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GROUP OF TECHNICAL AND LEGAL EXPERTS ON CONCEPTS, TERMS, WORKING DEFINITIONS AND SECTORAL APPROACHES IN THE CONTEXT OF THE INTERNATIONAL REGIME ON ACCESS AND BENEFIT-SHARING
Windhoek, 2-5 December 2008

COMPILATION OF SUBMISSIONS BY PARTIES, INTERNATIONAL ORGANIZATIONS, INDIGENOUS AND LOCAL COMMUNITIES AND STAKEHOLDERS ON CONCEPTS, TERMS, WORKING DEFINITIONS AND SECTORAL APPROACHES

Note by the Executive Secretary

INTRODUCTION

1. In its decision IX/12, paragraph 11, the Conference of the Parties decided, *inter alia*, to establish a group of technical and legal experts to further examine the issue of concepts, terms, working definitions and sectoral approaches in order to assist the Ad Hoc Open-ended Working Group on Access and Benefit-sharing in the elaboration and negotiation of the international regime on access and benefit-sharing.

2. In the same decision, the Conference of the Parties requested the Expert Group to provide legal and technical advice, including, where appropriate, options and/or scenarios. The terms of reference for the Group, set out in annex II B to the decision, are as follows:

> "The Group of Technical Experts will address the following questions:
>
> (a) What are the different ways of understanding biological resources, genetic resources, derivatives and products and what are the implications of each understanding for the development of the main components of the international regime on access and benefit-sharing, including in relation to sectoral and subsectoral activities and in relation to commercial and non-commercial research?
>
> (b) Identify different forms of utilization of genetic resources in relation to sectoral and subsectoral activities in the context of Article 15, paragraph 7, of the Convention;
>
> (c) Identify and describe sector specific characteristics of access and benefit-sharing arrangements and to identify the differences, if any, between approaches in sectors;
>
> (d) What are the range of options and approaches for taking these different characteristics into account and that may bring coherence to access and benefit-sharing related practices in different sectors?"

3. In paragraph 15 of decision IX/12, the Conference of the Parties invited Parties, Governments, international organizations, indigenous and local communities and relevant stakeholders to provide information and views related to the issues to be addressed by each expert group six weeks prior to the convening of each group.

4. Further to that request, notification 2008-104 of 18 August 2008 was sent to Parties, Governments, international organizations, indigenous and local communities and relevant stakeholders and a reminder notification was sent on 23 September 2008.

5. The present document provides a compilation of submissions provided by Parties, Governments, international organizations and relevant stakeholders on concept, terms, working definitions and sectoral approaches. The contributions have been reproduced in the form and language in which they were received. In addition, contributions provided in a language other than English have been translated into English.

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COLOMBIA

NOTIFICACIÓN SCBD/SEL/OJ/VN/GD/64650
Grupo de Expertos Jurídicos y Técnicos sobre conceptos, términos y expresiones, definiciones funcionales y enfoques sectoriales

En respuesta a la solicitud de la Secretaria a través de la notificación SCBD/SEL/OJ/VN/GD/64650 Colombia desea remitir para la consideración de los Expertos del Grupo, los siguientes comentarios:

En relación con la definición de recursos genéticos

1. Una definición de Recursos Genéticos es indispensable para determinar con claridad el ámbito de todo régimen de acceso y distribución de beneficios derivados de la utilización de los mismos, tal como lo establece el Convenio de la Diversidad Biológica.

2. Esta definición por lo tanto debe ~~tener~~ cumplir dos requisitos: a) ser sustentable desde el punto de vista científico, y b) ser operativa para permitir la implementación del objetivo de asegurar la distribución justa y equitativa de los beneficios a los países o comunidades o agentes que suministran los recursos genéticos o los recursos biológicos que los contienen y que son objeto de acceso a los recursos genéticos ~~suministran el acceso a los recursos genéticos.~~

3. La definición de *"recursos genéticos"* adoptada por la CDB es esencialmente correcta, pero es necesario evitar interpretaciones equivocadas que limiten ~~injustificadamente~~ el ámbito de la CDB y por lo tanto reduzcan las posibilidades de la distribución de beneficios.

4. Partiendo literalmente de las definiciones de la CDB, la definición es:

Por *"recursos genéticos"* se entiende el material genético (todo material de origen vegetal, animal, microbiano o de otro tipo que contenga unidades funcionales de la herencia) de valor real o potencial.

5. En términos prácticos los recursos genéticos son cualquier material biológico o de origen biológico, que pueda ser reproducido con el fin de aprovechar rasgos genéticos de interés actual o potencial.

6. Este hecho está claramente expresado en la definición de material genético de la CDB. La definición establece que a) material genético es <u>cualquier material biológico</u> (vegetal, animal, microbiano ~~microbiológico~~, o de otro origen; y b) siempre <u>que contenga unidades funcionales de la herencia</u>, que estos son el fundamental mecanismo que permite la reproducción de los rasgos genéticos de interés actual o potencial.

7. Lo que <u>no es posible es la interpretación de que los Recursos Genéticos son exclusivamente las unidades funcionales de la herencia</u>. Esta interpretación reduccionista presenta varios problemas.

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Desde el punto de vista científico podría reducir el ámbito a los ácidos nucleicos, con lo cual se contradice la experiencia práctica que muestra que los recursos genéticos, desde tiempos inmemoriales son usados y manipulados, independientemente del aislamiento y manipulación directa de estos ácidos nucleicos. Si bien los ácidos nucleicos son condición *sine qua non*, estos no son suficientes para tener un recurso genético.

8. De otra parte, esta interpretación reduccionista implicaría que la mayor parte de materiales genéticos o de materiales biológicos que contienen los recursos genéticos, que normalmente son es suministrados como base para ~~son la base del~~ aprovechamiento de cualquier propiedad o rasgo genético propio de la biodiversidad, quedaría excluida de una ~~remuneración~~ distribución justa y equitativa de los beneficios derivados del acceso a los mismos por su acceso y uso, impidiendo la aplicación de los objetivos de la CDB.

9. Los materiales biológicos que tienen unidades de herencia son muy variados y pueden ser aprovechados a través de técnicas muy diversas: domesticación y selección ancestral, mejoramiento genético convencional, y procedimientos biotecnológicos modernos incluyendo el ADN recombinante. Entre estos materiales están: los organismos completos o partes de éstos, las semillas, el polen, las esporas, el semen, los óvulos, los embriones, los tejidos, las células, los ácidos nucleicos, entre otros.

10. Debe precisarse, sin embargo, que equiparar u homologar Recurso Genético con Recurso Biológico, en la práctica puede conllevar a dificultades para la implementación de los mecanismos e instrumentos para su utilización, pues por ejemplo, para el caso colombiano, los dos tipos de recursos (Genético y Biológico) consideran sistemas de administración, sistemas regulatorios, instrumentos de manejo y control e incluso regímenes de propiedad diferenciales.

11. En este sentido, con la finalidad de considerar una propuesta que permita compatibilizar RG y RB a la vez que mantener las particularidades definidas para cada uno de ellos, se propone ajustar la definición en los siguientes términos (de tal manera que se mantienen las posibilidades de acceso a los recursos genéticos a partir de los diferentes niveles de organización jerárquica de la Diversidad Biológica, a la vez que se reiteran los elementos considerados de patrones de herencia/heredabilidad de rasgos o propiedades genéticas de interés actual o potencial):

Recursos Genéticos: "Moléculas de DNA y RNA **conjuntamente con las propiedades o rasgos heredables que les son característicos** y que poseen valor o utilidad real o potencial"

12. Una definición en este sentido se justificaría en la medida en que permite, sin desligarse de los establecido en el CDB, acercar el concepto técnico a los actuales avances de las ciencias, resolviendo ambigüedades entre genético / biológico, y con aplicación al acceso a los Recursos Genéticos que pueda derivarse del uso de cualquiera de los niveles de organización jerárquica de la biodiversidad, y

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posibilita el uso de la legislación de manera específica a los RG en cualquier contexto tecnológico actual o futuro.

13. Una definición en este sentido puede funcionar y tener aplicación en el contexto de jerarquías biológicas, que pueden entenderse como niveles diferenciales de acceso, siendo aplicable al acceso a RG de plantas, animales, microorganismos, entendidos en los diferentes niveles de organización jerárquica de la biodiversidad: **(i)** Comunidades bióticas (grupos de especies de diversos organismos compartiendo una localización especial determinada); **(ii)** Poblaciones (consideradas como grupos de individuos de una misma especie localizados en una región determinada, que tienen la capacidad de reproducirse entre sí); **(iii)** Individuos (bien sean del medio silvestre, de poblaciones domesticadas o mantenidos en condiciones *ex situ*); **(iv)** Propágulos sexuales o asexuales (incluyendo gametas sexuales aisladas); **(v)** Organos o partes de los individuos; **(vi)** Genomas dentro de los individuos (considerando en las especies animales el genoma nuclear y el genoma mitocondrial; adicionalmente el genoma cloroplastal para las especies vegetales y el genoma extracromosomal –plásmidos- en las especies microbianas),**(vii)** Grupos o familas de genes dentro de cada tipo de genoma; **(viii)** Genes específicos que codifican para proteínas de interés; **(ix)** Regiones Génicas determinadas dentro de cada gen.

En relación con la definición y consideración de los Productos Derivados

14. El objetivo de asegurar una distribución justa y equitativa resultante ~~derivados~~ del acceso y el uso de los recursos genéticos, debe incluir también el uso de los derivados de los recursos genéticos, que ~~resultan~~ obtenidos del metabolismo de los recursos genéticos, en la medida en que son materiales naturales, procesados y producidos en virtud del metabolismo de los dichos recursos, en virtud de sus propias características o propiedades genéticas.

15. Así las cosas, ~~En conclusión~~ una definición operativa en el contexto de la CDB, es la siguiente:

"Los derivados son laos *sustancias o productos naturales que resultan del metabolismo de los recursos genéticos*. En muchos casos el aprovechamiento de los recursos genéticos se realiza preferentemente a través de sus derivados: gomas, tintes, ingredientes activos, moléculas, antioxidantes, enzimas, o cualquier otro material no vivo, proveniente naturalmente de la actividad de ~~por~~ los recursos genéticos."

En relación con la definición y consideración de los Productos Derivados

16. En consideración a los elementos aquí señalados, ~~Finalmente,~~ se hace necesario definir también el término Producto, en el ámbito de la CDB. Este término por contraste con los de Recursos Genéticos y Derivados, que son productos naturales, se refiere a productos obtenidos artificialmente con base en procesos de investigación y desarrollo, y/o a través de la manipulación o transformación industrial de esos recursos genéticos o derivados. Así, una definición funcional podría considerar lo siguiente:

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"Los productos son aquellos bienes que han sido artificialmente obtenidos a partir del uso de un recurso genético, incluyendo su información genética, o a partir de un derivado, incluyendo su información molecular."

Comentarios sobre los enfoques sectoriales

17. Colombia es uno de los países caracterizados por ser megadiversos, siendo esta una de las razones por las cuales se ha asignado al Estado la obligación constitucional de proteger las riquezas naturales del país. En este sentido, la biodiversidad colombiana y la amplia oferta tanto de bienes y servicios ambientales como de recursos biológicos y genéticos, se consideran estratégicos y potenciales para la conservación, el aprovechamiento sostenible y como aspectos prioritarios para la consolidación de procesos de desarrollo local, regional y nacional. Vale la pena llamar la atención sobre este tema ya que existe un costo de oportunidad que implica una pérdida para el país a causa de la falta de una política clara de acceso que se hace evidente en los altos costos de transacción implícita en una flata de claridad sobre los esquemas de acceso a recursos genéticos y distribución de beneficios.

18. Bajo este contexto, los RG presentan alternativas viables y de alto potencial, orientadas hacia la satisfacción de problemas prioritarios nacionales en áreas de salud, seguridad alimentaria, producción y medio ambiente, que pueden además brindar herramientas para el fortalecimiento de la gestión pública en aspectos relacionados con caracterización, evaluación, colecta, conservación y manejo sostenible de los recursos genéticos; Recuperación de la biodiversidad amenazada por causas directas o indirectas; Biocomercio; Bioprospección; Bioseguridad; Producción, ajuste y transferencia del conocimiento científico y tecnológico y Derechos de propiedad intelectual e industrial.

19. Para el logro de lo anterior, se requiere adelantar acciones tendientes al fortalecimiento de la capacidad institucional con el fin de dar respuesta a los rápidos y permanentes avances que se presentan en materia de RG. Se hace por tanto necesario contar con un adecuado nivel científico y tecnológico, que con criterios éticos, de sostenibilidad, competitividad y efectividad de las políticas públicas para la protección al medio ambiente, sirva como un instrumento de apoyo para la formulación y ejecución de los Planes y Programas Nacionales de Desarrollo. En este sentido, la Política Nacional de Recursos Genéticos deberá ser concertada entre todas las instituciones, el sector privado, académico y de investigación y las comunidades locales que han desarrollado conocimientos tradicionales asociados al aprovechamiento de estos recursos.

20. Los objetivos, líneas de acción y estrategias de un enfoque multilateral en materia de acceso a RG y distribución de beneficios deben entonces superar las consideraciones ambientales e involucran el aparato productivo del país. La capacidad de aprovechamiento sostenible depende de la cadena de adición de valor, la cual está constituida por diferentes sectores económicos y productivos y actores sociales, que intervienen en distintas etapas del desarrollo de productos y servicios derivados del uso

de los RG. La cadena de adición de valor está integrada en general por las actividades de la comunidad científica y académica, el sector privado, el sector público y las comunidades locales. Desde el punto de vista productivo, esta cadena involucra y conecta las actividades de distintos ámbitos como el agrícola, farmacéutico, agroindustria y cosmética, con las actividades de investigación y conservación de los RG.

21. Este enfoque responde a las metas de interés social y a las limitantes para la optimización de los niveles de producción según las tendencias tanto nacionales como internacionales de los mercados y en aspectos institucionales, sociales y legales, mediante la definición de acciones de impacto positivo sobre el desarrollo socioeconómico, la competitividad, la calidad de vida y el uso y aprovechamiento sostenible de la base de recursos naturales para la optimización y posicionamiento de las ventajas comparativas que ofrece el país.

22. Para estos efectos, los enfoques sectoriales asociados al acceso deberán adelantar acciones en el marco de las Líneas de Acción de:

- Promoción y conservación in situ y ex situ de los RG y Productos Derivados por parte del sector público y privado.
- Promoción de la recuperación, protección y fomento del Conocimiento Tradicional.
- Fortalecimiento de los sistemas de inventarios y colecciones de los RG y de la capacidad científica nacional asociada para incorporarlos al Mecanismo de Facilitación del Convenio sobre Diversidad Biológica y el Protocolo de Cartagena sobre Seguridad en la Biotecnología.
- Fomento a la capacidad nacional para adelantar acciones de Bioprospección en forma competitiva.
- Promoción al desarrollo de la industria nacional con miras al aprovechamiento sostenible de los RG a través del fortalecimiento de cadenas para la adición de valor a los RG y promoción de Alianzas Estratégicas utilizando instrumentos de política como los incentivos tributarios y los programas de responsabilidad social corporativa.

Compiló: GSC /OAI
RMV /OGH

ENGLISH TRANSLATION

SCBD NOTIFICATION SCBD/SEL/OJ/VN/GD/64650
Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches

In response to the Secretariat's request through notification SCBD/SEL/OJ/VN/GD/64650, Colombia wishes to submit the following comments for the Expert Group's consideration

With regard to the definition of genetic resources

1. A definition of genetic resources is essential to clearly set the scope of any regime on access and benefit sharing established under the Convention on Biological Diversity.

2. Such a definition must ~~has to~~ therefore meet two requirements: a) be scientifically sound, and b) be operational, in order to be able to achieve the objective of ensuring fair and equitable sharing of benefits by the countries, communities or agents that provide genetic resources or the biological resources that contain them and through which genetic resources are accessed ~~that provide access to genetic resources~~.

3. The definition of *"genetic resources"* adopted by the CBD is essentially correct, but it is necessary to avoid misinterpretations that limit, ~~without justification~~, the CBD's scope, thereby reducing benefit-sharing opportunities.

4. If we take the CBD definitions word for word, according to the definition:
"Genetic resources" are genetic material (any material of plant, animal, microbial or other origin containing functional units of heredity) of actual or potential value.

5. In practical terms, genetic resources are any biological material, or material of biological origin, that can be reproduced in order to use genetic traits of actual or potential interest.

6. This fact is clearly expressed in the CBD's definition of genetic material. The definition establishes that a) genetic material is any biological material (of plant, animal, microbial, ~~microbiological~~ or other origin); and b) always containing functional units of heredity, which are the basic mechanism for reproducing genetic traits of actual or potential interest.

7. What is not possible is the interpretation whereby Genetic Resources are exclusively units of functional heredity. This reductionist interpretation raises a number of problems. Scientifically speaking, it could reduce the scope to nucleic acids. Such a view is contradicted by practical experience, which shows that genetic resources have been isolated and manipulated from time immemorial, independently from the isolation and direct manipulation of said nucleic acids. Although nucleic acids are a *sine qua non* condition, they are not sufficient to obtain genetic material.

8. Furthermore, this reductionist interpretation would mean that most genetic material, or biological material containing genetic resources usually provided as the basis for ~~are the basis of~~ making use of any genetic trait or property specific to biodiversity, would be excluded from the fair and equitable sharing ~~remuneration~~ of benefits arising from access to said materials and their use. This would prevent the implementation of the CBD's objectives.

9. There is a variety of biological material containing functional units of heredity and very diverse techniques can be used to take advantage of said material. The techniques include: domestication and ancestral selection, conventional genetic enhancement, and modern biotechnology procedures, including recombinant DNA. The various types of material include: complete organisms or parts thereof, seeds, pollen, spores, semen, ovules, embryos, tissue, cells, and nucleic acids, among others.

10. It should be pointed out, however, that likening or equating Genetic Resource (GR) and Biological Resource (BR) could lead to practical difficulties when it comes to implementing the mechanisms and instruments designed for their use. For example, in Colombia's case, each type of resource (Genetic and Biological) has its own administrative system, regulatory system, handling and control mechanisms, and even different property regimes.

11. Therefore, in order to consider a proposal that will make it possible to account for GR and BR while maintaining the defined characteristics of each, we propose to adjust the definition as set out below (so as to retain the possibility of access to genetic resources through the various levels of hierarchical organisation of Biological Diversity, while reiterating the elements considered to be patterns of heredity/inheritability of genetic traits or properties of actual or potential interest):

Genetic Resources: "DNA and RNA molecules, together with the inheritable properties or traits that are characteristic of them, and that have actual or potential value or use"

12. A definition along those lines is justifiable insofar as it makes it possible, without departing from the definitions in the CBD, to create a closer match between the technical concept and current scientific progress, thereby removing genetic/biological ambiguities. This would apply to access to Genetic Resources that can be derived from the use of any level of the hierarchical organisation of biodiversity. It also makes it possible to use legislation specifically for GR in any current or future technological context.

13. Such a definition could work and be applied in the context of biological hierarchies, which can be seen as different levels of access, applicable to access to the GR of plants, animals and micro-organisms belonging to the various levels of hierarchical organisation of biodiversity: (i) Biotic communities (groups of species of various organisms that share a specific, defined location); (ii) Populations (considered to be groups of individuals of a same species located in a given region, that have the capacity to reproduce among themselves); (iii) Individuals (either in the wild, as part of domesticated populations, or maintained in *ex situ* conditions); (iv) Sexual or asexual propagules (including isolated sexual gametes); (v) Organs or parts of individuals; (vi) Genomes within individuals (taking into consideration the nuclear genome and mitochondrial genome for animal species, as well as the chloroplast genome for plant species and extrachromosomal genome –plasmids– for microbial species); (vii) Groups or families of genes within each type of genome; (viii) specific genes codified for proteins of interest; (ix) Given genic regions within each gene.

With regard to the definition and consideration of derivatives

14. The objective of ensuring the fair and equitable sharing of benefits arising ~~derived~~ from access to and the use of genetic resources must also include the use of derivatives of genetic resources obtained ~~that result~~ from the metabolism of genetic resources, insofar as they are natural materials, processed and produced by the metabolism of said resources, in accordance with their own genetic properties or characteristics.

15. Given this, ~~in conclusion~~ a definition that would work within the context of the CBD would read as follows:

"Derivatives are *the substances or products arising from the genetic resources' metabolism.* In many cases, the use of genetic resources first takes place through their derivatives: gums, dyes, active ingredients, molecules, antioxidants, enzymes or any other non-living material generated naturally by the activity of the genetic resources.

With regard to the definition and consideration of Derivative Products

16. Given the points raised here, ~~finally~~, it is also necessary to define the term Product within the context of the CBD. As opposed to Genetic Resources and Derivatives, which are natural substances, Products in this sense are products that are obtained artificially, based on research and development, or

through the industrial processing or manipulation of said genetic resources or derivatives. A working definition could therefore be:

"Products are goods that have been obtained artificially, based on the use of a genetic resource, including its genetic information, or based on a derivative, including its molecular information."

Comments on the sector approaches

17. Colombia has the characteristic of being a megadiverse country, which is why the state has been given the constitutional obligation to protect the country's natural wealth. In this respect, Colombian biodiversity and the vast supply of environmental goods and services, as well as genetic and biological resources, are seen as being strategic, as having the potential for conservation and sustainable use, and as being priority aspects for consolidating national, regional and local development processes. It is worth drawing attention to this issue, seeing as there are opportunity costs that represent a loss for the country due to a clear policy for access. This is evident in the high transaction costs linked to a lack of clarity with regard to regimes for access to genetic resources and sharing of benefits.

18. In this context, GR are viable alternatives that show great potential for solving national priority issues in the areas of health care, food safety, production and the environments. They can furthermore provide tools for strengthening public administration of aspects linked to characterisation, evaluation, collection, conservation and sustainable management of genetic resources; recovering biodiversity under direct or indirect threat; Biotrade; Bioprospecting, Biosafety; Production; the adaptation and transfer of scientific and technological knowledge, and intellectual and industrial property rights.

19. Achieving the above will require action aimed at strengthening institutional capacity so as to deal with rapid and permanent advances with regard to GR. It is therefore necessary to have a proper level science and technology that, in conjunction with ethical criteria for sustainability, competitiveness, and efficient public policies for environmental protection, can be used as a tool to support the creation and implementation of National Development Plans and Programs. The National Policy for Genetic Resources must therefore be a concerted effort by all institutions, the private sector, the academic and research sectors, and local communities that have developed traditional knowledge associated with the use of said resources.

20. The objectives, lines of action and strategies of a multilateral approach to GR access and benefit sharing must consequently go beyond environmental considerations and involve the country's production apparatus. The capacity for sustainable use depends on the value-added chain, which is composed of various economic and production sectors, as well as social stakeholders, which are involved in the various steps of develop of products and services derived from the use of GR. The value added chain generally includes activities by the scientific and research sector, the private sector, the public sector and local communities. From the perspective of production, this chain involves and connects activities in different areas, such as agriculture, pharmaceuticals, agri-food and cosmetics, with GR research and conservation activities.

21. This approach meets social interest goals, with limitations on optimizing levels of production imposed by both national and international market trends, as well as by institutional, social and legal aspects through the definition of actions with a positive impact on socioeconomic development, competitiveness, quality of life, and the sustainable use of the natural resource base to optimize and position the country's comparative advantages.

22. To this end, the sector approaches linked to access must involve steps, as part of the Lines of Action, aimed at:

- *In situ* and *ex situ* conservation of GR, Derivatives and Products by the public and private sectors;
- Fostering the recovery, protection and promotion of Traditional Knowledge;

- Strengthening GR inventory systems and collections, and strengthening associated scientific knowledge, to include them in the Convention on Biological Diversity's clearing-house Mechanism, as well as the Cartagena Protocol on Biosafety;
- Building national capacity to carry out competitive bioprospecting activities;
- Promoting the development of national industry with a view to sustainable use of GR by strengthening value-added chains for GR, and fostering strategic alliances through policy instruments, such as tax incentives and corporate social responsibility programmes.

EUROPEAN COMMUNITY AND ITS MEMBER STATES

EU submission in response to Notification 2008-104 to the ABS Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches - Windhuk 2-5 December 2008

I - GENERAL COMMENTS

Article 2 of the CBD defines "biological resources" as including "genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity". "Genetic material" is defined as "any material of plant, animal, microbial or other origin containing functional units of heredity", while "genetic resources" are defined as "genetic material of actual or potential value".

Following from these definitions genetic resources are a subset of biological resources and genetic material. As such, all biological resources could contain a genetic resource. What distinguishes genetic resources is that they are material of plant, animal, microbial or other origin containing functional units of heredity of actual or potential value. In this regard, there seems to be a common understanding of the Parties that they do not wish an international regime to cover biological resources in the sense of bulk commodities, such as timber.

There is a diversity of interpretation of genetic resources. Given the context of Article 15, most of these interpretations focus on utilization, whether that is the "intended utilization" of a genetic resource or typical utilization activities that result in capturing the real or potential value of genetic resources

Genetic resources are used in a variety of different ways in different sectors. However, it is quite difficult to establish strict boundaries among different (economic) sectors using genetic resources as defined by the CDB. Pharmaceutical industries, plant breeding and animal breeding sectors, cosmetics and perfumes companies, food production and processing firms, have been identified as main users groups. The "biotechnological sector" is more difficult to characterize. Some biotechnology companies are involved in bio prospecting activities. Other biotechnology companies are best characterized as providers of genetic resources or genetic material for a diversity of economic activities and may thus resemble more what is commonly referred to as "intermediaries".

Research activities must be considered with particular attention. The research sector, including biodiversity research, and research on genetic resources, plays a key role in developing critical knowledge for the effective implementation of the CBD and the achievement of its three objectives. In that respect the EU wants to underscore the eminent importance of simplified access to genetic resources for non-commercial research while recognizing that steps to clearly identify non-commercial intent is important for generating confidence and trust with providers of genetic resources.

It is critical that the international ABS regime provides the flexibility to accommodate differences in the current or future utilization of genetic resources in and between different user groups. If this is not achieved, the international ABS regime risks preventing potential users from seeking access to genetic resources that fall within the scope of the international ABS regime. This would run counter to the CBD, its objectives and provisions relevant to access and benefit-sharing.

One important option for taking into account different characteristics of groups or sectors utilizing genetic resources while disseminating best practices in ABS across sectors is the development of sectoral model clauses for potential inclusion in Material Transfer Agreements. Such optional model clauses could enhance legal certainty for both providers and users of genetic resources and support the fair and equitable sharing of benefits arising.

II. SPECIFIC COMMENTS ON THE TERMS OF REFERENCE OF THE TECHNICAL EXPERT GROUP

What are the different ways of understanding biological resources, genetic resources, derivatives and products and what are the implications of each understanding for the development of the main components of the international regime on access and benefit-sharing, including in relation to sectoral and subsectoral activities and in relation to commercial and non-commercial research?

Genetic resource / biological resources

Article 2 of the CBD defines "biological resources" as including "genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity". "Genetic material" is defined as "any material of plant, animal, microbial or other origin containing functional units of heredity", while "genetic resources" are defined as "genetic material of actual or potential value".

It follows that genetic resources are a subset of biological resources and genetic material. As such, all biological resources could contain a genetic resource. What distinguishes genetic resources is that they are material of plant, animal, microbial or other origin containing functional units of heredity of actual or potential value.

In addition, Articles 15(1) and (2) recognise the ability fo Parties to determine access to genetic resources while requiring them to endeavour to facilitate access for environmentally sound uses. In addition, Article 15 (7) requires Parties to take appropriate measures with the "aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilisation of genetic resources with the Contracting party providing such a resource…". Article 15(6) also refers to scientific research based on genetic resources.

The actual or potential value of genetic resources is therefore determined by the potential for utilisation, i.e. it is their use of the functional units of heredity which will distinguish them from genetic material or biological resources.

Various interpretations of genetic resources have been put forward by commentators[1]. Given the context of Article 15, most of these interpretations focus on utilisation, whether that is the intended utilisation of a genetic resource or typical utilisation activities that result in capturing the real or potential value of genetic resources.

Derivatives and Products

The CBD does not include a definition of the terms "products" nor of "derivatives" in relation to Article 15. The terms are used in the Bonn Guidelines in the context of Mutually Agreed Terms (MAT)[2]. As such, the EU recognizes that users and providers will determine whether and to what extent "derivatives" or "products" will be covered by benefit-sharing arrangements established on mutually agreed terms. Mindful of Article 19(2), the EU maintains that "derivatives" or "products" should remain outside the scope of any additional and more specified international obligations established by an international ABS regime.

Implications for (a) sectoral approaches and (b) commencial/non-commercial research

As fas as the definition of genetic resources are concerned, it will be necessary to examine how genetic resources are used within different sectors. In focusing on specific uses within different sectors/groups of users, it may be easier to distil which activities would constitute a "utilization of functional units of heredity" of genetic resources, as compared to the use of biological resources as a commodity.

