CBD relating to ABS (55% of respondents). As of February 2004, fifty respondents stated that they had ABS policies in place, and about forty respondents stated that they had heard of the Bonn Guidelines. Ten respondents indicated that they had used the Guidelines to prepare their ABS policy, which they had found to be helpful; other respondents indicated that they had not found it necessary to update their policies in the light of the Bonn Guidelines, since they were already consistent with the terms of those guidelines. Some respondents raised concerns that the Bonn Guidelines were not sufficiently specific; that a sectoral approach would be more appropriate; or suggested that their voluntary nature created an unlevelled playing field (i.e. some use the Guidelines while others do not, or some use them with greater precision than others).

Those organisations most knowledgeable of the CBD and Bonn Guidelines are generally large; more actively involved and experienced stakeholders in the use/development/conservation and trade in genetic resources.

A 'level playing field' needs to be more fully achieved. There needs to be further informed and objective consideration as to how this might be best achieved, for example, by the dissemination of information nationally, regionally and internationally on CBD, Bonn Guidelines and ABS issues; and further clarity of and rationale for the guidelines; and/or consideration of new processes and instruments.

The ongoing Review on implementation in the UK will include specific recommendations for the dissemination of information on ABS in general and on the Bonn Guidelines in particular, by means of for example, the improvement of web pages and further contact and discussion with stakeholders.

Finally, in the run up to the negotiation of an international regime on ABS, the UK wants to reiterate its full endorsement and support of the Bonn Guidelines. Further experience of using them will crucially provide practical and realistic information about the substantive issues under negotiation.

2) Use of terms, definitions and/or glossary, as appropriate

- (a) Information on existing national definitions or other relevant definitions of the following terms: access to genetic resources, benefit sharing, commercialization, derivatives, provider, user, stakeholder, *ex situ* collection, and voluntary nature (as contained in annex II of document UNEP/CBD/COP/6/INF/4);
- (b) Views on whether additional terms need to be considered, such as arbitrary restrictions;

Belgium

- (a) *No specific national definitions of the terms referred to above in the context of biodiversity in Belgium.*
- (b) *Belgium would like to mention the basic common understanding of the meaning of the principle of free, prior and informed consent reached by participants in the United Nations Workshop on Indigenous Peoples, Private Sector Natural Resource, Energy and Mining Companies and Human Rights (held in Geneva from 5 to 7 December 2001), which is: "the right of indigenous peoples, as land and resource owners, to say "no" to proposed development projects at any point during negotiations with Governments and/or extractive industries" (E/CN.4/Sub.2/AC.4/2002/3, para. 52).*

This is mentioned back in the Preliminary working paper on the principle of free, prior and informed consent of indigenous peoples in relation to development affecting their lands and natural resources that would serve as a framework for the drafting of a legal commentary by the Working Group on this concept submitted by Mrs. Motoc and the Tebtebba Foundation at the 22nd session of the working group on Indigenous Populations, 19-23 July 2004 (E/CN.4/Sub.2/AC.4/2004/4, 8 July 2004, para. 12).

Germany

As part of a study commissioned by the German Environment Ministry consultants will explore whether definitions can be found in German legislation. The study will be finalized by the end of September 2004. Any result available?

Netherlands

An interesting discussion on definitions has taken place in the IT-PGRFA (FAO) circles. It is important to look at their findings as a basis for further discussion. A list of their definitions should be available soon.

Of particular interest to our discussion:

- *Definition of commercialisation is problematic. What are the criteria for commercialisation? A similar discussion is taking place in the FAO expert discussion on standard MTA.*

Definition of benefit sharing has never been defined properly. This is the conclusion drawn by the FAO Commission on Genetic Resources about "non-monetary benefit sharing". Interestingly, benefit sharing is usually applied to those goods that are difficult to define "concretely", like water and the environment.

Spain

Spain has no definitions beyond what is the text of the CBD itself. Some regional laws (that will be mentioned in point 7) have attempted to establish a framework for ABS decision-making but the bills that are being discussed are all very careful in preventing the introduction of definitions.

United Kingdom

Between 1997 and 2001 the Royal Botanic Gardens, Kew coordinated a project to bring together a group of botanical institutions to agree to common sectoral guidelines on ABS. The result was a set of Principles on ABS, Common Policy Guidelines and Explanatory Text which those initial 28 institutions adopted and committed to use when acquiring, using and supplying biological material. These documents were already distributed at WGABS 1 in October 2001. They contain definitions, which we now submit for consideration by CBD colleagues and for inclusion in a glossary.

The terms and their definitions are the following:

Access to genetic resources: means the permission to acquire and use genetic resources;

Benefit-sharing: means the sharing of benefits arising from the use, whether commercial or not, of genetic resources, and may include both monetary and non-monetary returns;

Commercialization: means applying for, obtaining or transferring intellectual property rights or other tangible or intangible rights by sale or licence or in any other manner, commencement of product development, conducting market research, and seeking pre-market approval and/or the sale of any resulting product;

Provider: means any individual or organisation, whether governmental or non-governmental, that provides genetic resources.

Stakeholder: means an individual, organisation or group whether formal or informal, affected by, or with an interest in, the activities relating to the acquisition, use or supply of genetic resources. Stakeholders involved in conservation and the granting of collecting permits and prior informed consent for access may include relevant departments of government, local authorities, private individuals such as landowners, indigenous peoples, local communities, farmers and non-governmental organisations. Stakeholders such as these are often described in law relating to access and benefit-sharing;

Ex-situ collection: means managed, documented biological material maintained in conditions other than in situ.

5) Measures, including consideration of their feasibility, practicality and costs, to support compliance with prior informed consent of the Contracting Party providing genetic resources and mutually agreed terms on which access was granted in Contracting Parties with users of such resources under their jurisdiction.

- a) Specific measures to support and ensure compliance with national legislation, prior informed consent of the Contracting Parties providing such resources, including countries of origin, in accordance with Article 2 and Article 15, paragraph 3, of the Convention, and of the indigenous and local communities providing associated traditional knowledge, and with mutually agreed terms on which access was granted;
- b) Existing measures to support compliance with national, regional, and international legal instruments;
- c) The extent and level of unauthorized access and misappropriation of genetic resources and associated traditional knowledge;
- d) Access and benefit-sharing arrangements existing in specific sectors;
- e) Administrative and judicial remedies available in countries with users under their jurisdiction and in international agreements regarding non-compliance with the prior informed consent requirements and mutually agreed terms;
- f) Existing practices and trends with regard to commercial and other utilization of genetic resources and the generation of benefits;
- g) Measures that preserve and promote legal certainty for users over the terms and conditions of access and use;

Belgium

(a and b) Following the outputs of the EC funded project MOSAICC, the BCCM consortium has developed its own MTA. BCCM has started to use the MTA since February 1 2004 and intends to test the effect of the use of the MTA on the flow of microbiological resources after eight months' use. The test is also intended to check the MTA polyvalence and to see where exceptional cases need specific answers. For instance, there is a difference between exchanges occurring between cultures collections and transfer from culture collections to customers. The distribution policy is thus different. How to conciliate both situations in one MTA? Is it possible?

In Belgium, beside the BCCM contribution to ABS in the field of microbiology, the National Botanic Garden is also involved in international talks to develop common ABS policy among Botanic Gardens in the world.

Belgium also hosts the Transit Centre of the International Network for the Improvement of Banana and Plantain (INIBAP) in Heverlee. INIBAP maintains germplasms of Banana and Plantain under the auspices of the Food and Agriculture Organization of the UN (FAO), in the framework of International Plant Genetic Resources Institute (IPGRI). The terms and conditions under which germplasm is being made available to the users are set out in the INIBAP MTA. The MTA covers material that is being transferred before the development of the MTA of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR). The Treaty envisages that IPGRI will enter into an agreement with the Governing Body of the Treaty. IPGRI has indicated its intention to conclude such an agreement that will provide for new MTA and benefit-sharing arrangements. INIBAP is thus also following closely the ABS issue and the ITPGR MTA development.

There are thus several Belgian teams working on the ABS issue related to different kind of biological resources: microorganisms, botanical resources and plant genetic resources for food and agriculture. The technical and legal approach being different for each kind of resources, the MTA design for each of these resources will also be different.

Having different MTA adapted to each kind of biological resources is not a problem as long as these MTA are compatible with each other and enable interoperability of legal systems. This in turn should make possible a general ABS system.

(c) No information available in Belgium.

(e) No administrative and/or judicial remedies available in Belgium regarding non-respect of PIC.

Germany

(g) The study finalised in September 2004 (already mentioned in response to questions 1 and 2) includes the evaluation of a questionnaire (sent to users) that might provide further suggestions from users. Any news??

Netherlands

The government has expanded cooperation with commerce, research and social organisations by means of a policy document (2002) "Sources of existence: Conservation and the sustainable use of genetic diversity". This document underlines the main Dutch policy aims.

Generally, legislation in the Netherlands has been introduced to protect important areas in the conservation of genetic resources in situ. There has also been legislation on the subjects of intellectual property rights and biotechnology. As the country of origin to only a few varieties or species, the government does not deem it necessary to secure its national sovereignty regarding access and use of these resources in its legislation.

With "Sources of existence" the government calls on businesses, institutions and individuals to deal carefully with regulations, legislation and policy convened internationally or instituted in other countries.

Spain

Regarding paragraph (c), we recognize that the issue is difficult since even if corporate involvement in the implementation of the Bonn Guidelines is ensured, it would be almost impossible to recognize misappropriations. One thing is certain, that the judicial records do not show any case in which a Spanish company has been brought before a Spanish court of law under a complaint of non-compliance with article 15 of the CBD. Neither has it got any notice of any Spanish company being sued on any country of origin.

On paragraph (e). In Spain it is clear that institutions from and/or countries party to the CBD could use all the judicial remedies under civil law to redress a situation of non-compliance with article 15 of the CBD. Under article 96 of the Spanish Constitution article 15 would be self executing (direct effect) and there is no doubt that Spanish courts could hear and remedy any case in which article 15 has not been respected whenever anybody having enough standing (and the law on standing is very open) might bring a case under contract law (if there is evidence of disregarding an MTA) or under general civil actions (civil damage caused by somebody's conduct) whenever the use of the genetic resource has not been subject to any MTA, or PIC.

That said, we have no recorded cases of misappropriations of Spanish genetic resources by non-Spanish institutions.

6) Capacity-building for access and benefit-sharing

Parties are invited to make **any new information** regarding capacity-building measures available to the Secretariat **on an ongoing basis** and to fill out the **data entry form** in Annex 2:

Belgium

The Royal Museum for Central Africa (RMCA), the Royal Belgian Institute of Natural Sciences (RBINS) and the National Botanic Garden of Belgium (NBGB) provide access to their natural history collections to experts from all over the world. The RBINS complements this by providing tailor-made training in taxonomy. The visits by experts from developing countries are for the most part sponsored by the Belgian Development Cooperation. The RMCA and NBGB also participate in a European project addressing repatriation of information (European Network for Biodiversity Information, work package 13: Making non-European biodiversity data in European repositories globally available).

Belgium also supports capacity-building activities contributing indirectly (though not explicitly) to the ABS objective of the Convention, through different development co-operation channels. Most of the ABS-related development aid deals with agronomic research, training and technical assistance, either through inter-universitarian co-operation or through support to international organisations (CGIAR and several of its components: IITA, ICRISAT, CIMMYT, IRRI, IPGRI, CIAT, ILRI, ICRAF). The overall support for the CGIAR-related institutes amounts to 6.000.000 euros for 2003, of which 4.000.000 € consists of earmarked funding through a dozen of programmes that include an ABS component.

Through UNEP's training programmes for national enforcement of MEA's, Belgium supported the elaboration of guidelines and training manuals issued from regional workshops. Belgium also provides support to UNEP's PADELIA programme (Partnership for the Development of Environmental Law and Institutions in Africa), which includes training of law experts, assistance in writing legal texts, supporting law training in universities, etc. This programme includes providing assistance to countries for the implementation of the Bonn Guidelines. (500.000 € in 2002 ; 1.100.000 € in 2003).

Through UNESCO, Belgium provides support (125.000 € in 2002; 180.000 € in 2003) to the ERAIFT (Ecole Régionale d'Aménagement et de gestion Intégrés des Forêts Tropicales) in the Democratic Republic of Congo, with a strong emphasis on high-degree education aiming at the conservation and the sustainable use of forest resources. A component herein addresses the issue of the access to and the equitable sharing of benefits from the rain forest genetic diversity for the local populations.

Inter-universitarian ABS-related cooperation includes research and training programmes in developing countries' universities in such topics as : crop protection and resistance improvement ; livestock food and livestock health improvement ; applied microbiology. These cover: Senegal, Kenya, China, Ecuador, Cuba.

Support to fair trade projects through development NGO's contributes to improve both the diversification of local production and the sharing of benefits from biodiversity resources in favour of small producers. Around 70.000 € yearly are devoted to this support by the Belgian Development Cooperation.

Germany

Germany supports capacity building for ABS through bilateral and multilateral or regional projects in development cooperation. Bilateral projects implemented through the GTZ project "Implementing the Biodiversity Convention" cover Bolivia, the Philippines, South Africa and Vietnam. Support is also given to the Genetic Resource Policy Initiative of IPGRI, the ABS project of the IUCN Environmental Law Centre as well as the ABS Capacity Building Project under the IUCN Regional Biodiversity Programme, Asia. Further details of these projects can be found in the SCDB ABS Capacity-building database (<http://www.biodiv.org/programmes/socio-eco/benefit/projects.aspx> - projects no. 4 to 8, 10, 11 and 13)

Netherlands

The government acknowledges that developing countries are at a particular disadvantage regarding information, knowledge, expertise and capacity concerning genetic resources. Regarding compensation and financial support to developing countries, the Dutch approach is outlined in the Netherlands Policy Document "Sources of Existence". This approach includes:

- a. Effective Exchange and accessibility of information (transparency)
- b. Empowerment and support for developing countries
- c. Conserving traditional knowledge
- d. Bilateral collaboration with selected countries
- e. Compensation

Spain

The National Institute for Research and Technology on Food and Agriculture (INIA) under the Spanish ministry for Science and Education, and more specifically the Phytogenetic Resources Centre (CRF) has a wide programme of capacity building both within and outside Spain, some of them include ABS related aspects. Some of the main courses that touch upon ABS are:

- International Course about Conservation and utilization of Phytogenetic Resources for food and agriculture.
- International Course about Forest Genetic Resources.
- INIA's capacity programme: Conservation and Utilisation of Phytogenetic Resources for Food and Agriculture.
- Visits to the CRF: graduate and postgraduate students.
- Conferences and courses in different associations, such as agriculture associations.

For more information visit the INIA's web page at www.inia.es.

There are also some other institutions that offer courses with well-defined parts on ABS. One of the best examples is the International Course of the International University of Andalucía, partly funded by the Spanish Ministry of Environment. This course focuses mainly in the aspects of CITES but also tackles problems of ABS. The participants on this course come from all around the world, with grants and scholarships for participants from developing countries.

Sweden

Through Swedish international development cooperation Sweden is supporting capacity development projects for third world countries. A list of such projects will be submitted later.

7) Information on access and benefit-sharing measures

Netherlands

The Netherlands government, in collaboration with the National Information Centre for Genetic Resources (CGR), consults with ABS interested parties via a Platform for Genetic Resources and has developed a "Netherlands CBD Focal Point for Access and Benefit Sharing" (January 2003).

The Focal Point has the sole aim of improving trust and transparency in all transactions of genetic resources. Via the website (www.absfocalpoint.nl), and its associated database, information is given about activities that are related to conservation and sustainable use of genetic resources in both the public and private sectors of the Netherlands. The National Information Centre for Genetic Resources will keep track of which codes of conduct and contracts are to be observed, and will function as a guide for institutions.

The ABS Focal Point database serves to keep the website and its offered information up to date. With regard to the substance of the website and database, the CGN cluster "Plant Genetic Resources" responsible for information about Genetic Resources of plants and micro-organisms while the cluster "Animal Genetic Resources" is responsible for all information about Animal Genetic Resources.

Throughout 2003, the website and database were thoroughly revised, at both a technical and "user-interface" level, as well as on substance and related publicity.

The National Information Centre for Genetic Resources is part of an international network of "national focal points". The information centre works closely with:

- *Centre for Genetic Resources, The Netherlands, in Wageningen and Lelystad (plant and animal genetic resources);*
- *Alterra (the main Dutch centre of expertise on rural areas);*
- *Fungal Biodiversity Centre (CBS; micro-biological genetic resources);*
- *Expert Centre for Taxonomic identification*

Spain

At this moment there is no national legislation regarding ABS issues. However, there are several measures regarding ABS at a national or regional level:

The Phytogenetic Resources Centre (CRF) of the National Institute for Agrarian Research (INIA-MAPA) manages the Phytogenetic Resources Bank on behalf of the Spanish government. The CRF has had the general policy of easing the access, without any restriction, to the germplasm of this bank. The CRF compromises not to claim any intellectual property rights over the germplasm as a policy to ease the research in the future and for its utilization.

THE CRF-INIA has developed different agreements regarding the transfer of materials, with the view of promoting the exchange or acquisition of genetic material. In particular, there are three models that are subject to changes to adapt them to the decisions taken at the international level.

- 1.- Material Acquisition Agreement for the foreign expeditions collecting material in Spain.*
- 2.- Material Transfer Agreement for the shipment of Spanish genetic material to foreigners or international companies. This model can be retrieved in the web
<http://www.inia.es/crfwww/WWWCRF/CRFesp/Paginaprincipal.asp>*
- 3.- Memorandum of Understanding for the shipment of material to the Collection of the Base Bank of the Network of the Programme, that it is located in the Nordic Bank in Arnalp (Sweden).*

There are also couple of Autonomous Communities that are preparing or enacting legislation regarding ABS. The examples are the Autonomous Community of Andalucia and the Canary Islands. The Law 8/2003 of Andalucia in article 13 refers to the research projects that use biological resources should present a Protocol of use and management that has to be approved by the regional government. Also, if the project implies the posterior use of genetic resources the CBD has to be observed at any time. The Canary Islands has a legal project in line with the Andalucia, but this one has not been approved yet.

Sweden

See section I above on the Bonn Guidelines. Specific information will also be provided to the CBD Secretariat in the format they have prepared.

United Kingdom

The UK is considering its national instruments and measures relevant to ABS. For example, a study on the legal framework for marine bioprospecting in the UK was published earlier this year by the Department for Environment, Food and Rural Affairs (DEFRA). The current Review of implementation of ABS arrangements in the UK will highlight particular gaps and grey areas in the current UK system and recommend further remedial action. In particular, given that the UK is not only a user country but also a provider country (a concept to which we attach great importance) the future emphasis is likely to focus on improving current policies and legal frameworks relevant to UK providers and potential providers in the ABS context.. Providers might include inter alia: Overseas Territories, the coastal and marine environment, and other in-situ sources.