As regards research on genetic resources, distinguishing between non-commercial research and other research activities seems to present similar issues. The difference seems to lie at the purpose of the research activity, rather than in the character of the research activity as such. In view of this, there may be a need to closely examine how access is granted for the two activities and the nature of the benefit sharing, rather than the inclusion of the activity within the international regime as such. It is therefore necessary to identify practical and meaningful steps for distinguishing non-commercial research from other, including commercial, uses of genetic resources and for ensuring that simplified access procedures for non-commercial research are established but will not be abused.

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1 Medagilia and Silva, "Addressing the Problems of Access: Protecting Sources, While Giving Users Certainty", IUCN EPLP 67/1 discusses these interpretations in more depth.

2 Bonn Guidelines, paragraphs 36 and 44(f)(i)

As far as derivatives and products are concerned, these should be addressed in the context of mutually agreed terms. Providers and users negotiating mutually agreed terms might benefit from loosely identified "typical" derivatives and products arising from different sectoral activities. It would also raise the level of information available to providers of genetic resources and thereby support levelling the playing field in negotiations on mutually agreed terms.

As regards steps to distinguish between non-commercial research and other research activities, discussions should include the following points : the appropriate classification of research depending on its varying form and objective; steps to ensure that obligations are passed on to subsequent users (see i.a. example of the International Plant Exchange Network IPEN Annex 6 or the Standard Material Transfer Agreement under the International Treaty on Plant Genetic Resources for Food and Agriculture); steps that address potential changes in intent by non-commercial users, including through identification of clear reference points for changes in intent, among other.

Identify and describe sector specific characteristics of access and benefit-sharing arrangements and to identify the differences, if any, between approaches in sectors

This section provides an overview of the main characteristics, different forms of utilization, as well as different ABS arrangements of a selected number of sectors, taking into account the following three questions raised in the terms of references of the technical expert group:

- Identification of stakeholders dealing with genetic resources and their main industrial characteristics;
- Identification of different forms of utilization of genetic resources in relation to sectoral and subsectoral activities in the context of Article 15, paragraph 7, of the Convention;
- Identification and description of sector specific characteristics of access and benefit-sharing arrangements and to identify the differences, if any, between approaches in sectors;

1. **Pharmaceutical industry**

Purpose and main characteristics:

Production and marketing of medicinal products

The pharmaceutical sector is characterised by a great diversity of products/drugs, technologies and markets. A significat part of the pharmaceutical sector's turnover is invested in research and development (R&D). In the interests of reducing research investments and product development time, the pharmaceutical industry relyies heavily on high technologies, such as combinatorial chemistry and computer-based drug design, based on pre-processed electronic data rather than plant material or similar.

Main forms of utilization of genetic resources:

To meet an increasing demand for new products to address a range of illnesses, the pharmaceutical industry is one of the most research intensive industries in the world. Genetic resources have been an important component of that research work. This research work can be characterised in two phases: drug discovery and drug development. Genetic resources contribute in a range of ways to drug discovery.

In the Holm-Muller, Richerzhagen and Tauber study of users of genetic resources in Germany, the pharmaceutical sector responses indicated that the majority of its uses for genetic resources were for development for marketable products, followed by research and development for intermediary purposes and research purposes3.

Typical acquisitions of genetic resources:

The sector organization is characterised by multiple partnerships with small and medium-sized biotechnology companies. These companies play a leading role in the identification of active ingredients. Pharmaceutical companies get access to

[3] Holm-Muller, Richerzhagen and Tauber, "Users of Genetic Resources in Germany. Awareness, participation and Positions regarding the Convention on Biological Diversity", BfN-Skripten 126, 2005, p. 96.

genetic material through this type of partnership and certain collaborations with research in provider countries, and more particularly those related to ex-situ collections.

Few pharmaceutical companies engage in bioprospecting activities in provider countries for the acquisition of in-situ genetic resource/material. In those cases where pharmaceutical companies undertake in-situ bioprospecting activities, there seems to be an increasing use of local partner institutions that take on responsibility for obtaining the required approvals and permits. This is one element of an increasing use of partnerships to gain and secure legal access in accordance with national legal requirements. These long term partnerships with bodies in provider countries seem to provide a more stable framework for access and benefit sharing arrangements4.

In terms of benefit sharing, a package of monetary and non-monetary benefits is standard practice5. As many agreements are confidential, it is difficult to provide an accurate guide for monetary benefits. Many will involve royalty payments, combined with certain milestones payments. Non-monetary benefits could include capacity building in the form of information sharing, training as well as establishing and developing scientific and technical facilities in provider countries. These capacity building benefits often form part of partnership arrangements.

In practice it can be noted that there is little standardisation of transactions. The industry is characterised by a web of agreements rather than just one agreement, as well as increasing use of phased agreements. In these cases, there may be an initial research agreement, which is followed by a commercial agreement where the research indicates potential products. In this way, the potential benefits can be more realistically agreed in light of advanced information on potential for development.

There is increasing evidence of pharmaceutical industry interest and engagement in ABS issues. In 2006 the International Federation of Pharmaceutical Manufactures and Associations (IFMPA) agreed "Guidelines for IFPMA members on access to genetic resources and equitable sharing of benefits arising out of their utilisation"6. The Guideline's objective refers to supporting a positive approach to CBD implementation, while providing an outline of industry best practice.

2. Biotechnology

Purpose and main characteristics:

Biotechnology is a cross-sectoral technology providing tools and solutions in various fields of research as well as for the improvement of processes to be used by various industries, e.g. pharmaceutical and seed industries as most common partners, but also used in a wider context such as chemical engineering, information technology or environmental remediation

The biotechnology sector is characterized by its variety of activities, thus acting both as a user and provider of genetic resources. Biotechnology industries span a range of sectors but are important features within the pharmaceutical and agricultural sectors.

Main forms of utilization of genetic resources:

The pharmaceutical industry contains the largest segment of biotechnology and its techniques are increasingly used in the research procedures describe above. The second largest segment of biotechnology is found in the agricultural sector. Biotechnology is speeding up the process of both drug development and development of new varieties of crops and breeds. In the seed industry, e.g. biotechnology processes are applied to improve plants, in particular the major crop varieties. In particular, they are used for the accurate selection and delivery of desired characteristics, to transfer genes from one species to another, to remove undesirable characteristics, such as allergenic and toxic compounds, and to produce varieties, e.g. with better performance and enhanced environmental adaptation.

Biotechnology companies are largely involved in the development of products and processes in a variety of sub sectors, including chemicals, pulp and paper, textiles, food, environmental technologies (e.g. disposal of waste and bioremediation) and energy. The industry is heavily reliant of the use of enzymes, many of which are derived from micro-organisms, in order to catalyse and speed up biological processes. For example, in environmental technologies,

[4] See in particular, Sarah Laird and Rachel Wynberg in "Access and benefit sharing arrangements in existing sectors", UNEP/CBD/WG-ABS/6/INF/4/Rev 1, p. 30, paragraph 16
[5] Sarah Laird and Rachel Wynberg , "Access and benefit sharing arrangements in existing sectors", p. 23.
[6] See http://www.ifpma.org/Issues/CBD

bioremediation systems are based on the degradation functions of micro-organisms7. In particular, there has been increasing interest within the biotechnology industry in micro-organisms for extreme environments, as they may provide novel and valuable characteristics that can withstand heat or cold or toxic environments, which can be utilised within industrial processes. As such, this sector is likely to continue to rely on genetic resources found in-situ, on farm as well as material in existing collections.8.

Typical acquisition of genetic resources:

Biotechnology industries acquire their genetic resources from ex-situ sources and intermediaries (catalogues, gene banks, certified centres). Some rare exceptions engage in-situ activities. Given the diversity within this sector, there is again little standardisation of transactions and multiple forms of arrangements and contracts.

The establishment of partnerships is one way of arranging transactions within this sector, with both monetary and non-monetary benefit sharing provisions. For example, the Novozymes and Derversa agreement with the Kenyan Wildlife Service and International Centre for Insect Physiology and Ecology includes running royalties on any commercial product developed (the rate of which is confidential), plus an upfront payment, a lump sum for the costs of collection and laboratory work and milestone payments, as well as establishment of a microbial discovery laboratory,and materials for screening and training9. In terms of royalties, Laird and Wynberg indicate the range of royalty payments for the industrial enzyme sector is lower than for the pharmaceutical given its lower profit margin approximately 0.5-2%10.

3. Agricultural sector

a. Plant Genetic Resources for Food and Agriculture (PGRFA, incl. Plant Breeding Sector and Horticulture)

Companies involved in the production of new varieties of plants are directly concerned by the use of genetic resources. An important part of the R&D in this sector is financed jointly by public research and private investments. The seed sector is mainly dependant on *ex-situ* collections. A great part of the genetic material is acquired via intermediaries, through gene banks and botanic gardens or/and using their own collections. Some companies have undertaken certain bio-prospecting activities in developing countries in order to obtain wild genetic resources. But these *in-situ* activities in provider countries are marginal compared to the rest of the plant breeding activity. Plant breeding industry consists in general of multiple of crosses of pre-existing varieties which themselves have been by using different gentic resources. Thus, it is difficult to make a distinction between the initial genetic resource and the final new variety. In the whole process to obtain of a new variety, the breeder is using different sources of genetic resources, making it virtually impossible to identify the precise contribution of each of them.

The plant breeding industry is characterized by free access for breeding purpose to any improved and protected material. It established rules for benefit–sharing according to the provisions of the International Union for the Protection of New Varieties of Plants (UPOV).

In 2004, the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), negotiated in harmony with the CBD, has entered into force and fixed common rules for access and benefit sharing for plant genetic resources of 64 plant species / genera of crucial importance for food and agriculture. Genetic resources of these 64 plant species/genera which are under the management and control of the Contracting Parties and in the public domain are included into the Multilateral System established under the ITPGRFA. They are freely accessible for the purpose of utilization and conservation for training, research and breeding for food and agriculture with the exemption of non-food/feed uses. In the case of commercialisation of a product incorporating plant genetic resources for food and agriculture (PGRFA) accessed from the Multilateral System, the recipient agrees to share the new product with others for further research and breeding. Where there is a condition limiting further use to research and breeding only, the recipient must pay a percentage of the sales of any commercialised product into a common fund to support the conservation of genetic resources and further development of agriculture.

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[7] Ten Kate and Laird, "Commercial Uses of Biodiversity", p229
[8] Laird and Wynberg, "Access and benefit sharing arrangements in existing sectors" UNEP/CBD/WG-ABS/6/INF/4/Rev 1, p. 8.
[9] Laird and Wynberg, "CBD Technical Series No. 38 "ABS in Practice: Trends in Partnerships Across Sectors", p. 57.
[10] Laird and Wynberg, "The Commercial Use of Biodiversity", UNEP/CBD/ABS/4/INF 5, p.28.

The Governing Body of the ITPGRFA and the FAO Commission on Genetic Resources for Food and Agriculture are further considering access and benefit-sharing issues in relation to PGRFA of plant species and genera as well as non-food/non-feed uses not included in the MLS under the ITPGRFA.

b. Animal Genetic Resources for Food and Agriculture (AnGRFA, incl. Animal Breeding Sector)

The EU sector of farm animal genetic resources is very diverse:

- A limited number of species are used for food and agriculture production, most of them is represented by many populations (breeds). Genetic variation between breeds is as high as within breeds; existence of variation between individuals within breed enables selection and genetic progress. In many circumstances breeds are overlapping and cannot be clearly dissociated from each other. In many cases the origin of breed cannot be clearly defined. Wild relatives are almost not used in animal breeding.

- Breeds are classified as local (kept in one country only), transboundary regional (kept in several countries in one region only) and transboundary international (common worldwide). Modern high input international breeds have major contribution to commercial food production.

- The majority of local and regional breeds are subject to local and/or national breeding, undertaken by farmers or groups of farmers/cooperatives. The international breeds are subject to intensive selection programmes and are developing dynamically. Their breeding programmes are usually run by breeders associations, farmers' co-operatives and private (international) companies.

- AnGR are privately owned (by farmers or by breeding companies) and are subject to private transaction practices. AnGR kept by pastoral people might be collectively owned with customary law guiding exchange of livestock. Public gene banks are very rare, end have been established for conservation purposes, so have no role in exchange of AnGR (in contrast to PGR).

- A significant international trade (in the form of semen, embryos or live animals for reproduction) is generally limited to international breeds or commercial lines. The gene flow essentially takes place between developed countries; there is a growing importance of the flow of highly performing breeds from developed to developing countries. There is currently hardly any gene flow from local breeds to commercial breeds. The use of wild relatives is almost negligible for farm animal genetic resources.

The current legal forms of AnGR exchanges and utilisations are the following:

- The possibility to attach IPRs to new animal breeds or lines is limited worldwide (impossible in Europe, while poultry lines can for example be protected in the US), but patent for biotechnological inventions based on AnGR can now be obtained almost worldwide11;

- With regard to animal breeding, the flows of genetic resources take the form of semen or breeding males sales or embryos or live animals for reproduction purposes, without any restriction on potential further uses as a genetic resource (such as breeding, biotechnology inventions…) ;

- Commercial trade of AnGR is subject to an established regulatory framework (EU - zootechnical legislation). These harmonised principles are directed to ensure free trade of breeding animals and their genetic material, sustainability of breeding programmes and preservation of genetic resources. For example, harmonised certificates exist for intra-Community trade of breeding animals, semen and embryos with detailed information on the origin and genetic values.

- With regard to research, exchanges of AnGR are generally covered by classical scientific cooperation contracts (where each party keeps the property of its inputs in the project and where they share the scientific results, publication and potential IPRs).

[11] Including the EU according to the Directive 98/44/EC on the legal protection of biotechnological inventions.

The FAO Global Plan of Action for Animal Genetic Resources provides a technical and operational framework for assisting countries in particular in the development of national strategies for the management of animal genetic resources, and supporting effective action in the sustainable intensification, conservation, characterization and access to AnGRs. The FAO Commission on Genetic Resources for Food and Agriculture (CGRFA), being the most relevant forum for farm animal genetic resources stakeholders and issues, addresses access and benefit-sharing for ANGRFA as part of its MyPoW .

The FAO Commission on Genetic Resources for Food and Agriculture (CGRFA) also addresses, as part of its MyPoW access and benefit-sharing for aquatic genetic resources for food and fisheries, forest genetic resources and genetic resources of micro-organisms and invertebrates for food and agriculture.

4. Fragrance and cosmetics

Purpose:

Marketable products for natural personal care.

Main forms of utilization of genetic resources:

The natural personal care industry increasingly seeks raw material for product development. Genetic resources are used in relation to extraction, identification and synthesis of new compounds. Botanicals, marine organisms and vitamins provide active compounds that can contribute to a products efficacy and replace petrochemicals and synthetic ingredients. Nevertheless, most of the fragrance and cosmetic industry is based on the use of biological material and products, which are exchanged according to trade rules principles.

Typical acquisition of genetic resources:

The "natural" characteristic of the products is a major asset in sales. For this reason, the fragrance and cosmetic sector is dependent on reputation and image to gain market shares. Even if most of their activity is not subject to ABS negotiations, the fragrance and cosmetic sectors ask for legal certainty for their activities.

As a result, the natural personal care industry and botanicals seems to develop business partnerships with their suppliers and they link the benefits more to the supply of the raw materials, for example by paying premium prices and capacity building through job creation provision of equipment and training to enhance the supply system. Again, there is growing evidence that some companies interest in corporate responsibility to meet consumers growing demands for ethical goods12. The case study of Aveda's sourcing partnerships in Western Australia for Sandalwood is a good example of an enhanced corporate responsibility partnership[13].

5. Non-commercial research and other research activities

Purpose:

Biodiversity research, including research on genetic resources, plays a key role in developing critical knowledge for the effective implementation of the CBD and the achievement of its three objectives. In that respect the EU wants to underscore the eminent importance of simplified access to genetic resources for non-commercial research (such as taxonomic work), while recognizing that steps to clearly identify non-commercial intent is important for generating confidence and trust with providers of genetic resources. [14]

Main forms of utilization of genetic resources:

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[12] For example the Union for Ethical Biotrade Verification Framework, http://www.ethicalbiotrade.org/verification/verifiers/

[13] Laird and Wynberg, "CBD Technical Series No. 38 "ABS in Practice: Trends in Partnerships Across Sectors", p. 75.

[14] For more information on definitions on non-commercial research see OECD (1994). "Main definitions and conventions for the measurement of research and experimental development (R&D)".

It is difficult to characterise "research" as a user sector of genetic resources as research on genetic resources includes a range of institutions, processes and activities. While this user sector is mainly characterized through its intent, namely not-for profit research on a genetic resource, it overlaps with other commercial uses. Areas where not-commercial research is untertaken are e.g. taxonomic research, the development of biodiversity inventories or biodiversity assessments. It is critical to underscore the eminent role of research on genetic resources with non-commercial intent.

Discussions on the utilisation of genetic resources for "research" should also give recognition to the special role of botanical gardens – or other ex-situ collection organizations such as museums and zoos- that identify, collect, preserve/conserve and exchange genetic resources. As such, ex-situ collection organizations make an important contribution to research on genetic resources and facilitate further research on genetic resources by others.

Typical acquisitions of genetic resources:

It has to be considered that a vast number of applications for access to genetic resources come from ex situ collections wishing to use genetic resources for non-commercial conservation or education related purposes, such as biodiversity inventories and ecological assessments and for increasing taxonomic knowledge. Benefits generated by non-commercial research activities are almost always non-monetary and generally arise from the comparative use of a library of specimens (such as taxonomic tools, phylogenies, vegetation maps and conservation assessments) and from institution-level capacity-building activities (such as technology transfer, staff exchange, student supervision and training courses). Only very rarely are benefits attributable to individual specimens. So far there are some helpful activities on compliance of researchers/ ex situ collections and public funding agencies in place. Non-commercial research activities have developed policies, strategies and instruments to promote ABS implementation in user countries. The main work has been so far on voluntary codes of conduct and information policy.

As regards Botanical Gardens, they have developed a set of principles on access to plant genetic resources and benefit sharing for participating institutions. These principles state that participating institutions should share fairly and equitably with the country of origin and other stakeholders, the benefits arising from the use of genetic resources and their derivatives (including non-monetary benefits) and in monetary benefits the case of commercialisation. In the Common Policy Guidelines for Participating Institutions15, the benefits set out in paragraph 9.2.2 are largely focussed on non-monetary benefit sharing such as sharing of research results, access to collections, augmentation of national collections, transfer of technology, training, institutional development and joint research and development. However, it includes monetary benefits, such as royalties, in the case of commercialisation.

These instruments, i.e. the International Plant Exchange Network (IPEN), the Principles on Access to Genetic Resources and Benefit-Sharing and MOSAICC (International Code of Conduct concerning micro organisms) present model systems which respond to ABS provisions and help to document transparently the transfer of plant genetic resources.

What are the ranges of options and approaches for taking these different characteristics into account and that may bring coherence to access and benefit-sharing related practices in different sectors?

It is critical that the international ABS regime provides the flexibility to accommodate differences in the current or future utilisation of genetic resources in and between different user groups. If this is not achieved, the international ABS regime risks preventing potential users of genetic resources from seeking access to those genetic resources that fall within the scope of the international ABS regime. This would run counter to the CBD, its objectives and provisions relevant to access and benefit-sharing.

One important option for taking into account different characteristics of groups or sectors utilising genetic resources while disseminating best practices in ABS across sectors is the development of sectoral model clauses for potential inclusion in Material Transfer Agreements (MTAs). Such optional model clauses could enhance legal certainty for both providers and users of genetic resources and support the fair and equitable sharing of benefits arising from the utilisation of genetic resources.

They should primarily be developed through sectoral processes in a bottom-up way with the involvement of stakeholders.

Elements that could serve as a starting point for inclusion in optional sectoral model clauses include:

[15] http://www.kew.org/conservation/agrbs-policy.pdf

- Model clauses stipulating that access for non-commercial research could be linked to an obligation to make the resulting knowledge publicly available[16];

- Model clauses on the settlement of disputes arising between parties of a MTA;

- Specifying notions of what constitutes an "utilisation" of genetic resources in the sense of Article 15.7 CBD in specific user chains and sectors using genetic resources.

- Identification of sectoral reference points that are characteristic for research and product development based on genetic resources in specific chains of users of genetic resources. E.g., identifying the typical boundary between non-commercial and commercial research.

- Specifying sectoral notions of non-monetary and monetary benefit-sharing.

- Confidential elements will generally be negotiated for individual contracts and do not seem to lend themselves for inclusion in optional model clauses.

EU available studies on the issue of sectoral approaches:

Holm-Muller, Richerzhagen and Tauber. 2005. "Users of Genetic Resources in Germany. Awareness, participation and Positions regarding the Convention on Biological Diversity", BfN-Skripten 126.

Sukhwani. 2008. «Caracterización del uso de los recursoss genéticos por parte de los distintos sectores de la industria y la ciencia". Ministerio de Industria, Turismo y Comercio; Oficina Espanola de Patentes.

FinaEnviro. 2006. Evaluation économique de l'utilisation des ressources génétiques en France. Rapport technique du Ministère de l'Ecologie, de l'Energie, du Développement Durable et de l'Aménagement du Territoire (in French only).

[16] This leaves room for properly negotiated agreements with a different content. An MTA could, for instance, grant exclusive access to research material for a limited time-span.

MEXICO

COMENTARIOS SEMARNAT
GRUPO DE EXPERTOS, SOBRE CONCEPTOS, TÉRMINOS Y DEFINICIONES
ACCESO A RECURSOS GENÉTICOS Y DISTRIBUCIÓN DE LOS BENEFICIOS

(a) What are the different ways of understanding biological resources, genetic resources, derivatives and products and what are the implications of each understanding for the development of the main components of the international regime on access and benefit-sharing, including in relation to sectoral and subsectoral activities and in relation to commercial and non-commercial research?

a)¿Cuáles son los distintos modos de comprensión de recursos biológicos, recursos genéticos, derivados y productos y cuáles son las repercusiones de cada comprensión en el desarrollo de los componentes principales del régimen internacional de acceso y participación en los beneficios, incluso en relación con las actividades sectoriales y con la investigación comercial y no comercial?

Para comenzar adecuadamente, es necesario reconocer las razones por las cuales existe la necesidad de construir un régimen internacional para el acceso a los recursos genéticos y la distribución de los beneficios derivados de dichos recursos. Una vez entendido este punto será más sencillo proceder a la búsqueda de las definiciones adecuadas.

> *Es de nuestro entender que, tomando en consideración que "los países proveedores (están tratando) de encontrar formas para reforzar las legislaciones ABS en el país donde se localizan los usuarios", el Régimen Internacional es percibido como de importancia primordial, y las dificultades de monitoreo y cumplimiento (debido a, que se carece de mecanismos para asegurar el cumplimiento) son citadas como la razón subyacente para contar con un "régimen vinculante" sobre ABS.* (Cabrera y López Silva, 2007 6)

Por lo tanto, los puntos clave a tratar durante las labores del Grupo de Expertos son las definiciones que sean verdaderamente prácticas para el instrumento internacional. El propósito de este instrumento es garantizar la validez transfronteriza de los contratos privados que se realicen sobre los recursos genéticos. México reconoce que los recursos genéticos son una mercancía muy peculiar como objeto de dichos contratos, por lo que el derecho internacional privado como hoy se conoce, no les da la cobertura necesaria.

Por otro lado, el avance de la ciencia y la tecnología tiene que ser una referencia para entender la necesidad de ampliar la concepción original que sobre los recursos genéticos tenía la CBD, como un recurso con amplios beneficios potenciales para compartir. El actual estado del arte en biotecnología, es diferente del que se tenía en 1992. La investigación no está basada únicamente en genes, pero sí principalmente en sus componentes. ¿Son esos componentes derivados? O ¿los derivados son genes y compuestos procesados por humanos

¿Si los compuestos de los genes y los genes mismos deberían formar parte del régimen, deberían los recursos biológicos, en tanto continentes de aquellos, formar parte de este Régimen Internacional?
El régimen internacional lo concebimos como el instrumento que permite la validez, más allá de las fronteras del país proveedor, de un contrato privado entre dos o más partes bajo el cual se realiza el acceso a los recursos genéticos de un territorio dado y que a cambio se definen una serie de beneficios, independientemente de si la bioprospección se dará con fines comerciales o no, o independientemente de si es para el sector farmacéutico o de alimentos. Los beneficios podrán ser monetarios o no monetarios independientemente de la finalidad del acceso.

En este sentido, el RI debería respetar los términos en los que se elaboren los contratos y proteger esos términos. Sin prejuzgar los contratos, sabemos que habrá beneficios monetarios y / o no monetarios. La actividad meramente científica, sin que de cómo resultado un producto comercializable, dará beneficios a aquellos que llevan a cabo la investigación científica, pues el conocimiento científico no responde a un proceso lineal, sino de la acumulación de una diversidad de experiencias. Estas experiencias por sí mismas contienen un valor que puede y debe ser compartido. Estos son una parte importante de los beneficios no monetarios que deben ser distribuidos con los proveedores.

De igual forma, si un beneficio se da en el sector farmacéutico o en el de alimentos, parte de ese beneficio deberá ser compartido con los proveedores, independientemente del mercado específico en que se de. Los términos de la distribución se fijarían en los contratos privados.

2

Lo que es importante para que todo lo anterior responda al tercer objetivo de la CBD es la construcción de capacidades y la difusión de la información correcta, para que el acceso se de bajo términos mutuamente acordados y con el consentimiento libre e informado previo, bajo la jurisdicción del país proveedor y el país usuario haga respetar dichos contratos en su derecho local entendiendo la dificultad (por las asimetrías económicas y políticas de las partes contratantes) de que la parte proveedora lo haga a través de los canales jurídicos tradicionales del derecho mercantil.

(b) Identify different forms of utilization of genetic resources in relation to sectoral and subsectoral activities in the context of Article 15, paragraph 7, of the Convention;

b) Determinar las diversas formas de utilización de los recursos genéticos en relación con las actividades sectoriales en el contexto del artículo 15, párrafo 7 de del Convenio:

De acuerdo con algunos autores, a lo largo de la cadena de adición de valor, dependiendo del material que se utiliza, se observan cinco rutas de aprovechamiento de los recursos biológicos y genéticos

a) moléculas para la producción de fármacos y otros productos industriales
b) enzimas especialmente para industria alimenticia y química
c) genes para la producción de mejoramiento genético
d) partes u organismos completos para el desarrollo de productos naturales, nutracéuticos, cosméticos, etc. y,

e) información para nuevos mercados de la bioinformática, la genómica, etc.

Como se menciona en el primer punto de este documento, no queda claro cuál debe ser la razón para tener diferentes tratos sectoriales en materia de acceso o de distribución de beneficios.

El acceso una vez realizado permite disponer el material de acuerdo con lo que las investigaciones subsecuentes vayan indicando. De la investigación, pueden generarse usos inesperados, cambios de sector como usuario intermedio o final. En principio, los contratos deberán cubrir estas eventualidades, también la eventualidad de que algún uso científico finalmente sea comercial, a menos que se obtenga nuevamente el consentimiento previo e informado del proveedor a través de términos mutuamente acordados. También podrían prohibirlo expresamente. Todas esas variantes pueden suceder y se deben entender en el marco de la elaboración del régimen internacional. Existen tantas variaciones posibles que el RI no puede ser casuístico, sino tener lineamientos generales. En este sentido, lo que debe quedar muy claro es que cuando existan beneficios, sean estos tangibles o no, deberá haber una distribución de los mismos por vía monetaria u otra no monetaria.

(c) Identify and describe sector specific characteristics of access and benefit-sharing arrangements and to identify the differences, if any, between approaches in sectors;

c) Determinar y describir las características específicas del sector y los arreglos de acceso y participación en los beneficios y determinar las diferencias, de haberlas entre los diferentes enfoques sectoriales;

De acuerdo con Casas, 2004, se pueden identificar cuatro grandes grupos sociales, como principales agentes de la cadena de adición de valor para el aprovechamiento de los recursos biológicos y genéticos:

La comunidad científica,
Los grupos étnicos y comunidades locales
La empresa privada y
El Sector Público

Se ha identificado que los sectores que utilizan los recursos genéticos son:
Industria Farmacéutica
Medicina Botánica
Fitomejoramiento
Horticultura
Biotecnología y Sectores Relacionados con la Salud, Industria y Agrícola
Control de Plagas
Industria Cosmética y Cuidado Personal
Pesca, Germoplasma pesquero, Recursos Genéticos en Fondos Marinos en aguas continentales
Bioremediación.

Cada uno de los sectores tiene sus características dinámicas y específicas en particular por los "productos" obtenidos o "derivados" del acceso a los recursos genéticos. En este sentido, es muy probable que la modalidad de los beneficios no monetarios pueda variar de acuerdo al sector usuario de los recursos genéticos. El segmento monetario de los beneficios, seguramente será referido en los contratos bajo modalidades más convencionales y homogeneizadas, independientemente del sector usuario.