Attachment A: FRANCE
Use of Terms

Terms	Existing definition/Source
Access to genetic resources	la Convention sur la Diversité Biologique définit l'accès aux ressources génétiques et le partage des avantages par son article 15, et le Traité International sur les ressources phytogénétiques pour l'alimentation et l'agriculture les définit (dans le cadre de son champ d'application) par ses articles 12 et 13 respectivement ;
Benefit-sharing	la Convention sur la Diversité Biologique définit l'accès aux ressources génétiques et le partage des avantages par son article 15, et le Traité International sur les ressources phytogénétiques pour l'alimentation et l'agriculture les définit (dans le cadre de son champ d'application) par ses articles 12 et 13 respectivement ;
Commercialization	On peut souligner également que les notions de commercialisation et de mise sur le marché existent toutes les deux en droit communautaire. Toutefois, la notion de mise sur le marché est plus largement utilisée et intègre la notion de commercialisation. Cette dernière est par ailleurs déclinée de manière différente selon les domaines couverts.
Derivatives	Les termes d'utilisateur ou de produit sont désormais des termes génériques, qui apparaissent à de multiples reprises dans un grand nombre de textes dans différents secteurs sans y être définis à aucun endroit (Code de la consommation, Code de la santé publique par exemple).
Provider	Dans le contexte particulier de la commercialisation des plants de légumes et des matériels de multiplication de légumes autres que les semences (Directive 92/33/CEE du Conseil, UE), « fournisseur » est défini comme : « toute personne physique ou morale qui exerce professionnellement au moins une des activités suivantes ayant trait aux matériels de multiplication ou aux plants de légumes : reproduction, production, protection et/ou traitement et commercialisation. » Cependant, la notion de fournisseur n'est pas présente dans toutes les directives.
User	les termes d'utilisateur ou de produit sont désormais des termes génériques, qui apparaissent à de multiples reprises dans un grand nombre de textes dans différents secteurs sans y être définis à aucun endroit (Code de la consommation, Code de la santé publique par exemple).
<i>Ex situ collection</i>	« collection ex situ » est définie dans le Traité International sur

	les ressources phytogénétiques pour l'alimentation et l'agriculture comme « une collection de ressources phytogénétiques pour l'alimentation et l'agriculture conservées en dehors de leur milieu naturel ».
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Commentaires:

La pratique qui prévaut généralement en matière de rédaction juridique consiste à :

- donner, en les regroupant dans un même article, des définitions aux termes susceptibles d'avoir, dans le contexte de la loi ou de l'accord international, une acceptation différente ou plus précise que celle qu'elle a dans d'autres contextes. Elles y sont alors précédées d'une formule du type « aux fins du présent traité » (exemple : « collection *ex situ* »).
- consacrer un article complet à définir un concept, qui donne généralement son titre à cet article (exemple : la Convention sur la diversité biologique définit l'accès aux ressources génétiques) ;
- ne pas définir les termes dont l'acceptation courante s'applique au contexte de la loi ou du traité en cause (exemple : notion d'utilisateur).

Mise en œuvre des lignes directrices de Bonn par la France

En matière de ressources génétiques, la France est à la fois fournisseur et utilisateur. Compte-tenu de la diversité de ses territoires et de ses milieux, y compris tropicaux et marins, la France détient sous souveraineté française une diversité génétique riche et variée, parfois associée à des pratiques locales.

Dans un premier temps, l'action nationale s'est concentrée sur la gestion de la diversité génétique, végétale, animale et microbienne. Une structure de coordination nationale, le Bureau des ressources génétiques (BRG) a été créée en 1983, et une « Charte Nationale pour la gestion des ressources génétiques » adoptée en 1998. Un ensemble de réseaux associant, par espèce ou groupe d'espèces, institutions publiques, entreprises privées et associations a été progressivement mis en place, soutenu par des appels d'offres de recherche réguliers. La France a désigné en mars 2001 le BRG correspondant national sur l'accès et le partage des avantages.

L'effort français en matière de mise en œuvre des Lignes Directrices de Bonn depuis leur adoption a porté essentiellement sur 3 axes : l'état du droit, l'association des parties prenantes et l'information.

1. Etat du droit

Des premières analyses sur l'état du droit applicable ont été réalisées sur le cadre juridique de la conservation et de l'échange des ressources génétiques végétales en France (1996, 2000). Elles ont été complétées depuis par deux communications, soumises en automne 2003 aux Ministères et organismes publics concernés par les ressources génétiques.

L'étude sur l'état du droit applicable en France en matière d'accès aux ressources génétiques ; compte tenu de la complexité des situations techniques et juridiques, elle doit être poursuivie par un travail interministériel afin de pouvoir proposer un cadre législatif et réglementaire, adapté

aux différents secteurs professionnels, désignant les autorités nationales et les procédures à suivre pour accéder aux ressources génétiques sous souveraineté française.

Des consultations se sont tenues, en particulier avec le Ministère de l'Outre Mer, dans le cadre de la modification constitutionnelle de mars 2003 introduisant le statut de « collectivités d'outre-mer ».

Une seconde expertise porte sur différents types de mesures susceptibles de contribuer au respect du consentement préalable en connaissance de cause et des termes d'accès et de partage des avantages mutuellement convenus. Elle identifie pour chacune d'elles l'état du droit et certaines options envisageables.

Plus spécifiquement, sont listées les procédures administratives ou judiciaires applicables en France en cas de conflit sur un contrat commercial, y compris pour des étrangers. La France est Etat partie nombre d'accords multilatéraux de droit international privé traitant de litiges en matière économique, dont pourraient relever des accords d'ABS :

- conflit de lois et rattachement (Convention sur la loi applicable aux obligations contractuelles, Rome, 19/06/1980, Convention sur la loi applicable aux contrats d'intermédiaires et à la représentation La Haye, 14/03/1978) ;
- conciliation (Résolution 57/18 AG NU) ;
- arbitrage (Nouveau Code de Procédure Civile régit l'arbitrage international dans ses articles 1492 à 1507) ;
- coopération judiciaire, aux différents stades de la procédure :
 - enquête, avec la Convention sur l'obtention des preuves à l'étranger en matière civile ou commerciale, La Haye, 18/03/1970 ;
 - notification des actes judiciaires, avec la Convention relative à la signification et à la notification à l'étranger des actes judiciaires et extrajudiciaires en matière civile ou commerciale, La Haye, 15/11/1965 ;
 - exécution de sentences arbitrales, avec la Convention pour la reconnaissance et l'exécution des sentences arbitrales étrangères, New York, 10/06/1958).
- L'ensemble s'accompagne d'un dispositif d'aide judiciaire, définie par la loi n°91-647 du 10 juillet 1991 relative à l'aide juridique complétée par le décret n°91-1266 du 18 décembre 1991.

Des dispositions législatives et administratives existent donc en France pour les différents aspects du règlement de litiges d'ordre économique impliquant des opérateurs privés.

Des initiatives volontaires existent également. Ainsi, les Jardins Botaniques français ont participé activement à l'élaboration, au sein de la région Europe, d'un Code de conduite sur l'accès et le partage des avantages. L'interprofession semencière est associée à la négociation sur le futur accord de transfert de matériel standard du Traité International sur les ressources phytogénétiques pour l'alimentation et l'agriculture.

2. Association des parties prenantes

Lors de la négociation des Lignes Directrices de Bonn, un mécanisme de consultation des parties prenantes regroupées en différentes catégories (agricole et alimentaire ; biotechnologie et génomique ; pharmacie, agro-chimie, cosmétologie ; recherche fondamentale et inventaires ; savoirs traditionnels) avait été constitué, et a permis de sensibiliser un grand nombre d'opérateurs aux Lignes Directrices dès leur adoption.

En 2003, le Ministère de l'industrie a organisé une réunion de réflexion sur la question de l'accès et du partage des avantages à destination des différents secteurs industriels, à l'occasion de laquelle les Lignes Directrices de Bonn leur ont été diffusées.

3. Information

En matière d'information, les évolutions du cadre juridique de l'échange international des ressources génétiques et les Lignes Directrices de Bonn sont présentées dans le plus grand nombre possible d'enceintes spécialisées : consortium de recherche sur les micro-organismes, réseau de conservateurs et d'utilisateurs de micro-organismes d'intérêt laitier, Comité technique permanent de la sélection végétale, associations de conservation des espèces végétales, Jardins botaniques...

Une information plus large sera faite via le volet ressources génétiques du centre d'échanges (CHM) français pour la biodiversité, par l'ajout de pages Web qui présenteront notamment l'état du droit et des procédures d'accès et de partage des avantages tant en France qu'à l'étranger, dès que les analyses en cours auront abouti.

Conclusion

La France poursuit activement la mise en œuvre des Lignes Directrices de Bonn, tant au niveau des autorités publiques qu'au niveau des parties prenantes. L'accent mis sur l'état du droit repose sur la conviction qu'améliorer la certitude juridique entourant les transactions de ressources génétiques est au bénéfice des fournisseurs comme des utilisateurs, et contribue à faciliter les négociations internationales menées dans les différentes enceintes spécialisées sur les sujets relatifs à l'accès aux ressources génétiques et au partage des avantages. Des réflexions sont également en cours sur les autres aspects des Lignes Directrices de Bonn, au niveau national, et visent à explorer la faisabilité des options proposées et l'intérêt qu'elles présentent pour la mise en œuvre concrète des obligations de la CDB en matière d'accès et de partage des avantages. L'ensemble de ces actions s'inscrit dans la perspective la réalisation conjointe des trois objectifs de la Convention sur la diversité biologique.

Attachment B: CZECH REPUBLIC

General information

Conservation and utilization of plant genetic resources has a long tradition in the Czech Republic. Some research and breeding institutions have been gathering crop cultivars since the beginning of the 20th century. Also collecting activities had been carried out by some Czech institutes since 1930s, systematic collecting of landraces and wild relatives of agricultural crops begun in the 1960th and has continued with different intensity till the present. Continuous efforts have been devoted to the conservation of collections. First, a system of regeneration using cyclic regeneration was implemented and since 1976, long-term storage under controlled conditions started. The Gene Bank in the Research Institute of Crop Production, Prague was completed in 1988 with total storage capacity for 100,000 accessions. Genetic resources studies were oriented on evaluation of the most important biological and agronomical characters, with respect to the effective utilization of genetic resources in breeding and agricultural practice.

The Czech National Programme on Plant Genetic Resources Conservation and Utilization was launched by the Ministry of Agriculture of the Czech Republic in 1993. Eleven research institutes and universities participated in the programme and effective coordination and rationalization of all activities on PGRFA has been developed. Also international cooperation has been extended significantly during this period. Conservation of biodiversity was enhanced in connection with the Convention on Biological Diversity ratification, which was adopted into the Czech legal system as the Act No. 134/1999. To reflect the principles of CBD and related commitments of the Czech Republic and to strengthen the care of agro-biodiversity, Act No. 148/2003 on Conservation and Utilization of Genetic Resources of Plants and Micro-organisms Important for Food and Agriculture was approved, as well as corresponding Decree 458/2003. Coming out from the CBD principles and following the national legislation, the updated "National Programme on Conservation and Utilization of Genetic Resources of Plants and Micro-organisms Important for Agriculture" has been adopted by the Czech Ministry of Agriculture and implemented since January 2004. Access to plant genetic resources and sharing of benefits are important issues of this Programme.

As to plants important mainly for agriculture, eleven Czech institutions hold at present over 50,000 accessions, among them 18 % vegetatively propagated species. The Research Institute of Crop Production in Prague has responsibility for the coordination of the National Programme. The institute itself holds more than half of all accessions in Czech collections, it is responsible for the national information system on plant genetic resources and provides long-term storage for all seed-propagated collections within the country. Dry seeds are stored under -5 °C or -15 °C respectively. Most vegetatively propagated species are maintained in field collections or *in vitro* (potatoes). The cry-conservation is being developed in selected vegetatively propagated species. All Czech collections are fully documented in passport data and evaluation data (based on the National Descriptor Lists for 40 crops) are available for 50% of accessions. Existing regular characterization and evaluation of genetic resources enhance their utilization in breeding and in agricultural practice. Annually, 2-3 thousands of accessions of PGR are provided to local and foreign users, when the principles of CBD and International Treaty on PGRFA (applied also in the national legislation) are respected.

Collecting missions in different Czech localities, monitoring of valuable resources conserved *in situ* contribute to the conservation and evaluation of local resources. Local landraces and cultivars are considered as valuable part of collections and as a unique contribution to the crop gene pool. Selected accessions are tested with the aim to find convenient forms for *on farm* conservation and for utilization in agricultural practice to enrich the existing diversity of crops and cultivars.

Agro- biodiversity studies are also supported by the national grant agencies (National Agency on Agricultural Research, Grant Agency of the Czech Republic). Through such support, local ecotypes of grasses and legumes were studied and utilized to enrich diversity of meadows and pasture land. Cultivars and landraces of neglected crops (buckwheat, millet, hulled wheat species) are successfully utilized for agro- biodiversity enrichment as well as for specific utilization in human nutrition. Close collaboration with producers (often organic farmers) and processing industry has been established. Also selected alternative crops and catch crops were studied with the aim to use them in growing practice and contribute to the soil fertility improvement. First steps have also been undertaken to use diversity of selected tree species in landscaping.

Use of Terms

In accordance with decision VII/19B, you are invited to provide to the Executive Secretary existing national definitions or other relevant definitions of the terms included in the following table along with the source of these definitions. Any views on whether additional terms should also be considered, including their definitions and source, are to be included in the last row of this table.

Terms to be defined	Existing definition/Source
Access to genetic resources *	Possibility given by provider to user(s) to acquire information and samples of genetic resources for declared way of utilization and under agreed terms
Benefit-sharing *	Taking part on benefit(s) of any kind arising from utilization of genetic resources
Commercialization	-----
Derivatives	-----
Provider *	Natural or juridical person providing genetic resources to user(s) under generally determined conditions
User *	Natural or juridical person requesting genetic resources for research, breeding or education; if not agreed otherwise
Stakeholder *	Subject involved and/or interested in study, conservation and utilization of genetic resources

<i>Ex situ</i> collection *	Collection of genetic resources conserved out of their natural occurrence
Voluntary nature	---
Other term(s) to be defined:	

Comments: * The definitions given above are not codified in national legislation (with exception of *ex situ* collection), however the terms are used on an agreed basis.

Term *ex situ* collection is codified in national acts, e.g. Act 148/2003 on Conservation and Utilization of Genetic Resources of Plants and microorganisms Important for Food and Agriculture

Views on International Regime on Access and Benefit Sharing (Japan)

October,2004

1. Our basic position on the international regime

(1) Current situation of business relating to genetic resources

Japan is convinced that biotechnology (BT) development will generate some of the most significant scientific and technological outcomes of the 21st century. That it will lead to the transformation of citizens' lives as well as industries worldwide. Based on this recognition, the Government of Japan developed national strategies for biotechnology (BT Strategies) in December 2002.

The BT Strategies consist of three main strategies, ① Strongly revamping Research & Development (R&D), ② Fundamentally enhancing the process of industrial application of biotechnology, ③ Ensuring community support thorough public understanding. They also contain 50 Action Guidelines and 200 detailed Action Programs. By implementing the above, Japan expects to contribute to resolving global environment problems and to alleviating poverty in global society as well as to creating new industries and enhancing the competitiveness of Japanese industries.

Genetic resources are a fundamental component for biotechnology research and commercialization. In order to ensure sound development of biotechnology and bioindustry, it is essential to create an environment that facilitates the access to genetic resources.

The BT Strategies note the importance of the Convention on Biological Diversity (CBD) as the basis on which Japan cooperates with other countries¹. A number of

¹ BT Strategies (BT Strategy Council December, 2002)

Biogenetic resources including animals, plants, microorganisms, human cells / tissues and genes are extremely useful, yet at the same time limited, in industrial applications and research. Enhancing these resources is truly important from the viewpoint of international competition. All relevant parties must join forces in gathering, securing and providing biogenetic resources, including genetic information, so as to strengthen the foundation of industrial competition, and help our nation protectourrights in this area.

In the spirit of the Biodiversity Convention, we must achieve coordination and cooperation with countries holding such resources in their gathering, securing and provision.

scientific and commercial projects have been in progress in recent years.

For instance, the National Institute of Technology and Evaluation (NITE), which is an independent administrative corporation under the Ministry of Economy, Trade and Industry (METI), established the NITE Biological Resource Centre (NBRC). NBRC has been conducting research cooperation projects with other countries using genetic resources for the benefit of both countries. Some private companies also have been conducting projects on the basis of the CBD.

In the private sector, many expect that biotechnology will create new business opportunities. There has been fierce global competition in the business world, resulting in mergers and acquisitions among companies worldwide. Therefore, rationalization of R&D costs and acceleration of product development speed have become critically important for companies to survive. For this reason, facilitated access is imperative as far as companies that use genetic resources are concerned.

(2) Current influence of the CBD on research and commercialization

The CBD recognizes the sovereign rights of countries over their genetic resources with the aim of fair and equitable sharing of benefits arising from the use of genetic resources between users and providing countries.

In pursuit of the objectives of CBD, the Parties to the Convention agreed to establish voluntary guidelines as a most realistic solution to achieving the fair and equitable sharing of benefits arising from the utilisation of genetic resources. As a result, the Bonn Guidelines were adopted at COP6 in Hague in 2002. Japan actively supported the adoption of the Guidelines. Both the government and the private sector of Japan have since been promoting the implementation of the Bonn Guidelines.

After the CBD came into force, the experiences of researchers in academia and the private sector indicated the emergence of elements that adversely affect access to genetic resources in providing countries. These include:

- i) Insufficient information about contact points for applications and approvals and about procedures for access to genetic resources,
- ii) Unpredictability in the time necessary for obtaining approvals and permits, and

iii) Uncertainty of the execution of the contract.

As a result, it has become difficult for users to access genetic resources in many countries, in spite of the CBD provisions that the aim of fair and equitable sharing of benefits arising from the use of genetic resources.

(3) Response of the private sector to the current situation

Japan was concerned that the private sector, facing the pressure of global competition, has become less interested in access to the genetic resources of other countries, due to the increase in transaction costs in the current situation caused by the CBD.

Japan conducted a questionnaire survey, targeting bio-related industries, including pharmaceutical and cosmetic industries, totalling approximately 1300 companies in Japan. The survey revealed unexpectedly low levels of interest in research that uses genetic resources from other countries. Furthermore, even companies that currently have an interest in using genetic resources expressed views that, if access regulations were tightened excessively or the way in which they were applied became insufficiently transparent in the future, they would reduce the level of their activity or even withdraw from research based on genetic resources from other countries.

Other research shows that in recent years, a substantial number of multinational pharmaceutical companies have drastically reduced or even terminated natural products screening, and shifted to drug discovery research based on synthetic chemical compounds.²

Commercialization processes often entail high risk. Business that involves genetic resources is no exception. In many cases, genetic resources as they occur in nature do not have commercial value in themselves. Even if companies acquire genetic resources that they are interested in, they cannot make a profit in the market without investing a great deal of time and money. We should recognize that companies generally must overcome a variety of huge risks in the commercialization processes to get an economically viable product on the market.

² Tony Buss "Natural Products and ABS strategy – From a Pharmaceutical Industry Perspective" JBA-UNU International Symposium Tokyo, 30 September, 2003

For example, in the pharmaceutical industry, Japanese experts reported that 17 Japanese companies used 290 thousand samples of resources (natural and chemical) for screening for drug discovery. Of those, only 98 samples out of the 290 thousand became new products³. Other surveys show it generally takes 10-12 years and costs up to \$800 million to commercialize one drug⁴.

Needless to say, huge risks and cost increases adversely affect business. This is particularly true in business sectors that require very substantial monetary expenditures and long-term R&D, such as the pharmaceutical industry. Therefore, we should recognize that stringent and unpredictable regulation would unavoidably lead companies to cut back or discontinue genetic resources-based research and use. As a result, there would be little, by way of benefits, to share with providers of genetic resources.

(4) Conclusion

If excessive regulation were imposed on access and benefit sharing in providing countries, it would inevitably affect companies in such a way as to lead to a reduction of activity or even withdrawal from genetic resources-based business. This would mean that commercial benefits would not be generated, and therefore, there would be no benefits to share with providing countries. This outcome would be unfortunate for users, providers, and all the other stakeholders.

On the other hand, our survey also shows that companies have a sense of responsibility to conduct fair and equitable benefit sharing with providers. Moreover, they are willing to promote and undertake projects on genetic resources-based research with other countries where conditions can be arranged for proper implementation of contracts based on mutual understanding and trust.

On the basis of this recognition, Japan is actively promoting the implementation of the Bonn Guidelines in both the public and private sectors (e.g. Japanese translation of the Bonn Guidelines is available and a total of six workshops and symposiums open to the public have been conducted to disseminate information on the Bonn Guidelines). The Bonn Guidelines are steadily diffusing into the private sector and academia. We intend to continue these efforts. Furthermore, we plan to

³ Report on Cooperative Research Project on Conservation of biological diversity and the Sustainable use (Japan Bio-industry Association 1997)

⁴ Ibid

keep monitoring the experiences of the private sector to ascertain whether or not the Bonn Guidelines are working effectively.

It is therefore essential, as a first step, to strive to develop mutual understanding for the current situation as it applies to the fair and equitable sharing of benefits arising from the use of genetic resources between the providers and users of genetic resources, instead of trying to immediately start discussion on the nature, scope and modalities of an International Regime. The most beneficial approach will be to discuss what steps we should take, and to identify practical arrangements that are truly necessary to develop such mutual understanding among stakeholders.

(2) Regarding an International Regime

After achieving mutual understanding on the issues discussed in paragraph 1, we consider it necessary to conduct a rational discussion on how to clarify the basic premises for constructing an international regime. In our view, it would be difficult even to start a discussion without clarifying these points.

- Clarification of what is to be regulated

Whatever regulatory systems were to be introduced, the objects to be regulated would need to be specified. If we consider a legally binding international regime for the ABS, it is necessary to determine how all the items of genetic resources would be specified. Besides, if genetic resources existing all over the world should be specified, it would be difficult to construct the workable system for an international regime.

- Prior Informed Consent (PIC)

If any regulatory system were to be introduced to implement this measure, we would (1) have to clarify who would issue PIC certificates, (2) have to clarify the procedure to issue them, and (3) need to conduct the process speedily. To achieve all these goals, providing countries would need to build infrastructure and train personnel at significant cost and time. A number of industry sectors have concerns that this approach would be unrealistic.

- Non-discrimination against foreigners in ABS regulation

Japan's social and economic system takes it for granted that sustainable use of genetic resources and fair benefit sharing will be promoted in a general

way. This leads us to believe that regulation for implementing benefit sharing should apply equally, whether users are foreigners or inhabitants of the providing country/country of origin. If we were to consider a legally binding international regime, there is a concern that such a legally binding international regime might encourage discrimination against foreigners, which has already occurred in some countries.

-----Original Message-----

From: Claudine RAMIARISON [mailto:ramiaris@wanadoo.mg]
Sent: 19 October, 2004 11:39 AM
To: secretariat
Subject: Re: Requests of the COP7 to the Parties (Decisions VII/19 and VII/30)

Dear sir,
Please find attached Madagascar views and information on access and benefit sharing. I am very sorry for the delay.

Best regards
Claudine RAMIARISON
CDB Focal Point for Madagascar

Convention on Biological Diversity

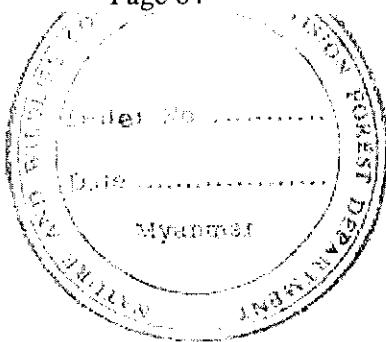
ANNEX I

Use of Terms

In accordance with decision VII/19B, you are invited to provide to the Executive Secretary existing national definitions or other relevant definitions of the terms included in the following table along with the source of these definitions. Any views on whether additional terms should also be considered, including their definitions and source, are to be included in the last row of this table.

Terms to be defined	Existing definition
Access to genetic resources	Access for research and for use of genetic characteristics of biodiversity resources without possession
Benefit-sharing:	Monetary advantages sharing deriving or not from exploitation of these genetic resources between possessors country and users , but also at the level of possessor country in taking into account local communities and traditional knowledge
Commercialization:	The fact to buy and to sell some goods
Derivatives:	Body gotten by the transformation of another
Provider:	The entity authorized to provide genetic material or traditional knowledge for various uses, <u>that is supposed facilitated the access to resources to the lowest cost and condition the access in all transparency</u>
User	The entity that exploits the genetic materials to commercial or research ends
Stakeholder	Participants in a contract
<i>Ex situ</i> collection	The conservation of constituent elements of biological diversity outside their natural habitat
Voluntary nature	Qualification of an act makes freely without constraint
Other term(s) to be defined:	

Comments:



GOVERNMENT OF THE UNION OF MYANMAR
MINISTRY OF FORESTRY
FOREST DEPARTMENT
YANGON

Letter. OFFICE / CBD / 6170 / 64
 Date . 10 . 11 . 2004

To.

Mr. Hamdallah Zedan
 Executive Secretary
 Secretariat of the Convention on Biological Diversity
 United Nations Environment Programme
 393 Saint-Jacques Street, Suite 300
 Montreal, Quebec, CANADA
 H2Y 1N9
 Fax: (514) 288-6588

From

U Soe Win Hlaing
 Director General
 Forest Department
 Bayintnaung Road, West Gyogone,
 Insein, Yangon, Myanmar
 P.O. 11011
 Fax: (95-1) 664 336, 681 761
 E-mail: <nwed-eas@mptmail.net.mm>, <teaknet@mptmail.net.mm>

Subject : Access to genetic resources and benefit-sharing

Dear Sir,

We received your request to provide information on access to genetic resources and benefit-sharing for preparation of pre-session documentation of Ad Hoc Open-ended Working Group meeting to be held from 14 to 18 February, 2005. As there has been no such case study conducted by Forest Department of Myanmar, we are unable to provide you information in this area at the moment.

With best wishes,

Yours sincerely,

For Director General

Khin Maung Zaw
 Director
 Nature and Wildlife Conservation Division
 Forest Department

**SUBMISSION FROM NORWAY ON THE FOLLOW-UP OF DECISION VII/19
ON ACCESS AND BENEFIT-SHARING AS RELATED TO GENETIC
RESOURCES****Experiences and lessons learned in the implementation of the Bonn
Guidelines**

The Norwegian government appointed in April 2001 an expert committee assigned to examine Norwegian legislation with the aim to strengthen legal measures for the protection of biodiversity in Norway, including how legislation responds to issues within the scope of the Convention on biological diversity and other relevant international instruments.

Access to genetic resources and benefit-sharing are identified as separate and priority issues in this legislative work as this is an area not yet subject to legislation in Norway. The Committee will naturally use the Bonn Guidelines amongst other instruments and examples as an input to this work. Norway is considered as both a provider and user country of genetic resources, and therefore the mandate is to propose legislation both with regard to access to genetic resources in Norway and regulations concerning the use of genetic resources originating from other countries when used in Norway.

The committee will submit its legislative proposal by the end of 2004. It will thereafter be followed by a broad government hearing.

In order to inform relevant actors, *inter alia* users of genetic resources of the Bonn Guidelines, a national seminar has been arranged under the auspices of the National Genetic Resource Council.

The Nordic Genetic Resources Council where all the Nordic countries are represented, is publishing a brochure in the Nordic languages and Finnish in order to inform relevant actors about the Bonn Guidelines.

The Nordic Genetic Resources Council, has also conducted a work on access to genetic resources and benefit-sharing, which resulted in a Nordic Ministerial Declaration (Nordic ministers for agriculture, forestry, fish, food and the environment) in August 2003. The respective Councils of ministers approved a declaration which established principles and objectives for how the Nordic countries should deal with the issues of access and rights to genetic resources (cf. Ministerial Declaration on Access and Rights to Genetic Resources, 2003).

Use of terms, definitions and/or glossary

Relevant definitions pertaining to genetic resources will be developed under the forthcoming legislative proposal on access to genetic resources and benefit-sharing (see above).

Other approaches as set out in decision VI/24B and follow-up of decision VII/19E, para. 10 with regard to measures to support compliance with prior informed consent

Norway has the following information to submit concerning other approaches and measures included in the national patent law, para. 8b to support compliance with prior informed consent of the Contracting Party providing the resources:

Patent Law, new para. 8b)

"If an invention concerns or uses biological material, the patent application shall include information on the country from which the inventor collected or received the material (the providing country). If it follows from national law in the providing country that access to biological material shall be subject to prior consent, the application shall inform on whether such consent has been obtained.

If the providing country is not the same as the country of origin of the biological material, the application shall also inform on the country of origin. The country of origin means the country from which the material was collected from *in-situ* sources. If it follows from national law in the country of origin that access to biological material shall be subject to prior consent, the application shall inform on whether such consent has been obtained. If information dealt with under this subsection is not known, the applicant shall provide information on that.

The duty to provide information under first and second subsection applies even if the inventor has altered the structure of the received material. The duty to provide information does not apply to biological material derived from the human body.

Infringement of the duty to provide information is subject to penalty in accordance with the General Civil Penal Code § 166. The duty to provide information is without prejudice to the processing of patent applications or the validity of granted patents."

The General Civil Penal Code § 166 reads as follows:

"Any person shall be liable to fines or imprisonment for a term not exceeding two years who gives false testimony in court or before a notary public or in any statement presented to the court by him as a party to or legal representative in a case, or who

orally or in writing gives false testimony to any public authority in a case in which he is obliged to give such testimony, or where the testimony is intended to serve as proof.

The same penalty shall apply to any person who causes or is accessory to causing testimony known to him to be false to be given by another person in any of the above-mentioned cases."

The information requirements are not applicable to international patent applications submitted through the Patent Cooperation Treaty system, as this would be contrary to the obligations pursuant to the Patent Cooperation Treaty.

The amended law applies to patent applications submitted from 1st February 2004 since this was the date when the law entered into force.

Measures, including consideration of their feasibility and costs, to support compliance with prior informed consent of the Contracting Party providing genetic resources

We refer to the recently amended Patent Law, new para. 8b (explanation above). This is an example of a measure to support compliance with prior informed consent as provided for in CBD.

Sultanate of Oman
Ministry of Regional Municipalities,
Environment & Water Resources
Coordination & Follow-up Department



شَاهِنْهَارِ سَهْمَانٌ
قَرْلَهُ الْبَلْدَهُ يَا هُوَ لِأَفْسِهِنَّا وَالْبَيْنَهُ وَمَوْلَادُ الْمَلِيَّهُ
كَارِلَهُ التَّسْبِيْحُ وَالْمَتَابِعُهُ

Ref. : MRMEWR/MO/CF-4-2/152/2004

١٣

Date: 16 / 10 / 2004

الكتاب

69.:

١٣٦

CBD Secretariat
World Trade Centre
393 Saint-Jaques Street
Suit 300
Montreal, Quebec
Canada H2Y 1N9

After Compliments ,

Subject : Decision VII/19 and VII/30 on Access and Benefit-Sharing as related to genetic resources .

Thank you for your letter dated 29.9.2004 regarding the above mentioned subject.

Please be informed that we have no comments on these two decisions.

Thanking you for your continued support and cooperation.

Best regards

*Ahmed bin Saeed Al-Kharroosi
Director of Coordination and Follow-up*





BUWAL Bundesamt für Umwelt, Wald und Landschaft
OFEFP Office fédéral de l'environnement, des forêts et du paysage
UFAPP Ufficio federale dell'ambiente, delle foreste e del paesaggio
SAEFL Swiss Agency for the Environment, Forests and Landscape

Division Affaires internationales

CH-3003 Berne, 25 novembre 2004

Téléphone: +41313229323
Télécax: +41313230349
E-Mail: beat.nobs@buwal.admin.ch
Internet: http://www.environnement-suisse.ch

Votre référence

Votre communication du

Nosre référence Py / D482-0309

Mr Hamdallah Zedan
Secrétaire exécutif
Convention sur la diversité biologique
World Trade Center
339, rue St Jaques Montréal
H2Y N9 Québec
Canada

UNEP/SCBD

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RECEIVED

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ACTION	<u>VN</u>
FILE	_____
INFO	_____

Objet: **Notifications 2004-034 et 2004-082**

Monsieur le Secrétaire exécutif,

La concrétisation des dispositions sur l'accès aux ressources génétiques et le partage juste et équitable des avantages constitue une des priorités de la Suisse dans le cadre de la mise en œuvre des 3 objectifs de la Convention sur la biodiversité. La Suisse va poursuivre l'engagement fourni lors de l'élaboration des lignes directrices de Bonn et soutenir activement les négociations du Régime international au sein du Groupe de travail spécial à composition non limitée sur l'accès et le partage des avantages.

Nous avons déjà eu l'occasion à maintes reprises, en particulier lors de la 7^{ème} Conférence des Parties (COP 7) de présenter notre position concernant le processus d'élaboration et la nature du Régime international. Nous sommes d'avis que les termes de référence adoptés par la COP 7 représentent une base solide pour débuter les négociations du Régime International. Dans ce contexte nous aimerais à nouveau insister sur la nécessité d'une étroite collaboration avec les travaux en cours au niveau international notamment au sein du Traité International de la FAO sur les ressources phytogénétiques pour l'agriculture et l'alimentation et de l'Organisation mondiale de la propriété intellectuelle.

En réponse à votre notification du 29 avril et dans l'optique de la préparation de la 3^{ème} réunion du Groupe de travail spécial à composition non limitée sur l'accès et le partage des avantages nous nous limiterons à une analyse préliminaire des objectifs potentiels du Régime international et à quelques suggestions concernant l'organisation du travail au sein du Groupe de travail spécial à composition non limitée.

Analyse préliminaire des objectifs du Régime International

La décision VII/19, ne contient aucune référence spécifique aux objectifs du Régime international. Le but, énoncé en termes généraux au 1^{er} paragraphe opérationnel, est « *d'adopter un ou plusieurs instruments qui puissent mettre en*

œuvre de façon efficace les dispositions des articles 15 et 8j et les 3 objectifs de la Convention ».

Nous sommes d'avis qu'une des premières priorités du Groupe de travail spécial à composition non limitée devra être de clarifier de manière concrète et opérationnelle les objectifs du Régime international. Ce travail devra être réalisée selon le processus défini par les termes de référence, c'est-à-dire à partir d'une analyse des instruments juridiques nationaux, régionaux et internationaux et autres instruments liés à l'accès et aux partages des avantages.

A ce stade initial des travaux, il nous semble utile que le secrétariat élabore dans les documents en vue de la réunion de février une première esquisse des objectifs potentiels afin de structurer le débat sur la problématique des objectifs du Régime international. Ceci faciliterait l'analyse en permettant au Groupe de travail d'aborder rapidement les questions substantielles,

Nous suggérons l'approche suivante:

- Initier la réflexion sur la base des 7 objectifs potentiels suivants obtenus en regroupant par thèmes les éléments à considérer figurant dans les termes de référence (les lettres entre parenthèses correspondent aux éléments figurant dans les termes de référence) :
 - Garantir le partage juste et équitable des bénéfices (ii, iii, v, vi, vii, xii) ;
 - Faciliter l'accès à des fins d'utilisation écologiquement rationnelle (iv, vii) ;
 - Garantir le respect du Consentement préalable en connaissance de cause (PIC) et des modalités mutuellement convenues (ix, x, xi, xiii, xiv, xx) y compris le règlement des différents (xxi) ;
 - Reconnaître et protéger les connaissances traditionnelles (xv, xvi, xviii) ;
 - Soutenir le renforcement des capacités (xvii, xix) ;
 - Promouvoir et encourager la collaboration en matière de recherche scientifique (i) y compris le transfert de technologie ;
 - Traiter spécifiquement la nature multiétablique, transfrontière ou hors juridiction de certaines ressources génétiques (viii).
- Compléter si nécessaire cette première esquisse en passant en revue les 12 objectifs figurant au chapitre E des Lignes directrices de Bonn ;
- Aborder l'analyse des besoins et lacunes en prenant en considération notamment les éléments suivants :
 - Spécificité, priorité et praticabilité ;
 - Equilibre entre droits et obligations en tant que pays utilisateurs et pays fournisseurs de ressources génétiques ;
 - Clarification entre ce qui est du ressort du droit national et ce qui nécessite une base légale au niveau international.

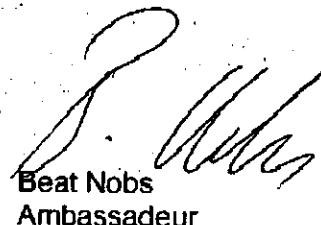
La mise à plat des objectifs facilitera par la suite les débats sur les éléments, la portée et la nature du Régime international

Organisation du travail :

La COP 7 a confié au Groupe de travail spécial à composition non limitée sur l'accès et le partage des avantages le mandat de négocier le Régime international. Or parallèlement aux négociations, le groupe de travail va devoir continuer à traiter

d'autres thèmes en relation avec la mise en œuvre de l'article 15. Afin de tenir compte de cette situation, l'ordre du jour provisoire annoté de la 3^{ème} réunion (UNEP/CBD/WG-ABS/3/1/Add.1) prévoit la mise sur pied de deux sous-groupes de travail. L'expérience passée, notamment lors des négociations du Protocole de Cartagena, a démontré la nécessité de confier la responsabilité de la gestion de la totalité des négociations à une ou deux personnes afin de garantir la continuité et le suivi des travaux en particulier durant les périodes intersessionnelles. Nous suggérerions dès lors de nommer à la présidence du sous-groupe chargé des négociations du Régime international une ou deux personnes prêtes à assumer cette tâche pour la durée complète des négociations. Il serait souhaitable que le Secrétaire exécutif mène à cet effet des consultations préalables afin de pouvoir débuter les travaux en février le plus rapidement possible.