Hablando de los Indígenas y las comunidades locales, las formas de utilización de los RG en realidad es a través del uso de ciertas características de los especímenes que están determinadas por su genética, más que la utilización misma de los recursos genéticos y sus derivados. Estos usos están asociados a: la Medicina tradicional (herbolaria), Gastronomía, Recolección y bancos de semillas, principalmente. Las actividades de este sector básicamente se enmarcan en el sector primario de la economía (caza, recolección y pesca) Este sector social suele hacer aprovechamientos directos de los ecosistemas en los que habitan, y su relación con los recursos es directa y se encuentra íntimamente relacionada con sus creencias y su vida espiritual. Es importante mencionar que a los recursos están asociados una gran cantidad de conocimientos tradicionales así como prácticas culturales que, desde la comprensión holística, determinan la función del recurso.

Las características de los pueblos indígenas y las comunidades locales que son sustancialmente diferentes al del resto de los sectores, básicamente radica en su comprensión holística de la realidad; en la secularización del pensamiento y la praxis político social así como espiritual. El acceso es directo desde el ecosistema, a través de la colecta, se relaciona con conocimientos heredados en cuanto a técnicas y procedimientos así como a los lugares y temporada de la colecta. Los beneficios del aprovechamiento de los recursos son directos, en salud, alimentación, vestido y en cuanto al beneficio de la permanencia de especies (biodiversidad) a partir de la colecta, por ejemplo de semillas para la siembra. A diferencia de otros sectores, la búsqueda del beneficio no es principalmente monetario, no es un asunto de ganancia en la lógica de la industria o el capital. Nuevamente la diferencia del enfoque es que el sector indígena concibe la realidad de forma integral y no fragmentada como el pensamiento de la sociedad no indígena.

La dificultad en el diseño del RI radica precisamente en el abismo que separan a la visión de mercado de la cosmovisión indígena. La aplicación de derechos de propiedad y, por tanto, la mercantilización de todos los bienes y servicios que nuestra sociedad contemporánea aplica, no corresponde a los usos y costumbres tradicionales de muchos grupos indígenas. La falta de un diálogo efectivo sobre ABS ha sido en múltiples ocasiones la causa de la polarización de los puntos de vista involucrados en la negociación.

(d) What are the range of options and approaches for taking these different characteristics into account and that may bring coherence to access and benefit-sharing related practices in different sectors?

d)¿Cuál es la gama de opciones y enfoques para tomar en cuenta éstas diferentes características que pudieran dar cohesión a las prácticas de acceso y participación de los beneficios afines a los distintos sectores?

El reparto equitativo de los beneficios depende del acceso a los recursos genéticos y su uso. "Un punto de vista legislativo menciona que las principales acciones que desencadenan la distribución de los beneficios son el acceso a los recursos genéticos" y el "uso de los recursos genéticos" y que ambos son conceptos ligados.

Se debe poner énfasis en que las condiciones mínimas deben respetar que sea bajo términos mutuamente acordados, basados en el consentimiento fundamentado previo entre el proveedor y el usuario de los recursos genéticos y el conocimiento tradicional a ellos relativo.

La participación de los beneficios en todo tipo de utilización ha generado confusión, pues hay varios países que proponen que la utilización con fines científicos tenga otro tratamiento. Se reconoce que la notificación de transferencias de materiales, tal como es hoy en día la investigación científica en la que puede haber varias al año, tal vez no debería de estar supeditada a autorizaciones previas por parte de alguna autoridad pertinente o de los proveedores, sino ser más libre. Este punto es digno de considerarse, pues es cierto, muy válido y no debe afectar el propósito del RI que es a partir de que los beneficios existen. La falta de seguimiento que ello implicaría, podría subsanarse responsabilizando a un solo sujeto jurídico en el lapso en el que esas transferencias se lleven a cabo, independientemente de quién tenga lo tangible y lo intangible sujeto del contrato.

También se pide a la hora del acceso un tratamiento más flexible, con menos requisitos a la comunidad científica. La realidad es que el acceso debe ser poco burocrático para todos los posibles usuarios que quieran el acceso legal, justo para combatir a la biopiratería, pero con las condiciones mínimas necesarias para que se garantice lo más posible la distribución equitativa de los beneficios potenciales.

Adicionalmente, las universidades alrededor del mundo están muy ligadas a financiamiento privado, con contratos de utilización de las innovaciones tecnológicas con potencial comercial por parte de las empresas que apoyan dichas investigaciones. Es decir, la línea de independencia de la investigación científica llevada a cabo en centro "no lucrativos" y la comercial es muy fina y porosa. Por tanto, una diferenciación entre ambos usos en los requisitos de acceso no es muy conveniente ni justificada. En esta línea, al referirse exclusivamente a "los beneficios", no debe haber duda de que si la actividad científica genera beneficios, estos deben entrar al ámbito del RI como una bioprospección comercial.

Se propone y espera que el uso definitivo de los beneficios sea para la conservación y utilización sostenible de la biodiversidad, en congruencia con el propio Convenio. No obstante, se argumenta con razón que los beneficios serán utilizados de acuerdo con las prioridades de los proveedores, principalmente, de acuerdo al CPI y los TMA.

Es importante tomar en cuenta que los beneficios a partir de los MAT, puedan abarcar un rango muy amplio que puede ir desde el pago inicial, hasta un porcentaje sobre la renta del producto desarrollado con el recurso; aún más si hay conocimiento tradicional asociado. También es importante mencionar aquí el origen del recurso.

Referencias:

Cabrera Medaglia, Jorge and Christian López Silva (2007). Addressing the Problems of Access: Protecting Sources, While Giving Users Certainty. IUCN, Gland, Switzerland. xiv + 77pp.

T.R Young 2004 "Recursos Genéticos", y "Utilización de los Recursos Genéticos." Taller Internacional de Expertos sobre el Acceso a los Recursos Genéticos y Distribución de los Beneficios (Cuernavaca, México, 2004)

ENGLISH TRANSLATION

SEMARNAT COMMENTS

EXPERT GROUP ON CONCEPTS, TERMS AND DEFINITIONS

ACCESS TO GENETIC RESOURCES AND BENEFIT SHARING

(a) What are the different ways of understanding biological resources, derivatives and products, and what are the implications of each understanding for the development of the main components of the international regime on access and benefit-sharing, including in relation to sectoral and subsectoral activities and in relation to commercial and non-commercial research?

In order to begin properly, we must recognize why it is necessary to create an international regime on access and benefit-sharing. Once this is understood, it will be easier to find the appropriate definitions.

> *As we understand it, taking into account that "provider countries (are trying) to find ways of strengthening ABS legislation in countries where users are located", the International Regime is considered to be of the utmost importance, and monitoring and compliance problems (caused by the lack of mechanisms to ensure compliance) are given as the underlying reason for having a "binding ABS regime". (Cabrera and López Silva, 2007 6)*

The key points to be addressed by the Working Group therefore consist of finding definitions that are truly practical for the international regime. The purpose of this instrument is to guarantee the transboundary validity of private contracts regarding genetic resources. Mexico acknowledges that genetic resources are very special merchandise under such contracts, which is why they are not adequately covered by private international law in its current form.

Furthermore, scientific and technological advances must be a reference point for understanding the need to broaden the CBD's original concept of genetic resources as being a resource with vast potential benefits to be shared. The current state of the art in biotechnology is very different today than it was in 1992. Research is not only based on genes, but mainly on the components of genes. Are these components derivatives? Or: are derivatives genes and compounds processed by humans?

If gene compounds and genes themselves should be included under the regime, should biological resources also be included, seeing as they contain gene compounds and genes?

We see the international regime as a tool that will make it possible to validate, beyond the borders of provider countries, a private contract between two or more parties for access to the genetic resources of a given territory, in exchange for which a series of benefits are defined, regardless of whether bioprospecting is for commercial purposes, or for the food or pharmaceutical sector. Benefits may be monetary or non-monetary, depending on the purpose of access.

In this respect, the IR must observe the terms set out in contracts and protect those terms. Without prejudging said contracts, we know that monetary and/or non-monetary benefits will exist. Purely scientific activity, which may not result in a marketable product, will generate benefits for those doing the scientific research, because scientific knowledge does not follow a linear process, but is rather the accumulation of a variety of experiences. These experiences are a significant part of the non-monetary benefits that must be shared with providers.

Similarly, if benefits arise in the pharmaceutical or food sector, some of said benefit should be shared with providers, regardless of the market in which those benefits occur. The terms for benefit-sharing would be set out in the private contracts.

There must be capacity-building and dissemination of accurate information for all of the above to match the CBD's third objective, and for access to take place under mutually agreed terms, with free prior informed consent, under the jurisdiction of the provider country, with the user country ensuring the observance of such contracts under local law, given the difficulty (due to economic and political asymmetry in contracting parties) involved in having the provider party enforce contracts using traditional commercial law channels.

(b) **Identify different forms of utilization of genetic resources in relation to sectoral and subsectoral activities in the context of Article 15, paragraph 7, of the Convention;**

According to certain authors, throughout the value added chain, depending on the material used, there are five ways of taking advantage of biological and genetic resources:

a) molecules for the production of pharmaceuticals and other industrial products

b) enzymes, especially for the food and chemical industries

c) genes, for genetic production and improvement

d) parts of or entire organisms for the development of natural, homeopathic, cosmetic and other products

e) information for new markets, such as biocomputing, genomics, etc.

As mentioned in the first point of this document, it is not clear why there should be sector differences when dealing with access or benefit sharing.

Access, once it has taken place, makes it possible to use the material as indicated by subsequent research. The research can lead to unexpected uses, and changes of sector, as well as of intermediate and end user. In principle, contracts must cover these possibilities, as well as the possibility that scientific use might end up being commercial, unless prior informed consent is obtained from the provider once again, using mutually agreed terms. in such a case,

commercial use could also be expressly prohibited. All of these options exist, and must be understood when creating the international regime. There are so many potential variations that IR cannot be case-based, but must rather have general guidelines. In this respect, it must be very clear that in the presence of benefits, be they tangible or intangible, there must be sharing of said benefits through monetary or non-monetary means.

c) Identify and describe sector-specific characteristics of access and benefit-sharing arrangements and to identify the differences, if any, between approaches in sectors;

According to Casas, 2004, four main social groups can be identified as the main agents in the value added chain when it comes to the use of biological and genetic resources:

The scientific community

Ethnic groups and local communities

Private enterprise and

The public sector

The sectors that use genetic resources have been identified as being:

The pharmaceutical industry

Botanical medicine

Plant breeding

Horticulture

Biotechnology and sectors linked to Health, Industry and Agriculture

Pest Control

The cosmetics and personal hygiene industry

Fishing, fish geoplasma, genetic resources from the seabed in continental waters

Bioremediation

Each of these sectors has its own dynamic and specific characteristics, particularly with regard to the “products” obtained or “arising” from access to genetic resources. It is therefore highly likely that the non-monetary benefit aspect will vary according to the sector using the genetic resources. The monetary aspect of benefits will surely be covered by contracts through more conventional and uniform clauses, regardless of the user sector.

With regard to indigenous and local communities, genetic resource use is more a matter of using certain genetically-determined characteristics of specimens, than of using the genetic resources and their derivatives as such. These uses are linked mainly to: traditional medicine (herb lore), gastronomy, gathering, and seed banks. For the most part, activities in this sector fall under the primary sector of the economy (hunting, gathering and fishing). This sector tends to engage in direct use of the ecosystems they inhabit, and their relationship with resources is intimately linked to their beliefs and spiritual life. It is important to mention that these resources are associated with a vast amount of traditional knowledge and cultural practices that determine a given resource’s function through holistic understanding.

The characteristics of indigenous and local communities, which are substantially different from the other sectors, are basically rooted in their holistic understanding of reality; in the secularisation of thought and in socio-political as well as spiritual practice. Access to resources is direct in the ecosystem, through gathering, and is linked to inherited knowledge about techniques and procedures, as well as the places and times for gathering. The benefits of use are also direct, in the form of health care, food and clothing, and species maintenance (biodiversity) through the gathering, for example, of seeds for planting. Unlike other sectors, benefits are not sought mainly for monetary gain, and it is not a matter of gains in the industrial or capital sense. Once again, the difference in perspective is that the indigenous sector sees reality as a whole, and not as being fragmented, which is the view of non-indigenous society.

It is basically this chasm between the market view and the indigenous world view that makes it so difficult to design the international regime. The application of property rights and the attendant commercialisation of all goods and services in modern society does not correspond to the traditional ways and customs of many indigenous groups. Lack of effective dialogue on ABS has, on multiple occasions, led to the polarization of views during talks.

(d) what are the range of options and approaches for taking these different characteristics into account, and that may bring coherence to access and benefit-sharing related practices in different sectors?

The equitable sharing of benefits depends on the type of access to and use of genetic resources. “A legislative point of view states that the main trigger activities for benefit sharing are access to genetic resources” and “use of genetic resources”, and that both concepts are connected.

It should be stressed that the minimum conditions to be observed must involve mutually agreed terms, based on prior informed consent between the provider and the user of genetic resources and associated traditional knowledge.

Benefit sharing has caused confusion for all types of use, because many countries propose that use for scientific purposes be treated differently. It has been acknowledged that material transfer notices, which can occur many times a year given the nature of modern scientific research, should not be subject to prior authorization by a relevant authority or by providers, but should take place more freely. It is worth considering this, seeing as it is very valid point, and should not affect the purpose of the IR, under which benefits must first exist in order to be shared. Any potential lack of monitoring could be remedied by holding a single legal entity responsible during the period of said transfers, regardless of who holds the tangible and intangible elements covered by the contract.

More flexible treatment upon access is also being requested, with fewer requirements for the scientific community. The fact is that there should be little red tape surrounding access for all potential users seeking legal access, simply to fight biopiracy, but with the necessary minimum conditions to guarantee, as much as possible, the equitable sharing of potential benefits.

Furthermore, universities around the world are very closely linked to private funding, with contracts for the use of technological innovations that have marketing potential by the companies that support the research leading to said innovations. In other words, there is a very thin and permeable line between research done in “non-profit” organisations and commercial research. It is therefore neither particularly appropriate nor justified to differentiate between these two types of use when it comes to access requirements. Accordingly, exclusively with regard to “benefits”, there should be no doubt that if scientific activity yields benefits, said benefits should be included under the IR as commercial bioprospecting.

The definitive use of benefits should ideally be for the conservation and sustainable use of biodiversity, consistent with the Convention itself. However, it is rightfully argued that the benefits shall be used according to provider priorities, primarily in accordance with PIC and MAT.

It is important to take into account that benefits based on MAT can range widely, from an initial payment to a percentage amount for leasing the product developed using the resources; even moreso if there is associated traditional knowledge. It is also important to mention the origin of the resource.

References:

Cabrera Medaglia, Jorge and Christian López Silva (2007). Addressing the Problems of Access: Protecting Sources, While Giving Users Certainty. IUCN, Gland, Switzerland. xiv + 77pp.

T.R. Young 2004 “Genetic Resources” and “Use of Genetic Resources”. International Workshop of Experts on Access and Benefit-Sharing (Cuernavaca, Mexico, 2004)

NIGERIA

NIGERIA'S VIEW ON CBD NOTIFICATION 2008-104-ACCESS AND BENEFIT SHARING

(a)

Question i): What are the different ways of understanding biological resources, derivatives and products?

Answer: i) The different ways are: physical identification of any part or whole of organisms their Compositions , their Uses, materials thereof and items/material that can be derived as a result of processing and manufacturing using an organism(s).

Question ii): What are the different ways of understanding genetic resources derivatives and products?

Answer: ii) Identification of the Compositions (hereditary Materials living and dead) of any part or whole of organisms and their Uses, materials thereof and items/material that can be derived as a result of processing and manufacturing using hereditary Materials living and dead.

Question iii): What are the implications of each understanding for the development of the main components of the international regime on access and benefit-sharing, including in relation to sectoral and subsectoral activities and in relation to commercial and non-commercial research?

Answer: iii) The implication is that Biological Resources, Genetic Resources, derivatives and products have to be identified, standards created for the regulation of access to each and to have common regime to reduce conflicting views.

(b)

Question: Identify different forms of utilization of genetic resources in relation to sectoral and subsectoral activities in the context of Article 15, paragraph 7, of the Convention;

Answer: Some of the forms of utilization of genetic resource sectorally are: Pharmaceutics, Scientific/Technological Research, food processing and Derivatives Production of ingredients. In all cases equitable and fair benefit sharing arrangements should be put in place in accordance with National regulation.

(c)

Question: Identify and describe sector specific characteristics of access and benefit-sharing arrangements and to identify the differences, if any, between approaches in sectors;

Answer: Pharmaceutics: The acquisition of Biological Resources for the purpose of pharmaceutics will require benefit sharing arrangement of providing jobs, technological transfer, Sharing of accruable profit.

Scientific/Technological Research: Establishment of Research Institute within area of location of biological resources and training of indigenous/local communities to make them employable in the research institute. Identify other benefits that will involve the elites, local people to meet their peculiar needs.

(d)

Question: What are the range of options and approaches for taking these different characteristics into account and that may bring coherence to access and benefit-sharing related practices in different sectors?

Answer: Some of the range of options and approaches include having meetings and dialogue with local people who are directly involved in the location of biological resources, local government, policy makers, relevant government institutions and other relevant stakeholders. There should be holistic regulatory and administrative framework in place.

NORWAY

Norwegian submission in response to Notification 2008-104 concerning Use of Terms, Working Definitions and Sectoral Approaches

What are the different ways of understanding biological resources, genetic resources, derivatives and products?

Biological resource / genetic resource
The definitions of the terms *biological resources/genetic resources* in the international ABS regime should be the same as the definitions in the CBD. We do not favour to change the existing CBD definitions. It is important to notice that the term *genetic resource* is defined from its utilisation. What is a genetic resource may therefore depend on the intended or the actual use of the genetic material. It can only be characterized as a genetic resource when the intended or actual use is based on the genetic information in the biological material.

The same biological material may have a function both as a biological resource and as a genetic resource. The actual or potential utilisation of the biological material will decide which of these two categories the biological material belongs to. When the biological material e.g. a soya bean is to be used as a commodity and to be sold in bulk on an international market, it is a biological resource. However the same biological material may represent a genetic resource when used in a plant breeding programme.

The definition on what is a genetic resource could vary from sector to sector. In the cosmetic industry a flower petal may represent a genetic resource, in food production it may be the seed. It may be important to address the definition in each of the sectors using genetic resources.

Derivates and products
The terms of reference for the ABS negotiations require parties "to address the issue of derivatives". The concern with regard to derivatives is addressed by the CBD through the Bonn Guidelines.

Derivates and products from a genetic resource will also differ between the different utilisations of the material.

First a comment with regard to the perceived limitation of the existing definition of genetic resources. In order to be covered by the CBD definition of genetic material, the material of plant, animal, microbial or other origin needs to contain functional units of heredity. No definition exists on "functional units of heredity". However, our understanding is that it refers to all the elements that are necessary to establish functional units of heredity. Functionality is expanding all the time in light of technology development. A functional unit of heredity is the sum of a number of interacting physical factors – not simply a piece of DNA. This is also the understanding with regard to the definition of genetic material in the preparatory work on new Norwegian legislation on access to genetic resources and benefit-sharing.

As a working definition we prefer using the term derivatives and products the way they are used in the context of Mutually Agreed Terms in the Bonn Guidelines (paras. 36 and 44(f)(i). It is then up to providers and users of genetic resources to decide to what extent derivatives or products should be covered by mutually agreed terms on benefit-sharing. As such, they should be considered as falling within the scope of the regime, taking also into account that benefits

arising from the commercial and other utilization of genetic resources are covered by the scope of the Bonn Guidelines.

In the International Treaty on Plant Genetic Resources it is the commercializing of a product which is a genetic resource that may trigger benefit sharing.

It should be borne in mind that countries can anyway exercise the general authority over their genetic resources as set out in Article 3 of the CBD.

Identify and describe sector specific characteristics of access and benefit-sharing arrangements and what are the range of options and approaches for taking these different characteristics into account and that may bring coherence to access and benefit-sharing related practices in different sectors?

Main and common components of the international regime should be elements that are relevant for all uses of genetic resources and for all the sectors. Even though a "one size fits all" approach may not be applicable, we need some overarching and common elements for all sectors.

Such elements could be cross-cutting issues such as the overarching concept of triggering mechanisms for PIC, MAT and benefit-sharing, requirement for disclosure of source and PIC, e.g. included in applications for governmental research funds or in patent applications, requirements for transparency in access and application procedures, international certificates of origin, capacity building/technology transfer, measures to support recognition and support for the rights of indigenous peoples and local communities and compliance and enforcement mechanisms.

In addition relevant sector-specific components could be included in model contracts/clauses for Mutually Agreed Terms. The development of such model contracts should be prioritized for those sectors where it is most urgent to ensure that benefit sharing is taking place. Such model contracts should look into relevant benefit sharing provisions in order to ensure fair and equitable benefit sharing systems and specific compliance and monitoring mechanisms. The different sectors have very specific and different needs in relation to an ABS regime and these need to be addressed separately. In addition, the relevant stakeholders may differ from sector to sector. The sectors/stakeholders need to participate and contribute to developing model standard clauses to be included in Material Transfer Agreements (MTAs). Such model standard clauses should be optional in order to allow for the necessary flexibility.

The international ABS regime should provide flexibility to respect existing and allow for the implementation and further development of other, more spesialised international ABS systems. Specific consideration needs to be given to the following ABS regulations: The International Treaty on Plant Genetic Resources for Food and Agriculture represents an example on this. Its standard Material Transfer Agreement represents a model contract that takes care of the specific features of PGRFA and introduces a mechanism of benefit-sharing which is adapted to the use of PGRFA. The ITPGRFA also addresses specific stakeholders and other specific needs for conservation and sustainable use of PGRFA, and includes ex situ collections established prior to the entry into force of the CBD.

Animal genetic resources may also require special attention in the form of standard model clauses.

SWITZERLAND

Expert Group Meeting of the CBD on Concepts, Terms, Working Definitions and Sectoral Approaches Windhoek, 2 - 5 December 2008

Non-Paper
Provided by Switzerland

I. Introduction

At its 9th meeting, the Conference of the Parties (COP) of the Convention on Biological Diversity (CBD) agreed on a roadmap to complete the negotiation of an International Regime (IR) on access to genetic resources and the fair and equitable sharing of benefits arising from the utilization of such resources (ABS). With decision IX/12 the COP decided to establish a group of technical and legal experts on concepts, terms, working definitions and sectoral approaches in ABS. According to Annex II of said decision, the experts shall "examine the issue of concepts, terms, working definitions and sectoral approaches […] The expert group shall provide legal and technical advice, including, where appropriate, options and/or scenarios."[1]

The decision defines specific questions the expert group has to address:

(a) What are the different ways of understanding biological resources, genetic resources, derivatives and products and what are the implications of each understanding for the development of the main components of the IR, including in relation to sectoral and subsectoral activities and in relation to commercial and non-commercial research?
(b) Identify different forms of utilization of genetic resources in relation to sectoral and subsectoral activities in the context of Article 15, paragraph 7, of the Convention;
(c) Identify and describe sector specific characteristics of access and benefit-sharing arrangements and to identify the differences, if any, between approaches in sectors;
(d) What is the range of options and approaches for taking these different characteristics into account and that may bring coherence ABS related practices in different sectors?

Decision IX/12 invites Parties to the Convention to provide information and views related to the issues to be addressed by this expert group. Switzerland submits this technical discussion non-paper in accordance with this decision. This technical input to the meeting of technical and legal experts is intended to serve as a contribution to the expert discussions.

[1] Decision IX/12, Annex II, B, § 1, UNEP/CBD/COP/9/29.

This non-paper concentrates on question (a) as the issues outlined there are very important for the drafting of the IR. Without a clear understanding of the terms and the basic concepts behind these terms, it will almost be impossible to develop a functioning system for ABS. While the experts gathered at the meeting are mandated to explain the different ways the various terms can be understood, the meeting is also an opportunity to develop a common understanding among the experts. However, the experts do not have to decide which terms to include in the IR as fully worded definitions. Their mandate does not go so far. That decision is left to the negotiators of the ad hoc open-ended Working Group on ABS (WG-ABS).

II. General Considerations

Since the start of the ABS discussions under the CBD, the interpretation of certain terms defined by the CBD is very contentious.[2] "Biological resources" and "genetic resources" belong to this category. Additionally, delegations made reference to terms such as "products" and "derivatives", which are not defined by the Convention and for which no common understanding exists. It has to be emphasized that however the terms used under the IR are defined they cannot go beyond the jurisdiction of the CBD.

In Decision VII/19, the COP recognized that the regime should be practical, transparent, and efficient.[3] It should also avoid arbitrary treatment of the stakeholders involved in access and benefit sharing. Hence, the IR should allow for legal certainty and consistency in its operation. These characteristics are important criteria against which the interpretation and use of terms have to be measured. Whatever understanding of the terms in question is eventually going to be integrated into provisions of the IR, it should facilitate the effective and operational implementation across all provider and user sectors of the ABS-provisions of the CBD.

III. Biological and Genetic Resource

The Convention defines "biological resources" and "genetic resources" as follows:

- "Biological resources" includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.
- "Genetic resources" means genetic material of actual or potential value.

The CBD defines "genetic material" as any material of plant, animal, microbial or other origin containing functional units of heredity. This means that while every genetic resource is a biological resource, not every biological resource is also a genetic one.

The definitions are quite openly formulated and could benefit from further clarification. The call for further clarification does not mean in any way that the definition used in the CBD should be reviewed and newly worded. It only means that negotiators, legislators, experts and other practitioners involved in ABS should be aware of what the CBD intends to achieve. As Cabrera

[2] As an example see UNEP/CBD/COP/6/INF/40 for a range of views of an expert group nominated by the Executive Secretary of the CBD to determine the use of terms for the Bonn Guidelines before the COP 6 in 2002.
[3] UNEP/CBD/COP/7/21.

and Lopez illustrate, different approaches and options regarding the terms in question have very different consequences for ABS legislation.[4]

Art 15, the central ABS provision of the CBD, refers to genetic resources only and not to biological resources. Hence, it seems important to develop a clear understanding of genetic resources. The most straightforward approach could consists in further clarifying the terms contained in the CBD-definition of genetic resources, i.e. "genetic material", "of actual or potential value" and "functional units of heredity".

To clarify the term "genetic material" it should be recognized that genetic material is used to store the genetic information of any organic life form. For all currently known organisms, the physical property of genetic material is almost exclusively Deoxyribonucleic Acid (DNA). Some viruses use Ribonucleic Acid (RNA) as their genetic material. Hence, some biological resources, as for example Artemisinin that is isolated from the medicinal plant *Artemisia annua* and used to treat malaria, are not a genetic resource (but Artemisinin can be understood as the result of the utilization of a genetic resources, see below).

Having said this, it is important to understand which biological resources contain genetic material. Genetic material can be isolated from different levels of the biological diversity, i.e. a) the ecosystem level (e.g. genetic material contained in a soil sample), b) the organism level (e.g. genetic material contained in a plant or a bacterium); c.) the cellular and sub-cellular level (e.g. genetic material contained in a stem cell or an organelle); d.) the genetic level (e.g. isolated DNA/RNA). Moreover, genetic material can at least to some degree be synthesized from the genetic information of an organic life form (e.g. from the genetic code or a specific sequence). Hence, the genetic information could be seen as another level of genetic resources.

All levels are regularly used in research, be it in academic research or in the more commercially oriented research and development processes. Nothing in the CBD speaks against the inclusion of the first four of the five levels in the understanding of the term "genetic resources". With regard to the information level, the mentioning of material in the definition of the CBD indicates its exclusion. The general criteria of practicability, legal certainty and consistency as well as efficiency will assist negotiators to assess whether or not all or only some levels should be included in the IR.

This understanding of "genetic resources" is still too broad, as two additional triggers have to be met according to the definition of the CBD: The reference made to "functional units of heredity" and to "of actual and potential value" in this definition is important. This points to the interest of using the genetic traits of the material in order to create value. A broad understanding of creating value would include trade with and utilization of a crop harvested for food or feed processing, such as canola grain for oil production or sugar cane for sugar processing. Such an understanding would run counter to the intention of Art. 15 CBD, as given early on by the negotiators of the Convention: the ABS provisions should not alter conventional market activities and markets of

[4] Cabrera Medaglia, Jorge and Christian Lopez Silva (2007). Addressing the Problems of Access: Protecting Sources, While Giving Users Certainty. IUCN, Gland, Switzerland, pp 30. See also Tvedt, Morton Walloe and Tomme Young (2007). Beyond Access: Exploring Implementation of the Fair and Equitable Sharing Commitment in the CBD. IUCN, Gland, Switzerland, pp. 63.

biological products and commodities.[5] The same has to be true for the IR if it is to stay within the jurisdiction of the CBD. The Regime could follow the example of the International Treaty and specifically state that the definitions used under the IR are not intended to cover trade in commodities.[6]

To summarize, a genetic resource under the CBD can be understood as genetic material with specific genetic properties of interest for academic and commercial use, which can be analyzed, characterized, multiplied, propagated, transferred into other organisms, synthesized or otherwise submitted to a biotechnological[7] process.[8]

IV. Derivatives and Products

Neither the CBD nor the Bonn Guidelines define the terms "derivatives" or "products" of genetic resources. Difficult discussions were already going on during the negotiations leading to the adoption of the Bonn Guidelines about whether or not such terms were needed at all.[9] Some delegations wanted the terms to be included in the Bonn Guidelines with regard to access and benefit-sharing provisions while others strongly opposed their mentioning. Cabrera/Lopez[10] and Burton[11] give some explanations about why these terms caused so tense discussions. Some of these discussions are rooted in a misunderstanding: some derivatives may have maintained the characteristics of a genetic resource while others may have lost it. It is not always clear to what type of derivative delegates refer. Therefore it is important to develop a clear understanding.

A. Developing an Understanding

According to the Oxford Dictionary of English, a "derivative" is something that is based on another source. A derivative is thus distinct from but originates in the original source. In the setting of ABS, the distinction is rooted in a human activity. A "derivative" is the result of the utilization of a genetic resource. The Oxford Dictionary of English defines a "product" as a substance or article manufactured or refined through natural, chemical or manufacturing processes for sale. Thus, a "product" is also the result of a utilization of genetic resources in the framework of ABS. The difference between a "derivative" and a "product" is that the latter is a subcategory of the former. Every "product" is a "derivative" but not every "derivative" is a "product". A "derivative" becomes a "product" if it has been developed with the aim to be sold and when it is ready to be sold, i.e. ready for a form of commercialization.

The outlined understanding of "product" is supported by the only multilateral legally binding agreement in the area of ABS, the International Treaty on Plant Genetic Resources for Food and Agriculture (International Treaty, ITPGRFA) and its standard material transfer agreement

[5] Cabrera/Lopez, p 29.
[6] The intention not to alter markets of and trade in commodities is reflected in the International Treaty on Plant Genetic Resources for Food and Agriculture and its Standard Material Transfer Agreement, see Art. 2 of the Treaty and the definition of "product" in the Standard Material Transfer Agreement.
[7] Biotechnology is the exploitation of biological processes for industrial and other uses, such as the use of yeast in bread production, beer brewing or genetic engineering.
[8] Very similar, Cabrera/Lopez, p.32.
[9] See UNEP/CBD/COP/6/INF/40 for some views expressed prior to COP 6.
[10] Cabrera/Lopez, pp. 38.
[11] Burton, Geoff. Derivatives. Discussion Paper. International Expert Workshop on Access to Genetic Resources and Benefit Sharing. Mexico, 2004.

(SMTA). According to Art. 2 SMTA a "product" means a plant genetic resource for food and agriculture that incorporates (as evidenced, for example, by pedigree or notation of gene insertion)[12] the Material or any of its genetic parts or components that is ready for commercialization […][13].

Hence, the qualifier for a "product" is its readiness for commercialization.[14] No further development is necessary for its commercialization. This qualification also represents one trigger for monetary benefit sharing under the MLS of the International Treaty.

The complex question is how this concept could be translated to the CBD. Within the ITPGRFA, a product is mainly a result of breeding and constitutes always a genetic resource. This is not necessarily the case under the CBD.[15] Hence, the understanding of the term "product" under the CBD's IR should refrain from stating that a product is a genetic resource. It could read as follows: A product is the result of the utilization of the accessed genetic resource and is ready for commercialization.

One way the Parties to the CBD can make use of the terms "derivatives" and "products", is to relate them to the steps in the ABS process as they are identified by the Bonn Guidelines[16]:

a. activities prior to access;
b. research and development on the genetic resource accessed; and
c. commercialization and other uses of the genetic resource accessed.

Lit. a is not of relevance for the terms discussed here. While the term "derivative" covers lit. b and c, "product" relates to lit. c only. In order to further differentiate "derivatives", the term "product under development" can be used for an accessed genetic resource, which is submitted research and development with a commercial aim. The International Treaty again supports this differentiation. The SMTA contains a definition for plant genetic resources for food and agriculture under development.[17] The remaining category of derivatives, hence cases where research and development is conducted without commercial intent, could be called "used genetic resources under research".

To summarize, the understanding of "derivative" could be differentiated into the following three categories. This understanding of "derivatives" can help the experts at the meeting to

[12] Brackets and text included by the author. The SMTA includes the same text in an explanatory footnote.
[13] The definition in the SMTA continues as follows: "[…], excluding commodities and other products used for food, feed and processing." We have already mentioned that the IR should not apply to commodities.
[14] Art. 2 SMTA: "To commercialize" means to sell a Product or Products for monetary consideration on the open market, and "commercialization" has a corresponding meaning. Commercialization shall not include any form of transfer of Plant Genetic Resources for Food and Agriculture under Development.
[15] Cabrera/Lopez, p. 39 give the example of a natural molecule that has resulted from a genetic resource use.
[16] Bonn Guidelines, para. 23.
[17] Art. 2 SMTA: "Plant Genetic Resources for Food and Agriculture under Development" means material derived from the Material, and hence distinct from it, that is not yet ready for commercialization and which the developer intends to further develop or to transfer to another person or entity for further development. The period of development for the Plant Genetic Resources for Food and Agriculture under Development shall be deemed to have ceased when those resources are commercialized as a Product.

conceptualize the difference between commercial and non-commercial research as asked for in the terms of reference for the expert meeting:

1. used genetic resources under research (research not aiming at commercialization);
2. products under development (R&D aiming at commercialization); and
3. products (commercialization).

To fully understand the term "derivative" and the three categories just mentioned, we have to apply yet another perspective. The question we have to ask is whether the "derivative" has maintained or lost the characteristics of a genetic resource as described in chapter III above in the process of utilization of the original genetic resource. There is the type of derivatives that still are genetic resources, but distinct from the genetic resource they derived from, e.g. an orchid with a new genetic trait obtained through breeding. Hence they represent new genetic resources. And there is the type of derivatives that lost the characteristics of genetic resources, e.g. a secondary metabolite isolated from a plant or a fungus. This differentiation in these two types is important when considering the implications of the understanding of the terms for the main component of the future IR.

B. Implications for the IR

As already mentioned there were long and tense deliberations going on during the finalization of the Bonn Guidelines at COP VI in The Hague about the question of including a reference to "derivatives and products". These discussions also circled around the issue of whether prior informed consent procedures (PIC) should apply to "derivatives and products" resulting from the use of genetic resources or whether these terms should only be mentioned with regard to benefit sharing provisions. Finally, the parties to the CBD agreed to include these terms in the Bonn Guidelines in relation to benefit sharing only.[18] Hence, the Bonn Guidelines reflect an international understanding that "derivatives and products" should not be submitted to PIC.

Does the understanding of "derivatives" and "products" developed above allow us to maintain this conclusion the negotiators of the Bonn Guidelines drew? Or does the IR have to take a different approach?

Implications for the Main Component B of the IR: Access to Genetic Resources

The scope of Art. 15 CBD refers to access to genetic resources and the fair and equitable sharing of benefits arising from the utilization of such resources. Art. 15.2 – to 15.5 CBD set the regulative framework for access to genetic resources. The wording of these paragraphs makes it clear that derivatives that are not genetic resources are not subject to the access provisions in Art. 15 CBD. Hence, PIC does not apply with regard to such derivatives, no matter what category the derivative belongs to.

What about derivatives and products that maintain the characteristics of a genetic resource? In order to respond to this question, it is important to keep the categories of derivatives in mind: accessed genetic resource under research and development, product under development, and product. This non-paper already mentioned that it is not the intention of the CBD to change

[18] Bonn Guidelines, para. 36(l) and 44(i).

markets in commodities. It follows that products, because they are commercialized on open markets, should not be submitted to PIC or other procedures under access legislation.

Art. 15 CBD does not exclude the application of PIC with regard to access to derivatives that kept the characteristics of a genetic resource in the form of "accessed genetic resources under research and development" or to "products under development". The CBD does not differentiate between existing genetic resources and new ones. But the question arises what country is responsible for and has the authority to determine PIC for the access to the derivative – the country providing the original genetic resource or the country providing the derivative?

Art. 15.5 CDB states that access to genetic resources shall be subject to PIC of the Contracting Party providing such resources, unless otherwise determined by that Party. Bearing in mind the relevant definitions of the CBD[19] and the fact that a derivative is distinct from the genetic resource it originated from, the country is competent for the PIC where the development of original genetic resource into a derivative has taken place. This may or may not be the country of origin of the genetic resource the derivative is based on. It all depends on the location where this genetic resource has been utilized.[20]

Hence, it is the country where the derivative has been developed that has the legal authority to determine whether a derivative other than a product is subject to PIC. In executing this authority, the country will have to take into account the more general criteria for an ABS-regime, such as the efficiency and the practicability of the system. Certainly other considerations such as the freedom of research and economic value creation are other important criteria for the providing country to take into account. From this viewpoint, it would almost be impossible in practical terms to submit such derivatives under PIC procedures. Hence, the IR should follow the approach taken for good reasons by the Bonn Guidelines and refrain from relating PIC to derivatives that have maintained the characteristic of a genetic resource.

Implications for Main Component A of the IR: Fair and Equitable Benefit-Sharing
The situation with regard to benefit sharing and derivatives is different. According to Art. 15.7 CBD, benefits that arise from the utilization of genetic resources shall be shared with the Party providing such resources, and be based on mutually agreed terms (MAT).

As mentioned before, the three categories of "derivatives" are results of such utilization, no matter whether they maintained or lost the characteristics of a genetic resource. Therefore, the fact that the country of origin of a genetic resource may have lost its authority to determine PIC to a derivative[21] of such a resource does not mean that this country would not be entitled to benefit sharing anymore. Hence, the IR should state that benefits are to be shared with regard to derivatives on the basis of an agreement between the provider and the user of the genetic resource. The IR should highlight the importance of passing on the benefit-sharing obligation

[19] For the wording of the relevant definitions see Art. 2 CBD: "Country of origin of genetic resources", "country providing genetic resources", "domesticated or cultivated species", and "in-situ conditions".
[20] Art 2 CBD: "Country providing genetic resources" means the country supplying genetic resources collected from in-situ sources, including populations of both wild and domesticated species, or taken from ex-situ sources, which may or may not have originated in that country. In the light of the above, Art. 15.6 CBD is becoming significant for countries of origin. Until now, this Article has drawn little attention.
[21] See above, fn 20 and corresponding text.

from the user to a subsequent user in case the genetic resource is transferred to another entity during the development. Only the commercialization of the finished product ends the transferral obligation. In order to foster confidence in the regime, the main component of the IR on compliance will have to consider ways and means to assist the transfer of the benefit-sharing obligation.

Art. 15.7 distinguishes two different types of benefits: the results of research and development and the benefits arising from the commercial and other utilization of genetic resources. The Bonn Guidelines offer a more detailed list of possible monetary and non-monetary benefits this framework. The utilization is the central element linking a genetic resource to benefit sharing.[22] Both, the Convention and the Guidelines, embed the concept of value creation and value addition through utilization as trigger for benefit sharing. Looking at the values created is also a means to identify the kind of benefits to be shared.

The understanding of "derivative" and "product" as mentioned in part IV A above reflects this concept. It assists providers and users of genetic resources to identify the potential kinds of benefits to be shared:

Category of derivative	Primary benefit sharing option	Secondary benefit sharing option
used genetic resource under research	Results of R&D	Non-monetary/monetary
Product under development	Non-monetary	Monetary
Product	Monetary	Non-monetary

The closer the utilization gets to the commercialization stage, the more feasible monetary benefit sharing becomes. The specific benefits to share in a particular ABS setting need of course to be agreed upon in a MAT.

V. Summary

The main findings can be summarized as follows:

General considerations:

- The general criteria to guide the development of an understanding of the terms are the following: practicability; efficiency; transparency; legal certainty and consistency of the IR.
- The scope and the objectives of the CBD set the limits for the development of a common understanding of the terms.

Biological and genetic resources:

- There is no need to further clarify the understanding of "biological resources" as Art. 15 CBD refers only to "genetic resources".

[22] Tvedt/Young, pp. 58.

- The term "genetic resources" should not be understood in a way as to cover trade in biological and other commodities.
- "Genetic material" can be obtained from five levels: the ecosystem level; the organism level; the cellular and sub-cellular level; the genetic level; and the information level. The general criteria have to assist negotiators to assess whether all or only some levels should be included in the IR.
- CBD's definition of "genetic resources" should be understood as genetic material with specific genetic properties of interest for academic and commercial use, which can be analyzed, characterized, multiplied, propagated, transferred into other organisms, synthesized or otherwise submitted to a biotechnological process. This material is within the scope of Art. 15 CBD.

Derivatives and products:

- The term "derivatives" can be differentiated into the categories of a) accessed genetic resources for research; b) products under development; and c) products.
- There are two types of "derivatives": the ones that maintain the characteristics of a genetic resource, and the ones that lost this characteristic.
- The type of "derivatives" that lost the characteristic of genetic resources falls outside the scope of Art. 15.2 – 15.5 CBD and should not be dealt with in the component B of the IR dealing with access to genetic resources. Alternatively, the IR could state that these derivatives are not subject to PIC and other access procedures according to the CBD.
- In principle, "derivatives" that maintained the characteristics of a genetic resource are submitted to the authority of the country providing these derivatives to determine PIC for these derivatives. However, based on general considerations about practicability and efficiency of the ABS system, the IR should not relate PIC provisions to derivatives that have maintained the characteristic of a genetic resource. Alternatively, the IR should explicitly exempt derivatives from PIC.
- All types and categories of derivatives can be subject to benefit sharing.
- The categories of derivatives assist providers and users to determine the benefits to be shared and to be included in MAT.

II. SUBMISSIONS FROM NON-PARTIES

UNITED STATES OF AMERICA

United States Department of State

Bureau of Oceans and International Environmental and Scientific Affairs

Office of Ecology and Natural Resource Conservation

October 16, 2008

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

Dear Dr. Djoghlaf:

This is in response to Notification SCBD/SEL/OJ/VN/GD/64650 (2008-104), inviting written submissions to the meeting of the group of technical experts on concepts, terms, working definitions and sectoral approaches. The United States appreciates the opportunity to contribute to these discussions, and I submit the following points for consideration by the group of technical experts with a view to advancing the work of the Working Group on Access and Benefit Sharing.

Different ways of understanding genetic resources

Taking the definition of "genetic resources" and "genetic material" in the CBD as a reference point, it does seem that it would be expeditious to exclude certain types of resources from coverage by the "international regime" currently under negotiation. We understand that there is substantial support among other governments and stakeholders for narrowing the scope of the regime to avoid overlap with other fora. Therefore, as a practical matter for the purpose of these negotiations, the scope of genetic resources covered should at least exclude *inter alia* the following:

(a) Human genetic resources;

(b) Pre-convention specimens, or those genetic resources that were acquired before the entry into force of the Convention on Biological Diversity on December 29, 1993;

(c) Genetic resources acquired between December 29, 1993, and the adoption of an ABS regime;

(d) *Ex-situ* genetic resources;

(e) Commodities in trade;

(f) Marine genetic resources found in areas beyond national jurisdiction;

(g) Genetic resources located in the Antarctic Treaty area;

(h) Plant genetic resources covered by the FAO International Treaty of Plant Genetic Resources for Food and Agriculture;

(i) Plant pathogens covered by the International Plant Protection Convention (IPPC).

We note that the United States believes that the centerpiece of any regime needs to be rules at the national level regarding access and benefit sharing. Therefore, taking into account the above-mentioned exclusions, it must be up to each national government to determine a definition of "genetic resources."

Different ways of understanding derivatives and products

The United States is concerned by proposals to include derivatives and products under any adopted ABS regime(s). In our view, inclusion of either goes beyond the scope of the Convention. Further, it is clear there is a divergence of views among Parties with regard to what constitutes a derivative or a product, and there are strong differences in how different sectors (pharmaceutical, industrial, chemical, agricultural, etc.) define these terms and concepts. There was prolonged discussion of this issue during the lengthy negotiations of the Bonn Guidelines and it does not seem expeditious or worthwhile to pursue this discussion again in these negotiations.

Regarding different ways of understanding biological resources

Under the terms of the CBD, "biological resources" extends well beyond the subset of "genetic resources" and therefore is beyond the scope of Article 15 of the Convention and outside the mandate of the Working Group

Sectoral approaches

The U.S. national experience has shown that access and benefit sharing arrangements are currently effectively negotiated on a case-by-case, contract basis. Such contracts allow the flexibility necessary to provide for sector-specific approaches and best practices. Further, contracts clearly identify responsibilities of the provider and recipient and provide a mechanism for compliance through dispute settlement. These contracts are readily enforced under national law, therefore providing clear relief in the case of a dispute.

We also note that governments, prominent industry organizations and other stakeholders in various sectors make available sample Material Transfer Agreements (MTA) to their

members. We encourage the Technical Experts Group to analyze samples of such agreements for commonalities within and among sectors.

I am including samples of MTAs for consideration by the Technical Experts Group from key stakeholders in the United States. The attached MTAs are from Michigan State University, the Biotechnology Industry Organization (BIO), and the National Institutes of Health (NIH). They represent three of the leading sectors utilizing genetic resources. The NIH MTA is a model that is basic to collaboration. Also included is a sample NIH letter of collection that anticipates cooperation to collect, research, develop and license the resulting technology to a company with a specific condition that it would share benefits with the source country. Additionally, while not included with this letter, the USDA Agricultural Research Service has a number of MTA samples that can be reviewed at this Website: http://www.ars.usda.gov/Business/docs.htm?docid=2075

I would like to express my appreciation for the Secretariat including the U.S. comments in the synthesis paper presented to the Technical Experts Group in December.

Sincerely,

A. David Miller
ABS Focal Point
United States of America

Attachments: As stated.

Please note that the "Suggested Model Material Transfer Agreement" of the Biotechnology Industry Organization (BIO), also submitted by BIO, is available from page 80 to 90.

MICHIGAN STATE UNIVERSITY
OFFICE of INTELLECTUAL PROPERTY
MATERIAL TRANSFER AGREEMENT

In consideration of the mutual covenants contained herein and with the intention of being legally bound under the laws of the State of Michigan, the parties agree as follows:

1. The Parties to this Agreement are: Michigan State University, 246 Administration Building, East Lansing, Michigan 48824 (hereinafter referred to as "MSU") and _____ (hereinafter referred to as "RECIPIENT")

2. The "Material" covered by this Agreement is defined as and includes the following: _____, (hereinafter referred to as "MATERIAL") developed by _____.

3. RECIPIENT agrees that this MATERIAL will not be released to any person other than the signatories of this Agreement except co-workers working directly under a signatory's supervision who have agreed to abide by the terms and conditions of this Agreement. No one is permitted to take or send this MATERIAL to any other location, unless prior written permission is obtained from MSU; such permission will not be withheld unreasonably.

4. This Agreement and the resulting transfer of MATERIAL constitute a restricted license for RECIPIENT to use the MATERIAL solely for research purposes. MATERIAL will not be used for any purpose inconsistent with this Agreement. Commercial use of this Material is strictly prohibited. Nothing in this Agreement grants RECIPIENT any additional rights, either expressed or implied, to MSU patents, trademarks, copyrights, know-how, or other intellectual property. Upon completion of the work for which this restricted license is granted, MATERIAL which has not been destroyed will be disposed of as explicitly directed by MSU. MSU retains title to the MATERIAL, and RECIPIENT shall not obtain any ownership rights in MATERIAL. MATERIAL is experimental in nature and it is provided WITHOUT WARRANTY OF ANY SORT, EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR USE. MSU makes no representation and provides no warrant that the use of the MATERIAL will not infringe any patent or proprietary rights of third parties.

5. RECIPIENT agrees that it will follow all applicable guidelines, laws, regulations, and government agency guidelines regarding the use, transport, security, and disposal of such MATERIAL.

6. If the RECIPIENT desires to use or license the MATERIAL for commercial purposes, the RECIPIENT agrees, in advance of such use or licensing, to obtain a commercial license from MSU. It is understood by the RECIPIENT that the MSU shall have no obligation to grant such a license to the RECIPIENT, and may grant exclusive or non-exclusive commercial licenses to others, or sell or assign all or part of the rights in the MATERIAL to any other third party(ies), subject to any pre-existing rights held by others and obligations to the United States Government.

7. RECIPIENT hereby agrees, upon the request of MSU, to provide MSU with a report of observations related to the MATERIAL by providing MSU with a description of the results of research using the MATERIAL. To the extent that it is able, RECIPIENT will acknowledge MSU's contribution.

8. RECIPIENT hereby grants MSU a nonexclusive, royalty-free right to use for its internal research purposes any information or new material developed by RECIPIENT using the MSU MATERIAL. MSU agrees not to publish results involving RECIPIENT'S data without citing its source and giving credit of authorship/creatorship to RECIPIENT, provided that is desired by RECIPIENT.

9. This Agreement will terminate on the earliest of the following dates: (1) when the MATERIAL becomes generally available from third parties, for example, through reagent catalogs, (2) on completion of RECIPIENT'S current research with the MATERIAL, or (3) on thirty (30) days written notice by either party to the other.

10. The RECIPIENT assumes all liability for damage that may arise from its use, storage or disposal of the Material. MSU will not be liable to the RECIPIENT for any loss, claim or demand made by the RECIPIENT, or made against the RECIPIENT by any other party, due to or arising from the use of the Material by the RECIPIENT, except to the extent permitted by law when caused by the gross negligence or willful misconduct of MSU.

11. RECIPIENT agrees to pay MSU _____ United States Dollars ($_____ USD) for its preparation ad distribution costs.

12. This Agreement shall be executed by all Parties through a duly authorized representative and shall be effective as of the date of last signing.

MICHIGAN STATE UNIVERSITY

By:_____

Typed Name: Michael R. Poterala

Title: Executive Director

Address: 2727 Alliance Drive
Second Floor, Suite D
Lansing, MI 48910

Date: _____

RECIPIENT:_____

By:_____

Typed Name: _____

Title: _____

_____

_____

Date: _____

MICHIGAN STATE UNIVERSITY
Scientist

By: _____

Typed Name:_____

Address:_____

Date:_____

RECIPIENT
Scientist

By: _____

Typed Name:_____

Address:_____

Date:_____

LETTER OF COLLECTION

Agreement Between
[Source Country Organization, SCO]
and the
Developmental Therapeutics Program
Division of Cancer Treatment and Diagnosis
National Cancer Institute

The Developmental Therapeutics Program (DTP), Division of Cancer Treatment and Diagnosis ("DCTD"), National Cancer Institute (NCI) is currently investigating plants, micro-organisms, and marine macro-organisms as potential sources of novel anticancer drugs. The DTP is the drug discovery program of the NCI which is an Institute of the National Institutes of Health (NIH), an arm of the Department of Health and Human Services (DHHS) of the United States Government. While investigating the potential of natural products in drug discovery and development, NCI wishes to promote the conservation and sustainable utility of biological diversity, and recognizes the need to compensate [Source Country, SC] organizations and peoples in the event of commercialization of a drug developed from an organism collected within their country's borders.

As part of the drug discovery program, DTP has contracts with various organizations for the collection of plants, micro-organisms and marine macro-organisms worldwide. DTP has an interest in investigating plants, micro-organisms and marine macro-organisms from [Source Country], and wishes to collaborate with the [Source Country Government (SCG) or Source Country Organization(s) (SCO)] as appropriate in this investigation. The collection of plants, micro-organisms and marine macro-organisms will be within the framework of the collection contract between the NCI and the NCI Contractor [Contractor] which will collaborate with the appropriate agency in the [SCG or SCO]. The NCI will make sincere efforts to transfer knowledge, expertise, and technology related to drug discovery and development to the [appropriate Source Country Organization (SCO] in [Source Country] as the agent appointed by the [SCG or SCO], subject to the provision of mutually acceptable guarantees for the protection of intellectual property associated with any patented technology. The [SCG or SCO], in turn, desires to collaborate closely with the DTP/NCI in pursuit of the investigation of its plants, micro-organisms and marine macro-organisms, subject to the conditions and stipulations of this agreement.

A. The role of DTP, DCTD, NCI in the collaboration will include the following:

1) DTP/NCI will screen the extracts of all plants, micro-organisms and marine macro-organisms provided from [Source Country] for anticancer activity, and will provide the test results to [SCO] on an annual basis. Such results will be channeled via Contractor.

2) The parties will keep the test results and subsequently-developed data confidential until approved for publication by the parties. Before either party submits a paper or abstract containing test results for publication, the other party shall have 60 days to review and, as necessary file a sole or joint patent application in accordance with Article 6.

3) Any extracts exhibiting significant activity will be further studied by bioassay-guided fractionation in order to isolate the pure compounds(s) responsible for the observed activity. Since the relevant bioassays are only available at DTP/NCI, such fractionation will be carried out in DTP/NCI laboratories. A suitably qualified scientist designated by [SCO] may participate in this process subject to the terms stated in Article 4. In addition, in the course of the contract period, DTP/NCI will assist the [SCO], thereby assisting the [Source Country], to develop the capacity to undertake drug discovery and development, including capabilities for the screening and isolation of active compounds from plants, micro-organisms and marine organisms.

4) Subject to the provision that suitable laboratory space and other necessary resources are available, DTP/NCI agrees to invite a senior technician or scientist

designated by [SCO] to work in the laboratories of DTP/NCI or, if the parties agree, in laboratories using technology which would be useful in furthering work under this agreement. The duration of such visits would not exceed one year except by prior agreement between [SCO] and DTP/NCI. The designated visiting scientist(s) will be subject to provisions usually governing Guest Researchers at NIH. Salary and other conditions of exchange will be negotiated in good faith. Costs and other conditions of visits will also be negotiated in good faith prior to the arrival of the visiting scientist(s).

5) In the event of the isolation of a promising agent from a plant, micro-organism or marine macro-organism collected in [Source Country], further development of the agent will be undertaken by DTP/NCI in collaboration with [SCO]. Once an active agent is approved by the DTP/NCI for preclinical development, [SCO] and the DTP/NCI will discuss participation by SCO scientists in the development of the specific agent.

The DTP/NCI will make a sincere effort to transfer any knowledge, expertise, and technology developed during such collaboration in the discovery and development process to [SCO], subject to the provision of mutually acceptable guarantees for the protection of intellectual property associated with any patented technology.

6) DTP/NCI/NIH will, as appropriate, seek patent protection on all inventions developed under this agreement by DTP/NCI employees alone or by DTP/NCI and [SCG or SCO] employees jointly, and will seek appropriate protection abroad, including in [Source Country], if appropriate. All resulting patent applications and patents shall be assigned to the U.S. Department of Health and Human Services and managed by NIH. Under current NIH policy, all inventors of such assigned patents may receive royalties in accordance with said NIH policy for any royalty-bearing license(s) for these patent(s).

7) All licenses granted on any patents resulting from this collaboration shall contain a clause referring to this agreement and shall indicate that the licensee has been apprised of this agreement.

8) Should an agent derived from an organism collected under the terms of this agreement eventually be licensed to a pharmaceutical company for production and marketing, DTP/NCI will request that NIH/OTT require the successful licensee to negotiate and enter into agreement(s) with the appropriate [SCG] agency(ies) or [SCO] within twelve (12) months from the execution of said license. This agreement(s) will address the concern on the part of the [SCG or SCO] that pertinent agencies, institutions and/or persons receive royalties and other forms of compensation, as appropriate.

9) The terms of Article 8 shall apply equally to invention**s** directed to a direct isolate from a natural product material, a product structurally based upon an isolate from the natural product material, a synthetic material for which the natural product material provided a key development lead, or a method of synthesis or use of any aforementioned isolate, product or material; though the percentage of royalties negotiated as payment might vary depending upon the relationship of the marketed drug to the originally isolated product. It is understood that the eventual development of a drug to the stage of marketing is a long term process which may require 10-15 years.

10) In obtaining licensees, the DTP/NCI/NIH will require the license applicant to seek as its first source of supply the natural products from [Source Country]. If no appropriate licensee is found that will use natural products available from [Source Country], or if the [SCG] or [SCO] as appropriate, or its suppliers cannot provide adequate amounts of raw materials at a mutually agreeable fair price, the licensee will be required to pay to the [SCG] or [SCO] as appropriate, compensation (to be negotiated) to be used for expenses associated with cultivation of medicinal organisms that are endangered or for other appropriate conservation measures. These terms will also apply in the event that the

licensee begins to market a synthetic material for which a material from [Source Country] provided a key development lead.