Nous vous prions d'agréer, Monsieur le Secrétaire exécutif, nos salutations distinguées



Beat Nobs
Ambassadeur

Copie : - DFAE, M. Krebs
- OFAG, H. Hänni
- SECO, A. Werthmüller
- IPI, M. Girsberger
- Intème: Ka, Ho, Py, LAR, SAP

-----Original Message-----

From: Neimatullo Safarov [mailto:NSafarov@biodiv.tajikiston.com]
Sent: 15 September, 2004 7:01 AM
To: Hamdallah Zedan
Cc: secretariat
Subject: Re: Requests of the COP7 to the Parties (Decisions VII/19 and VII/30)
Importance: High

Response to the letter from 3 May 2004, Notification 2004-034

Dear Mr. Hamdallah Zedan,

At present Tajikistan is actively implements the activity on National Biodiversity Strategy and Action Plan. Thus, under the priorities identified in the Strategy the relevant activity is implemented on the issue of development the mechanisms of access to genetic resources according to COP decisions VII/19 и VII/30:

- Priorities are identified concerning the activity on genetic resources,
- Developing of toolkits on inventory of genetic resources and defining their habitats;
- The country is launching the development of Second National Report on Biodiversity where the key issue will be identifying of invasive species impact on genetic resources.

Also genetic resources issues and development of mechanisms to solve COP7 decisions are elaborated while implementing thematic projects, including those on ecological network, biodiversity conservation in Dashtijum species protected management. Activity under these projects provides elaboration of goals 2,3,4,8 and 9 Decision VII/30 "Strategic Plan: future evaluation of progress".

Goal 2. Promote the conservation of species diversity

Goal 3. Promote the conservation of genetic diversity

Goal 4. Promote sustainable use and consumption.

Goal 8. Maintain capacity of ecosystems to deliver goods and services and support livelihoods

Goal 9 Maintain socio-cultural diversity of indigenous and local communities

Tajikistan participates in regional workshops on genetic resources where the possibilities of legal document unification are considered, as well development of information network on genetic resources and creation of regional database in Central Asia. However, these activities are not efficient to cover the whole framework of decisions made to meet the Convention goals. Besides, to realize the decisions we are planning organization of the workshop on genetic resources and moreover development a strategy to provide target works on mechanisms of access and benefit sharing.

Sincerely yours,
Dr.Neimatullo Safarov
CBD and CPB National Focal Point
Republic of Tajikistan

VENEZUELA

Apreciaciones sobre la Decisión VII/19 del CDB relativas al “Acceso y participación en los beneficios en relación con los recursos genéticos (Artículo 15)”

La Decisión VII/19 de la Conferencia de las Partes es probablemente la más comprensiva y detallada de todas aquellas que han tratado el tema del acceso a los recursos genéticos.

DIRECTRICES DE BONN SOBRE ACCESO A LOS RECURSOS GENETICOS Y PARTICIPACION JUSTA Y EQUITATIVA EN LOS BENEFICIOS DERIVADOS DE SU UTILIZACION

Con relación a este punto hay que considerar que no se ha hecho un esfuerzo suficiente en la aplicación de estas directrices fundamentalmente por dos razones.

- Son de naturaleza voluntaria.
- Las guías prestan poca atención a las medidas a ser emprendidas por los países donde se ubican usuarios (países desarrollados con empresas que usan recursos genéticos) para cumplir sus obligaciones en el marco del Convenio, especialmente las relativas a tomar medidas administrativas, de política y legislativas para compartir beneficios.

Sin embargo, en Venezuela estamos tratando de que sean tomadas en cuenta en la formulación de nuestra legislación nacional de acceso y participación en los beneficios. Por otra parte estamos tratando de implementar algunas de las recomendaciones señaladas en las Directrices de Bonn en un proyecto que adelanta del Instituto de Ideas Avanzadas del Ministerio de Ciencia y Tecnología relacionado con la “Caracterización de las poblaciones de plantas con potencial medicinal en la Biorregión de los Llanos del Orinoco, Venezuela”.

USO DE TERMINOS, DEFINICIONES Y/O GLOSARIO, SEGUN PROCEDA

Ciertamente, con los fines de hablar un lenguaje común y evitar malentendidos, se requiere un análisis comparativo sobre las definiciones existentes en diferentes países relativas a los siguientes términos y expresiones: acceso a recursos genéticos, participación en los beneficios, comercialización, derivados, proveedor, usuario, interesado, recolección *ex situ*, carácter voluntario.

OTROS ENFOQUES, DE CONFORMIDAD CON LA DECISION VI/24 B

Es saludable la necesidad de un examen de las Directrices de Bonn y la consideración de otros enfoques que sirven para la aplicación de las disposiciones sobre acceso y participación en los beneficios del Convenio.

REGIMEN INTERNACIONAL SOBRE ACCESO A LOS RECURSOS GENETICOS Y PARTICIPACION EN LOS BENEFICIOS

Se ha hecho una convocatoria al Grupo de Trabajo sobre ABS para que "...en colaboración con el Grupo de Trabajo del artículo 8 inciso J sobre conocimiento tradicional y asegurando la participación de comunidades y pueblos indígenas, organizaciones no gubernamentales, industria e instituciones académicas e intergubernamentales, **elabore y negocie un régimen internacional sobre acceso a recursos genéticos y distribución de beneficios** con el propósito de adoptar un instrumento o instrumentos para implementar efectivamente las disposiciones del artículo 15 y 8 inciso J y los 3 objetivos de la Convención". Dicho grupo deberá reunirse en dos oportunidades y presentar sus resultados a la Octava Conferencia de las Partes a celebrarse en Brasil en el 2008.

El grupo operará de conformidad con los términos de referencia que consideran la elaboración y la negociación de la naturaleza, ámbito y elementos del régimen internacional de acceso a recursos genéticos y distribución de beneficios en el marco del Convenio, fundamentándose, entre otros, en el análisis de instrumentos legales y de otra naturaleza en el ámbito nacional, regional e internacional, incluyendo contratos, experiencias con su implementación; mecanismos de cumplimiento y otras opciones. Como parte del proceso el grupo examinará los elementos indicados en el mismo anexo y como abordar las lagunas.

Con relación a la naturaleza del régimen este puede estar integrado por uno o más instrumentos, principios, normas, reglas y procedimientos legalmente vinculantes o no.

Su ámbito es dual, dado que trata: a) el acceso a los recursos genéticos y b) la promoción y salvaguarda de la justa y equitativa distribución de beneficios derivados de la utilización de los recursos genéticos y las innovaciones, conocimientos y prácticas tradicionales de conformidad con el artículo 8 inciso J.

Los elementos del régimen están constituidos por una lista no taxativa. Se incluyen una amplia gama de opciones (23 en total), las cuales van desde medidas para promover y incentivar la investigación científica colaborativa, la investigación con propósitos comerciales y la comercialización en materia de recursos genéticos, hasta el espinoso asunto del certificado internacionalmente reconocido de origen-fuente-proveniencia legal, la consideración de los derivados de los recursos genéticos, etc.

Cual debe ser el camino a seguir

El proceso iniciado presenta retos importantes para los países en desarrollo entre los cuales podemos indicar los siguientes:

- No está claro el resultado último del proceso y del ejercicio pero se supone que será, al menos, un instrumento jurídicamente vinculante. El significado y alcance de lo que constituye un régimen no resulta del todo claro, particularmente si esta palabra se utilizó en sustitución de la idea de un negociar un protocolo jurídicamente vinculante, como el Protocolo de Cartagena sobre Seguridad en Biotecnología Moderna.
- El proceso de negociación puede distraer las iniciativas legislativas y de política nacionales o al menos afectar los mismos. A la vez, los países en desarrollo requerirán fortalecer sus capacidades de negociación internacional, especialmente debido a la vaguedad que aún persiste respecto a la naturaleza y particularmente el contenido concreto del régimen. Las medidas que el régimen podría contener también podrían conllevar nuevos objetivos legislativos y modificaciones a los marcos legales nacionales.
- De forma relacionada con lo anterior, el régimen también traerá cambios y modificaciones legales para los países en desarrollo, los cuales son inciertos (tómese en cuenta adicionalmente que según reconoce la misma Decisión VII-19 todos los países son usuarios y proveedores de recursos). Lo anterior puede influir en los proyectos nacionales de establecimiento de normas de acceso. Es importante tener claras las necesidades en términos de construcción de capacidades, que el régimen puede traer consigo.
- Se requerirá un importante esfuerzo para establecer sinergias con otros procesos internacionales
- Los países podrían considerar qué tipo de medidas interinas deben ser puestas en práctica mientras el proceso concluye. La decisión VII-19 insta a las Partes a implementar medidas en países con usuarios (intercambio de información, incentivos, etc), las cuales pueden contribuir a satisfacer las aspiraciones que han conducido a lanzar la negociación del régimen
- Cabe destacar que si bien es cierto el Plan de Acción de Johannesburgo se refiere únicamente a salvaguardar la distribución de beneficios derivados de la utilización de los recursos genéticos, la decisión de la VII-19 incluyó por igual la protección del conocimiento tradicional (artículo 8 inciso J).

- Los interesados (y no solo los Gobiernos) deben tener claro de que forma el régimen puede resolver los problemas prácticos que impiden la distribución de beneficios, y si estos se han identificado apropiadamente. De lo contrario, se corre el riesgo de negociar un instrumento cuyo resultado al final no permita solventar adecuadamente las causas subyacentes tras la falta de cumplimiento del tercer objetivo del CBD.
- Finalmente, la Decisión VII-19 menciona, a lo largo de su texto, al denominado certificado de origen-legal procedencia-fuente como un elemento central del régimen, esto hay que discutirlo.

MEDIDAS, INCLUIDO EL EXAMEN DE SU VIABILIDAD, APLICACIÓN EN LA PRÁCTICA Y COSTOS, PARA APOYAR EL CUMPLIMIENTO DEL CONSENTIMIENTO FUNDAMENTADO PREVIO DE LA PARTE CONTRATANTE QUE PROPORCIONA DICHOS RECURSOS Y DE LAS CONDICIONES MUTUAMENTE ACORDADAS CON ARREGLO A LAS QUE SE CONCEDIÓ ACCESO EN LAS PARTES CONTRATANTES CON USUARIOS DE RECURSOS GENÉTICOS BAJO SU JURISDICCIÓN

En un proyecto que adelanta del Instituto de Ideas Avanzadas del Ministerio de Ciencia y Tecnología relacionado con la “Caracterización de las poblaciones de plantas con potencial medicinal en la Biorregión de los Llanos del Orinoco, Venezuela”, estamos intentando la aplicación del Consentimiento Fundamentado Previo en comunidades llaneras para el acceso de conocimientos tradicionales sobre el uso de plantas medicinales.

NECESIDADES DE CREACIÓN DE CAPACIDAD RECONOCIDAS POR LOS PAISES PARA la CREACIÓN DE CAPACIDAD PARA EL ACCESO A LOS RECURSOS GENÉTICOS Y LA PARTICIPACION EN LOS BENEFICIOS EN CONJUNCIÓN CON LA APLICACIÓN DE LAS DIRECTRICES DE BONN

Ciertamente hay una necesidad imperiosa hacia la adopción de algunos tipos de acción que toquen el tema de la facilitación y apoyo al desarrollo y fortalecimiento de capacidades de los individuos, las instituciones y las comunidades para la aplicación efectiva de las disposiciones del Convenio relativas al acceso a los recursos genéticos y participación en los beneficios, y en particular de las Directrices de Bonn sobre acceso a los recursos genéticos y a la participación justa y equitativa en los beneficios que se derivan de su utilización, tomando en cuenta su naturaleza voluntaria.

Apreciaciones sobre la Decisión VII/30 del CDB relativas al “Plan Estratégico: Información para evaluar el progreso logrado en el futuro” y relacionadas con el “Acceso y participación en los beneficios en relación con los recursos genéticos”

En particular hay que tomar en cuenta la solicitud que se hace al Grupo de trabajo especial de composición abierta sobre acceso y participación en los beneficios y al Grupo de trabajo especial de composición abierta sobre el Artículo 8 j) y disposiciones conexas del Convenio sobre la Diversidad Biológica, respectivamente, que exploren **la necesidad y posibles opciones de indicadores** para acceso a los recursos genéticos y en particular para la participación justa y equitativa en los beneficios provenientes del uso de recursos genéticos e innovaciones, conocimientos y prácticas afines de las comunidades indígenas y locales, y para la protección de los conocimientos, innovaciones y prácticas de las comunidades indígenas y locales, y que informe acerca de los resultados a la Conferencia de las Partes en su octava reunión.

II. SUBMISSIONS FROM NON PARTIES

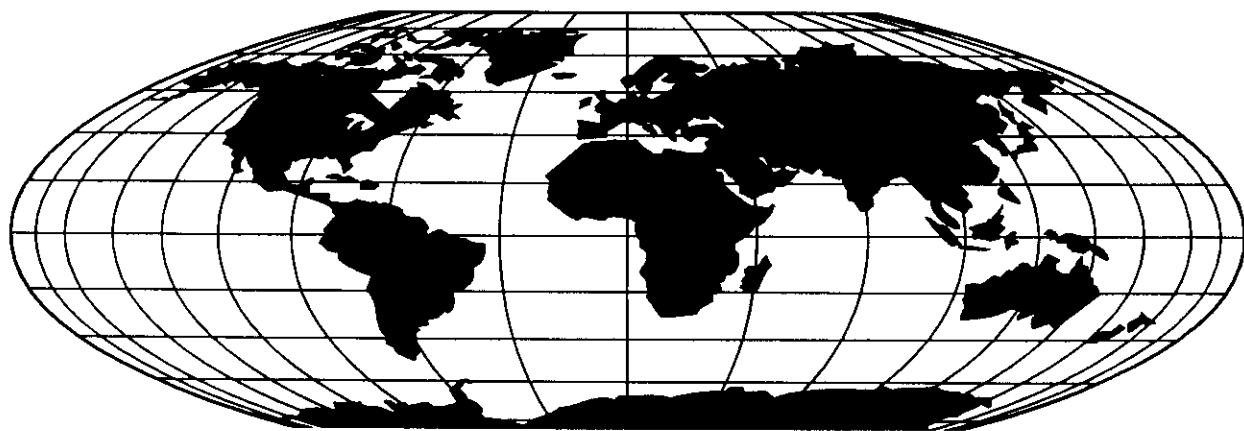
FY2005 GUIDELINES FOR PLANT EXPLORATION PROPOSALS

(Deadline for submission: July 6, 2004)

The United States Department of Agriculture (USDA), Agricultural Research Service (ARS) funds foreign and domestic plant explorations to acquire plant germplasm for inclusion in the U.S. National Plant Germplasm System. Plant exploration proposals must be supported by the appropriate Crop Germplasm Committee (CGC), or other qualified crop specialists when there is no appropriate CGC. Proposals are recommended for funding by the Plant Germplasm Operations Committee (PGOC) and approved by the ARS National Program Staff. Plant Exploration Proposals may be submitted by any qualified scientist. The Guidelines presented here are for proposals to be funded during the period October 1, 2004 - September 30, 2005 (Fiscal Year 2005); previous versions are obsolete. The Guidelines for Plant Exploration Proposals are revised annually and may be obtained from the Plant Exchange Office (PEO), Beltsville, Maryland.

The format for plant exploration proposals is designed to guide prospective explorers through the necessary background study required to obtain the information necessary for sound planning and effective implementation of field programs, to fully inform reviewers, and to provide a basis for judging and prioritizing proposals. The format for the project summary (Attachment A) is designed to comply with ARS Directive 281.1 (Extramural Research-Grant Agreements) so that grants can be used to fund explorations by non-ARS scientists. The policy of the PEO is that funds are not provided for institutional overhead. When ARS funds an exploration by a non-ARS employee, the exploration is considered to be in the mutual interest of that person's institution and ARS, and a waiver of overhead is warranted. The format requires that the grantee certify that overhead will be waived. The format also requires certification that the collector will provide complete "passport" data, including latitude and longitude, for each collection.

Scientists planning to submit a proposal are advised to first consult Karen Williams in the PEO. The PEO can provide suggestions and assistance with technical matters when preparing a proposal.



Participants on foreign ARS-supported explorations are required to follow the NPGS Code of Conduct for Foreign Plant Explorations (Attachment B). Participants should also be aware of the voluntary FAO Code of Conduct for Plant Germplasm Collecting and Transfer (<http://www.fao.org/WAICENT/FAOINFO/AGRICULT/AGp/agps/pgr/icc/icce.htm>). Explorations must be made in compliance with the host country's laws governing access to germplasm. Regulations in different countries vary significantly. Permission for access to germplasm must be obtained from the host country authority designated by the national government. A useful resource on this topic is the U.S. Department of State's "Information for U.S. Government Funded Researchers Collecting *In Situ* Genetic Resources Outside the United States" (<http://www.state.gov/g/oes/rls/or/25962.htm>). Permission may also be required by regional, state or individual landholding authorities. Scientists are strongly encouraged to consult with the PEO regarding access issues before submission of proposals. Some host country governments require an official agreement to cover the ownership, distribution, and/or use of the collected germplasm. The PEO reviews all agreements to ensure that they are consistent with U.S. government policies and arranges for their signature by an authorized representative of ARS.

Laws in some countries require benefit sharing beyond that routinely associated with plant explorations in order to obtain access to plant genetic resources. Depending on the situation in the host country, a limited amount of funds may be requested in the budget for additional non-monetary benefits. These expenditures should increase the country's capacity to conserve plant genetic resources and may include supplies, training of host country scientists, and workshops conducted by exploration participants. The host country authority for access will determine the acceptability of the non-monetary benefits. Please consult with the PEO before including benefits of this type in your proposal.

All germplasm obtained from ARS-funded plant explorations is added to the National Plant Germplasm System (NPGS) where it is curated, evaluated and made available for distribution. Germplasm in the NPGS is available to all bona fide users, public, private and foreign. Germplasm collected on ARS-funded explorations is distributed to non-NPGS participants after deposition in the NPGS, and is subject to the conditions of any agreements signed with the host country.

The prevention of accidental introduction of noxious weeds, insects, diseases and other organisms into the United States is of utmost concern to ARS. Participants on ARS-supported explorations are required to closely follow U.S. plant quarantine laws and regulations administered through the USDA Animal and Plant Health Inspection Service (APHIS). All germplasm must be accompanied by an original phytosanitary certificate from the country of origin. Participants must declare all germplasm upon their return to the U.S. The germplasm should be inspected by an APHIS inspector for evidence of insects, disease or weed contamination and treated appropriately, when necessary.

A separate proposal format entitled "Guidelines for Germplasm Exchange Proposals" is available from the PEO for proposals involving expeditions to exchange germplasm with foreign genebanks when the expedition plans do not include exploration.

Preparation of proposal: The format for preparing proposals is outlined in Attachment A. For specific advice on proposal items 19 and 20, consult Maryann Loftus (Telephone: 301-504-5020; Email: mloftus@ars-grin.gov) of the PEO. Request a written endorsement for the proposal from the appropriate Crop Germplasm Committee (CGC), or other qualified crop specialists when there is no appropriate CGC. The NPGS curator(s) responsible for the proposed collections must sign a statement (see item 20) to certify that they anticipate having the capacity to curate the collections.