11) Article 10 shall not apply to organisms which are freely available from different countries (i.e., common weeds, agricultural crops, ornamental plants, fouling organisms) unless information indicating a particular use of the organism (e.g., medicinal, pesticidal) was provided by local residents to guide the collection of such an organism from [Source Country], or unless other justification acceptable to both the [SCG or SCO] and the DTP/NCI is provided. In the case where an organism is freely available from different countries, but a phenotype producing an active agent is found only in [Source Country], Article 10 shall apply.

12) DTP/NCI will test any pure compounds independently submitted by the [SCG or SCO] scientists for antitumor activity, provided such compounds have not been tested previously in the DTP/NCI screens. If significant antitumor activity is detected, further development of the compound may, as appropriate, be undertaken by DTP/NCI in consultation with the [SCG or SCO].

Should an NCI/NIH patent on an agent derived from the submitted compound(s) eventually be licensed to a pharmaceutical company for production and marketing, DTP/NCI will request that NIH/OTT require the successful licensee to negotiate and enter into agreement(s) with the appropriate [SCG agency(ies) or SCO] within twelve (12) months from the execution of said license. This agreement will address the concern on the part of the [SCG or SCO] that pertinent agencies, institutions and/or persons receive royalties and other forms of compensation, as appropriate.

13) DTP/NCI may send selected samples to other organizations for investigation of their anti-cancer, anti-HIV or other therapeutic potential. Such samples will be restricted to those collected by NCI contractors unless specifically authorized by the [SCG or SCO]. Any organization receiving samples must agree to compensate the [SCG or SCO] and individuals, as appropriate, in the same fashion as described in Articles 8-10 above, notwithstanding anything to the contrary in Article 11.

B. The role of the Source Country Government ("SCG") or Source Country Organization(s) ("SCO") in the collaboration will include the following:

1) The appropriate agency in [SCG or SCO] will collaborate with Contractor in the collection of plants, micro-organisms and marine macro-organisms, and will work with Contractor to arrange the necessary permits to ensure the timely collection and export of materials to DTP/NCI.

2) Should the appropriate agency in [SCG or SCO] have any knowledge of the medicinal use of any plants, micro-organisms and marine macro-organisms by the local population or traditional healers, this information will be used to guide the collection of plants, micro-organisms or marine macro-organisms on a priority basis where possible. Details of the methods of administration (e.g., hot infusion, etc.) used by the traditional healers will be provided where applicable to enable suitable extracts to be made. All such information will be kept confidential by DTP/NCI until both parties agree to publication.

The permission of the traditional healer or community will be sought before publication of their information, and proper acknowledgment will be made of their contribution.

3) The appropriate agency in [SCG or SCO] and Contractor will collaborate in the provision of further quantities of active raw material if required for development studies.

4) In the event of large amounts of raw material being required for production, the appropriate agency of the [SCG or SCO] and Contractor will investigate the mass propagation of the material in [Source Country]. Consideration should also be given to

sustainable harvest of the material while conserving the biological diversity of the region, and involvement of the local population in the planning and implementation stages.

5) [SCG or SCG] and SCO scientists and their collaborators may screen additional samples of the same raw materials for other biological activities and develop them for such purposes independently of this agreement.

This agreement shall be valid as of the date of the final authorized signature below for an initial period of five (5) years, after which it can be renewed by mutual agreement. It may be amended at any time subject to the written agreement of both parties. Copies of such amendments will be kept on file at both of the addresses indicated below.

For the National Cancer Institute:	**For [SCI] or [SCO]:**
_____	_____
John E. Niederhuber, M.D.	Name (typed):
Director, National Cancer Institute	Title:
_____	_____
Date	Date
mailing and contact address:	mailing and contact address:
Technology Transfer Branch National Cancer Institute at Frederick Fairview Center, Suite 500 1003 - W. 7th Street Frederick, Maryland 21701-8512 U.S.A. Telephone: 301-846-5465 Facsimile: 301-846-6820	

MASTER AGREEMENT REGARDING USE OF THE
UNIFORM BIOLOGICAL MATERIAL TRANSFER AGREEMENT
dated March 8, 1995

Upon execution of an Implementing Letter in the form attached, which specifies the materials to be transferred, this organization agrees to be bound by the terms of the attached Uniform Biological Material Transfer Agreement ("UBMTA") published in the Federal Register on March 8, 1995.

Attachments: UBMTA
Implementing Letter

Organization: _____

Address: _____

_____

_____

Authorized Official: _____

Title: _____

Signature: _____ Date: _____

Please return an executed copy of this Master Agreement to:
The UBMTA Project
Association of University Technology Managers (AUTM)
60 Revere Drive, Suite 500
Northbrook, IL 60062

AUTM will be maintaining signed originals and the official list of signatory organizations.

THE UNIFORM BIOLOGICAL MATERIAL TRANSFER AGREEMENT

(dated March 8, 1995)

I. Definitions:

1. **PROVIDER**: Organization providing the **ORIGINAL MATERIAL**. The name and address of this party will be specified in an implementing letter.

2. **PROVIDER SCIENTIST**: The name and address of this party will be specified in an implementing letter.

3. **RECIPIENT**: Organization receiving the **ORIGINAL MATERIAL**. The name and address of this party will be specified in an implementing letter.

4. **RECIPIENT SCIENTIST**: The name and address of this party will be specified in an implementing letter.

5. **ORIGINAL MATERIAL**: The description of the material being transferred will be specified in an implementing letter.

6. **MATERIAL**: **ORIGINAL MATERIAL**, **PROGENY**, and **UNMODIFIED DERIVATIVES**. The **MATERIAL** shall not include: (a) **MODIFICATIONS**, or (b) other substances created by the **RECIPIENT** through the use of the **MATERIAL** which are not **MODIFICATIONS**, **PROGENY**, or **UNMODIFIED DERIVATIVES**.

7. **PROGENY**: Unmodified descendant from the **MATERIAL**, such as virus from virus, cell from cell, or organism from organism.

8. **UNMODIFIED DERIVATIVES**: Substances created by the **RECIPIENT** which constitute an unmodified functional subunit or product expressed by the **ORIGINAL MATERIAL**. Some examples include: subclones of unmodified cell lines, purified or fractionated subsets of the **ORIGINAL MATERIAL**, proteins expressed by **DNA/RNA** supplied by the **PROVIDER**, or monoclonal antibodies secreted by a hybridoma cell line.

9. **MODIFICATIONS**: Substances created by the **RECIPIENT** which contain/incorporate the **MATERIAL**.

10. **COMMERCIAL PURPOSES**: The sale, lease, license, or other transfer of the **MATERIAL** or **MODIFICATIONS** to a for-profit organization. **COMMERCIAL PURPOSES** shall also include uses of the **MATERIAL** or **MODIFICATIONS** by any organization, including **RECIPIENT**, to perform contract research, to screen compound libraries, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license, or transfer of the **MATERIAL** or **MODIFICATIONS** to a for-profit organization. However, industrially sponsored academic research shall not be considered a use of the **MATERIAL** or **MODIFICATIONS** for **COMMERCIAL PURPOSES** per se, unless any of the above conditions of this definition are met.

11. **NONPROFIT ORGANIZATION(S)**: A university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute. As used herein, the term also includes government agencies.

II. Terms and Conditions of this Agreement:

1. The **PROVIDER** retains ownership of the **MATERIAL**, including any **MATERIAL** contained or incorporated in **MODIFICATIONS**.

2. The **RECIPIENT** retains ownership of: **(a) MODIFICATIONS** (except that, the **PROVIDER** retains ownership rights to the **MATERIAL** included therein), and (b) those substances created through the use of the **MATERIAL** or **MODIFICATIONS**, but which are not **PROGENY**, **UNMODIFIED DERIVATIVES** or **MODIFICATIONS** (i.e., do not contain the **ORIGINAL MATERIAL**, **PROGENY**, **UNMODIFIED DERIVATIVES**). If either 2(a) or 2(b) results from the collaborative efforts of the **PROVIDER** and the **RECIPIENT**, joint ownership may be negotiated.

3. The **RECIPIENT** and the **RECIPIENT SCIENTIST** agree that the **MATERIAL**:

   (a) is to be used solely for teaching and academic research purposes;

   (b) will not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects without the written consent of the **PROVIDER**;

   (c) is to be used only at the **RECIPIENT** organization and only in the **RECIPIENT SCIENTIST's** laboratory under the direction of the **RECIPIENT SCIENTIST** or others working under his/her direct supervision; and

   (d) will not be transferred to anyone else within the **RECIPIENT** organization without the prior written consent of the **PROVIDER**.

4. The **RECIPIENT** and the **RECIPIENT SCIENTIST** agree to refer to the **PROVIDER** any request for the **MATERIAL** from anyone other than those persons working under the **RECIPIENT SCIENTIST's** direct supervision. To the extent supplies are available, the **PROVIDER** or the **PROVIDER SCIENTIST** agrees to make the **MATERIAL** available, under a separate implementing letter to this Agreement or other agreement having terms consistent with the terms of this Agreement, to other scientists (at least those at **NONPROFIT ORGANIZATION(S)** who wish to replicate the **RECIPIENT SCIENTIST's** research; provided that such other scientists reimburse the **PROVIDER** for any costs relating to the preparation and distribution of the **MATERIAL**.

5. (a) The **RECIPIENT** and/or the **RECIPIENT SCIENTIST** shall have the right, without restriction, to distribute substances created by the **RECIPIENT** through the use of the **ORIGINAL MATERIAL** only

if those substances are not **PROGENY**, **UNMODIFIED DERIVATIVES**, or **MODIFICATIONS**.

(b) Under a separate implementing letter to this Agreement (or an agreement at least as protective of the **PROVIDER**'s rights), the **RECIPIENT** may distribute **MODIFICATIONS** to **NONPROFIT ORGANIZATION(S)** for research and teaching purposes only.

(c) Without written consent from the **PROVIDER**, the **RECIPIENT** and/or the **RECIPIENT SCIENTIST** may **NOT** provide **MODIFICATIONS** for **COMMERCIAL PURPOSES**. It is recognized by the **RECIPIENT** that such **COMMERCIAL PURPOSES** may require a commercial license from the **PROVIDER** and the **PROVIDER** has no obligation to grant a commercial license to its ownership interest in the **MATERIAL** incorporated in the **MODIFICATIONS**. Nothing in this paragraph, however, shall prevent the **RECIPIENT** from granting commercial licenses under the **RECIPIENT**'s intellectual property rights claiming such **MODIFICATIONS**, or methods of their manufacture or their use.

6. The **RECIPIENT** acknowledges that the **MATERIAL** is or may be the subject of a patent application. Except as provided in this agreement, no express or implied licenses or other rights are provided to the **RECIPIENT** under any patents, patent applications, trade secrets or other proprietary rights of the **PROVIDER**, including any altered forms of the **MATERIAL** made by the **PROVIDER**. In particular, no express or implied licenses or other rights are provided to use the **MATERIAL**, **MODIFICATIONS**, or any related patents of the **PROVIDER** for **COMMERCIAL PURPOSES**.

7. If the **RECIPIENT** desires to use or license the **MATERIAL** or **MODIFICATIONS** for **COMMERCIAL PURPOSES**, the **RECIPIENT** agrees, in advance of such use, to negotiate in good faith with the **PROVIDER** to establish the terms of a commercial license. It is understood by the **RECIPIENT** that the **PROVIDER** shall have no obligation to grant such a license to the **RECIPIENT**, and may grant exclusive or non-exclusive commercial licenses to others, or sell or assign all or part of the rights in the **MATERIAL** to any third party(ies), subject to any pre-existing rights held by others and obligations to the Federal Government.

8. The **RECIPIENT** is free to file patent application(s) claiming inventions made by the **RECIPIENT** through the use of the **MATERIAL** but agrees to notify the **PROVIDER** upon filing a patent application claiming **MODIFICATIONS** or method(s) of manufacture or use(s) of the **MATERIAL**.

9. Any **MATERIAL** delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. The **PROVIDER** MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE **MATERIAL** WILL NOR INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

10. Except to the extent prohibited by law, the **RECIPIENT** assumes all liability for damages which may arise from its use, storage or disposal of the **MATERIAL**. The **PROVIDER** will not be liable to the **RECIPIENT** for any loss, claim or demand made by the **RECIPIENT**, or made against the **RECIPIENT** by any other party, due to or arising from the **MATERIAL** by the **RECIPIENT**, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the **PROVIDER**.

11. This agreement shall not be interpreted to prevent or delay publication of research findings resulting from the use of the **MATERIAL** or the **MODIFICATIONS**. The **RECIPIENT SCIENTIST** agrees to provide appropriate acknowledgement of the source of the **MATERIAL** in all publications.

12. The **RECIPIENT** agrees to use the **MATERIAL** in compliance with all applicable statutes and regulations, including Public Health Service and National Institutes of Health regulations and guidelines such as, for example, those relating to research involving the use of animals or recombinant DNA.

13. This Agreement will terminate on the earliest of the following dates: (a) when the **MATERIAL** becomes generally available from third parties, for example, through reagent catalogs or public depositories, or (b) on completion of the **RECIPIENT**'s current research with the **MATERIAL**, or (c) on thirty (30) days written notice by either party to the other, or (d) on the date specified in an implementing letter, provided that:

    (i) if termination should occur under 13(a), the **RECIPIENT** shall be bound to the **PROVIDER** by the least restrictive terms applicable to the **MATERIAL** obtained from the then-available sources; and

    (ii) if termination should occur under 13(b) or (d) above, the **RECIPIENT** will discontinue its use of the **MATERIAL** and will, upon direction of the **PROVIDER**, return or destroy any remaining **MATERIAL**. The **RECIPIENT**, at its discretion, will also either destroy the **MODIFICATIONS** or remain bound by the terms of this agreement as they apply to **MODIFICATIONS**; and

    (iii) in the event the **PROVIDER** terminates this Agreement under 13(c) other than for breach of this Agreement or for cause such as an imminent health risk or patent infringement, the **PROVIDER** will defer the effective date of termination for a period of up to one year, upon request from the **RECIPIENT**, to permit completion of research in progress. Upon the effective date of termination, or if requested, the deferred effective date of termination, **RECIPIENT** will discontinue its use of the **MATERIAL** and will, upon direction of the **PROVIDER**, return or destroy any remaining **MATERIAL**. The **RECIPIENT**, at its discretion, will also either destroy the **MODIFICATIONS** or remain bound by the terms of this agreement as they apply to **MODIFICATIONS**.

14. Paragraphs 6, 9, and 10 shall survive termination.

15. The **MATERIAL** is provided at no cost, or with an optional transmittal fee solely to reimburse the **PROVIDER** for its preparation and distribution costs. If a fee is requested by the **PROVIDER**, the amount will be indicated in an implementing letter.

UBMTA IMPLEMENTING LETTER

The purpose of this letter is to provide a record of the biological material transfer, to memorialize the agreement between the PROVIDER SCIENTIST (identified below) and the RECIPIENT SCIENTIST (identified below) to abide by all terms and conditions of the Uniform Biological Material Transfer Agreement ("UBMTA") published in the *Federal Register* on March 8, 1995, and to certify that the RECIPIENT (identified below) organization has accepted and signed an unmodified copy of the UBMTA. The RECIPIENT organization's Authorized Official also will sign this letter if the RECIPIENT SCIENTIST is not authorized to certify on behalf of the RECIPIENT organization. The RECIPIENT SCIENTIST (and the Authorized Official of RECIPIENT, if necessary) should sign both copies of this letter and return one signed copy to the PROVIDER. The PROVIDER SCIENTIST will forward the material to the RECIPIENT SCIENTIST upon receipt of the signed copy from the RECIPIENT organization. This Implementing Letter is effective when signed by all parties. The parties executing this implementing Letter certify that their respective organizations have accepted and signed an unmodified copy of the UBMTA, and further agree to be bound by the terms, for the transfer specified above. Please fill in all of the blank lines below:

1. ORIGINAL MATERIAL (Enter description)

2. Optional Termination Date: _____

3. Optional Transmittal Fee (to reimburse the PROVIDER for preparation and distribution costs)
Amount: $ _____

4. PROVIDER (Organization providing the ORIGINAL MATERIAL)

a. Name of Organization: _____
b. Street Address: _____
c. City/State/Zip+4: _____

5. PROVIDER SCIENTIST

a. Name and Title: _____
b. Street Address: _____
c. City/State/Zip+4: _____
d. Signature _____ Date: _____

6. RECIPIENT SCIENTIST

a. Name and Title: _____
b. Street Address: _____
c. City/State/Zip+4: _____
d. Signature _____ Date: _____

7. RECIPIENT ORGANIZATION CERTIFICATION (Organization receiving the ORIGINAL MATERIAL)

I hereby certify that the RECIPIENT organization has accepted and signed an unmodified copy of the UBMTA (may be the RECIPIENT SCIENTIST if authorized by the RECIPIENT organization).

a. Name and Title: _____

b. Street Address: _____

c. City/State/Zip+4: _____

d. Signature _____ Date: _____

e. Name and Title: _____

III. SUBMISSIONS FROM INTERNATIONAL ORGANIZATIONS, NON-GOVERNMENTAL ORGANIZATIONS AND STAKEHOLDERS

ACCESS AND BENEFIT SHARING ALLIANCE (ABSA)

Access and Benefit Sharing Alliance

ABSA

October 17, 2008

Mr. Ahmed Djoghlaf
Executive Secretary
Convention on Biological Diversity
413 St. Jacques Street, 8th Floor
Montreal, Quebec
Canada H2Y 1N9

Dear Ahmed:

As noted, members of the Access and Benefit Sharing Alliance (ABSA) have been working closely with the International Chamber of Commerce (ICC), as well as other national and regional industry advocacy organizations, on sectoral issues before the upcoming Technical Experts Group (TEG) on Concepts, Terms, Working Definitions and Sectoral Approaches.

In response to CBD Notification SCBD/SEL/OJ/VN/GD/64650, reissued 18 August 2008, the ABSA is writing to associate itself with the ICC's paper: Access and Benefit Sharing: Sectoral approaches, Concepts, Terms, Working Definitions. In addition, we are taking this opportunity to formally submit the ABSA ABS Negotiating Principles for consideration by the CBD TEG on Concepts, Terms, Working Definitions and Sectoral Approaches, scheduled for Windhoek, Namibia, 2-5 December 2008. We hope that these documents will be helpful.

History teaches us that it is difficult to predict the course of science and the needs of society. Accordingly, it is important that the ABS IR be realistic in its jurisdictional scope and provide as much flexibility as possible for all stakeholders. One key concern shared by ABSA Members and reflected in the cross-industry ICC paper is that ensure a transparent, non-discriminatory (i.e. domestic vs. foreign), and predictable ABS International Regime that will enable the parties to ABS agreements to reach mutual agreed terms (MAT) in a non-bureaucratic framework for creation of meaningful benefits from sustainable uses of genetic resources.

ABSA Members look forward to continuing our close engagement on these important issues in the coming weeks and months and to gaining greater clarity on concepts, terms and working definitions to identify options and outcomes that broadly reflect concerns of innovative life sciences companies.

Warm regards,

Susan K. Finston
Executive Director

1101 Pennsylvania Avenue NW, Suite 600 Washington, DC 20004 1.202.756.7749 voice 1.202.330.5550 fax www.abs-alliance.org

Access and Benefit Sharing Alliance

ABSA

ABS Negotiating Principles

Introduction:

As a core stakeholder in development of any International Regime (IR) relating to Access and Benefit Sharing (ABS), Members of the Access and Benefit Sharing Alliance (ABSA) are committed to identifying practical ABS approaches with demonstrated real-world benefits at the Convention on Biological Diversity's (CBD) Ninth meeting of the Conference of the Parties (COP 9) in Bonn, Germany.

In this practical approach, we note that a number of prior ABS approaches have fallen short of expected benefits, including policies relating to mandatory disclosure of source, origin and proof of benefit sharing. Equally important, negotiation of the ABS IR should be based on organizational principles that ensure a transparent, equitable, consistent and predictable ABS negotiating process and outcomes.

In that spirit, ABSA Members provide the following principles.

Preamble:

ABSA Members:

- Reaffirm their commitment to respect the sovereign rights of CBD members over their *in situ* genetic resources (GR) and to the equitable sharing of the commercialization of GR and any related relevant traditional knowledge (TK) derived from indigenous and local communities, assuming a clear, internationally accepted definition of TK.

- Underscore industry's established track record of compliance with the Bonn Guidelines, including Prior Informed Consent (PIC), Mutually Agreed Terms (MAT) and equitable benefit sharing.

- Support development of comprehensive digital libraries or registries to help identify holders of GR; capacity building to promote best practices for IP management; and the use of model Material Transfer Agreements (MTAs) to ensure effective compliance with PIC and MAT and to provide front-loaded benefits and clarity and fairness in the disposition or sharing of intellectual property rights.

- Believe that there is an increasing recognition among the parties, indigenous communities and NGOs of industry's critical role as a key stakeholder and generator of commercial benefits from biological diversity.

1101 Pennsylvania Avenue NW, Suite 600 Washington, DC 20004 1.202.756.7749 voice 1.202.330.5550 fax www.abs-alliance.org

PRINCIPLES:

- An ABS International Regime (ABS IR) should include measures that ensure equitable and non-discriminatory terms for access to GR, demonstrably generate benefits, and provide positive incentives to encourage mutually beneficial and environmentally sustainable commercialization of genetic resources.

- An ABS IR should be based on reality and the actual experiences of stakeholders either at the local, regional or state level, including the actual experiences of countries, indigenous communities, NGOs, and industry.

- An ABS IR should recognize the ground realities by which businesses operate so that appropriate incentives are balanced against necessary enforcement provisions for the benefit of all stakeholders.

- To ensure a workable system, all stakeholders (countries, indigenous communities, NGOs and industry) should participate broadly in the elaboration of an ABS IR.

- NGO and industry groups should be encouraged to participate in the elaboration of an ABS IR, regardless of whether their national governments are currently CBD Members.

- Development of ABS elements should reflect the individual needs and experiences of CBD Members at various stages of economic development, which suggests a bottom-up, "cafeteria-style" approach rather than a "top down" one-size-fits-all regime based on a single legally binding instrument.

- An ABS IR should be amenable to simple and expeditious implementation, taking into account the individual needs and experiences of CBD Members.

- An ABS IR should include national regulation and enforcement mechanisms. The Parties, with the participation of stakeholders, should also consider issues of extra-territorial enforcement.

- An ABS IR should ensure transparency, predictability, consistency, durability and non-discriminatory treatment with respect to both access and compliance through the inclusion of clear definitions consistent with the terms and jurisdictional limitations of the CBD itself.

- The CBD ABS WG should continue to rely on such other international organizations as the FAO, WIPO, WTO, as appropriate, for technical input during the 2007-2010 period.

- Supporting work by other international organizations, while essential to the work of the ABS WG, should respect the CBD's unique mandate and remit for

comprehensive ABS negotiations and not prejudge the outcomes of the deliberations of the ABS WG. In this respect, the CBD should continue to rely upon the unique expertise and mandate of WIPO with regard to the harmonization of intellectual property standards.

AREAS OF CONTINUING DISAGREEMENT

- **New Additional Mandatory Disclosure Obligations**

Patent disclosure obligations enacted by CBD Members have had a documented chilling effect on bioprospecting and GR commercialization. By making patent protection for GR commercialization contingent on an *ex post* examination of the sufficiency of the disclosure, mandatory patent disclosure regimes place at risk the very basis for the recoupment of investment. [Patent disclosure obligations do not create ABS benefits, are polarizing and drive stakeholders further apart].

- **Certificates of Source, Origin and Legal Provenance**

ABSA Members do not support the development of a certificate system that would create an additional formality or condition of patentability for biotechnology inventions. They also do not view the CBD Experts Group on Certificates as fully representing the broad spectrum of views found in the biotechnology sector. The group, if reconvened in the future for additional work, should be broadened to reflect the diverse needs and experiences of industry. The CBD Experts Group on Technology Transfer may provide a model for inclusion of more than one industry representative allowing representation of different segments of the biotechnology sector.

- **Areas Beyond the Jurisdiction of the Convention**

Difficult issues for the ABSA include suggested coverage of both *in situ* and *ex situ* resources; pre-CBD vs. post 1994 GR bioprospecting; human vs. plant and animal GR; and products vs. derivatives of GR. Boundary lines should be drawn consistent with the obligations and explicit legal boundaries of the CBD Treaty, as exemplified by the Bonn Guidelines.

All stakeholders require clear boundaries to commit resources to participation in an ABS IR Without a precise understanding of important terms such as "genetic resources, products and/or derivatives," it is impossible for any private company to enter into an agreement with indigenous communities or other holders of traditional knowledge.

- **Lack of Clarity Over the Definition of Traditional Knowledge (TK)**

A precise understanding of this important term is also needed before private companies are able to enter into agreements with indigenous communities or other holders of TK. Moreover, if more than one indigenous community (within a country or

otherwise) states a claim to the same TK, there needs to be a clear approach to TK rights that does not threaten a private company that has acted in good faith and is working on the basis of PIC and MAT with one of these communities (or with a focal point of a CBD Member that has entered into good faith PIC and MAT with a community). Unless and until further international consensus is reached on the issue of TK, the ABS IR should follow the precedent established by the Bonn Guidelines.

BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO)

COMMENTS OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO) ON ISSUES TO BE ADDRESSED BY THE TECHNICAL EXPERTS GROUP ON CONCEPTS, TERMS, WORKING DEFINITIONS AND SECTORAL APPROACHES

Introduction:

Decision IX/12 of the Ninth Session of the Conference of the Parties (COP-9) of the Convention on Biological Diversity (CBD) "*[i]nvites* Parties, Governments, international organizations, indigenous and local communities and relevant stakeholders to provide information and views related to the issues to be addressed by each expert group."

The Biotechnology Industry Organization (BIO) appreciates this opportunity to set forth its views on matters to be addressed by the Technical Expert Group on Concepts, Terms, Working Definitions and Sectoral Approaches ("Concepts TEG"). BIO respectfully requests that the experts selected for the Technical Experts Group take these comments into consideration during their deliberations.

General Comments:

Scope of the International Regime:
BIO members firmly believe that the proposed international regime on access and benefit-sharing should be within the scope of the CBD. For example, under the CBD, the access and benefit-sharing provisions only apply to access of "genetic resources." Therefore, the rules in the international regime imposed with respect to genetic resources should be applied consistently with the definition of genetic resources in CBD Article 2 and should not cover the broader concept of biological materials or categories such as derivatives or products, however defined. Suppliers and recipients of genetic resources, however, may elect to assess benefits on biological materials or derivatives arising from the use of those resources through mutually agreed terms.

The international regime should provide for appropriate exclusions, including those areas already explicitly excluded from the CBD, such as human genetic resources.[1] In addition, pathogens and commodities (genetic resources already made freely available) should be excluded from the international regime. The paradigm underlying the CBD access and benefit-sharing rules is "bio-prospecting" for genetic resources. That is, a research entity seeks to access a genetic resource *in situ* or in an *ex situ* collection and to develop a commercially viable product therefrom. Access to pathogens and to genetic resources that are made freely available do not fit this paradigm. Thus, applying the access and benefit-sharing obligations in the CBD to pathogens and commodities does not appear to be socially beneficial, and it would be inappropriate to apply these rules in the international regime based on the paradigm to pathogens and commodities.

No "One Size Fits All" Approach for Access and Benefit-sharing:
It is also our strong belief that suppliers and recipients of genetic resources will obtain optimum economic and social benefits through the negotiation of "mutually agreed terms" for access and benefit-sharing at the "point of access", rather than applying a fixed access scheme and a fixed "basket" of benefits mandated by a treaty. Negotiations at the point of access would allow suppliers and recipients to determine the appropriate balance between "up-front" and "back-end" benefits for the relevant transaction as well as to determine an appropriate level of benefits arising from the contemplated arrangement.

[1] *See* COP Decision II/11.

Specific Comments:

The terms of reference of the Concepts TEG provide that the experts group will consider the following questions, labeled as (a) – (d). The questions are reproduced below, along with BIO's comments.

(a) What are the different ways of understanding biological resources, genetic resources, derivatives and products and what are the implications of each understanding for the development of the main components of the international regime on access and benefit-sharing, including in relation to sectoral and subsectoral activities and in relation to commercial and non-commercial research?

CBD Article 2 provides the following definitions:

> "Biological resources" includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.
>
> "Genetic resources" means genetic material of actual or potential value.
>
> "Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity.

Consequently, genetic resources are a subset of biological resources that have "functional units of heredity." An example of a genetic resource is a seed of a tree or young tree plant. An example of a biological resource that is not a genetic resource is a chemical extract from that seed or plant. Some genetic resources may be commercial commodities. Many biological resources would be commercial commodities. The "benefit-sharing" objective in CBD Article 1 is limited to "genetic resources" – it does not encompass "biological resources." CBD Article 15, which sets forth the obligations on access and benefit-sharing, is also limited to genetic resources.

The concept of "derivatives" is not contained in the CBD provisions on benefit-sharing. This concept is further not defined in the agreement, although the term is used in the definition of "biotechnology" in CBD Article 2.[2] We firmly believe that the proposed international regime on access and benefit-sharing should be within the scope of the CBD. The access obligations in the CBD only apply to genetic resources and the benefit-sharing obligations only apply to use arising from the accessed genetic resources. Therefore, the rules in the international regime imposed with respect to genetic resources should not be applied to "derivatives" (regardless of the definition of the term) of acquired genetic resources. Providers and recipients of genetic resources should define "derivatives" for the purposes of their individual endeavors and determine what benefits, if any, should be based on such derivatives on an endeavor-by-endeavor basis.

Similarly, the term "product" is not used in CBD Article 15 or in any other provision relevant to benefit-sharing. BIO reiterates that the international regime should be commensurate in scope with the CBD. Similarly as above, any definition of "product" should be left to providers and recipients in the development of material transfer agreements (MTAs) that will reflect the specific terms of access and benefit-sharing that will apply to the particular transaction at issue. Consistent with this notion, the Food and Agriculture Organization (FAO) International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGRFA) also does not contain the term "product" or seek to define it. Nonetheless, it is

[2] CBD Article 2 defines "biotechnology" as "any technological application that uses biological systems, living organisms, or *derivatives* thereof, to make or modify products or processes for specific use(*emphasis added*)."

defined as part of the Standard Material Transfer Agreement (SMTA) under that treaty.[3] BIO does not believe that an SMTA is workable in respect of the International Regime. The FAO ITPGRFA context is much narrower and therefore more amenable to a standard agreement. Nonetheless, the FAO system is instructive in that the SMTA is where the term is defined. Similarly, the "mutually agreed terms" (usually envisioned to be an MTA) between the recipient and provider are the appropriate mechanism to define such terms if needed with respect to the broader range of transactions envisioned under the International Regime.

(b) Identify different forms of utilization of genetic resources in relation to sectoral and subsectoral activities in the context of Article 15, paragraph 7, of the Convention;

Genetic resources are used in a wide variety of ways in the biotechnology sector. For example, when used in the research-intensive biopharmaceutical industry, genetic resources are generally used as instruments to create an "end" product either as a research tool or as a component in the process of making the product. Although with respect to certain products, such as vaccines, the genetic resource itself may be in the end product.

(c) Identify and describe sector specific characteristics of access and benefit-sharing arrangements and to identify the differences, if any, between approaches in sectors;

Benefit-sharing arrangements in the research-intensive pharmaceutical and agricultural biotechnology sectors vary widely and may involve sharing benefits before and/or after the marketing of a product arising from use of accessed genetic resources. There is some sentiment among commentators that suggests that emphasis on benefits that accrue after marketing may be misplaced, particularly given that many genetic resources are investigated for pharmaceutical potential but few give rise to a marketable product.

Agreements involving the research-intensive biopharmaceutical sector are nearly always individually negotiated, albeit negotiators may start with a familiar, model agreement as a starting point.[4] IFPMA and BIO have published guidelines to educate and assist their members on access and benefit-sharing practices. BIO has also published a model material transfer agreement (MMTA). While not intended to be standard agreements or codes of conduct, these guidelines help identify "best practices" in the industry and also are intended to be updated as practices change. A copy of the BIO guidelines and the BIO MMTA are attached as an Annex to this document.

(d) What are the range of options and approaches for taking these different characteristics into account and that may bring coherence to access and benefit-sharing related practices in different sectors?

BIO supports a flexible approach for the International Regime that takes into account different needs of different industry sectors and other stakeholders. The International Regime should facilitate the implementation of clear and transparent national ABS systems. This includes providing for clear points-of-contact for national authorities that can be easily identified by those who seek access.

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[3] Under the FAO SMTA, "product" is defined as "plant genetic resources for Food and Agriculture that incorporate the Material or any of its genetic parts or components that are ready for commercialization, excluding commodities and other products used for food, feed and processing."

[4] *See* "Access and Benefit-sharing in Practice: Trends in Partnerships across Sectors" (hereinafter "ABS in Practice"), part 4.4, p. 27, *available at* http://www.cbd.int/doc/publications/cbd-ts-38-en.pdf).

In addition, flexibility with respect to "mutually agreed terms" should be employed. The International Regime should not attempt to regulate specific terms applicable to all agreements or to otherwise attempt to impose strict conditions that go beyond the ABS principles enshrined in the CBD. This would not only be counterproductive, but would not be consistent with the notion of "mutually agreed terms used in the CBD itself. A system that permits the provider and recipient to come to agreement based on the specific circumstances surrounding the proposed access will help to provide a workable framework that will facilitate implementation of the ABS objectives of the CBD at the national level, while, at the same time, be able to provide necessary flexibility to meet the goals of both parties.

A number of options can be employed to meet these goals and thereby bring coherence to ABS-related practices that may apply to different sectors under the International Regime. Broad measures to build capacity in developing countries will help in establishing clear, transparent national ABS regimes that are more easily understood by others. Efforts to increase awareness of national ABS laws among those seeking access to genetic resources will assist in compliance. In addition, detailed guidance could be incorporated into the International Regime with respect to access rules in order to facilitate implementation of systems with clear points of contact that give legal security and certainty to those who seek access in good faith. Further, aspects to be dealt with in the area of compliance, e.g., use of mediation and arbitration dispute settlement mechanisms, may help to build greater confidence in the implementation of appropriate mechanisms to reach mutually agreed terms.

ANNEX I

Guidelines for BIO Members Engaging in Bioprospecting

Preamble

The Biotechnology Industry Organization,

- recognizing that the conservation of biological diversity has significant long-term advantages for all and desiring to play a role in achieving those advantages for all;
- recognizing the importance of promoting the sustainable use of biodiversity and of equitably sharing the benefits arising from use of genetic resources with the parties providing access to those resources;
- recognizing the importance of scientific research on genetic resources and the important benefits to society as a whole that arise from such research;
- wishing to promote the adoption of clear and transparent provisions governing use of genetic resources so as to promote the greater use of such resources as well as the flow of more benefits to parties providing such access and society as a whole; and
- desiring to conduct their activities, and those of their agents, in relation to collection of genetic resources, as well as the evaluation and use of those collected genetic resources in a manner that complies with relevant national and international regimes;

hereby establishes the following Guidelines for bioprospecting.

I. **Definitions; Scope of the Guidelines**

A. Definitions: As used in these Guidelines, the following terms shall have the meaning provided below.

1. *"Benefit Sharing"* means the providing of any form of compensation or consideration, monetary or otherwise, by a *BIO Member* to a *Providing Party* in exchange for the *BIO Member* being provided access to and authorization to use *Regulated Genetic Resources*.
2. *"BIO Member"* means a Member of the Biotechnology Industry Organization.
3. *"Bioprospecting"* means the collection by a *BIO Member* of physical samples of *Regulated Genetic Resources* existing *in situ* or in maintained in an *ex situ* collection of such resources.
4. *"Bioprospecting Agreement"* means a written agreement between a *BIO Member* and either a *Contracting Party* or a *Providing Party* that concerns (i) *Prior Informed Consent* and (ii) the terms and conditions governing collection and use of the *Regulated Genetic Resources*, including, *inter alia*, *Benefit Sharing*.
5. *"Collected Genetic Resources"* means physical samples of *Regulated Genetic Resources* that have been acquired by a *BIO Member* through *Bioprospecting*.
6. *"Contracting Party"* means a country that has accepted, ratified or acceded to the Convention on Biological Diversity and thus is a Contracting Party within the meaning of Convention.
7. *"Ex situ collection"* means a collection of physical samples of *genetic resources* that have been previously obtained from an *in situ* location and which are preserved or maintained in a location external to that *in situ* location.
8. *"Focal Point"* means the entity designated or recognized by the government of a country as having the authority to (i) identify the P*roviding Party* or Parties within the *Contracting Party* with authority over the *genetic resources* to be collected, (ii) provide information concerning the requirements and procedures for obtaining *Prior Informed Consent* to collect and use *Regulated Genetic*

Resources within the territory of that country, (iii) provide information regarding *Benefit Sharing* requirements applicable within the *Contracting Party*, and (iv) identify the representative of local and indigenous communities located within the territory of the country.

9. *"Genetic Resource"* means material of non-human animal, plant or microbial origin containing functional units of heredity.
10. *"In-situ"* means the location in which genetic resources exist within ecosystems and natural habitats within a Country;
11. *"Providing Party"* means any entity within a *Contracting Party* that has been given the legal authority to grant *Prior Informed Consent* or authorization to access and use *Regulated Genetic Resources*, and may include, *inter alia*, an authority of the national government, an authority of a local government, or an indigenous or local community or any combination of these entities.
12. *"Prior Informed Consent"* means an agreement between a *BIO Member* and a *Providing Party* establishing that the *BIO Member* has provided to the *Providing Party* information that meets the requirements of Section III of these Guidelines with respect to a *Regulated Genetic Resource* to which the *BIO Member* has been granted access.
13. *"Regulated Genetic Resource"* means a *Genetic Resource* in respect of which a *Providing Party* in a *Contracting Party*, on or after the date that the Convention on Biological Diversity Party took effect in that *Contracting Party*, imposes requirements concerning *Prior Informed Consent*, collection or use.

B. Scope of the Guidelines:

1. These Guidelines establish principles to govern the conduct of *BIO Members* that are engaged in *Bioprospecting* activities, as defined in section A.3.
2. The Guidelines shall not apply to the acquisition or use of:
   a. any materials obtained from humans or are of human origin;
   b. *Genetic Resources* that are not *Regulated Genetic Resources* within the meaning of these Guidelines;
   c. *Genetic Resources* maintained in an *ex situ* collection where such resources were obtained from a *Contracting Party* prior to the date the Convention on Biological Diversity took effect in that *Contracting Party*;
   d. *Genetic Resources* that are made available to the public on an unrestricted basis, either on commercial or non-commercial terms; or
   e. publicly available information, including, in particular, information published in the scientific literature, disclosed in a patent or published patent application, or disseminated in an unrestricted fashion.

II. Conduct of Bioprospecting

A. Steps to take before engaging in Bioprospecting.

1. Identify and contact the *Focal Point* of the *Contracting Party* for the *Regulated Genetic Resources*.
   a. For samples of *Regulated Genetic Resources* to be collected *in situ*, or from an *ex situ* collection located within the territory of or controlled by the *Contracting Party*, contact the *Focal Point* identified by that *Contracting Party*.
   b. For samples of *Regulated Genetic Resources* to be collected from an *ex situ* collection located outside the territory of or not controlled by the *Contracting Party*, identify the *Focal Point* specified by the custodian of the *ex situ* collection or, if the *Focal Point* is not known to that custodian, take reasonable steps to identify the *Focal Point* for the *Regulated Genetic Resources* to be collected.
2. In cooperation with that *Focal Point*, use all reasonable efforts to identify all entities that comprise the *Providing Party*, and ascertain requirements applicable to *Bioprospecting*.
3. Obtain *Prior Informed Consent* from the *Providing Party* to collect and use *Regulated Genetic Resources* lawfully controlled or held by the Providing Party.
4. Reach agreement with the *Providing Party* on the terms and conditions governing collection, handling and use of physical samples of the *Regulated*

Genetic Resources, including, *inter alia*, the sharing of benefits arising from the use of such samples, and measures governing the handling or transfer of such samples.

5. Conclude a *Bioprospecting Agreement* with the *Providing Party* that reflects the terms and conditions of *Prior Informed Consent* and concerning the collection, handling and use of the collected physical samples of the *Regulated Genetic Resource(s)* including, *inter alia*, terms and conditions regarding *Benefit Sharing*.
6. Take reasonable steps to confirm that the *Bioprospecting Agreement* will be binding on the Government of the *Contracting Party*, either directly or through the authority conferred by the *Contracting Party* on a *Providing Party*.

B. After Prior Informed Consent has been obtained and a Bioprospecting Agreement concluded regarding collection and use of the Regulated Genetic Resources, conduct Bioprospecting, and use the Collected Genetic Resources, in a manner that complies with the terms and conditions specified in the Bioprospecting Agreement.

III. **Prior Informed Consent**

A. Make reasonable efforts to determine if any specific requirements for *Prior Informed Consent* apply to the collected *Regulated Genetic Resources*. To do so:
1. Determine if a *Contracting Party* has established requirements for *Prior Informed Consent*, or, if that authority has been delegated to a *Providing Party*.
2. Identify the nature of the requirements for *Prior Informed Consent* established by the *Contracting Party* or the *Providing Party*, as the case may be.
3. Meet the identified requirements to comply with Prior Informed Consent obligations of the *Contracting Party* or the *Providing Party* applicable to the collected Regulated Genetic Resources, and incorporate evidence of such compliance into the *Bioprospecting Agreement*.

B. If a *Contracting Party* has not established requirements for *Prior Informed Consent*, make reasonable effort to provide at least the following information to the *Providing Party*:
1. The general nature of the activities to be conducted with the *Collected Genetic Resources* (e.g., screening of samples for biological properties, growth and study of samples of materials, extraction and isolation of chemical compounds from the samples, genomic analysis of the sample).
2. The anticipated field of use of any products or services that may be developed through the use of the *Collected Genetic Resources* (e.g., pharmaceutical, agricultural, industrial processing, environmental remediation).
3. The identity and contact information of the expected lead researcher in the *BIO Member*, or a contact point in the *BIO Member* for such research activities.

IV. **Benefit Sharing and Sharing of Research Results, Intellectual Property Procurement and Related Provisions**

A. *BIO Members* that enter into a *Bioprospecting Agreement* with a *Providing Party* should give good faith consideration to specific terms for the sharing of benefits arising from use of collected *Regulated Genetic Resources*, and should define such commitments in the terms and conditions in the *Bioprospecting Agreement*.

B. Types of benefits to be considered for inclusion in a *Bioprospecting Agreement*:
1. Monetary and non-monetary benefits arising from the use or commercialization of the Collected Genetic Resources, including provision of equipment and materials, up-front payments and royalty payments;
2. The sharing of scientific information generated through the conduct of research upon the *Collected Genetic Resources* in conformity with standard industry practices regarding timing and conditions of public disclosure to preserve options for procurement of patents or preservation of rights in undisclosed information;
3. The granting of rights to use technology resulting directly from the *BIO Member's* use of the *Collected Genetic Resources* where the granting of such rights and the nature of the rights granted, are consistent with the commercial needs and interests of the *BIO Member*;

4. The provision of training for scientists designated by the *Providing Party*;
5. The inclusion of scientists from the Providing Party in research activities of the *BIO Member* on the *Collected Genetic Resources*;
6. The conduct of research on *Collected Genetic Resources* in the territory of the *Contracting Party* from which such resources have been collected.
7. The transfer to a *Providing Party* of scientific knowledge, expertise, and technology in the control of the *BIO Member* that (a) results from the study of the collected genetic resources and (b) pertains to the conservation, preservation or physical handling of the *Collected Genetic Resources*.
8. Commitments to only seek patents on inventions that arise from the use or study of *Collected Genetic Resources* and that are claimed in a manner clearly distinguishable from the form in which the *Collected Genetic Resources* are provided by the *Providing Party*.

V. **Measures to Protect Interests and Rights of Indigenous or Local Communities**

A. Respect the customs, traditions, values and customary practices of indigenous and local communities within a *Contracting Party* and from which *Collected Genetic Resources* have been obtained.
B. Respond to requests from indigenous and local communities for information concerning the handling, storage or transfer of *Collected Genetic Resources* consistent with the terms of an applicable *Bioprospecting Agreement*.
C. Take all reasonable steps to prevent the disclosure of information provided in confidence by a member of an indigenous or local community, and handle such information in accordance with the terms specified by the community that has provided the information. Where feasible, include such terms in the *Bioprospecting Agreement*.
D. Avoid taking actions in the course of use or commercialization of *Collected Genetic Resources* that impede the traditional use of Regulated Genetic Resources provided by a *Providing Party*.

VI. **Conservation and Sustainable Use of Biological Diversity**

1. Take reasonable steps to prevent harm or alteration to the local environment incidental to acts of collecting samples of genetic resources from an *in situ* location in a *Contracting Party*.
2. Avoid taking actions that pose a threat to the conservation or sustainable use of biological diversity incidental to acts of collecting samples of genetic resources from an *in situ* location in a *Contracting Party*.
3. Take all reasonable steps and give good faith consideration to sharing data with the *Contracting Party* and/or the *Providing Party* which was derived from research on the *Collected Genetic Resources* and which may be useful in the support of conservation efforts related to a species, environment, or habitat from which the *Collected Genetic Resources* were collected.

VII. **Compliance with Terms of a Bioprospecting Agreement and the Guidelines**

0. Use *Collected Genetic Resources* in a manner consistent with the terms and conditions specified in an applicable *Bioprospecting Agreement*.
1. Do not use *Collected Genetic Resources*, for purposes other than those specified in the *Prior Informed Consent* provisions of an applicable *Bioprospecting Agreement*, unless first obtaining a separate *Prior Informed Consent* in writing for the other use of the *Collected Genetic Resource*.
2. After acquiring *Collected Genetic Resources* pursuant to these Guidelines, maintain records concerning the handling, storage and physical movement of the *Collected Genetic Resources*, and be prepared to share such records with the *Providing Party* upon the request of the *Providing Party*, within reasonable limitations.
3. Ensure that the terms and conditions specified in a *Bioprospecting Agreement* entered into with a *Contracting Party* or a *Providing Party* apply to (i) any successor in interest to their rights under the agreement, and (ii) to any party that obtains a sample of a *Collected Genetic Resource* from it, unless those parties have independently obtained from the *Contracting Party* or the *Providing Party* the right to obtain such samples of the *Collected Genetic Resources*.
4. Do not transfer samples of *Collected Genetic Resources* to third parties unless such transfer is consistent with the terms and conditions of an applicable *Bioprospecting Agreement*.
5. Do not accept samples of *Collected Genetic Resources* from a third party that is not able to provide evidence that it has obtained such samples in compliance with obligations of *Prior Informed Consent* and conditions governing use that are applicable to the sample.

6. Include provisions in the *Bioprospecting Agreement* that provide for effective and fair resolution of disputes regarding compliance with the terms and conditions in the *Bioprospecting Agreement*, either by commitments to international arbitration consistent with the procedures specified in the Annex to these Guidelines or as otherwise agreeable to the *Contracting Party* or *Providing Party*.

ANNEX II

BIOTECHNOLOGY INDUSTRY ORGANIZATION
Suggested Model Material Transfer Agreement

Introduction

The Biotechnology Industry Organization developed *Guidelines for BIO Members Engaging in Bioprospecting* (Guidelines) in 2005 to educate BIO Members about the relevant issues that could arise in the conduct of bioprospecting activities and to provide assistance to those Members seeking guidance. (See www.bio.org/ip/international/200507guide.asp and www.bio.org/ip/international/200507memo.asp).

These Guidelines envisioned that BIO Members would enter into a "Bioprospecting Agreement" before collecting physical samples of "regulated genetic resources" *in situ* or accessing such resources maintained *ex situ*. That Agreement would include the grant of prior informed consent as well as enumerate the terms and conditions governing the collection and use of the regulated genetic resources including benefit-sharing. Depending on the manner of collection, the Agreement could also include provisions that would transfer the collected physical samples of regulated genetic resources from the Providing Party to the BIO Member. Alternatively, a separate agreement to transfer the regulated genetic resources could be concluded after the physical samples were identified or collected.

At present, transfers of regulated genetic resources are not handled in a consistent manner or a comprehensive fashion within countries or at the international level. This leaves uncertainty as to what provisions should be included in a transfer agreement entered into by a BIO Member. This "Model Material Transfer Agreement" (Model) is intended to provide an outline for a transfer agreement that is consistent with the best practices set forth in the Guidelines. This Model may be incorporated into a Bioprospecting Agreement; it may be the basis for an transfer agreement entered into after the completion of collection activities undertaken pursuant to a Bioprospecting Agreement; or, it may take the place of a Bioprospecting Agreement when a BIO Member seeks a specific regulated genetic resource or a group of regulated genetic resources from an *ex situ* holding.[5]

This Model is intended to supplement and be considered in conjunction with those Guidelines. As such, it is designed only for use with "regulated genetic resources" as that term is used in paragraph I.B.2 of the Guidelines – essentially materials of non-human animal, plant or microbial origin that contain functional units of heredity and that are subject to the requirements of prior informed consent, *etc.* under the Convention on Biological Diversity.

It is recognized that in some instances it is beneficial to transfer "traditional knowledge" associated with a regulated genetic resource along with samples of the resource. While this version of the Model does not include provisions for the transfer of traditional knowledge, this Model

[5] BIO Members note that some use the term "material transfer agreement" to mean any contract to collect genetic resources, to transfer genetic resources, or to transfer traditional knowledge. BIO Members, however, use the term "material transfer agreement" to refer to a contract the primary purpose of which is to transfer possession of genetic resources. The term "bioprospecting agreement" is used for a contract the primary purpose of which is to collect genetic resources. The term "confidentiality agreement" is used for a contract the main purpose of which is to protect undisclosed information, such as traditional knowledge, that is transferred from one entity to another. These types of contracts may be merged into a single contract in appropriate circumstances.

could be expanded to transfer traditional knowledge. It should be noted that Part V of the Guidelines entitled "Measures to Protect Interests and Rights of Indigenous and Local Communities" should be applied.

The terms used in the Model, including the commentaries, are intended to have the same meaning as they have in the Guidelines, unless specified otherwise.

As with the Guidelines, there is no legal obligation that attaches from membership in BIO to use the Model.

This Model is not intended to supplant national requirements that regulate the transfer of regulated genetic resources.

This Model is not intended to be a static document. It is envisioned that it will change over time as BIO Members gain more experience in this area. Comments on the contents of the Model are welcome.

Agreement between the [Transferor/s] and the [Transferee]
Concerning the Transfer of [Certain Regulated Genetic Resources]

Preamble

Whereas:

[*Name of "Transferee" BIO Member*] is a [*company description, location,* etc.];

[*Name or names of the "Transferor(s)*] is a [*description of the Transferor(s), location(s),* etc.];

[The [Transferee] identified and/or collected physical samples of regulated genetic resources under the [Bioprospecting Agreement] with the [Transferor(s);]

The [Transferee] desires to take possession of certain [identified and/or collected] regulated genetic resources held by the [Transferor(s)]; and

The [Transferee] has informed the [Transferor(s)] about the intended uses of those regulated genetic resources for which possession is sought and about the identity and contact information of its lead researcher on these regulated genetic resources; and

The [Transferor(s)] consents to the transfer of possession to the [Transferee] for those uses based on the information provided by the [Transferee];
The [Transferor(s)] and the [Transferee] hereby agree as follows.

Commentary: If the Transferee or a Transferor is acting as an agent for another entity (or the Transferee is under an obligation to transfer the regulated genetic resources to another entity), the other entity should also be identified.

Clause three of the Preamble would only be included if there was a pre-existing Bioprospecting Agreement between the Transferor(s) and the Transferee.

The Transferor(s) would normally be a Providing Party that is defined in paragraph I.A.11 of the Guidelines as the entity that has legal authority to grant prior informed consent or authorization to access and use regulated genetic resources, and may include, inter alia, *an authority of the national government, an authority of a local government, an indigenous or local community or any combination of these entities. Also, a Transferor could be an agent of a Providing Party. If a Bioprospecting Agreement exists, it would normally list the Providing Parties. Additional Transferor(s) may be identified during the identification or collection of regulated genetic resources under that Agreement, however.*

The Preamble notes that prior informed consent has been given for the "transfer" of the regulated genetic resources subject to the Agreement. A pre-existing Bioprospecting Agreement would indicate that prior informed consent was given for collection but may not specifically give prior informed consent for the transfer and use of regulated genetic materials. Part III of the Guidelines entitled "Prior Informed Consent" should be applied.

Article 1. Definitions

As used in this Agreement, the following terms shall have the meaning provided below.

[*"Bioprospecting Agreement"* means the written agreement between the [Transferor(s)] and the [Transferee] entitled "_____" and executed on _____, a copy of which is attached to this Agreement.]

***"Genetic Resource(s)"* means material of non-human animal, plant or microbial origin containing functional units of heredity.**

"*The Parties*" means the [Transferor(s)] and the [Transferee].

Commentary: Definitions of terms used in the Commentaries may be found in Section I.A. of the Guidelines.

Article 2. Materials

The Material(s) that are subject to this Agreement are:

[*Identify the physical samples of the regulated genetic resources to be transferred.*]

Commentary: The identification of the Materials, for which physical samples will be transferred, should include as many of the following as possible:

1. The taxonomical identity of the Materials (If the taxonomical identity is not known, a description of the physical attributes of the Materials.);

2. Photographs, drawings, or other written means of describing the Materials;

3. The location from which the samples of the Materials have been obtained and any information provided by the Transferor(s) as to the geographical origin of the samples (e.g., country of origin); and

4. A sample of the specimen may be deposited in a facility that will maintain the integrity of the sample and permit future characterization of it. Such facilities would include "international depositary institutions" designated under the "Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure". Acceptable facilities are not limited to those international depositary institutions, however, and could include other facilities that are deemed suitable by the Transferor and the Transferee.

To the extent possible, identification of the Materials should be provided by the Transferor(s). In the alternative, the Transferee should work with the Transferor to develop an agreed upon means of identifying and describing the Materials. If a large number of Materials are to be transferred, descriptions of the materials may be placed in an annex. Alternatively, several transfer agreements may be used, particularly if Materials have different uses or are subject to different benefit-sharing arrangements.

Article 3. Transfer

3.1. The [Transferor(s)] shall transfer the samples of the Material(s) identified in Article 2 of this Agreement to the [Transferee] under the conditions specified in the following paragraphs.

3.2. [Conditions for the transfer of the samples, including number of samples, packaging, place and date of delivery, *etc.*]

3.3. The [Transferee] may not further transfer the samples of the Materials provided by the [Transferor(s)] and may not transfer genetic resources made using those samples to others except to:

3.3.1. Those for whom the [Transferee] is acting as agent, identified above, and who are bound by this Agreement;

3.3.2. Those who are authorized in writing to receive samples by the [Transferor(s)]; and

3.3.3. Successors in interest of the [Transferee] who are bound by this Agreement.

3.4. The [Transferee] shall maintain records concerning the handling, storage and physical movement of the samples and provide such records to [Transferor(s)].

Commentary: If the samples are to be removed from the country in which the transfer occurs, government permission may be required for export and/or import. If a government agency is the Transferor, it should be made clear whether it is authorized and/or grants permission to export. In any event, responsibility for obtaining authorization for export and import should be assigned. Similarly, government regulations may require specific procedures for handling the Materials. Responsibility for fulfilling these requirements should be assigned and all such requirements should be fulfilled.

Article 4. Use of the Materials

4.1. The [Transferee] [and the entity for which the Transferee is any agent] shall only use the samples of Materials transferred under Article 3 of this Agreement for the purposes

> ***Alternative 1:*** **enumerated in Article __ of the Bioprospecting Agreement.**
>
> ***Alternative 2*****: enumerated in Article __ of the Bioprospecting Agreement and for the purposes described below.**
>
> ***Alternative 3:*** **described below.**

4.2. The [Transferee] [and the entity for whom the Transferee is acting as agent] shall return the samples of the Materials transferred under Article 3 of this Agreement [and genetic resources or other materials made from those samples or will destroy those samples and genetic resources or other materials, as directed by [Transferor(s)] when the [Transferee] completes the uses referred to in paragraph 1 of this Article, except as necessary to fulfill disclosure requirements for applications for patents or patent variety protection.

4.3. The [Transferee] shall not seek patents or plant variety protection rights in the Materials as such as they are listed in Article 2 (*i.e.*, materials in the form they are transferred to the [Transferee]). The [Transferee] may apply for the grant of patents claiming inventions developed using samples of the transferred Materials, including inventions embodied in modified forms of the materials, or for the grant of plant variety protection claiming varieties developed using samples of the transferred Materials.

Commentary: If the Transferee wishes to use the transferred samples for uses other than those enumerated in paragraph 4.1, the Transferee must negotiate an amendment to this Agreement with the Transferor(s) or negotiate *a new agreement.*

Paragraph 4.3 authorizes the Transferee to apply for patents or plant variety protection on inventions made using the samples. Article 5 on the sharing of benefits, however, may provide that the Transferor(s) are licensees of the Transferee(s) or joint owners of such applications as part of the benefit-sharing arrangements. The prohibition against seeking rights in the materials transferred as such is intended to assure Transferor(s) that rights will not be sought that might limit or otherwise affect use of the materials as such by parties other than the patent owner/plant variety right owner

Article 5. Sharing of Benefits

5.1. The [Transferee] [and the entity for which the Transferee is any agent] shall provide, at a mutually agreed time, benefits arising from use of the transferred materials:

Alternative 1: **as enumerated in Article __ of the Bioprospecting Agreement.**

Alternative 2: **as enumerated in Article __ of the Bioprospecting Agreement and as described below.**

Alternative 3: **as described below.**

Commentary: The definition of benefits to be shared will vary widely depending on the needs of the Transferor(s), the needs of designated beneficiaries such as indigenous or local communities, the commercial value of the transferred physical samples, the intended use of the samples, the likelihood of using the samples to create a commercially viable product, and other factors. As a consequence, it is not appropriate to suggest a model formulation for the nature of benefits, or the manner in which benefits should be shared, as no single definition will be appropriate in all circumstances.