Draft proposal: Because the assistance of PEO is frequently required in acquiring host country approvals for explorations, please submit a draft proposal to the PEO by April 15, 2004. The draft should include items 1, 2, 3, 4, 5, 6, and 7 (brief explanation of need). Early notification will allow the PEO to assist with meeting host country requirements for access to germplasm and with negotiating terms.

Final submission of proposals: Submit the proposal to the PEO no later than July 6, 2004. This deadline may be waived to permit response to real emergencies.

Review of proposals: Proposals are reviewed by a committee composed of members of the Plant Germplasm Operations Committee (PGOC) and a representative of each of the four NPGS Regional Technical Committees. CGC recommendations are considered by the committee when it reviews proposals for funding. The committee prioritizes acceptable proposals and recommends these for approval by the ARS Administrator.

Notification of funding decision: Scientists will be notified in writing by PEO of the decision regarding funding of their proposal. This notification may occur as late as December 2004. Scientists whose explorations are funded will receive instructions on funding arrangements and importing germplasm to the U.S., and a checklist of program requirements.

Documentation requirements: Each collection must be documented with sufficient data. A sample data collection sheet is attached (Attachment C). Explorers are urged to develop their own similar data collection formats tailored to the target crop species.

The PEO can assist with preparing data collections forms for specific expeditions.

It is important that collectors carefully record locality data (including latitude, longitude, and elevation), associated vegetation, habitat description, plant characteristics and local uses of the plant for all germplasm. Use of Global Positioning System (GPS) devices for determining accurate longitude and latitude and altimeters for accurate altitude is required. Such devices are available on loan from the PEO. A copy of the data should accompany all germplasm sent to the USDA Plant Germplasm Quarantine Center (Bldg. 580, BARC-East, Beltsville, MD 20705).

Collectors are requested to use an identification system for germplasm samples that combines characters and numbers. Characters can refer to the collectors' initials, the country in which the exploration is conducted, or the species collected. This will greatly facilitate the tracking of accessions in the Germplasm Resources Information Network (GRIN) database.

A herbarium voucher specimen should be prepared for any collection that cannot be identified authoritatively in the field, for a collection that possesses uncharacteristic morphological traits, and especially for all collections of wild relatives. A description of the methods for preparing herbarium specimens may be found in "Field Techniques Used by the Missouri Botanical Garden," available on the Internet at <http://www.mobot.org/MOBOT/molib/fieldtechbook/welcome.shtml>. At least two herbarium vouchers should be made for each collection, with additional vouchers recommended as availability of plant material allows. Herbarium vouchers should be deposited with a herbarium in the host country and at least one duplicate herbarium voucher should be deposited in the U.S. National Arboretum Herbarium (contact Kevin Conrad, Telephone: 202-245-4513, kconrad@ars-grin.gov) or in another internationally recognized U.S. herbarium. The U.S. National Arboretum Herbarium is a USDA/ARS facility.

Early Warning System on Plant Genetic Erosion: If evidence of genetic erosion is observed in the field, an FAO report form may be completed in collaboration with host country scientists and submitted to the FAO World Information and Early Warning System for Plant Genetic Resources (WIEWS) by the host country government. The FAO report form for assessment of genetic erosion of wild crop relatives is available on the Internet at <http://apps3.fao.org/wiews/EWS/EWSAssess2EN.htm>. The FAO report form for assessment of genetic erosion of local varieties is available on the Internet at <http://apps3.fao.org/wiews/EWS/EWSAssess3EN.htm>.

Reporting requirements: Within 30 days of completion of the exploration, a summary report (see Attachment D for format) must be submitted to the PEO. Within 90 days of completion of the exploration, a final report is required. **Future exploration proposals by the same participants will not be approved for funding until the final report is received.** The final report should include:

- a. Catalog of collections: a record of all collections including all passport data. This may be in electronic form.
- b. Narrative report: 3 to 5 single-spaced pages (more, if necessary). Include significant observations likely to be of interest to germplasm users, or other explorers who may visit the same areas in the future. Provide a list of contacts (domestic and foreign) with complete addresses and indicate how they contributed to the mission and how they might contribute to future missions in the same country.
- c. Copies of permits for the exploration.
- d. Page-size map showing itinerary: identify principal points on the itinerary and most important collection sites.
- e. Information on any threats to genetic resources in the area visited.

ARS scientists: ARS scientists are required to follow USDA and ARS regulations in obtaining travel authorization, implementing travel, accounting for expenses and submitting a trip report.

Requests for further information and plant exploration proposals should be directed to:

Karen Williams
Plant Exchange Office/National Germplasm Resources Laboratory
Rm. 402, Bldg. 003, BARC-West
Beltsville, MD 20705-2350
Telephone: 301-504-5421
FAX: 301-504-6305
Email: kwilliams@ars-grin.gov

PLANT EXPLORATION PROPOSAL FORMAT

The proposal must have a cover page with project title and summary. The following is an example and should be modified as appropriate.

PROJECT TITLE: PLANT EXPLORATION IN [NAME OF STATE(S)/COUNTRY(IES)] TO COLLECT [NAME OF CROP] GERMPLASM FOR CROP IMPROVEMENT.

PROJECT SUMMARY

The [name of Crop Germplasm Committee (CGC), or if no appropriate CGC, name of crop specialist] has determined there is a need for additional [name of crop] germplasm from [list of countries]. This germplasm is desired for breeding programs for crop improvement, does not exist in other germplasm collections and can only be obtained by collection. Additionally, [list of threats] threaten its continued existence if not placed in an *ex situ* collection. Explorations will be made in compliance with [list of countries]'s laws governing foreign access to germplasm. Samples of the germplasm will be deposited in the [designated genebank] in [country] and in the U.S. National Plant Germplasm System (NPGS). Germplasm in the NPGS will be curated on behalf of the U.S. Government and will be available to all qualified scientists/organizations, domestic and foreign, who are eligible to receive it. Germplasm will be collected as seeds, bulbs, cuttings, or other propagules. When possible, collections will be documented with voucher herbarium specimens. All collections will be documented with complete "passport" data (description, locality of collection, including latitude and longitude, etc.). All germplasm will be shipped or carried to the USDA Plant Germplasm Quarantine Center, Beltsville, Maryland, from which it will be distributed according to policies in effect at time of receipt.

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CERTIFICATION

(The leader of each exploration must sign on the signature line of section 1 below. When grants will be used to provide funding, non-ARS participants must also sign on the signature line of section 2.)

1. For foreign plant explorations, I certify that I have read and will abide by the Guidelines for Conduct of Foreign Plant Explorations. I agree to abide by all rules and regulations of host countries concerning collection of plant genetic resources and understand that proper permission is required in advance of collection.

I will promptly comply with reporting requirements explained in the Guidelines for Plant Exploration Proposals. I will provide a summary report, a narrative report, information on genetic erosion in the region visited and a catalog of collections. The catalog will include collector's name and number, plant name, collection locality, including latitude, longitude and elevation, and appropriate descriptive information (of plant and environment), etc.

I understand that all germplasm obtained from ARS-funded plant explorations will be added to the National Plant Germplasm System (NPGS) where it will be curated on behalf of the U.S. Government.

Signature

Date

2. As a non-ARS employee, I agree to the above and certify that I have consulted the appropriate official of my institution who has agreed to waive overhead.

Signature

Date

1. Submitted by:
[Name, title, full address, telephone number, fax, and email.]
2. Objectives:
 - a. Taxa to be collected:
 - b. Specific or general characteristics sought:
 - c. Use to be made of germplasm collected:
3. Dates of travel:
[Specify dates and briefly explain why this period is appropriate.]
4. Host country(s) or state(s):
[If proposal is for collecting in a foreign country indicate, as specifically as possible, the part of that country that will be visited (i.e., section of the country, states, or provinces).]
5. Suggested participants:
[Identify each suggested participant and explain their qualifications including foreign language capabilities and previous foreign travel experience. If this proposal is for exploration in a foreign area, show date and place of birth and passport number for each participant. The inclusion of more than two U.S. scientists requires justification.]
6. Host country (or state(s) or other) requirements to obtain collection permit and permit for export of germplasm:
[For foreign plant explorations, the appropriate procedure for obtaining access to plant genetic resources varies widely among countries. The PEO will assist in identifying host country authorities for access to germplasm. Depending on the regulations in the host country, the PEO may assume responsibility for communicating with host country authorities regarding access. Documentation of host country approval for the exploration will be required before funding is provided.
In this section of the proposal, identify the authority in the host country, describe requirements (such as application forms) for obtaining permission for collection of germplasm, and give details on any progress made in requesting and obtaining permits.

For domestic plant explorations, plant collection permits must be obtained from landholders, both public and private. Landholders, including federal agencies, may require considerable time for processing applications.]
7. Justification:
[Explain the need for collection and why the proposed field collection area will meet that need. Consider the abundance and distribution of the species to be collected; append distribution maps showing their known distribution. Statements on genetic erosion should be documented. The appropriate Crop Germplasm Committee (<http://www.ars-grin.gov/npgs/cgcweb.html>) should have identified the target germplasm as a priority for acquisition.]

Note any political factors that may have an impact on the exploration, especially with reference to accessibility of field areas. Limit this section to three pages or less.]

8. Germplasm currently available:
[What germplasm of the species to be collected is now available in U.S. or foreign collections from the proposed field area? Information on germplasm currently in the NPGS is available from the Germplasm Resources Information Network (<http://www.ars-grin.gov/npgs/>).]
9. How does the exploration relate to earlier explorations or subsequent expeditions?
[Discuss previous explorations for the same or related species in the proposed area of exploration. Karen Williams of the PEO can provide information on prior NPGS-supported explorations. Explain any future plans for exploration for the same or related species.]
10. CGC or other concurrence:
[Attach a copy of a letter from the appropriate CGC endorsing this exploration. If the target species are not covered by a CGC, letters from other specialists may be substituted. If the exploration is proposed in response to a CGC or other recommendation, so indicate.]
11. Benefits to host country:
[In this section, discuss both routine benefits that the host country will receive as a result of the exploration and any additional non-monetary benefits that are requested. Routine benefits include strengthened professional ties, transfer of information and technology, and conservation of native germplasm in the host country. Additional non-monetary benefits are discussed in paragraph 2 on page 2 of these guidelines. Omit this section for domestic exploration.]
12. Status of mapping and map requirements:
[What useful maps, especially road maps and topographic maps, are available? Which have been consulted?]
13. Vehicle and fuel requirements, availability, and cost:
[What type of vehicle will be needed in view of road conditions likely to be encountered, distances to be traveled, and persons and supplies to be transported? Will 4-wheel drive be required? Where will the vehicle be obtained; what will it cost to rent; what is the cost of gasoline? Is gasoline readily available in remote areas?]
14. Currency/exchange rates:
[Omit this section from proposal for domestic exploration.]

15. Holidays:

[American embassies honor local as well as U.S. holidays. Traveler should be aware of foreign holidays and, if possible, should avoid travel immediately before, during, and after major holidays. Omit this section for domestic exploration.]

16. Supplies and equipment:

To be shipped or carried from U.S.:

By participant(s):

By Plant Exchange Office:

To be obtained in host country:

[Omit these details from proposal for domestic exploration, but indicate any supplies and equipment to be provided by PEO.]

17. Field plan:

[How will collector(s) proceed after arrival in the field area? Will a reconnaissance be conducted before collection of germplasm? If the field party includes more than one person, will they travel together or independently? If independently, what will be the objectives of each? Will the entire itinerary be covered by motor vehicle? If not, to what extent, where, and for how long a period will travel by boat, foot, horse, helicopter, etc., be required? Consider condition of roads and physical accessibility of target areas, availability of food and lodging, etc. If international borders must be crossed (other than by air) address the feasibility of crossing such borders.]

18. APHIS requirements for import of germplasm (foreign explorations only):

[APHIS requires that all germplasm coming into the U.S. be accompanied by an original phytosanitary certificate from the country of origin. Prohibited materials entering under a Departmental Permit are exempt from this requirement. The proposal should reflect contact with the USDA APHIS Plant Protection and Quarantine Permit Unit, Riverdale, Maryland (Karen Brady, Telephone: 301-734-5208) regarding any quarantine restrictions and prohibitions for the taxa to be collected. Consulting the APHIS website at <http://www.aphis.usda.gov/ppq/permits/plantproducts/index.html> is recommended. If the collector plans to bring prohibited category germplasm to the U.S. from abroad, by hand or as part of his/her baggage, a USDA Departmental Permit issued by APHIS is required (see additional information at <http://www.aphis.usda.gov/ppq/permits/plantproducts/prohibited.html>)]

19. How collections will be shipped to U.S. or other destination:

(For foreign explorations only)

[Explain how collections will be packed and shipped. Coordinate importation of germplasm with Maryann Loftus in PEO (see contact information on page 2), who will inform port inspectors about your arrival time and type of materials being imported. All materials will be sent from the port of entry to the Plant Germplasm Quarantine Center in Beltsville, Maryland for inspection. Funded explorers will be provided with a detailed protocol developed by PEO and approved by the Department of Homeland Security for handling germplasm imported into the U.S.]

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20. Disposition of germplasm after collection:
[All germplasm is deposited in the appropriate NPGS collection. For all foreign explorations, proposal should reflect contact with the appropriate NPGS crop curator(s) and Maryann Loftus. Ms. Loftus will provide the appropriate contact in the Plant Germplasm Quarantine Office for explorations resulting in the introduction of germplasm that must be quarantined. Note any special distribution arrangements made for quarantine, propagation, or increase. For domestic collections, work out distribution arrangements with the appropriate crop curator(s).

Have the appropriate NPGS curator(s) sign the Crop Curator Statement (Attachment A, page 7) to certify that they anticipate having the capacity to curate the collections. Include this statement with your proposal.]
21. Contacts and cooperators:
[Provide name, title, address, etc. for each and indicate how they have contributed or will contribute to the success of the mission.]
22. References consulted:
[If personal communications are cited, attach copy.]
23. Itinerary (in target area):
[Show enough major points on the itinerary and distances between them in kilometers or miles to permit a determination as to whether there will be sufficient time for transit and collecting. Provide an outline map showing the general itinerary. If any side trips by foot, horse, boat, etc. are planned, indicate approximate amount of time allowed for each.]

[NOTE: Begin Item 24 on a new page.]
24. Budget estimate:
[Show best estimate of cost for each participant for each budget item (air fare, excess baggage, per diem, vehicle rental, gasoline, driver, interpreter, supplies, etc.) for which the cost is \$100 or more. For per diem, do not exceed official US government per diem rates (for domestic rates, refer to:
<http://policyworks.gov/org/main/mkt/homepage/mkt/perdiem/perd04d.html> and for foreign rates, refer to <http://www.state.gov/m/a/als/prdm/>). Costs for most explorations are much less than the maximum rates, especially for travel in remote areas. Salaries of participating scientists cannot be included. Indicate all sources of funds (USDA, State, or other).]
25. Attach vitae:
[Vitae are required to comply with the following requirement of Directive 281.1. "Vitae of key personnel to include principal investigator(s), senior associate(s), and other senior professionals should be provided in order to assist evaluators to assess the competence and experience of the project staff." Limit publications to the last five years.]

CROP CURATOR STATEMENT

I have been in contact with [] concerning the planned plant exploration to []. I expect to have the capacity to curate the collections anticipated from this exploration.

Comments:

Curator's name	Location	Crop(s)
Signature	Date	

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Plant Exchange Office
USDA/ARS, Beltsville, Maryland

NPGS CODE OF CONDUCT FOR FOREIGN PLANT EXPLORATIONS

This code of conduct is intended to guide NPGS plant explorers when collecting germplasm in foreign countries. Explorations are the main means of acquiring plant genetic resources that are not available in national or international collections. The successful implementation of a plant exploration in a foreign country requires careful consideration of scientific, political, and cultural matters. A plant explorer on an NPGS-sponsored exploration must respect the laws, customs, and environment of the host country. NPGS plant explorations abide by the principle of national sovereignty over plant genetic resources recognized in the UNEP Convention on Biological Diversity and the UN FAO International Treaty on Plant Genetic Resources for Food and Agriculture. Accordingly, access to genetic resources is subject to prior informed consent of the national authority in the host country and shall be on mutually agreed terms.

The process of executing an NPGS-supported plant exploration can be broken down into several elements: 1) Planning and preparing an exploration proposal, 2) Pre-trip preparation following funding, 3) Pre-travel preparation in host country prior to collecting, 4) Fieldwork and collecting, 5) Post-fieldwork sorting and cleanup at host institution, 6) Follow-up upon return to home country. The requirements for completing each of these phases following legal, ethical, and conservation standards are presented below.

PLANNING AND PREPARING AN EXPLORATION PROPOSAL

Foreign plant exploration must include a host country collaborator. The ideal collaborator is a scientist already working with the target crop or crop group who would also benefit from the collection of the genetic resources. Collaboration with the national genetic resources programs in host countries is strongly encouraged. Host country scientists must be included in the planning process. Therefore, contact your potential host country collaborators as early as possible when planning an expedition.

Collectors are required to comply with all host country rules and regulations on access to genetic resources. Obtain prior informed consent from host country authorities as early as possible in the planning process. Your host may be able to assist you with application for access permission. However, your host may not be aware of the national requirement to obtain access permission and may only know about the need for local permissions. The Plant Exchange Office can assist with communication with host country authorities and establishing the terms of

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access agreements. This process should be started well in advance of the exploration.

Determine how your proposed expedition may benefit national programs in the host country. Typical benefits include training in germplasm exploration methods, establishment of national germplasm collections with backups in international genebanks, transfer of information and technology, and collaboration in publication of research results. Additional non-monetary benefits may be provided based on the specific needs of the host country.

Determine in advance where collections will ultimately be deposited and who will have access to them. All germplasm collected on NPGS explorations will be shared between the appropriate host country institutions and the NPGS. Germplasm deposited in the NPGS will be curated on behalf of the U.S. Government and become available to bona fide users, domestic or foreign. Germplasm collected on NPGS-supported explorations is considered in the public domain and cannot be patented by the U.S. Government. While the NPGS will notify recipients of any restrictions on particular accessions, it does not have control over how the end user might utilize germplasm. Host countries may request certain restrictions or requirements concerning intellectual property rights. The Plant Exchange Office reviews requested restrictions to ensure agreement with U.S. government policy. All potential restrictions must be clarified in advance of any collecting.

Determine who will provide transportation and how costs will be shared for the exploration. If host country institutions provide a vehicle, it is customary for visitors to cover all operating expenses, maintenance, and most repairs (except perhaps full cost of major repairs). In addition, it is not unreasonable for hosts to require reimbursement in the form of a rental agreement. This should be agreed to in advance to avoid later misunderstanding. Besides expenses, host institutions may require that U.S. collaborators provide per diem for host collaborators.

When a proposal is submitted to the NPGS, written proof of host country interest and collaboration is required, both from collaborating scientists and their institutions.

Collaborators should be notified when the proposal is submitted to the NPGS and be given a copy of the final proposal.

PRE-TRIP PREPARATIONS

Notify collaborators upon NPGS approval of proposal.

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Prepare a list of equipment and supplies that must be purchased and carried to host country. Unless prior arrangements have been made, do not assume that host institutions will be able to supply expeditions with plant presses, corrugates, paper bags, envelopes, field labels, etc. Find out in advance if you can bring hard-to-get supplies or materials needed by host country collaborators.

Ask host country scientists if they are interested in receiving germplasm

that can be provided from the NPGS collections. If so, arrange to carry the germplasm with you. Obtain any necessary import permits and phytosanitary certificates before departure. Consider taking copies of PCGRIN for crops of interest to host country scientists.

Visiting scientists should offer to present guest lectures at host institutions. They should travel with one or more lectures on activities of their home institution or their current research. Powerpoint presentations or other visual aids are useful. Scientific literature and a scientist's reprints are often the most valued gifts that can be left behind in host countries. Difficult to obtain publications and books are usually welcome contributions to host institutions. Ask in advance what literature is most needed.

TRAVEL PREPARATION IN HOST COUNTRY

Meet all collaborators, hosts, and essential government officials. Visits to government offices are important and appropriate.

Present seminars, share research activities and talk to graduate students.

Discuss with host colleagues the final responsibilities for trip expenses, itinerary, and how germplasm will be collected and divided.

FIELDWORK AND COLLECTING

Approach all plant collecting with a conservation ethic in mind. Do not collect so as to endanger any natural plant population. Leave sufficient material behind so that a plant population can naturally regenerate. For cultivated material, acknowledge the contribution of germplasm shared by farmers.

Respect the local farmers, who are the trustees of local genetic material, for their knowledge and continued preservation of the crop landraces they grow. Work with them; in most cases they have extremely useful information to share about how and why certain plants are grown.

Do not expect your hosts to work on national holidays. Respect their political or religious holidays as well as any important religious observances.

Follow your hosts' lead in observing local customs and behavior. While your preferred field attire may seem entirely appropriate in your home country, it may not be appropriate in foreign settings.

Be respectful when photographing people and sensitive sites. Always ask permission to take photographs of people. It is appropriate for people to ask for duplicates of photographs that you take of them. An instant camera that produces photos immediately can be extremely useful. Do not take photos that would be embarrassing to your hosts.

Avoid "pushing" your hosts to travel to areas where they feel uncomfortable. There may be good reasons for their reluctance to venture into areas of local unrest, even though desired germplasm is known to occur there.

Consider the need for voucher herbarium specimens for study by specialists in the NPGS and host countries. Wild species in particular should be documented by herbarium specimens and duplicates offered to herbaria in the host country. Photos documenting plant habit and habitat provide a valuable reference.

Take detailed notes and collecting information. Your hosts may want to take their own notes, but your data and notes should still be shared with them.

Approach foreign travel as a learning experience, keeping an open mind. There is usually a reason for everything. Do not criticize what may seem unusual or unnecessary by your standards.

A successful expedition requires that foreign and host scientists work together. Sharing of expertise and knowledge while undertaking fieldwork is essential.

POST-FIELDWORK CLEANUP

Equally divide all collected germplasm and herbarium specimens, unless otherwise prearranged. If only three seeds are collected, two go to the host institution and one to the NPGS. An alternate arrangement, which may be better under some circumstances, is for the host institution to grow out all of the seed and later ship a modest sample to the NPGS.

Obtain a phytosanitary certificate from the host country regulatory office. It is not unreasonable for a host to require a few days to help procure the necessary phytosanitary certificates or other export permits prior to departure.

Leave a photocopy of your field notes with the host institution. Specify when you expect to send typed notes or labels. Some institutions appreciate copies on diskette.

Draft at least a short joint trip report including all collaborators prior to departing the

host country.

Discuss with your hosts how they can take part in publishing results from the field collecting. They should be involved in publications that result from fieldwork in which they participated.

Be sensitive to host country constraints to germplasm exchange! Host institutions may not be able to release germplasm prior to your departure. Respect their requirements. Your hosts may be following government directives on policy over which they have no control. Do not place your hosts in an embarrassing situation.

FOLLOW-UP UPON RETURN

Promptly send a complete trip report and field collection data in final form to your collaborators, the NPGS site where the germplasm will be deposited, and the Plant Exchange Office. Acknowledge all host country participants as collectors in report and field collection data.

Arrange for shipment of any NPGS germplasm requested by your collaborators.

Maintain contacts with collaborators through timely correspondence.

Promptly follow through with non-monetary benefit sharing provisions of access agreements.

Acknowledge all exploration participants in presentations and papers.

Send letters to collaborators, hosts and government officials acknowledging their assistance. Duplicates of select photographs taken on the trip are always appreciated.

Provide the host country with a list of assigned identification numbers when collections have been incorporated into the NPGS.

Do not discuss problems encountered on any trip more widely than is necessary.

Plant Exchange Office
National Germplasm Resources Laboratory
Rm. 402, Bldg. 003, BARC-West
Beltsville, MD 20705-2350
Telephone: 301-504-5421
FAX: 301-504-6305
Email: kwilliams@ars-grin.gov

DATA COLLECTION FORM

Collector No. _____ Site Number _____ Date (DD/MM/YY) _____

Genus _____ Species _____ Subspecies/variety _____

Local Name (s) _____ Local name (s) in English _____

Country _____ Province/Subdivision _____ Village/town _____

Directions _____

Latitude _____ N S Longitude _____ E W Lat/lon source: GPS Map Elevation (m) _____

Sample source: wild farm house garden market (specify size): _____ research collection other: _____

Plant description

Collectors _____

Type Propagule Collected: Seed Cuttings Root Other (specify): _____

Improvement status: wild weedy landrace improved line advanced cultivar other: _____

No. plants found _____ No. plants sampled _____ Site size (m²) _____

Sampling method _____ Herbarium specimen: yes no Herb. spec. #: _____

Pop. abundance: abundant frequent occasional rare Pop. distribution: irregular uniform pure

SITE DESCRIPTION:

Exposure _____ Slope _____ Aspect _____

Site Physical _____

_____Site Vegetative _____

_____Soil _____ Soil sample: yes no Soil sample #: _____ Soil ph: _____
Stoniness _____ Drainage(1-well,4-poor): _____ Rhizobium sample: yes no Rhiz. sample #: _____Other notes _____

PLANT EXPLORATION REPORT
(Summary, not to exceed 1 page)

Participants:

(Name, title, full address, telephone number, FAX)

Countries visited:

Dates of travel:

Objectives:

Accomplishments:

III SUBMISSIONS FROM RELEVANT ORGANIZATIONS AND STAKEHOLDERS



聯合國
粮 舟 及
农 业 组 织

FOOD AND
AGRICULTURE
ORGANIZATION
OF THE
UNITED NATIONS

ORGANISATION
DES NATIONS
UNIES POUR
L'AUMENTATION
ET L'AGRICULTURE

ORGANIZACION
DE LAS NACIONES
UNIDAS PARA
LA AGRICULTURA
Y LA ALIMENTACION

منظمة
الأغذية
والزراعة
للمجتمع
المتحدة

Viale delle Terme di Caracalla,
00180 Roma, Italy

Cables:
FOODAGRI ROMI

Telex: 623KJ2 FAO I
610181 FAO I

Fax/indic: +39 0657053152

Telephone: +39 0657051

Our Ref.: UN 62/11

Your Ref.:

21 October 2004

Dear Mr Zedan,

Your letter of 29 April 2004, addressed to all relevant intergovernmental organizations and non-governmental organizations, requested views and information on a number of matters related to decision VII/19 of the Conference of the Parties, in preparation for the third meeting of the *Ad Hoc Open-ended Working Group on Access and Benefit-sharing*. I would be grateful if the attached comments could be taken into account.

Yours sincerely,

John H. Monyo
Assistant Director-General
Sustainable Development Development

45524

OCT 21 2004

ACTION VN

FILE

INFO GD, OT

Mr Hamdallah Zedan
Secretariat of the Convention on Biological Diversity
United Nations Environment Programme
393 Saint-Jacques Street, Suite 300
Montreal, Quebec
Canada H2Y 1N9

*2 of 3***CONVENTION ON BIOLOGICAL DIVERSITY: DECISION VII/19 ON ACCESS AND BENEFIT-SHARING AS RELATED TO GENETIC RESOURCES****REQUEST FOR INFORMATION****General**

As you know, since the 1970s, the FAO has been the major international forum dealing specifically with all aspects of agricultural genetic resources. The Inter-Governmental Commission on Genetic Resources for Food and Agriculture was established in 1983, and celebrates its tenth meeting and twentieth anniversary in November this year. The Commission, to which the majority of FAO's Members (165 countries) belong, and which is attended by other countries as observers, and by observers from other international inter-governmental organizations and international non-governmental organizations, has for twenty years been the only permanent international forum where governments debate and seek consensus on all aspects of genetic resources for food and agriculture. The CBD has, on several occasions, recognized the role of the FAO and its Commission in relation to agricultural biodiversity, including on access and benefit-sharing in relation to genetic resources for food and agriculture.

Like FAO, the CBD has recognized "the special nature of agricultural biodiversity, its distinctive features, and problems needing distinctive solutions" and has supported the work of the FAO Commission on Genetic Resources for Food and Agriculture. In particular, the CBD strongly supported the negotiations for, and welcomed the adoption of, the FAO International Treaty on Plant Genetic Resources for Food and Agriculture. It is of note that Bonn Guidelines are "without prejudice to the access and benefit-sharing provisions of the [Treaty]".

The CBD has also recognized the Commission's role in relation to farm animal genetic resources and has invited countries to "participate fully in the preparatory process for the first Report on the State of World's Animal Genetic Resources, and implement follow-up actions identified through the process that will contribute to conservation, sustainable use, access and benefit-sharing of animal genetic resources for food and agriculture".

Use of terms, definitions and/or glossary, as appropriate

It should be understood that all terms, definitions and/or glossary developed for the Bonn Guidelines apply only for the purposes of those Guidelines.

A number of the terms specified in paragraph 1(a) of decision VII/19B appear in the International Treaty on Plant Genetic Resources for Food and Agriculture, of which one is defined for the purposes of the Treaty:

"*Ex situ collection*" means a collection of plant genetic resources for food and agriculture maintained outside their natural habitat.

In addition, a Standard Material Transfer Agreement is being developed for the implementation of the Multilateral System of Access and Benefit-sharing under the Treaty, in the context of which the question of definitions will be considered.

International regime on access to genetic resources and benefit-sharing

An international regime on access and benefit-sharing should take full account of existing instruments and of the on-going work of the FAO's Commission on Genetic Resources for Food and Agriculture. In particular, it should:

- recognise the role and status of the International Treaty on Plant Genetic Resources for Food and Agriculture and its Multilateral System of Access and Benefit-sharing and, if appropriate, exclude it from the scope of the international regime;
- not contain language that may appear to define the scope and coverage of the Treaty and its Multilateral System, which is the sole prerogative of the Contracting Parties to the Treaty; and
- provide space for the possible development of a regulatory framework for farm animal genetic resources and other genetic resources of interest to food and agriculture, including on access and benefit sharing, which takes account of the special needs of agriculture, should the FAO's Commission consider this appropriate.

Measures, including consideration of their feasibility, practicality and costs, to support compliance with prior informed consent of the Contracting Party providing genetic resources and mutually agreed terms on which access was granted in Contracting Parties with users of such resources under their jurisdiction

On the question of the disclosure of origin of generic resources in applications for intellectual property rights, including the proposed International certificate of origin/source/legal provenance, it should be recalled that the International Treaty provides for a multilateral system of access and benefit sharing. Consequently, where such disclosure of origin or international certificate of origin/source/legal provenance relates to plant genetic resources for food and agriculture obtained from the Multilateral System, the Multilateral System should be identified as the origin/source/legal provenance of that material.

In relation to the questions raised in paragraph 10 of decision VII/19E, it should be noted that Contracting Parties to the Treaty, in exercise of their sovereign rights, agree to provide facilitated access to the plant genetic resources for food and agriculture covered by the Multilateral System and to share the benefits in a fair and equitable way on a multilateral basis. In addition, the terms under which access is provided, including the sharing of benefits arising from commercialization, will be contained in a standard Material Transfer Agreement (MTA) to be established by the Treaty's Governing Body. Compliance with the provisions of the Multilateral System (and all other aspects of the Treaty) by Contracting Parties will be promoted through procedures and mechanisms to be determined by the Governing Body (Article 21 of the Treaty). Contractual disputes arising under the standard MTA will be determined under normal national contract law, or in such other way as may be specified in the standard MTA.

Capacity building for access and benefit-sharing

In the area of plant genetic resources for food and agriculture, the Global Plan of Action for the Conservation and Sustainable Utilization of Plant Genetic Resources for Food and Agriculture was adopted in 1996. This contains twenty priority activities grouped in four theme areas:

- *In situ* conservation and development
- *Ex situ* conservation
- Use of plant genetic resources
- Institution and capacity building.

Work on the first Report on the State of World's Animal Genetic Resources could lead to the development of a similar plan of action for animal genetic resources. If the Commission so decides, similar plans could also be developed for other genetic resources of interest to food and agriculture.


UPOV

INTERNATIONALER
VERBAND
ZUM SCHUTZ VON
PFLANZENZÜCHTUNGEN
GENF, SCHWEIZ

UNION INTERNATIONALE
POUR LA PROTECTION
DES OBTENTIONS
VÉGÉTALES

GENÈVE, SUISSE

UNIÓN INTERNACIONAL
PARA LA PROTECCIÓN
DE LAS OBTENCIÓNES
VEGETALES

GINEBRA, SUIZA

INTERNATIONAL UNIÓN
FOR THE PROTECTION
OF NEW VARIETIES
OF PLANTS
GENEVA, SWITZERLAND

CBD

August 12, 2004

Dear Mr. Zedan,

I refer to the Notification 2004-035 Ref: SCBD/SEL/VN/GD/43652, dated April 29, 2004, in which relevant intergovernmental and non-governmental organizations have been invited to contribute to the work of the *Ad Hoc* Open-ended Working Group on Access and Benefit-sharing, the third meeting of which is tentatively planned to be held in February 2005.

As was specified in the letter dated April 7, 2004, of Dr. Kamil Idris, Secretary-General of UPOV, UPOV's contribution to the work of the *Ad Hoc* Open-ended Working Group on Access and Benefit-sharing would be based on the reply of UPOV to the Notification of June 26, 2003, "Access to Genetic Resources and Benefit-Sharing", adopted by the Council of UPOV on October 23, 2003, and sent to you under cover of a letter dated October 27, 2003. The Position is also placed on the UPOV Website as follows:

http://www.upov.int/en/news/2003/intro_cbd.html (in English)
http://www.upov.int/fr/news/2003/intro_cbd.html (in French)
http://www.upov.int/es/news/2003/intro_cbd.htm (in Spanish)
http://www.upov.int/de/news/2003/Intro_cbd.html (in German)

/...

Mr. Hamdallah Zedan
Executive Secretary
Secretariat of the Convention on Biological Diversity
United Nations Environment Programme
393 Saint-Jacques Street, Suite 300
Montréal, Québec H2Y 1N9
Canada

By fax: 001-514-288 6588 (6 pages)

UNEP/SCBD
44594
AUG 12 2004
ACTION <i>V/N</i>
FILE _____
INFO <i>03.6D</i>

2.

Mr. Hamdallah Zedan, Montreal – August 12, 2004

In the annex to this letter you will find UPOV's contribution to the following two specific areas:

- International regime on access to genetic resources and benefit-sharing;
- Measures, including consideration of their feasibility, practicality and costs, to support compliance with prior informed consent of the Contracting Party providing genetic resources and mutually agreed terms on which access was granted in Contracting Parties with users of such resources under their jurisdiction

I would appreciate it if you could arrange for the UPOV position as annexed to be made available to the participants of the *Ad Hoc Open-ended Working Group on Access and Benefit-sharing*.

Sincerely yours,



Rolf Jördens
Vice Secretary-General

Annex to the letter dated August 12, 2004, addressed to Mr. Hamdallah Zedan

International regime on access to genetic resources and benefit-sharing

General Comments

The International Union for the Protection of New Varieties of Plants (UPOV) is an intergovernmental organization, established by the International Convention for the Protection of New Varieties of Plants (the "UPOV Convention"). The UPOV Convention was adopted on December 2, 1961, and revised in 1972, 1978 and 1991. The Mission of UPOV, based on the UPOV Convention, is: "*To provide and promote an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants, for the benefit of society.*"

As of August 1, 2004, UPOV has 55 members¹. Furthermore, 21 States and two intergovernmental organizations have initiated, with the Council of UPOV, the procedure for becoming members of the Union and 46 other States have been in contact with the Office of the Union for assistance in the development of legislation on plant variety protection. It is therefore anticipated that more than 100 States or intergovernmental organizations may be members of UPOV in the future.

UPOV supports the view that the Convention on Biological Diversity (CBD) and relevant international instruments dealing with intellectual property rights, including the UPOV Convention, should be mutually supportive. Therefore, UPOV recommends that any international regime on access to genetic resources and benefit-sharing should be established and implemented in harmony with the UPOV Convention which provides an effective system for the protection of new varieties of plants while safeguarding access to plant genetic resources in the form of protected varieties and benefit-sharing.

Measures, including consideration of their feasibility, practicality and costs, to support compliance with prior informed consent of the Contracting Party providing genetic resources and mutually agreed terms on which access was granted in Contracting Parties with users of such resources under their jurisdiction

In the course of the development of an international regime, the *Ad Hoc Open-ended Working Group on Access and Benefit-sharing* should be invited to take into consideration the following:

¹ More detailed information concerning UPOV's membership can be found at:
<http://www.upov.int/en/about/members/index.htm>

Access to Genetic Resources

UPOV considers that plant breeding is a fundamental aspect of the sustainable use and development of genetic resources. It is of the opinion that access to genetic resources is a key requirement for sustainable and substantial progress in plant breeding. The concept of the "breeder's exemption" in the UPOV Convention, whereby acts done for the purpose of breeding other varieties are not subject to any restriction, reflects the view of UPOV that the worldwide community of breeders needs access to all forms of breeding material to sustain greatest progress in plant breeding and, thereby, to maximize the use of genetic resources for the benefit of society.

Disclosure of Origin

The requirement for "distinctness" in the UPOV Convention² means that protection shall only be granted after an examination to determine if the variety is clearly distinguishable from all other varieties, whose existence is a matter of common knowledge³ at the date of filing of the application, regardless of the geographical origin. Furthermore, the UPOV Convention provides that, if it is discovered that a breeder's right has been granted for a variety that was not distinct, that right shall be declared null and void.