The Model envisions that specific benefits, the conditions giving rise to obligations for benefit sharing will be identified, and the date on which such benefits are to be provided will be specified in this section (e.g., immediate payment of a fee, payment of a fixed fee upon use of the material in a research or experimental setting). Alternatively, this section may contain a commitment to negotiate benefit sharing terms and conditions by a point certain in the future.

The point certain may be (i) a date certain, (ii) a date when certain types of research activities are performed on the transferred material, or (iii) a date when a commercial product has been identified and is being prepared for commercial production and marketing. It is generally inadvisable to defer negotiation of benefit sharing to later dates, given the potential for a lack of agreement over such benefit sharing terms to disrupt the commencement of commercial marketing, and/or the possibility of distorting the valuation of the materials.

Part IV.B of the Guidelines lists specific types of benefits that should be considered for inclusion in the formulation of benefits to be provided under the Bioprospecting Agreement. It should also be noted that Annex II to the 'Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of their Utilization" lists various types of benefits that can be provided to the Transferor(s) and their beneficiaries. See http://www.biodiv.org/decisions/default.aspx?m=COP-06&id=7198&lg=0.

Article 6. Conservation and Sustainable Use of Biodiversity

The [Transferee] shall take all reasonable steps and give good faith consideration to sharing data with the [Transferor(s)] which is derived from research on the transferred samples of the Materials enumerated in Article 3 and which may be useful in the support of conservation efforts related to a species, environment, or habitat from which the samples were collected.

Commentary: This obligation is drawn from Part VI.3 of the Guidelines (Parts VI.1 and 2 relate only to collection and are not relevant). The Bioprospecting Agreement may contain a similar provision.

Article 7. General Provisions

7.1. This Agreement shall be in effect for a term of ten years from the date of execution of this Agreement unless otherwise agreed to by the Parties. The Agreement shall be terminated if any of the Parties provides notice in writing to the others of its intent to terminate the Agreement on a date no less than six-months from the date of the notice. [*Insert requirements for notice.*]

7.2. The obligations and rights contained in Article 4.3 and Article 6 shall survive the expiration or other termination of this Agreement.

7.3. Upon the termination or expiration of this Agreement, the [Transferee] [and the entity for whom the Transferee is acting as agent] shall return the samples of the Materials transferred under Article of this Agreement [and genetic resources or other materials made from the transferred samples of the Materials] to the [Transferor(s)] or will destroy those samples and genetic resources or other materials, as directed by [Transferor(s), except as necessary to fulfill disclosure requirements for applications for patents or patent variety protection.

7.4. The provisions of this Agreement constitute the entire Agreement between the Parties relating to the subject matter and the Parties do not make any representations or warranties except those contained in this Agreement. The Agreement shall not be considered extended, cancelled, or amended in any respect unless done so in writing signed on behalf of the Parties.

7.5. None of the rights or obligations under this Agreement are assignable or otherwise transferable without the prior written consent of the other Party(ies).

7.6. Nothing contained in this Agreement shall constitute a partnership or agency between the Parties.

7.7. This Agreement is governed by and shall be construed in accordance with the laws and regulations of [*jurisdiction*], without regard to its conflict of law principles.

7.8. [*Reserved for indemnity and confidentiality provisions*]

7.9. [*Reserved for dispute settlement procedures.]*

Signatures

Commentary: Paragraph 7.1 envisions development of appropriate notice provisions, which are likely to vary significantly depending on the Transferor(s). For example, a notice procedure appropriate for a botanical garden may be very different than notice provisions for an indigenous or local community. If there is a Bioprospecting Agreement, the notice provisions should reflect the notice provisions in that Agreement.

In paragraph 7.2, it may be appropriate to specify that some "uses" from Article 4 and some "benefits" from Article 5 survive the Agreement.

With respect to reserved paragraph 7.9, appropriate dispute settlement provisions could vary significantly depending on the Transferor(s). If there is a Bioprospecting Agreement, the provisions in this agreement should be similar to the dispute settlement provisions in the Bioprospecting Agreement. It should be noted that under Part VII.7 of the Guidelines state that the dispute settlement provisions should provide for "fair and effective resolution" and could include international arbitration consistent with the procedures outlined in the Annex to the Guidelines.

EUROPEAN SEED ASSOCIATION (ESA)

From: Isabelle Klopstein [mailto:IsabelleKlopstein@euroseeds.org]
Sent: Tuesday, October 21, 2008 11:54 AM
To: secretariat
Cc: Garlich von Essen
Subject: ESA supports to ICC submission for TEG on Sectoral Approach

To:

Secretariat of the Convention on Biological diversity
att. Mr Ahmed Djoghlaf, Executive Secretary
Montreal, Canada
Via e-mail: secretariat@cbd.org

Dear Mr. Ahmed Djoghlaf,

In view of the meeting of the TEG on Concepts, Terms, Working Definitions and Sectoral to be held on 2-5 December 2008 in Namibia, ESA European Seed Association would like to state its full support for the submission from ICC (International Chamber of Commerce) "*Access and Benefit Sharing: Sectoral approaches, Concepts, Terms, Working Definitions"* (n° 450/1041) and associated documents as sent last Friday to the CBD Secretariat.

In addition, ESA will continue to work on a specific position of the plant breeding sector for submission to the 7th meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-Sharing.

Yours sincerely,

Isabelle Klopstein
Legal Advisor

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INTERNATIONAL CHAMBER OF COMMERCE (ICC)

Access and Benefit Sharing: Sectoral approaches, Concepts, Terms, Working Definitions

Submission to the Technical Experts Group on Concepts, Terms, Working Definitions and Sectoral Approaches

Industry supports the creation of a practical and workable International Regime (IR) on Access and Benefit Sharing adapted to the different sectors working with genetic resources. As reflected by record levels of attendance at the Ninth Conference of the Parties, the business community remains engaged and focused on substantive discussions in the access and benefit sharing (ABS) negotiations, including on the objectives, scope and main components of an IR (the Regime). In this paper, business seeks to provide information as requested in the Terms of Reference for the upcoming Technical Experts Group (TEG) on Concepts, Terms, Working Definitions and Sectoral Approaches.

The business community has been an active participant in negotiations concerning access to and the sharing of benefits from genetic resources even before the entry into force of the Convention on Biological Diversity (CBD) in 1993. The business delegation, coordinated by the International Chamber of Commerce (ICC), today represents various business sectors with diverse interests in genetic resources and their sustainable commercial uses. Many of these consist in large part of small and medium-sized enterprises (SMEs) and include, in alphabetical order: agricultural biotechnology, animal breeding, cosmetics, farming, flavours and fragrances, forestry, herbal medicines and supplements, industrial biotechnology, pets, pharmaceutical products, and plant breeding. All these industries may access, use and create value from resources covered by the CBD in different ways[1].

If the IR is to be effective in promoting economic activity, it should maintain and foster the diversity of uses of these resources as well as of the commercial arrangements through which they are acquired. ICC believes that it is of key importance that the IR should be a transparent, non-discriminatory, predictable, and facilitative structure that is narrowly targeted. It should not be a heavy regulatory framework that will stifle the creation of value from genetic resources, trade and sustainable uses. This will promote not only the efficient organization of access and benefit sharing, but also the conservation and sustainable use of genetic resources.

[1] See EFPIA (European Federation of Pharmaceutical Industries and Associations) brochure "Good business practice and case studies on biodiversity" http://www.efpia.eu/content/default.asp?PageID=559&DocID=3787

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Biological resources, genetic resources, derivatives and products

The terms of reference for this TEG seek clarification on the implications of different ways of understanding biological resources, genetic resources, derivatives and products. Clear definitions of these terms are essential for defining the scope and other key elements of the IR.

The IR should only cover genetic resources

Consistent with the terms of its mandate from Decision VII/19 D, the IR should be limited to effective implementation of Article 15, Article 8(j) and the three objectives of the Convention. As such, it should be limited to "genetic resources," as defined in the Convention and should seek only to elaborate matters relating to access and benefit-sharing with respect to such genetic resources, based on "mutually agreed terms" (MAT's) between the acquirer and the provider (Article 15(4) and 15(7).

The inclusion of biological resources as defined in Article 2 of the CBD would bring under the IR biological resources that are currently traded by countries all over the world as commodities, such as ornamental and garden plants, timber, agricultural produce (like apples or rice), and even household pets. There are good reasons to draw clear lines between commodity trade in biological resources and the sustainable use of genetic resources. The IR will have to draw clear boundaries between what is included and what is excluded or it will risk inadvertently stifling trade in several areas.

The IR should not regulate downstream products or activities

The IR should also only regulate the relationship between the provider and party gaining access to genetic resources and not seek to regulate downstream activities and/or derivatives or products being developed from them. Based on its experience of working with genetic resources, it is clear to business that any IR which tries to regulate downstream activities and products will be unworkable, unenforceable and extremely costly to implement. Broadening the scope of the IR to downstream products would bring under the IR common household items such as wine, bread and wood products – it would be extremely difficult to know where to draw the line.

Benefit sharing arrangements in relation to derivatives and downstream products should instead be determined through mutually agreed terms in the ABS contract between the providing and accessing parties, as provided for in Article 15(7)[2]. Concepts such as "derivatives" or "products", however they may be defined, should not be part of the IR itself, but instead should be determined between contracting parties.

[2] Article 15(7) "….Such sharing shall be on mutually agreed terms."

Certain genetic resources should be excluded

When defining which genetic resources should be covered by the IR, Parties should consider the following:

- Consistent with Decision II/11, the IR should exclude human genetic resources.

- The IR should recognize existing international instruments and also exclude resources that are already the subject of agreements or negotiations in other fora such as the FAO International Treaty on Plant and Genetic Resources for Food and Agriculture (ITPGRFA) and the International Technical Conference on Animal Genetic Resources for Food and Agriculture under FAO.

- The IR should not include genetic resources that were already made publicly available without any restriction by the provider country.

- The IR should not seek to regulate transactions involving human, plant and animal pathogens. Pathogens are arguably not included within the scope of the CBD itself. For example, such "resources" do not appear to fit within the CBD objectives of "conservation" and "sustainable use" in the sense used in the CBD. Therefore it is best to exclude pathogens from this framework.

Issues to be considered for a sectoral approach

The terms of reference also seek specific information on how different sectors use genetic resources and possible differences in access and benefit sharing arrangements used by various sectors. It should be noted that genetic resources may be used in different ways in the same sector and that, conversely, different sectors may have similar methods of using genetic resources. This paper therefore sets out below the different variables affecting how businesses access, use, and create value (and thus benefits) from genetic resources, instead of describing the different practices of various sectors, which may change with time.

Some of the issues should be explicitly dealt with in the IR, while others should be decided upon by users and providers. For the sake of completeness, the latter issues are also reiterated below.

Availability of genetic resources: widely distributed versus rarely present/ *in situ* versus *ex situ*

- Genetic resources might be available in *in situ* conditions in one or multiple countries. If species are widely distributed, different users may be able to obtain the same material from different places under different conditions. This may cause confusion and uncertainty with respect to Prior Informed Consent requirements and the accessing party's rights to use the genetic resource. On the other hand some resources may only be present in *in situ* conditions in one or few countries.

- Materials may be still existent *in situ* in countr(y)(ies) of origin, but could also be available *ex situ* in one or more public and/or private collections. *Ex situ* collections are wide-spread and range from gene banks, zoos and aquariums to herbaria, botanical gardens as well as other public and private collections. Getting access from *ex situ* collections may be easier and more practical in some cases. In other cases, access to genetic resources in their natural surroundings may be more relevant.

- The vast majority of genetic resources is accessed by businesses from *ex situ* collections and through intermediaries – *in situ* bio-prospecting is relatively rare and, when undertaken, is usually carried out by businesses through local institutions.

The distribution of genetic resources should be considered in Access and Benefit Sharing arrangements. Furthermore, it should be realized that access can be obtained both *in situ* and from *ex situ* collections, according to what is most appropriate. The route chosen may have an impact on the access and benefit sharing arrangements used.

Use: direct versus indirect; in full versus in part; relationship to final product

Genetic resources are utilized in many different ways:

- They are not always present in a final product. Rather, the genetic resource may be a step in a process, a research tool or catalyst, a part of a raw material, or an inactive component of a vaccine or herbal medicine;

- They may be used in their original form, a modified form, or simply as a source of information (e.g. as a digital gene sequence) or be completely substituted by synthetic models;

- They may be used as a fully functional organism or only as a sub-unit of an individual gene;

- They may be consumed in an end-market sale or may be reusable;

- The relationship between the accessed genetic resource and final products may be one-to-one, one-to-many, many to one or many to many.

These multiple types of uses should be considered in the development of the IR.

Use: common versus new

- Many genetic resources have long since been extracted from their original natural environment (examples include vectors, plasmids, and cell lines). Many have become commodities or staple commercial products in the trading system. They are also used for education and research by academic and public research institutes around the globe.

- The value of, and specific information on, the genetic resource may already be known, while in other cases, research has to be undertaken to discover new innovative uses of the resource.

- Only in some cases are rare/new (previously unknown or unappreciated) genetic resources used.

The "commonness" of many genetic resources, and/or of the ways in which they are used should be taken into account in the IR.

Relevance of genetic resource for end product: structural versus marginal

- The genetic resources obtained may contribute structurally and add value to the end products.

- Alternatively, genetic resources may be used, but do not contribute to the added value of the end product. In plant breeding, for example, a cross may be made with a certain genetic resource which has been obtained. It could be that no relevant genes from the genetic resources obtained are actually introduced in the end product that is finally developed after many more years of research, crossing and selection.

- Genetic resources that are used to test another product should be considered as biological resources which, as stated above, should not fall within the scope of the IR.

- Gene recombination including genetic resources should not automatically lead to benefit sharing. If neither a structural amount of genes from the genetic resource nor a relevant characteristic of the genetic resource is involved, then benefit sharing should not be obligatory.

The contribution of the genetic resource to the ultimate commercial product should have an influence on the level of benefit sharing; however these specific arrangements should be made between the acquirer and provider. Some genetic resources may be very relevant for the process, but are used as biological resources. As indicated before, biological resources should not be encompassed within the scope of the IR.

Research and investment: No previous knowledge versus knowledge of specific characteristics or information/product development risks

- The value of, or specific information about, the genetic resources obtained may sometimes be known. However, in most cases a considerable amount of research and further product development is required before there can be commercialization arising from use of the genetic resources.

- Product development out of genetic resources involves long-term risk and investments:

    - The duration of a product development cycle may take decades;

- The success rate of new product development may vary, but often is very low;

- Even when the success rate is high, margins may be low.

Parties should realize and take into account the varying degrees and types of information available in relation to different genetic resources. The investment in time and money that is required for research and product development should also be considered.

Complexity in movements of genetic resources

- The number of intermediate sales and purchases of genetic resources between access and end-market sale may vary from one to dozens;

- Every day, there are millions of common transactions (sales and uses) of genetic resources and of items in some way derived from or using genetic resources.

- Genetic resources move within as well as between countries. Moreover, they move between and among both developed and developing countries[3].

It is important for the Parties to consider the frequency and interdependency of movements of genetic resources, as well as their implications on costs of enforcement for governments and costs of compliance for users.

Size of the sectors

- The total size of the various industry sectors dealing with genetic resources varies tremendously;

- The proportion of small, medium-sized and large companies varies from sector to sector - however, many sectors using genetic resources consist mainly of small and medium-sized companies;

- Small and medium-sized companies probably depend more on access to genetic resources.

One important issue to consider in this context is that it is smaller companies that are likely to undertake *in situ* bioprospecting; these companies face margins and economic realities more akin to those encountered by non-commercial researchers than by larger firms. Accordingly, a regime that draws a line between commercial and non-commercial use may erect barriers that preclude activities by the important SME segment. Similarly, this is where it is critical that the IR

[3] See "Plant Genetic Resources for Food and Agriculture: A Common Heritage of Mankind?" presentation by Radha Ranganathan at ICC Panel Discussion " Making Intellectual Property Work for Development", WIPO, 26 April 2007 at http://www.iccwbo.org/uploadedFiles/ICC/policy/intellectual_property/pages/R_Ranganathan26April07.pdf

not discriminate between foreign and domestic users, as smaller local companies often rely on foreign companies for funding of commercial research.

Benefit sharing systems currently used

There is a long history of successful agreements relating to both access and benefit sharing. Benefit sharing can be either direct or indirect.

- Direct benefits can include:
  - Payments upfront or during the development process;
  - Exchange of knowledge and skills which can be valuable for both the providing country and the user;
  - The collection and conservation of genetic resources through financing or specific support activities, thereby helping conserve and enhance biodiversity.
- Even more important are indirect forms of benefit-sharing like:
  - Improved productivity of agricultural crops;
  - The development of new health, food and other products;
  - The immediate availability of improved products for further research and breeding without any consent, through the breeders' exemption in the plant breeding sector. As much cumbersome work had already been carried out to develop these varieties, any subsequent users can save resources, and society obtains faster access to further R&D results;
  - The positive impact on economies since these new products are often the motor for further development, creation of new employment opportunities and improvement of education, infrastructure, etc.

The manner in which benefits are currently shared should be considered in the development of the IR. Existing systems should not be unnecessarily disturbed. Moreover, current systems should be recognized and appreciated.

Standard/Model contract versus individual contract

- To avoid long, expensive and complex negotiations, some sectors would find simple standard contracts for access and benefit sharing of genetic resources more appropriate for their businesses.
- Other sectors would find individually-negotiated contracts based on specific uses more relevant to the manner in which they access and use genetic resources.

- In some cases, certain sectors would find it appropriate to use contracts pertaining to the different phases of product development.

The IR should provide sufficient flexibility to accommodate different sectoral needs, possibly with standard/model contracts, depending on the need of certain sectors.

Other internationally recognized Access and Benefit Sharing systems

There are existing access and benefit sharing mechanisms through other treaties and conventions that affect particular sectors. For example, part of the plant breeding sector is already working with the Standard Material Transfer Agreement of the FAO international Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). This system recognizes that the freedom to use products for further research and development should be recognized as a benefit in its own right, as this allows future research to benefit from past work.

Another example of such international access and benefit sharing mechanisms is the International Technical Conference on Animal Genetic Resources for Food and Agriculture under FAO.

Rules and agreements of other relevant international conventions should be carefully considered for the development of the IR when applicable in the same sector. The IR should not contradict other international agreements. An example is the breeders' exemption under Plant Variety Protection (PVP) law governed by the International Union for the Protection of New Varieties of Plants (UPOV). The freedom to use developed varieties that are protected solely by PVP for further breeding without the consent of the breeder, should be recognized and maintained.

Document n° 450/1041

17 October 2008

Presentation made at ICC Panel Discussion
" Making Intellectual Property Work for Development", WIPO, 26 April 2007

Plant Genetic Resources for Food and Agriculture: A Common Heritage of Mankind?[1]

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International Seed Federation, 7 Chemin du Reposoir, 1260 Nyon, Switzerland

Introduction

Plant genetic resources for food and agriculture that are exchanged and used in a successive and continuous release of improved varieties through plant breeding have brought great benefits to society. Since the origins of agriculture farmers have selected crop cultivars from the genetic diversity available to them. They have moulded genetic resources over centuries through phenotypic selection, allowing and even facilitating genetic exchange between cultivars and weedy relatives by transporting cultivars from one region of the globe to another. By incorporating and re-mixing genetic diversity in new varieties, modern plant breeding has created more variation in food crops than has ever been available to farmers and consumers.

Farmers and breeders have traditionally relied on "open" access to genetic resources. In recent years, however, decision makers at the national level have come under increasing pressure from a wide range of stakeholders to draft laws and policies affecting the exchange, use, conservation and ownership of plant genetic resources for food and agriculture. Of course, these issues aren't being considered in a policy vacuum. At the international level, the International Treaty for Plant Genetic Resources for Food and Agriculture creates a framework for access, use and conservation based on international co-operation. The Convention on Biological Diversity (CBD) recognises the sovereign rights all countries have over their natural resources and their authority to determine access to genetic resources within their borders for which they are the countries of origin. The Bonn Guidelines adopted by the Parties to the CBD encourages bilateral regulatory mechanisms to negotiate the terms and conditions of access to their genetic resources. Under the obligations required by TRIPs, some countries have created *sui generis* forms of intellectual property rights for farmer varieties and related traditional knowledge. There are similar demands within the context of the meetings of WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore meetings.

Some countries have instituted national laws that establish bilateral systems of access to genetic resources and negotiate agreements on a case-by-case basis. More are in the process of doing so. Often these laws do not treat plant genetic resources for food and agriculture (PGRFA) differently from other forms of genetic resources. But is there a case for treating plant genetic resources for food and agriculture any differently?

Interdependency and Genetic Resources

Most of the food crops were developed over millennia in parts of the world that are today considered to be developing countries. The arrival of Columbus in the Americas in 1492 set in motion the so-called 'Colombian exchange' of domesticated crops and animals from different parts of the world. Wheat was introduced to the Americas from Europe over 500 years ago and on his return from the Americas Columbus introduced maize to Europe. Rice was introduced to the Americas from Asia 200 years ago. Secondary centres of diversity became widespread for a large number of crops and once foreign foods are now well

[1] This paper draws on a previous piece written by the author late in 2005.

Presentation made at ICC Panel Discussion
" Making Intellectual Property Work for Development", WIPO, 26 April 2007

integrated into national/regional diets.

In a study assessing the degree of a country's dependence on non-indigenous crops (measured in terms of calorific contribution to nutrition contributed by crops whose centre of diversity is outside the country in question), Palacios (1998) showed all countries grow or import crops that come from distant lands (Table 1). Ghana is just as dependent on crops originating outside of Ghana (70-81%), as Italy is on crops originating outside of Italy (71-81%). No nation today is completely independent in terms of genetic resources for food and agriculture and both, developed and developing countries have come to rely on non-indigenous crops for their food supply.

Table 1 - Levels of dependency for some countries in the world

Country	Degree of dependence (%)	Main source of energy supply	Primary region of diversity of crops
China Japan Republic of Korea	46 – 55 43 – 61 30 – 54	Non-native – wheat, sugar, maize, potato Native – rice, soybean	**East Asia** - rice, onion, tea, soybean, orange, Brassica, millet
Indonesia Philippines Vietnam	29 – 33 28 – 38 13 – 19	Non-native – wheat, maize cassava, soybean, sweet potato Native – rice, sugarcane, banana, coconut	**Southeast Asia** – rice, yam, banana, sugarcane, coconut/copra and citrus
Bangladesh India Nepal	14 – 21 35 – 47 47 – 57	Non-native – wheat, maize Native – rice, sugarcane, millet	**South Asia** - rice, sugarcane, banana, sesame, millet, *Brassica rapa, B juncea*
Australia New Zealand Fiji	88 – 100 87 – 100 65 – 77	Non-native – wheat, rice, barley, potato, maize, soybean, sweet potato	**Pacific** - sugarcane and coconut/copra
Ethiopia Kenya Uganda South Africa Zimbabwe	28 – 56 89 – 98 76 – 88 90 – 98 89 – 95	Non-native – *Phaseolus*, maize, sweet potato, potato, cassava, banana, plantain, wheat, rice Native (for Ethiopia) – tef, *Avena Abyssinian*, *Brassica carinata*	**East and Southern Africa** - sorghum, millet, yam
Brazil Andean Region Argentina Colombia	81 – 94 89 – 95 84 – 94	Non-native – wheat, sugar, rice, maize, soybean, plantain, banana Native – potato, *Phaseolus* (for Andean Region); cassava (Brazil)	**Andean region** - potato, sweet potato, tomato, cocoa, *Phaseolus*, cassava, groundnut, pineapple
Western Europe (on average)	70 – 95	Non-native – wheat, soybean, barley, potato, maize, rice sugar,	**Europe** - apple (Mediterranean region - olive, grape)
United States Canada	77 – 100 84 – 99	Non-native – wheat, sugar, soybean, potato, maize, barley, rice, groundnut	**North America** - sunflower

Multilateral versus bilateral systems of exchange of germplasm

As policy makers debate options in regulating the exchange, use and ownership of, and benefits from PGRFA, data on the magnitude and direction of germplasm flows might shed some light on whose interests would be served by placing restrictions on access to PGRFA.

Presentation made at ICC Panel Discussion
" Making Intellectual Property Work for Development", WIPO, 26 April 2007

The Consultative Group on International Agricultural Research (CGIAR), often called the international public sector, was the first formal system in place that provided plant breeders access to germplasm available beyond their borders. The CGIAR collections comprise over half a million samples of crop, forage and tree germplasm of major importance for food and agriculture. Data from the System-wide Information Network for Genetic Resources (SINGER) (http://singer.cgiar.org), an information exchange network of the CGIAR and associated partners, provides some insight into flows of genetic resources around the world. Table 2a indicates the number of samples of accessions originally collected from a region that were distributed to another over the years 1973 – 2003. For instance, 12,584 samples of accessions originally collected in the Asia Pacific region were distributed to recipients located in Europe.

Table 2a - Flows of genetic resources within and between regions

To Region	Samples of accessions collected originally from						Total
	Asia Pacific	Europe	N America	S America	S S Africa	WANA	
Asia Pacific	209,095	11,074	30,547	30,665	133,908	46,039	461,328
Europe	12,584	6,952	3,499	10,406	17,633	27,469	78,543
N America	13,458	2,332	3,410	11,729	18,745	9,313	58,987
S America	10,677	4,635	4,881	60,246	11,140	4,776	96,355
Sub Saharan Africa	21,658	3,593	6,959	19,213	61,228	8,374	121,025
West & N Africa	13,796	5,435	3,089	2,450	10,138	44,533	79,441
Total	**281,268**	**34,021**	**52,385**	**134,709**	**252,792**	**140,504**	**895,679**

Note: The data reflects samples of single accession that have been provided

A further analysis of the data in Table 2b demonstrates the benefits that all regions obtained from an 'open access' system. If requests for a sample are indicative of a need for germplasm for crop research and development, the table below is illustrative of interdependency between regions and furthermore, the benefits from a co-operative and multilateral system of access to genetic resources.

Table 2b – Dependency between regions on genetic resources

Region	Accessions originally collected from region	Samples distributed to region	Gain (%)	Flows to region from within (%)	Material 'borrowed' (%)
Asia Pacific	158,153	461,328	292	74	55
Europe	35,560	78,543	221	20	91
N America	16,557	58,987	356	7	94
S America	105,680	96,355	91	45	37
Sub Saharan Africa	116,695	121,025	104	24	49
West & N Africa	86,447	79,441	92	32	44
	519,092	**895,679**			

Using genebank data from the CGIAR and other sources, M Halewood et al. (unpublished) focussed on exchanges of PGRFA in and out of Kenya and Uganda. Over the course of twenty years (approximately 1974 – 2001) Kenya and Uganda together received (from all of the 11 CGIAR genebanks) a total of 12,000 unique accessions that were collected from other countries. During the same period of time, the genebanks distributed 4,000 accessions originally collected in Kenya and Uganda to other countries of the world. Kenya and Uganda therefore gained access to 300% more accessions than they distributed.

A breakdown by crop is presented in Table 3. This data on germplasm transfers indicates

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that Kenya and Uganda have gained access to a wide range of material from both, the region and the rest of the word. Halewood et al. point out that even when Kenya and Uganda are actually the centre of diversity of the crop in question, their proportionate gain in access to material of that crop far outstrips the region's or the rest of the world's gain. They highlight this is so because of Kenya's and Uganda's participation in a relatively open system of facilitated access the CGIAR operates for its *ex situ* collections.

Table 3 - Germplasm accessed by Kenya and Uganda (K+U), 1974 - 2001

Crop	Centre of diversity	Material collected from (%)		
		K+U	SSA*	Rest of the world
Groundnut	South America	18	47	35
Finger millet	East Africa	20		80
Beans	South America (secondary centre South Africa)	4	17	79
Pigeonpea	East Africa	15	40	45
Sorghum	East Africa	3	74	23
Tropical forages CIAT		20	33	47
Forages ILRI		2		98

* Sub Saharan Africa

Kenya and Uganda are not alone in their need for genetic resources from around the world. In 1994, the International Fund for Agricultural Research (IFAR) produced a series of case studies based on fifteen countries (Chile, Colombia, India, Indonesia, Kenya, Madagascar, Pakistan, Peru, Philippines, Rwanda, Saudi Arabia, Syria, Tanzania, Uruguay and Zimbabwe) that showed that together they received 47,502 vegetable and 16,928 forage samples from international agricultural research centres. Their own contribution to the collections were 2,712 and 7,381 samples of vegetables and forages, respectively. In other words, the number of germplasm they received from the collections was many more times than that they contributed.