The breeder is usually required, in a technical questionnaire that accompanies his application for protection, to provide information concerning the breeding history and genetic origin of the variety. UPOV encourages information on the origin of the plant material, used in the breeding of the variety, to be provided where this facilitates the examination mentioned above, but could not accept this as an additional condition of protection since the UPOV Convention provides that protection should be granted to plant varieties fulfilling the conditions of novelty, distinctness, uniformity, stability and a suitable denomination and does not allow any further or different conditions for protection. Indeed, in certain cases, for technical reasons, applicants may find it difficult, or impossible, to identify the exact geographic origin of all the material used for breeding purposes.

Thus, if a country decides, in the frame of its overall policy, to introduce a mechanism for the disclosure of countries of origin or geographical origin of genetic resources, such a mechanism should not be introduced in a narrow sense, as a condition for plant variety protection. A separate mechanism from the plant variety protection legislation, such as that used for phytosanitary requirements, could be applied uniformly to all activities concerning the commercialization of varieties, including, for example, seed quality or other marketing-related regulations.

² Reference to the UPOV Convention in this document should be understood as a reference to the latest Act of the UPOV Convention (the 1991 Act). The full text of the UPOV Convention can be found at: <http://www.upov.int/en/publications/conventions/1991/content.htm>

³ The matter of common knowledge is considered further in UPOV document "The Notion of Breeder and Common Knowledge" (C(Extr.)/19/2 Rev.). This document can be found at: http://www.upov.int/en/about/key_issues.htm

3.

Prior Informed Consent

With regard to any requirement for a declaration that the genetic material has been lawfully acquired or proof that prior informed consent concerning the access of the genetic material has been obtained, UPOV encourages the principles of transparency and ethical behavior in the course of conducting breeding activities and, in this regard, the access to the genetic material used for the development of a new variety should be done respecting the legal framework of the country of origin of the genetic material. However, the UPOV Convention requires that the breeder's right should not be subject to any further or different conditions than the ones required to obtain protection. UPOV notes that this is consistent with Article 15 of the CBD, which provides that the determination of the access to genetic resources rests with the national governments and is subject to national legislation. Furthermore, UPOV considers that the competent authority for the grant of the breeder's rights is not in a position to verify whether the access to genetic material has taken place in accordance with the applicable law in this field.

Summary

Since the legislation on access to genetic material and the legislation dealing with the grant of breeders' rights pursue different objectives, have different scopes of application and require a different administrative structure to monitor their implementation, UPOV considers that it is appropriate to include them in different legislation, although such legislation should be compatible and mutually supportive.

Benefit-Sharing

Breeder's Exemption

UPOV would be concerned if any mechanism to claim the sharing of revenues were to impose an additional administrative burden on the authority entrusted with the grant of breeders' rights and an additional financial obligation on the breeder when varieties are used for further breeding. Indeed, such an obligation for benefit-sharing would be incompatible with the principle of the breeder's exemption established in the UPOV Convention whereby acts done for the purpose of breeding other varieties are not, under the UPOV Convention, subject to any restriction and the breeders of protected varieties (initial varieties) are not entitled to financial benefit-sharing with breeders of varieties developed from the initial varieties, except in the case of essentially derived varieties (EDV). Furthermore, a benefit-sharing mechanism within the legislation to grant breeder's rights, would seem to tax only "protected" varieties and, instead of creating incentive mechanisms to develop new varieties, may provoke the opposite effect, whereby breeders would not develop new varieties or would not seek protection (favoring a legally insecure environment).

The Food and Agriculture Organization of the United Nations (FAO), at its 31st Conference, on November 3, 2001, adopted the International Treaty on Plant Genetic Resources for Food and Agriculture. This Treaty (Article 13.2. (d)(ii)) recognizes the concept of the breeder's exemption, in that breeders are exempted from financial benefit-sharing whenever their products are "available without restriction to others for further research and breeding ...".

Subsistence Farmers

In addition to the breeder's exemption and the research exemption, the UPOV Convention contains another compulsory exception to the breeder's right whereby the breeder's right does not extend to acts done privately and for non-commercial purposes. Therefore, activities of subsistence farmers, where these constitute acts done privately and for non-commercial purposes, are excluded from the scope of the breeder's right and such farmers freely benefit from the availability of protected new varieties.

Farm-Saved Seed

The provision on "farm-saved seed" (also known as the "farmer's privilege") is an optional benefit-sharing mechanism provided by the UPOV Convention, under which UPOV members may permit farmers, on their own farms, to use part of their harvest of a protected variety for the planting of a further crop. Under this provision, members of UPOV are able to adopt solutions, which are specifically adapted to their agricultural circumstances. However, this provision is subject to reasonable limits and requires that the legitimate interests of the breeder are safeguarded, to ensure there is a continued incentive for the development of new varieties of plants, for the benefit of society. For example, certain members of UPOV apply the provision on farm-saved seed only to certain species or limit its application using criteria such as the size of the farmer's holding or the level of production.

Summary

Mechanisms of benefit-sharing should take into account the need for a relationship of mutual supportiveness in respect of the essential principles of the UPOV system of plant variety protection and, in particular, of the breeder's exemption provision.

Conclusion

UPOV considers that plant breeding is a fundamental aspect of the sustainable use and development of genetic resources. It is of the opinion that access to genetic resources is a key requirement for sustainable and substantial progress in plant breeding. The concept of the "breeder's exemption" in the UPOV Convention, whereby acts done for the purpose of breeding other varieties are not subject to any restriction, reflects the view of UPOV that the worldwide community of breeders needs access to all forms of breeding material to sustain greatest progress in plant breeding and, thereby, to maximize the use of genetic resources for the benefit of society. In addition, the UPOV Convention has inherent benefit-sharing principles in the form of the breeder's exemption and other exceptions to the breeder's right and UPOV is concerned about any other measures for benefit-sharing which could introduce unnecessary barriers to progress in breeding and the utilization of genetic resources. UPOV urges the Ad Hoc Open-ended Working Group on Access and Benefit-sharing to recognize these principles in its work and to ensure that any measures it develops are supportive of these principles and, therefore, of the UPOV Convention.

-----Original Message-----

From: Otten, Adrian [mailto:Adrian.Otten@wto.org]
Sent: Tuesday, September 14, 2004 3:59 AM
To: gordana dosen
Cc: Watal, Jayashree; Smith, Sandra; Wu, Xiaoping
Subject: RE: Decision VII/19 on Access and Benefit-sharing as related to genetic resources

In the e-mail below the WTO was invited to take specific actions to contribute to preparatory work for the third meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing and submit relevant information on access and benefit-sharing as related to genetic resources by 15 September 2004 for dissemination in accordance with decision VII/19 of the Conference of the Parties to the Convention on Biological Diversity.

The issue of the relationship between the WTO TRIPS Agreement and the CBD, including the question of access and benefit sharing, was raised in the TRIPS Council in 1999 under the agenda item "Review of Article 27.3(b) of the TRIPS Agreement" and has been under discussion since that time. The Doha Ministerial Declaration of November 2001 specifically mandated the TRIPS Council *inter alia* to continue its examination of the issue of the relationship between the TRIPS Agreement and the CBD and the protection of traditional knowledge and folklore. Since then these two subjects have been specifically put on the agenda of the TRIPS Council.

The work on these issues has, however, not been concluded and hence no agreements have been reached in the WTO on such matters as the use of terms, definitions and/or glossary or other approaches that we can convey to you in response to your questions. The same applies to measures to support compliance with prior informed consent or on access and benefit-sharing.

With regard to capacity building, while the WTO Secretariat has no specific project relating to access and benefit sharing, we do provide technical assistance to developing countries on an ongoing basis to facilitate their effective participation in the work programme of the TRIPS Council, including on the subject of the relationship between the TRIPS Agreement and the CBD and the protection of traditional knowledge and folklore. Our technical cooperation activities take place in Geneva as well as at the regional, sub-regional and national levels in accordance with our annual technical assistance plan.

Should you need any further assistance, please feel free to contact me or my colleague Mrs. Jayashree Watal.

Adrian Otten

Adrian Otten
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EXPLANATORY NOTE

IUCN ACTIVITIES ON ABS

This document provides a list of ongoing and recent initiatives on ABS undertaken by IUCN. It also provides a list of documents, publications and briefs. Most of this information has already been submitted to the CBD Secretariat. All documents listed and detailed information about projects, workshops and initiatives are available upon request.

IUCN has a longstanding involvement in ABS related initiatives. IUCN work includes legal and policy aspects and is implemented at the national, regional and global levels through our regional and country offices and different global programmes. Recent and ongoing projects include:

The Policy, Biodiversity and International Agreements Unit (PBIA)

The Policy, Biodiversity and International Agreements Unit (PBIA) is carrying out a project entitled *Supporting the Global Biodiversity Agenda (2003-2005)* with funds from the German Ministry of Development Cooperation (Bundesministerium für wirtschaftliche Zusammenarbeit und Entwicklung - BMZ). The prime objective of this project is to provide policy options for the implementation of paragraph 44 (o) of the WSSD Plan of Implementation which establishes a mandate to negotiate, within the framework of the Convention on Biological Diversity, an international regime "to promote and safeguard the fair and equitable sharing of benefits arising out of the utilisation of genetic resources." The development of such an international regime must be supportive of, national and regional efforts in order to lead to effective outcomes. In addition, these efforts must be coherent with each other, as well as with related global regimes of the World Trade Organisation (WTO) (especially TRIPS), the World Intellectual Property Organisation (WIPO), and the FAO International Treaty on Plant Genetic Resources for Food and Agriculture, as well as regional regimes. In sum the PBIA project focuses on providing policy options for an international regime on ABS with a particular focus on the following three areas - (i) Trade and Development Aspects, (ii) Protecting Traditional Knowledge, (iii) Ensuring Gender Equity.

The project has organised three regional workshops in Asia, Africa and Latin America and supported the organisation of a workshop on ABS for the Countries of the Indian Ocean. The discussion of ABS issues allowed for an active participation and the production of key information material as well as dialogues and side events in the context of the CBD, WIPO and WTO (list of technical papers and policy briefs below and online: <http://www.iucn.org/themes/pbia/>).

Future work include a Global Synthesis Workshop to exchange experiences and opinions about the International Regime on ABS, a publication on key issues of the three regional workshops; the development of technical papers on ABS and trade; traditional knowledge and customary law; and, the completion of draft papers on gender and Prior Informed Consent.

IUCN Environmental Law Centre, ELC

The ABS Project, being implemented by the IUCN Environmental Law Centre, with funding from the German Ministry of Development Cooperation (Bundesministerium für wirtschaftliche Zusammenarbeit und Entwicklung - BMZ). The project has developed researched analytical tools, legislative development tools and informational documents in support of the work of national delegations in all-important decisions regarding the creation of an "international regime on ABS" and providing direct and indirect assistance at the national level to the creation of national ABS frameworks and contractual arrangements.

The first stages of this work have produced legal analyses and interim reports and hypotheses (available online at <http://www.iucn.org/themes/law/abs01.html>) that have already provided a sound analytical basis for early work at the international and national levels on the international ABS regime.

It has produced a detailed evaluation of national ABS legislation (J. Cabrera - "A Comparative Analysis On the Legislation And Practices On Access To Genetic Resources And Benefit Sharing: Critical Aspects For Implementation And Interpretation" (IUCN, 2004 pamphlet) which includes a table of specific provision from national law on many issues, including definitions, PIC and MAT, and ABS processes. A copy of this pamphlet was already provided to the CBD Secretariat.

In 2003, the IUCN ELC project has sponsored (with SPDA, INE, and INRENA) a workshop to discuss and develop the idea of an international certificate of origin. The report of that workshop has been made available to the CBD Secretariat.

The ELC Project is also co-sponsoring with the University of California at Davis, the publication of a formal compendium of analyses of ABS in the Pacific Rim countries, again addressing many of these issues in detail. Our co-sponsor UC Davis, has provided (or is in the process of providing) the CBD Secretariat with a pre-publication copy of this work as well.

**Asian Regional Office
Regional Biodiversity Programme, Asia (RBP)**

IUCN RBP is working on strengthening the capacities of countries to deal with ABS issues by supporting training programs, workshops and development of communication material. Working closely with the ASEAN Secretariat, RBP is committed to strengthening the implementation options for ASEAN of the regional ABS framework.

IUCN's Regional Office for Asia is actively working on building the capacities of countries in the region to work towards the development of national regimes of ABS, through training programmes, workshops; development of communication material; publication of issue and policy briefs, guidelines and a hand-book. The office is also supporting policy making on ABS at ASEAN level and to further discussions on the International Regime on ABS. Current activities include training on development of bioprospecting, negotiating agreements and developing national ABS Frameworks for Vietnam and Bangladesh (for more information please see www.biodiversityasia.org

SOUTH AFRICA NATIONAL PROJECT ON ABS

'Support for the Implementation of Access and Benefit-Sharing Legislation in South Africa',
(September 2001 to July 2003)

The project had four main components: The preparation of international and national studies, and the publication of these studies (list provided below); the development of recommendations to influence the drafting of regulations on ABS and promote the recommendations with relevant agencies, institutions and other stakeholders; drafting and development of regulations and guidelines to facilitate the implementation of the legislation on ABS; and, capacity building workshops for provincial governments and stakeholders on the use of such regulations and guidelines in South Africa.

The research studies produced served as a valuable resource to a number of government officials, on both the national and provincial level. The consultation processes with provincial and national government officials during the research process stimulated debate and also facilitated the sharing of information between the different conservation agencies playing a role in regulating bioprospecting.

An output of this process is the publication of a book, which contains all the research studies. It is entitled 'Developing access and benefit-sharing legislation in South Africa: a review of international and national experiences'. It is expected that this book will be used as resource material by different stakeholders in the process of the development of the regulations and procedure guidelines, and in the development of the National Biodiversity Strategy and Action Plan (NBSAP).

Currently, a second phase of this project is been implemented. The focus of the project is to support the South African government in the development of best practice models for the administration and implementation of legal mechanisms for access to genetic resources and benefit sharing.

OTHER WORK ON ABS

IUCN Canada Office, the Environmental Law Centre and the SCBD have established an agreement to undertake research on ABS arrangements and measures to promote legal certainty for users of genetic resources.

LIST OF PUBLICATIONS, BRIEFS, TECHNICAL DOCUMENTS AND OTHER RELEVANT INFORMATION

I. POLICY BRIEFS AND INFORMATION PAPERS FOR CBD RELATED MEETINGS

1. CBD-SBSTTA8 and MYPOW 10 – 20 March, 2003, Montreal, Canada
 - Policy Brief: International Regime on Access and Benefit-Sharing- María Fernanda Espinosa and Tomme Young.
2. AHWG ABS, 1- 5 December, 2003, Montreal, Canada
 - Information Paper: Access to Genetic Resources, Intellectual Property Rights and Biodiversity: Processes and Synergies– Manuel Ruiz

3. WIPO IGC, 15 –19 March, 2004 Geneva, Switzerland

- Integrating African Perspectives and Priorities into Genetic Resource Regulations: A Resource Guide for Policymakers - Kent Nnadozie
- International Negotiations on Biodiversity, Genetic Resources and Intellectual Property: Implications of the WIPO Intergovernmental Committee's New Mandate - By David Vivas-Eugui, María Fernanda Espinosa and Sebastian Winkler
- Vision of Indigenous Peoples in the context of the decisions pertaining Access to Genetic Resources and Benefit Sharing (ABS) and Article 8j: An Analysis of the Impacts of CBD/COP Decisions with respect to WIPO's IGC Mandate - Rodrigo de la Cruz

4. CBD-COP7, 9- 20 February, 2004, Kuala Lumpur, Malaysia

Recommendation paper:

- Access and benefit-sharing as related to genetic resources - Tomme Young, María Fernanda Espinosa, and Martha Chouchena- Rojas.

Information papers:

- Access and Benefit Sharing in the Context of the Convention on Biological Diversity (Agenda item 19.11) by Tomme Young.
- ABS: Access to Genetic Resources, Intellectual Property Rights and Biodiversity: Processes and Synergies (Agenda item 19.11) by Manuel Ruiz.
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Susan Kling Finston
ASSOCIATE VICE PRESIDENT
INTERNATIONAL AFFAIRS

October 5, 2004

Hamdallah Zedan
Secretariat, Convention on Biological Diversity
World Trade Center
393 St. Jacques St., Suite 300
Montreal, Quebec
Canada H2Y 1N9

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REC'D BY:
OCT 8 2004
ACTION VN
FILE
INFO GD, OJ, HZ

Dear Mr. Zedan,

The international research-based pharmaceutical and bio-pharmaceutical industry appreciates the opportunity provided by the Convention on BioDiversity (CBD) Secretariat to provide our views in response to the Notification (Ref: SCBD/SEL/VN/GD/43652, 29 April 2004, Decision VII/19) relating to upcoming negotiations under the CBD in the areas of Access and Benefit Sharing (A/BS) for non-human genetic resources. Based on consideration of relevant issues in consultation with pharmaceutical industry organizations in Europe and Japan and the broader biotechnology sector, members of the Pharmaceutical Research and Manufacturers of America (PhRMA) are pleased to provide a brief summary of our views on A/BS. We hope that this will serve as a first step towards the proactive and positive engagement by the research-based pharmaceutical and bio-pharmaceutical industry in the upcoming negotiations scheduled for initiation in Bangkok, Thailand in early 2005.

As you may be aware, PhRMA members continue to support sharing of benefits relating to access to non-human genetic resources, and have been pioneers in establishing durable benefit sharing arrangements going back nearly 25 years. PhRMA members also recognize that the CBD is the major international multilateral organization enjoying full jurisdiction over the negotiation of a comprehensive regime for Access and Benefit Sharing relating to non-human genetic resources. Accordingly, given the remit provided by Ministers at the Conference of Parties (COP-7) in Malaysia for the negotiation of a comprehensive international instrument in the A/BS area relating to non-human genetic resources, PhRMA members seek to provide clarity and transparency in industry's views by communicating our position directly to the CBD Secretariat.

As we move forward on further development of these principles, we value your insights and candor both on substance and process. Logistically, PhRMA members will follow up with your staff, to ensure accreditation of business originated non-government organizations in the Bangkok meeting and other preparatory meetings open to NGOs, as well as on the scheduling of parallel

Pharmaceutical Research and Manufacturers of America

-2-

non-official events and any other opportunities for industry to exchange views with CBD members on these important issues. Finally, we would also appreciate the opportunity to explore precedents in other UN organizations on the possible engagement of non-CBD members in participation in the upcoming A/BS negotiations.

Thank you in advance for your consideration of industry perspectives on these important issues. I hope that you find the attached statement of industry A/BS principles to be helpful in the run-up to Bangkok.

Sincerely yours,

Susan Kling Finston

Susan Kling Finston

Industry Proposal for an International Regime on Access and Benefit Sharing of Genetic Resources (“A/BS”)

Introduction: Industry recognizes the sovereign rights of countries over their genetic resources, and supports equitable sharing of the commercial benefits from the sustainable development of such non-human genetic resources. Key open issues are (i) the appropriate balance of those benefits and (ii) the identification of mechanisms to ensure that the appropriate commercial development of genetic resources and related traditional knowledge (“TK”) is encouraged, with incentives to ensure mutual benefits to developing countries and private industry.