Legislation that poses restrictions on a multilateral and open system of access may alter these patterns of germplasm flows. Had the fifteen countries studied by IFAR obtained the needed germplasm through a bilateral system, they would have had to negotiate with the 125 and more countries that had made material available to the centres (Fowler et al., 2001). Simple transaction costs associated with bilaterally accessing material would be substantial for any country. If the ratio of inflow to outflow of genetic resources remains as it is, but access were subject to restrictions and became monetary-based, all developing countries stand to lose. Access would be particularly severe for poorer countries with small markets and weak institutions.

The Convention on Biological Diversity

Article 15 of the CBD affirms the sovereign rights of all countries over their natural resources and their authority to determine access to genetic resources based on "prior informed consent" and "mutually agreed terms". Under the CBD, countries may provide access to genetic resources for which they are "countries of origin", countries possessing the material in *in-situ* conditions. *In-situ* is defined as:

> …conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.

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This framework, while useful, does not provide an explanation or advice on what a "distinctive property" is. Neither does it clarify what "property" is: is it a gene, a trait, a particular combination of otherwise common alleles? Centres of crop diversity have not always occupied a limited area and moreover, secondary centres of diversity exist in areas with a long history of continuous cultivation. If a crop is oligo-centric or non-centric in its origin, how can one know where a particular "distinctive property" first arose? What happens when a single seed contains numerous distinctive properties, each with a potentially different country of origin?

The historic wide spread use of PGRFA is evident in the ancestry of individual crop varieties. Numerous publications cite examples of the complex parentage of crop varieties used widely in breeding programmes all over the world. VEERY, a wheat variety widely released in the 1980s, and still used in breeding programmes around the world, was developed through 3170 crosses involving 51 parents from 26 different countries. A study of 1709 rice varieties released in 15 countries, showed that only 145 varieties (8.5%) were developed entirely from own-country parents, grandparents and other ancestors. Thirteen of these 15 countries were more than 80% dependent on foreign progenitors for their rice-breeding programme. Table 4 presents a summary of international flows of rice ancestors in selected countries.

Table 4 - International flows of rice ancestors

Country	Landrace progenitors in released varieties (no.)	Own landraces (%)	Borrowed landraces (%)
Bangladesh	233	2	98
Brazil	460	17	83
Burma	442	7	93
China	888	18	82
India	3917	40	60
Indonesia	463	9	91
Nepal	142	1	99
Nigeria	195	8	92
Pakistan	195		100
Philippines	518	7	93
Sri Lanka	386	17	83
Taiwan	20	15	85
Thailand	154	18	82
United States	325	67	33
Vietnam	517	4	96

Source: IPGRI (2005)

Sorting out which country has the right to negotiate the terms of access to genetic resources for food and agriculture led delegates to the CBD to recognise that there was a need "to seek solutions to outstanding matters concerning plant genetic resources" and led to negotiations that concluded in the International Treaty on Plant Genetic Resources for Food and Agriculture.

The International Treaty on Plant Genetic Resources for Food and Agriculture

After seven years in negotiation, the International Treaty (the "Treaty") on Plant Genetic Resources for Food and Agriculture was adopted in November 2001 and came into force in

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June 2004. It is the first treaty that provides a legal framework that not only recognizes the need for conservation and sustainable use of plant genetic resources for food and agriculture but also delineates a regime for access and benefit sharing, and in this process provides direct and indirect links to intellectual property right instruments.

How will the Treaty work?

A Reaffirmation of the Common-Heritage Approach to Genetic Resources

The main institutional innovation of the International Treaty is found in the novel scheme devised to regulate access and benefit sharing of PGRFA. For the most important food crops the Treaty establishes a Multilateral System of facilitated access that tempers the concept of national sovereignty with the recognition that all countries depend largely on PGRFA originating in other countries, thereby implicitly affirming the scientific and historical soundness of the "common heritage" approach.

The Treaty also provides facilitated access to all material that are listed in Annex 1 held in trust under the auspices of the FAO by Centers of the CGIAR. "In trust" refers to material collected before 1994 when the CGIAR entered into an agreement with FAO bringing its gene bank material under the auspices of FAO. Non-Annex 1 material held by the CGIAR gene banks in trust collections will be distributed by a Material Transfer Agreement that is substantially similar to the one adopted for Annex 1 material.

In response to calls for benefits flowing from the use of biological diversity to be shared with the country of origin of the material, discussions have tended to focus solely on monetary benefits often as a precondition to access. This approach, although well intentioned, has led to a disregard of the significant non-monetary benefits that result from the use of genetic resources. The Treaty reiterates that facilitated access under a multilateral system is probably the largest single benefit also to the providers of the material.

The tool for translating the language of the Treaty into contractual obligations for materials from the multilateral system is a Standard Material Transfer Agreement.

Intellectual Property Rights

In addressing the thorny issues of ownership of genetic resources and benefits resulting from their use, the Treaty acknowledges that they are inextricably linked with the more practical questions of not only access to, but also development and use of these resources. And in so doing the Treaty recognises intellectual property rights. This is of significance as modern varieties, those important building blocks for the plant breeding industry, are often protected either according to the UPOV system known as Plant Breeder's Right (PBR) or by patents, and in certain circumstances they are protected by PBR and contain patented elements. The Treaty's respect for intellectual property rights is also evident in its restriction of the multilateral system to genetic resources "under the management and control of the Contracting Parties (States) and in the public domain".

The benefit-sharing regime of the Treaty constitutes another part of the process that seeks to make PGRFA a common concern of humankind. Providers are granted the right to receive some forms of benefits for facilitating access. Recipients of PGRFA who commercialise a product that incorporates material from the multilateral system will pay a share of the benefits arising from the commercialisation of the product into a financial mechanism set up by the Governing Body of the Treaty. Mandatory benefit sharing will not apply in cases where the product is available without restriction to others for further research and breeding.

Mandatory Benefit Sharing

Mandatory benefit sharing will not apply to cultivars that have incorporated material from the

multilateral system and subsequently been protected by plant variety protection certificates under the UPOV or other *sui generis* systems with a breeders exception. It will apply to products protected by utility patents for instance or other systems where access is restricted, unless the holder of the rights voluntarily waives some of the rights that such laws typically provide. Intellectual property rights are, however, cannot be applied for anything "in the form received." The question is whether this will be experienced as a limitation.

The International Seed Federation (ISF) interprets this article as follows: It is possible to claim intellectual property or other rights that limit access to the genetic parts or components isolated or inherited from the material received, provided that the criteria for patentability (in particular the utility patent on plants) are fulfilled. A genetic sequence without proven industrial activity as such should not be patentable. Nevertheless, the rights granted should in no case limit access to the initial genetic material. If so, then the recipient of the material will pay, according to the prescribed norms, into the funding mechanism set up by the Treaty.

This interpretation is logical in the context of Article 13 of the Treaty, which through its use of the word "incorporate", presumes that material received will be used in the development of new products which would in turn be protected by intellectual property rights. Some forms of property rights may limit the use of new products. In exchange for this privilege, benefit sharing is mandatory.

Fowler (2005) wrote, "Patents cannot typically be acquired for something that is pre-existing, known and described. Different countries, however, may interpret "in the form received" differently. In the U.S., for example, patents are available for "the isolated and purified form of the DNA molecule." The U.S. authorities might argue that this isolated and purified form was not the form in which it was received from the Multilateral System. Others might argue that this is an irrelevant distinction. It would appear, however, that since the Treaty explicitly respects intellectual property rights and since such rights are national in character, it will be difficult for the Treaty to be interpreted in a manner that does not allow "parts and components" to be patented in the U.S., if the application meets U.S. requirements. Denial of this right would be counter to other provisions of the Treaty".

Multilaterism and Development

Access to plant genetic resources is indispensable for research and development of improved crops. Exclusion of a crop from a multilateral system such as the Treaty could condemn it to an "orphan" status, as according to the provisions of the CBD - under whose purview such material falls - access to genetic resources would be purely on terms mutually agreed between those wishing access and the 'owners'. New breeding programmes would probably not be initiated and existing programmes may be confined to using the germplasm countries already had.

A list of 35 crops and crop complexes (e.g. Brassicas) and 29 forage species is included in the Treaty's multilateral system for access and benefit sharing, bringing an anticipated stability and predictability to their access and transfers. However, numerous crops including many that are important to the poor are not included in the multilateral system. Even as countries agreed to include those crops most important for food security and for which there was interdependency, the list of crops was the subject of intense negotiation. Politically motivated caution on the part of many 'gene-rich' countries won the day.

Rice, maize, wheat and potatoes are there. Soybean, tomato and groundnut are absent while asparagus, strawberry and grass pea are on the list. Most vegetables, fruits and tropical forages, as well as crops that also have industrial uses, are excluded and thus outside the scope of the agreement. Crops such as African leafy vegetables not globally widespread but important to the nutritional well being of many people in developing countries are also not listed.

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Minor food crops with limited exchange and less complex negotiations may be amenable to bilateral arrangements but a multilateral approach as proposed by the Treaty offers opportunities for developing common and cost-effective conservation strategies, and for coordination and mutual support among partners. It offers participants access to a far greater range of germplasm than is generally possible in bilateral arrangements such as those provided under the CBD. Additionally, it provides access to a wider range of information than is available bilaterally and offers opportunities to use information cost-effectively, avoiding duplication of efforts and unnecessary expense by sharing databases. It is preferable for crops with a wide geographical distribution. The advantage is even greater if one considers a multilateral agreement covering a range of crop species.

The ability to exploit genetic resources worldwide coupled with the creation of a system of national and international research centres in the 1960s revolutionised the supply of improved cereal varieties to developing country farmers. However, the financial and political environment of the last decade has seen significant reductions to the development of agricultural research capacity in many developing countries.

Traxler and Pingali (1999) subdivided 31 developing country national agricultural research systems (NARS) with wheat breeding programmes by the output of their research activities. They concluded that 25 did not have effective breeding capacities and were only able to release useful varieties by testing imported varieties and releasing those best suited to their environment. Such a situation creates an even stronger economic incentive for cooperation among countries and to free ride on research spillovers.

Summing up

The use of biological diversity is perhaps the most important prerequisite for the long-term conservation and sustainable use of PGRFA. Better use of plant genetic resources is critical to meeting the challenges of increasing food production and of alleviating poverty. All countries depend on plant genetic resources originating beyond their borders. Interdependence demands co-operation. International agreements are also necessary to guarantee the conservation of genetic resources. These were the views that the international community took while developing the legally binding multilateral system for access and benefit sharing in the framework of the International Treaty. Although far from perfect, the design of the Treaty reflects the nature of plant genetic resources for food and agriculture and the uses to which they are put.

Facilitated access to a wide range of crops for food and agriculture under a multilateral system, as promised by the Treaty, is essential to farmers and plant breeders.

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INTERNATIONAL ORGANISATION FOR BIOLOGICAL CONTROL (IOBC), INTERNATIONAL BIOCONTROL MANUFACTURERS ASSOCIATION (IBMA) AND AFRICAN INSECT SCIENCE FOR FOOD AND HEALTH (ICIPE)

Dear Executive Secretary, Mr Ahmed Djoghlaf

As a preparation for the next ABS AHTEC meeting held in Windhoek Namibia on the 2-5 December 2008, you called for a submission of views on the terms of reference in the Para 11 of Decision IX/12.

On behalf of the IOBC-Global, the organization representing more than 2000 biocontrol researchers and practitioners (International Organisation for Biological Control), the IBMA, representing 150 companies in this area (International Biocontrol Manufacturers Association), and icipe, an international research centre working on Biocontrol in Africa and for Africa, I would like to submit our views.

Do allow me to use your template of questions and annex them to this letter, as well as the contact persons.

Yours sincerely

Dr. Fabian Haas
icipe Nairobi

Annex I

Views on Para 11 of Decision IX/12

(a) What are the different ways of understanding biological resources, genetic resources, derivatives and products and what are the implications of each understanding for the development of the main components of the international regime on access and benefit-sharing, including in relation to sectoral and subsectoral activities and in relation to commercial and non-commercial research?

In Classical Biological Control the whole organism is used as a natural enemy of the targeted pest. This organism is released into a new environment where it is expected to get establish. It then becomes a new component of the biodiversity. The organism and its action, i.e. the suppression of a pest, thus become a public good, serving everybody, every farmer and every person in its range for free and no body/company receives any continued monetary benefit from its existence and actions as contemplated in the scope of the current national access and benefit s sharing regimes, or in the on-going negotiations.. Classical Biological Control programmes are supported through national or international initiatives in which donors, national administration and universities/research centres work closely together during the whole process.

In case of Inoculative Biological Control an organism is most often released to confined environments (e.g. greenhouses) and controls/kills the pest for a certain time but usually does not become established. Therefore long-term control requires the continued and repeated release of the organism, to be supplied by an institution.

In both cases, however, the organism is not genetically modified, IPRs,as contemplated in the current national access and benefit sharing regimes and biosafety (Cartagena Protocol) issues are therefore not involved, and the organism remains available in its natural (and new) environment to all possible users (other biocontrol firms, local people, and scientists) and uses. What is usually charged for where commercialization of the organism occurs, is for the mass rearing and handling of the organism on its premises.

Further, the natural enemy is in neither case not continually extracted from nature and no genes or substances are isolated and used independently, neither is the organism genetically modified. Therefore, no Intellectual Property Rights are granted nor infringed, and derivatives do not occur.

With regard to the natural population it should be stressed that the organism is not continually extracted from nature, since once released it will build up a new independent population, and in case of Inoculative Biological Control, the company mass rears the organism producing the high number necessary for effective release.

Since the organism is used as a whole, no genes or substances are isolated, which are used directly or could be used for other products. So the issues of derivates do not apply here.

In Biological Control the organism is seen as whole, as a biological resource, and not reduced to genes.

(b) Identify different forms of utilization of genetic resources in relation to sectoral and subsectoral activities in the context of Article 15, paragraph 7, of the Convention;

Because it does not generate income to companies, Classical Biological Control is usually implemented and conducted through cooperation between research institutes from several countries, often on several continents, and donors. The results and techniques are published in reports to donors and scientific contributions and become thus available to everybody. The cooperation increases the scientific and administrative capacities to deal with future pests.

Inoculative Biological Control stimulates the research in ecology and biology of the species involved. As the organisms themselves are not protected by IPR, all biocontrol companies can mass rear the organism for commercial use. Prices drop through competition between companies offering the same organisms. The natural population is not affected despite this use.

(c) Identify and describe sector specific characteristics of access and benefit-sharing arrangements and to identify the differences, if any, between approaches in sectors;

Specific to this sector is that is deals with Invasive Alien Species brought from their natural range to new areas. So, allowing biological control is very much along the lines of CBD's call for cooperation, managing IAS and preventing damage to biodiversity in other countries through an invasive alien species. It also affirms the principle that biodiversity is of common heritage to mankind.

Specific to the sector of biocontrol is the access to a –compared to the natural population- minute number of specimens of the wild population of the natural enemy. The biocontrol agent is then mass reared and released without modifying its genetic material, thus no patents can be granted.

Specific to this sector is that natural enemies become established as new elements of the local biodiversity and become a public good, with costs for nobody but benefits for all.

Specific to this sector is the very strong aspect of cooperation amongst scientist and donors across continents and countries, and the publication of the results in freely accessible media. Even in the case of companies, the result of their research work, i.e. the finding of a natural enemy of a pest organism, becomes immediately public knowledge when the company starts marketing. Anybody can start using the same organism for the same purpose.

(d) What are the ranges of options and approaches for taking these different characteristics into account and that may bring coherence to access and benefit-sharing related practices in different sectors?

The current practice could be molded into a SMTA (Standard Material Transfer Agreement) which is capturing the aforementioned customs and restricting the activities to exactly the uses common in biological control.

At this point it should also be noted that the sector of biocontrol is already regulated under the roof of the FAO and IPPC to minimize the risks related to introduction of new species. So, ABS would actually add to these requirements.

The biocontrol community is also in favour of the MLS found under the ITPGRFA or 'The Plant Treaty', as it is colloquially called. This treaty is appealing because it has a 'commons approach' for access and distribution of benefits while allowing simple and easy access to biodiversity components.

Annex II

Contact Persons (alphabetic to organization)

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INTERNATIONAL SEED FEDERATION (ISF)

ISF Position on Access to Plant Genetic Resources for Research and Breeding
(Oct 2008)

Plant genetic resources are used for very diverse purposes such as pharmaceutical products, cosmetics and plant breeding. Consequently, any regime on access and benefit sharing (ABS) for such plant genetic resources must take into account the specificity of each sector of users.

Since the beginning of agriculture and horticulture farmers have selected cultivars from the genetic diversity available to them. Over centuries they moulded these genetic resources through phenotypic selection, facilitated genetic exchange between cultivars and their weedy relatives, and transported their cultivars from one region of the globe to another. By incorporating and recombining genetic diversity available worldwide into new varieties, modern plant breeding has created, and continues to create, more variation in crops than has ever been available to growers and consumers.

All countries are strongly dependent on each other for plant genetic resources. Each country grows or imports numerous crops whose centres of diversity lie outside its national boundary making it inherently dependent on multiple foreign genetic resources. The widespread use of plant genetic resources, historically based on open access, is evident in the ancestry of individual varieties.

Access to genetic resources used in plant breeding is best facilitated through a multilateral approach that recognises and takes into consideration this dependency between countries. Public research institutions and small breeding companies in developing countries, those who access an overwhelming majority of plant genetic resources from gene banks, are particularly at risk of being unable to negotiate bilateral agreements. A multilateral system and standard terms of access would also encourage the sustainable use and conservation of plant genetic resources.

The CBD is debating a certificate of origin, source or legal provenance that would be required to guarantee benefit sharing once genetic resources had left the provider country. ISF is not in favour of such a certificate, as neither its need nor true value has been demonstrated. The complex parentage of genetic resources used for plant breeding and the continuous recombination of genes render its implementation impractical.

ISF believes that the Multilateral System (MLS) of the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (the "Treaty") is the right approach for ABS of genetic resources used in plant breeding programs. ISF strongly recommends that all plant genetic resources used regularly in plant breeding programs be brought into the MLS of the Treaty.

For plant genetic resources used in plant breeding that are not in the MLS of the Treaty, ISF supports a sectoral approach in CBD's International Regime on ABS. They should be accessed through an MLS-like system using a standard Material Transfer Agreement. Benefit sharing provisions should take into consideration the specificities of the plant-breeding sector.

INTERNATIONAL UNION FOR PROTECTION OF NEW VARIETIES OF PLANTS (UPOV)

Dear Executive Secretary Djoghlaf,

I have the pleasure to refer to notification reference SCBD/SEL/OJ/VN/GD/64650 of August 18, 2008, concerning Access and Benefit-sharing: Group of technical and legal experts on concepts, terms, working definitions and sectoral approaches - nomination of experts and submission of views.

Views and proposals of the International Union for the Protection of New Varieties of Plants (UPOV) in relation to the elaboration and negotiation of the international regime on access and benefit-sharing were expressed in 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 the Secretariat of the Convention on Biological Diversity under cover of a letter dated October 27, 2003.

./. I have the pleasure to send you herewith the reply of UPOV as mentioned above, and I would appreciate it if you could arrange for this document to be distributed to the participants of the meeting to be held in Windhoek, Namibia, from December 2 to 5, 2008.

Sincerely yours,

Rolf Jördens

Rolf Jördens
Vice Secretary-General

ZUM SCHUTZ VON PFLANZENZÜCHTUNGEN
GENF, SCHWEIZ

UNION INTERNATIONALE POUR LA PROTECTION DES OBTENTIONS VÉGÉTALES
GENÈVE, SUISSE

UNIÓN INTERNACIONAL PARA LA PROTECCIÓN DE LAS OBTENCIONES VEGETALES
GINEBRA, SUIZA

OF NEW VARIETIES OF PLANTS
GENEVA, SWITZERLAND

ACCESS TO GENETIC RESOURCES AND BENEFIT-SHARING

Reply of UPOV to the Notification of June 26, 2003, from the Executive Secretary of the Convention on Biological Diversity (CBD)

adopted by the Council of UPOV
at its thirty-seventh ordinary session
on October 23, 2003

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Introduction

1. 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."*

2. As of July 31, 2003, UPOV has 53 members[1]. Furthermore, 18 States and two intergovernmental organizations have initiated, with the Council of UPOV, the procedure for becoming members of the Union and 53 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.

3. 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.

4. It should be recalled that the Conference of the Parties to the CBD, in its Decision IV-24, taken at its sixth Meeting (COP-6) held in The Hague, Netherlands, from April 7 to 19, 2002, acknowledged relevant work being carried out by other intergovernmental organizations, such as the World Intellectual Property Organization (WIPO), the World Trade Organization (WTO), the United Nations Conference on Trade and Development (UNCTAD), the Food and Agriculture Organization of the United Nations (FAO) and UPOV, on issues related to access to genetic resources and benefit-sharing.

5. UPOV has developed a reply based on the principles of the UPOV Convention in order to provide some guidance on UPOV's views on the "process, nature, scope, elements and modalities of an international regime on access to genetic resources and benefit-sharing."

Access to Genetic Resources

6. 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.

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

Disclosure of Origin

7. The requirement for "distinctness" in the UPOV Convention[2] 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 knowledge[3] 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.

8. 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.

9. 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.

Prior Informed Consent

10. 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.

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[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

Summary

11. 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

12. 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).

13. 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 excepted from financial benefit-sharing whenever their products are "available without restriction to others for further research and breeding ...".

Subsistence Farmers

14. 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

15. 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

16. 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

17. 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.

[End]

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Cover Sheet

Submission of Views in Accordance with SCBD Notification: SCBD/SEL/OJ/VN/GD64650.

Subject: Access and Benefit-sharing: Group of Legal and Technical Experts on Concepts, Terms, Working Definitions, and Sectoral Approaches

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Submission by: Geoff Burton, Principal Consultant Genetic Resources Management
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Understanding Access to Biological Resources, Genetic Resources and its relationship to Derivatives and Products

The Problem

The Convention on Biological Diversity does not define access to biological resources or genetic resources nor does it clarify the relationship between biological resources, genetic resources and their derivatives and products. This has lead to concerns that the application of the Convention is flawed. This concern in turn leads to consistent calls for the inclusion of derivatives and products in the development an international regime on Access and Benefit-sharing.

Such calls have been resisted by other Parties in the belief that national law implementing the terms of the Convention and developed in accordance with Convention's Bonn Guidelines, are sufficient to provide legal certainty and to promote the fair and equitable sharing of benefits from the utilisation of genetic resources. Moreover, it has been argued that inclusion of derivatives would expand the scope of any regime so as to make it unworkable.

This latter view is commonly held among developed countries and particularly by those whose common law heritage has given them confidence in the regulation of commerce by contracts - within an over arching legal framework. The historic experience of many developing countries does not provide them with the same confidence and countries with a civil law tradition often find themselves more comfortable with a clear and explicit expression of terms, rights and obligations.

The continuing nature of this concern about 'derivatives' and 'products' is most recently demonstrated in annex I to COP9 decision IX/12[1] *The International Regime*. Here, references to the terms 'derivatives' and to 'products' are included as bracketed text in the paragraph setting out the Regime's Objective, in Option 1 under Scope, and are continued in Options 4 and 6. Option 7 under Scope calls for the clarification of the term "utilization of genetic resources". This may be interpreted as an indirect call for the issue of derivatives and products to be resolved.

Progress?

This seeming impasse is showing signs of breaking with the scope for flexibility at the national level being recognised in 2007.

1/ See COP9 decision IX/12, annex 1.

This recognition was reflected in the agreed position adopted by the Group of Technical Experts on An Internationally Recognised Certificate of Origin/Source/Legal Provenance in its report to the 5th Meeting of the Ad Hoc Open Ended Working Group on Access and Benefit-Sharing 2/ where they said:

> "The Group considered that the sovereign rights of Parties over their natural resources allowed them to regulate access and to determine the range of genetic resources and associated traditional knowledge that could be covered, providing flexibility to the Parties and avoiding the need to harmonize national access legislation and thereby significantly reducing implementation costs. This may also allow Parties to include derivatives in the national system if they so wish. It was felt that some harmonization of user measures and checkpoints may be necessary."

While flexibility at the national level is welcome, it does not resolve the need for consistency in any international regime.

Linking Purpose to Use of Resources

The Convention defines the terms *Biological resources* and *Genetic resources* but it does not define *access to resources*. The opportunity to do so opens the door to providing clarity about what resources are to be obtained and for what purpose. In doing so, providing such a definition it is one way in which the concerns about the limitations of the existing definitions of biological and genetic resources may be addressed.

For example, in 2005 Australia adopted the following definition of 'access' in its national ABS legislation:

> ***"access to biological resources*** means the taking of biological resources of native species for research and development on any genetic resources, or biochemical compounds, comprising or contained in the biological resources (other than an activity mentioned in subregulation (3))."3/

In this instance the scope of the definition is initially wide with the reference to 'taking biological resources' but is then narrowed by the reference to 'native species" and by "for research and development" and then is made specific by reference to 'genetic resources and biochemical compounds' found within the biological resources.

Another plain words definition of Access can be found in the United Nations University Institute of Advanced Studies *Pocket Guide* (to) *Access to Genetic Resources, Benefit Sharing and Bioprospecting*. It defines 'Access' as:

> "Access to genetic resources means to obtain samples of biological and/or genetic material from areas within national jurisdiction for purposes of research on conservation, commercial application or industrial use"4/

The inclusion of a reference to biochemical compounds in the first definition ensures that any and all parts (derivatives) found within a biological resource are covered even if the material obtained no longer contains any genetic material of functional heredity. The second definition addresses this issue by including biological resources - which necessarily includes any, and all, of its constituent components.

Does such an pragmatic approach also cover 'products'? Yes. By linking the grant of access to a defined purpose (scientific research and development or commercial application or industrial use) any product of the research and development process comes within the benefit sharing provisions of the system. This is

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2/ See page 7 paragraph 10, UNEP/CBD/WG-ABS/5/7

3/ See environment protection and biodiversity conservation regulations 2000**:** part 8a access to biological resources in Commonwealth areas <http://www.comlaw.gov.au/comlaw/legislation/legislativeinstrumentcompilation1.nsf/0/6762c4f433643bdaca25728800075f3c?opendocument>

4/ This UNU IAS report was prepared by Balakrishna Pisupati and published by the UNU IAS in 2007

consistent with the express intention at CBD Articles 15(7) and 19(2) to secure and promote fair and equitable benefit sharing.

At the same time, this type of approach ensures that commodity harvesting involving fishing, forestry, and other uses of biological resources including traditional indigenous and local community uses are not wrongfully included.

Other approaches to resolving 'Derivatives'

The CBD defines 'Genetic material' as:

> "… any material of plant, animal, microbial or other origin containing functional units of heredity."

And goes on to define 'Genetic resources' as:

> '… genetic material of actual or potential value.'

In circumstances where benefits arising from biotechnologies are no longer based simply on the genetic material of organisms but rather on the proteins produced by genes (Proteomics and Metabolics)5 or from the interaction of genes or from the interaction of RNA and DNA within an organism, or indeed, from proteins that are the consequence of the symbiotic interactions of organisms, it is clear that a more inclusive a working definition of 'genetic resources' may be useful.

Such a working definition should be sufficiently broad as to capture advances in biotechnology. Moreover, it ought cover biological processes as well as physical content. There are various ways of expressing this: For example a working definition might provide that:

> 'Genetic resources':
>
> '… are genetic material of actual or potential value, including its constituent components, biological processes and products engendered, produced, supported or otherwise involving the material.'

The principal of any such working definition is that it captures the products of genes, and the interactive processes involved as well as the genes themselves. The inclusion of processes is both physical (in so far as it involves collecting something live) and abstract, in so far as it involves recognition that value lies in the knowledge of the operation of genes, their metabolic processes and their interactions with living and non-living biological components.

Such a working definition can add greater clarity to national ABS law. Where a consensus on specific wording can be reached it can make a significant contribution to bilateral, regional and international common practice.

Accordingly, the adoption of a practical definition of *access* that encompasses the concerns of developing countries can remove a significant obstacle to the development of a successful international regime.

5/ Proteomics may be regarded as the study of proteins expressed by genes within an organism, with applications in the understanding of disease and in drug development while Metabolomics may be understood as the study of cell metabolism and involving the measurement of the metabolites of low molecular weight in an organism's cells at a specific time under specific environmental conditions.

Authority for a working definition

The CBD recognises that countries have national sovereignty over their resources1. This authority is quoted at Article 15 (1) as the basis for its access and benefit sharing provisions. While the CBD sets out standards and responsibilities for Parties it does not prevent additional action in furtherance of the objectives of the Convention.2 With this in mind the development of useful working definitions is a valuable contribution to the international regime.

1/ See CBD Article 3

2/ See CBD Article 1