Industry supports the negotiation of a binding international A/BS regime in the Convention on Biological Diversity (“CBD”). The CBD is the sole international organization that has the full remit on non-human plant, animal, or microbial materials found *in situ* from 1992 onwards, and is the only international organization considering A/BS that does not have a strictly intellectual property mandate. As opposed to the WTO or WIPO, the CBD is not required to focus solely on intellectual property-based approaches to A/BS.

An intellectual property-based approach to A/BS that affects patentability is undesirable: it would raise important practical difficulties, threaten certainty in patent rights and result in very little benefit to the owners of the genetic resources and TK. Should a patent be rescinded or not granted, there would be no benefits to share, and future investment in natural-products development would be chilled. Furthermore, an approach that relies solely on the sharing of revenue streams from patents fails to take into account other benefits, such as technology transfer and capacity building assistance, that are not linked to patenting, which could accrue to developing countries in exchange for access to their genetic resources. Finally, support for a patent-based approach in the CBD may be more limited than we had previously assumed -- there are a number of different groupings of developing countries that may prefer an alternative system.

Essential elements of the industry proposal for a binding international agreement on A/BS:

- It would follow a contractual model with up-front full disclosure and transparency, in the larger context of an international agreement signed by CBD members. Prior to removal of any genetic resources from the territory of a CBD member, companies would be required to enter into agreements or memoranda of understanding with the CBD members as owners of the genetic resources and/or the TK. These agreements would spell out benefit sharing arrangements and would include sanctions for non-compliance.
- CBD members of the international agreement would be obliged to establish and maintain a database of all non-human genetic resources found within their borders and all TK attaching to those genetic resources. The database would provide

certainty and predictability by including reference to the "owners" of the TK.*
(This is similar to the focal points included in the Bonn Guidelines.)

- The international agreement would also include a commitment by CBD Member Countries to establish and maintain a national registry that would track the individual agreements ("MOUs") negotiated under the terms of the international agreement. CBD member registries would not disclose business sensitive terms of the MOUs, but would provide information on the genetic resources, private party, and the date of the agreement.
- Companies failing to enter benefit sharing agreements prior to conducting *in situ* bio-prospecting, or to otherwise disclose bio-prospecting activities, would face possible civil penalties under the terms of the agreement, including, for example, suspension of rights in the country and links to research institutions, suspension of visas, a civil monetary penalty, etc.
- International arbitration or other possible dispute settlement processes could be developed to ensure enforcement of commitments made between parties.
- Developed country members would be obligated to provide technical and capacity building assistance to accelerate the ability of developing country members to negotiate effectively with companies.

Next steps: In the run-up to the February 2005 launch of the two-year CBD negotiations on Access and Benefit Sharing, industry seeks to begin a series of consultations with key Parties and stakeholders.

Date: September 27, 2004

* CBD Members, and not industry, would be responsible for any separate benefit sharing arrangements with indigenous peoples or other local communities with TK interests, along the lines of the South African CSIR/San Tribe arrangements.

15 de setiembre del 2004

Secretariado Convención en Diversidad Biológica
S.D.

En relación a la invitación hecha por Ustedes para brindar contribuciones sobre diversos tópicos relacionados con Acceso y Distribución Justa y Equitativa de los Beneficios Derivados (ADB), remitimos lo siguiente:

1.- La utilización de términos, definiciones y/o glosarios, según proceda.

Este punto lo consideramos importante ya que a través de esos conceptos, se define un modelo específico de acceso a los recursos genéticos. Por lo tanto, una consulta como esta, debe responder a criterios de información previa para que exista amplia participación, justicia y equidad ya que en la mayoría de las oportunidades, las consultas obtienen respuestas de únicamente, los respectivos gobiernos. Consideramos que, para que exista un proceso como el mencionado, deben implementarse a nivel nacional y desde el Secretariado de la CDB, mecanismos que aseguren en primer lugar acceso a la información para que luego los diversos grupos, en especial Pueblos Indígenas, comunidades campesinas y locales así como ONGs, puedan participar. Una vez implementados estos mecanismos deberán definirse de igual forma cómo se incorporaran o no las diversas contribuciones y cómo se hará llegar los documentos enriquecidos mediante este proceso de participación a quienes formaron parte de este proceso. La participación debe buscarse y construirse más allá de las vías electrónicas ya que el acceso a las mismas siempre es limitado.

Para nuestra organización, la participación ciudadana es un Derecho Humano fundamental que poseen las personas y que debe ser garantizado por el Estado y las instituciones internacionales. Funciona como eje vitalizador dentro de regímenes democráticos ya que solamente a través de esta, se puede cumplir con los objetivos tendientes al mejoramiento de la calidad de vida. Lo anterior, cobra todavía mayor importancia cuando se relaciona a otro Derecho Humano cual es el Derecho Humano a contar con un ambiente sano y ecológicamente equilibrado ya que este posee una estrecha relación con el anterior.

"La participación ciudadana es la base y el modo legítimo de actuar en democracia. (...) Asimismo, la participación es un proceso por el cual los diferentes grupos sociales influencian y comparten el control sobre el desarrollo de iniciativas o políticas que los afectan. Estos grupos sociales cuyos intereses se ven afectados por políticas, acciones, actividades o medidas que se tomen en determinado momento, deben tener, a su vez la oportunidad de expresar su opinión sobre las consecuencias de esas decisiones y de cómo les puede afectar."

Del mismo modo, la participación puede verse como un principio jurídico, entendido como la consagración de disposiciones jurídicas generales que orientan la interpretación en esta materia y así, se configuran al mismo tiempo como normas de aplicación inmediata.

Como Derecho Humano, la participación ciudadana es tomada por la Declaración de Río en diversos de sus artículos. Este principio jurídico y Derecho Humano se encuentra íntimamente relacionado a la democracia y no puede restringirse a la elección de representantes ante el gobierno sino que se relaciona con la toma de decisiones con respecto al modelo de desarrollo y gestión de los recursos naturales por ejemplo. De este modo, la Declaración de Río en el principio X sostiene lo siguiente:

"El mejor modo de tratar las cuestiones ambientales es con la participación de todos los ciudadanos interesados en el nivel que corresponda. En el plano nacional, toda persona deberá tener acceso adecuado a la información sobre el medio ambiente de que dispongan las autoridades públicas, incluida la información sobre los materiales y las actividades que ofrecen peligro en sus comunidades, así como la oportunidad de participar en los procesos de adopción de decisiones.

Los Estados deberán facilitar y fomentar la sensibilización y la participación del público poniendo la información a disposición de todos. Deberá proporcionarse acceso efectivo a los procedimientos judiciales y administrativos, entre éstos el resarcimiento de daños y los recursos pertinentes."

Este principio es de gran importancia porque no aísla la participación de la información. Para que los diversos actores sociales puedan participar en igualdad de condiciones y tomar decisiones con respecto al estilo de desarrollo que se quiere, es necesario contar con la información necesaria para tal efecto. El ligamen encuentra sustento jurídico ya que ambos – participación e información – son en primer término, derechos humanos. En ambos además, el titular es la comunidad y por ende, poseen carácter colectivo y uno es sustento del otro. Por último, podemos señalar que los dos se sitúan por sus características, en lo que se ha denominado Derechos Humanos de la tercera generación. Es necesario señalar que siendo necesaria la información para la participación en cualquier espacio, quienes los coordinan, tienen la obligación de brindar toda la información necesaria, disponible y requerida en aras de que todos los actores y actoras participen en igualdad de condiciones.

Encuentra sustento en los siguientes convenios internacionales: Declaración Universal de los Derechos Humanos (artículos 2, 7, 19, 25), Declaración Americana de los Derechos y Deberes del Hombre (artículos IV, XXIV), Convención Americana sobre Derechos Humanos (artículo 23,2), Pacto Internacional de Derechos Civiles y Políticos (artículo 1).

Por lo tanto, podemos concluir que la participación es un derecho humano fundamental que debe ser garantizado por el Estado.

Con respecto a los conceptos consultados manifestamos lo siguiente:

- ❖ **acceso a recursos genéticos:** es la acción mediante la cual una parte interesada habiendo cumplido con todos los requisitos legales correspondientes en la legislación nacional e internacional, hace uso de los recursos genéticos. La

autorización correspondientes es personal e intransferible y deberá ser otorgado por la autoridad nacional competente siempre y cuando se compruebe fehacientemente que existe consentimiento previamente informado de parte del poseedor o dueño del recurso a accesar y que existen los suficientes mecanismos de control y seguimiento al uso que se le dará a esos recursos.

- ❖ **participación en los beneficios:** es una obligación que debe cumplirse en toda acción de acceso a recursos genéticos o al conocimiento tradicional que exista. Esta obligación se deriva de la Convención en Diversidad Biológica. Esta participación debe ser justa y equitativa y para que cumpla con estos requisitos esenciales, deben existir previo al otorgamiento de los permisos respectivos acceso a información, plazos para que el proveedor del recurso analice en forma independiente esa información y definición de mecanismos de control sobre el uso que se le dará a los elementos objeto del acceso.
- ❖ **comercialización:** aprovechamiento económico de recursos genéticos o del conocimiento tradicional.
- ❖ **proveedor:** es una persona física o jurídica que es responsable, posée o es dueño de bienes donde se encuentren los recursos genéticos que quieren accesarre. Igualmente son las personas o grupos de personas (Pueblos Indígenas o comunidades campesinas y locales) que son responsables del conocimiento tradicional.
- ❖ **Usuario y parte interesada:** es quien solicita el acceso, sea persona física o jurídica, nacional o extranjera interesada en obtener el acceso a los recursos genéticos o al conocimiento tradicional. Este obtendrá un derecho personalísimo que por lo tanto es intransferible.

2.- Otros enfoques conforme se establece en la decisión VI/24 B: los enfoques adicionales se ven como complementos a las Directrices de Bonn y como herramientas que pueden ayudar a las Partes y partes interesadas en la aplicación de las disposiciones sobre el acceso a los recursos genéticos y la participación en los beneficios del Convenio. Estos enfoques adicionales se refiere a marcos jurídicos regionales (como el del Pacto Andino, un proyecto centroamericano, otro asiático y uno africano); otros tratados internacionales así como algunas directrices voluntarias provenientes de sujetos interesados en contar con el acceso tales como jardines botánicos y otras empresas privadas. Todos estos enfoques adicionales, lejos de cuestionar los derechos intelectuales sobre formas de vida contenidos en disposiciones de la Organización Mundial del Comercio (OMC), los legitiman.

Un aspecto importante es la discusión en torno al certificado internacional de origen, un instrumento por medio del cual se busca enunciar siempre de donde provienen los recursos genéticos o el conocimiento tradicional que es objeto del acceso y que incluye además el consentimiento previamente informado. La discusión sobre si este certificado, puede constituirse en un requisito para el patentamiento implica su supeditación a las normas del Acuerdo sobre Derechos de Propiedad Intelectual relacionados al Comercio (ADPIC) de la OMC. Bajo esta propuesta, habría que indicar siempre el origen de por ejemplo, el conocimiento tradicional más su caracterización haciendo público de esta forma, detalles que pueden ser sagrados para determinados Pueblos Indígenas o comunidades locales. Bajo esta premisa, se favorece la

cosificación del conocimiento tradicional así como de la diversidad biológica: todo giraría en torno al patentamiento de la biodiversidad y del conocimiento tradicional, que es al final de cuentas, uno de los aspectos centrales de la industria que busca el acceso ya que según su discurso, no invierten si no se les garantiza los derechos monopólicos a través de los derechos de propiedad intelectual. Es un asunto de control de los recursos genéticos. De esta forma, aspectos que podrían constituirse en herramientas para la promoción de la participación en la toma de decisiones, se convierten en meros requisitos de la patentabilidad. Por lo tanto no compartimos que este instrumento sea un mero requisito para obtener patentes.

3.- Sobre el régimen en general: en el anexo número I adjuntamos varios artículos publicados a raíz de la recién finalizada COP 7 en esta materia.

4.- Medidas, incluido el examen de su viabilidad, aplicación en la práctica, factibilidad y costos, para apoyar el cumplimiento del consentimiento fundamentado previo de la Parte Contratante que proporciona dichos recursos y de las condiciones mutuamente acordadas con arreglo a las que se concedió el acceso en las Partes Contratantes con usuarios de recursos genéticos bajo su jurisdicción: el consentimiento previamente informado, ha sido vendido como un instrumento que asegura que cualquier permiso de acceso que se brinde, se otorgue una vez se informe al proveedor del recurso. Se dice que pone en vigencia los derechos a la información y a la participación en la toma de decisiones sin embargo, en las propuestas examinadas, se le supedita a los derechos de propiedad intelectual y no se hace referencia a mecanismos existentes como la consulta del artículo 6 del Convenio 169 de la Organización Internacional del Trabajo y otros aspectos de fondo que posee este Convenio. El consentimiento previamente informado es un aspecto que necesita de mayor discusión sobretodo de parte de los pueblos indígenas y comunidades locales, quienes si lo aceptan, deben de conceptualizarlo según sus prácticas culturales. En el documento respectivo, sentimos que este procedimiento se debilita al sugerir, que este se convierta en un requisito para el patentamiento tal y como fue expuesto cuando nos referimos al certificado de origen. ¿A favor de quien se está si un instrumento del que se dice puede permitir la participación informada de comunidades locales o pueblos indígenas se supedita a otros criterios como los económicos?

5.- Las necesidades de creación de capacidades de los países para aplicar las Directrices: que hace énfasis en políticas y legislación nacionales, medidas para los usuarios, ciencia y tecnología y mejor participación de los interesados. Por medio de los puntos anteriores se facilita el acceso sin tomar en cuenta los aspectos apuntados en los primeros párrafos de este documento.

Agradeciendo su atención al presente documento,

Se despide de Usted,

Isaac Rojas
Amigos de la Tierra

ANEXO I

PROFUNDIZANDO LA PRIVATIZACIÓN Y LA COMERCIALIZACIÓN

Elaborado por Isaac Rojas
COECOCeiba-Amigos de la Tierra Costa Rica

Durante los últimos años, la temática relacionada con acceso a recursos genéticos y la distribución justa y equitativa de los beneficios derivadas del mismo (ADB), ha tomado una importancia central en las discusiones sobre biodiversidad. De esta forma hemos presenciado como desde diversos foros previos a la celebración de la séptima Conferencia de las Partes del Convenio en Diversidad Biológica, se recomendaba impulsar negociaciones para contar con un instrumento internacional en esta materia.

La temática de ADB es controversial porque necesariamente se relaciona con otra serie de temas igualmente controversiales: derechos colectivos de Pueblos Indígenas y Comunidades Locales en cuanto a los elementos de la biodiversidad, propiedad intelectual y marcos jurídicos son algunos de ellos.

La CDB afirma que el desarrollo de esta temática se debe al cumplimiento de uno de sus tres objetivos principales y por esto es que desde 1999 hasta la fecha, ha convocado y desarrollado varias reuniones que culminan una etapa en la recién celebrada COP 7 donde se lanzan las negociaciones para contar con un borrador sobre un régimen internacional sobre ADB. Pensamos sin embargo, que el gran desarrollo de este objetivo de la CDB no se ha realizado en forma equilibrada con otros aspectos claves sujeto de negociaciones dentro de esta convención internacional: derechos de Pueblos Indígenas y Comunidades Locales contenidos en la CDB es un ejemplo de ello. Así, mientras por un lado se empuja por el ADB, se deja de lado el fortalecimiento de los derechos de grupos sociales que juegan un papel clave en esta discusión. Lo referido al desarrollo del consentimiento previamente informado (CPI) puede ilustrarnos lo anterior. Este instrumento podría ser una herramienta que, bajo ciertas circunstancias, podría asegurar el respeto a la decisión que los Pueblos Indígenas o las Comunidades Locales en cuanto a permitir si puede concederse o no el acceso sobre determinados elementos de la biodiversidad. Podríamos pensar que desde la CDB y en lo relacionado a este punto, debe discutirse cómo hacer pleno este derecho mediante el acceso a la información necesaria para ser analizada en forma independiente de parte de los Pueblos Indígenas o Comunidades Locales (para lo cual deben de brindarse las condiciones necesarias) o bien, sobre mecanismos de control que aseguren que el acceso se utiliza para lo que fue solicitado además de posteriores controles que aseguren verificaciones sobre el uso de los recursos objeto del acceso. De igual forma desde la CDB podría discutirse sobre mecanismos que aseguren que tanto Pueblos Indígenas como Comunidades Locales toman sus decisiones de acuerdo a sus tradiciones y que esta decisión tiene que ser respetada. Sin embargo, las recomendaciones emanadas desde la CDB en relación a este tema, hacen énfasis más bien en otros aspectos como la posibilidad de que el CPI sea un requisito para el patentamiento de los recursos accesados: no solo se enfatiza en determinadas discusiones, sino que a priori, se acepta la apropiación de recursos que en muchos casos llevan derechos colectivos o conocimiento tradicional (que indirectamente es apropiado igualmente).

La misma tendencia la podemos observar en las recomendaciones sobre creación de capacidades donde el énfasis está de lado de la creación de condiciones (marcos jurídicos, conocimiento de qué biodiversidad posee cada quien –inventarios-, bioprospección entre otros

más) para facilitar el acceso que del lado del fortalecimiento de aspectos como los mencionados en el párrafo anterior.

La discusión en la CDB se abocó principalmente a lanzar negociaciones sobre un régimen internacional en ADB. La COP 7 discutió y aprobó (resolución VII/19) los términos de referencia bajo los cuales desarrollará su gestión un Grupo de Trabajo de Composición Abierta en ADB. Estos términos aunque generales posee la tendencia descrita en este artículo y los temas que tendrá que abordar, presagian fuertes discusiones.

Esta discusión además, no se circunscribe solamente a la CDB. En diversos países, especialmente en América Latina, esta en boga la ratificación de tratados de libre comercio bilaterales con Estados Unidos donde en el caso centroamericano por ejemplo, la bioprospección asume la categoría de servicio por lo que, se convierte en una actividad privilegiada. Así, normas que vengan a garantizar el CPI por ejemplo, podrían ser consideradas como obstáculos técnicos al comercio y por lo tanto, podrían ser anuladas. Lo mismo puede pasar con otros puntos de la normativa de acceso a nivel nacional.

La necesidad de un régimen internacional en ADB se escudó bajo el lema de que es necesario luchar contra la biopiratería. Esta actividad asegura el control de los recursos genéticos para usos privados y comerciales y por lo tanto es considerada no solo como un robo o saqueo, sino también como una de las actividades que mayor deuda ecológica genera. Afirmando entonces que luchar contra la biopiratería, es luchar contra esa apropiación y privatización de los recursos genéticos y por el fortalecimiento de los derechos colectivos enunciados en la CDB. Sin embargo y luego de analizar el acuerdo alcanzado, creemos que la lucha ni siquiera se posterga, ni siquiera da inicio y más bien se avanza en su legalización. La tendencia de asumir la Naturaleza y los recursos naturales como mercancías se acentúa así como lo hace, la privatización de nuestros recursos.