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COMPILATION OF SUBMISSIONS PROVIDED BY PARTIES, GOVERNMENTS, INTERNATIONAL ORGANIZATIONS, INDIGENOUS AND LOCAL COMMUNITIES AND RELEVANT STAKEHOLDERS RELATED TO THE INTERNATIONAL REGIME ON ACCESS AND BENEFIT-SHARING

Note by the Executive Secretary

INTRODUCTION

In its recommendation 3/1, paragraph 3, the Working Group invited Parties, Governments, indigenous and local communities, international organisations and relevant stakeholders to submit to the Executive Secretary written comments and proposals on the items in annex I to the recommendation relating to the international regime on access and benefit-sharing. It also requested the Executive Secretary to prepare a compilation and a consolidated text of the comments and proposals submitted for consideration during the fourth Ad Hoc Open-ended Working Group on Access and Benefit-sharing and the Working Group on Article 8(j), pursuant to decisions VII/19 D and VII/16 of the Conference of Parties.

In light of the above, notification 2005-044 of 14 April 2005 was sent out to Parties, Governments, indigenous and local communities, international organizations and all relevant stakeholders.

On the basis of submissions received by the Secretariat, a consolidation of comments and proposals relating to the international regime was prepared and is available as document UNEP/CBD/WG-ABS/4/2.

In addition, this document contains a compilation of the comments and proposals relating to the international regime submitted to the Secretariat pursuant to decision 3/1. The contributions have been reproduced in the form and language in which they were received.

* UNEP/CBD/WG-ABS/4/1.

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Annex

COMPILATION OF SUBMISSIONS RELATING TO THE INTERNATIONAL REGIME PROVIDED BY PARTIES, GOVERNMENTS, INDIGENOUS AND LOCAL COMMUNITIES, INTERNATIONAL ORGANISATIONS, AND RELEVANT STAKEHOLDERS

CONTENTS

I. SUBMISSIONS FROM PARTIES

CANADA

Nature, Scope and Objectives of an International Regime on Access and Benefit-sharing

1. Nature

Canada is of the view that the current statement on "nature" is appropriate at this time, given the early stages of discussions on ABS:

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

As the ABSWG is currently in the midst of a gap analysis, it is premature to conclude at this time whether or not any new instrument is called for. It is therefore equally premature to comment on the form and legal status of any new instrument.

2. Scope

Canada is of the view that the scope of the international regime should be harmonized with the scope of the Convention on Biological Diversity, the International Treaty on Plant Genetic Resources and other relevant international instruments, and cover:

- The facilitation of access to genetic resources (in a non-discriminatory fashion)
- The promotion and safeguarding of the fair and equitable sharing of the benefits arising out of the utilization of genetic resources and associated traditional knowledge—in the context of mutually agreed terms.

In our view, Option 4, with the addition of a reference to "mutually agreed terms", best reflects our ideas on scope. Options 2 and 6 are also of interest.

We note the term "protection" of traditional knowledge associated with genetic resources is viewed as rather limiting. Considerations around TK associated with genetic resources could also include its promotion, among other things, and we are open to discussions on this matter. We remain of the view that the scope of ABS should encompass TK only if associated with genetic resources.

We also note that a number of the options under "scope" presume that there will be a legally binding instrument, which contradicts the neutral stance of the current text under "nature", cited above. Canada further believes that the "nature" of the instrument is not an appropriate issue for the "scope" section of the paper.

3. Objectives

Discussion of an objective was not included in the terms of reference given to the ABSWG by COP-7. Rather, the mandate is to "elaborate and negotiate an international regime on access to genetic resources and benefit-sharing with the aim of adopting an instrument/instruments to effectively implement the provisions in Article 15 and Article 8(j) and the three objectives of the Convention".

Therefore the objective of any regime on access and benefit-sharing should: (1) reflect the objectives of the Convention (2) aim to effectively implement the Convention's provisions on access and benefit-sharing.

In that vein, we support Option 4, which follows:

The objectives of the international regime, equally are:

(i) The conservation and sustainable use of biological diversity;

(ii) Facilitated access to genetic resources;

The fair and equitable sharing of the benefits arising out of the utilization of genetic resources and associated traditional knowledge.

Participation of indigenous and local communities in the elaboration of an International Regime on Access and Benefit-sharing

It has been Canada's longstanding view that the appropriate involvement of Indigenous communities and organizations is crucial for developing ABS rules respectful of their social, political, and legal circumstances.

One of the key goals of Canada's current policy development process is to establish a dialogue with Canadian indigenous[1] communities and organization as a means of ensuring that ABS-related measures developed in Canada, but also in international agreements, will be respectful of values, rights, and decision-making processes of Canadian indigenous peoples. Canada feels its approach has merits and is worthy of consideration by other Parties.

In general, where they already exist, Indigenous governance arrangements (such as traditional knowledge protocols) may be helpful in trying to determine how access should be granted, and by whom, in cases where genetic resources and associated traditional knowledge are found on lands of indigenous peoples. Options for measures relating to PIC, compliance, negotiation of MAT and benefit-sharing arrangements may also be found in existing models and/or policies.

Determination of the most appropriate model should come from the appropriate Indigenous authorities and be designed in a fashion that facilitates access (i.e. time and cost-effective manner) and ensures appropriate monetary and non-monetary benefit-sharing to the sanctioned provider, while being respectful of Indigenous communities decision-making processes.

A dialogue is needed between policy-makers and representatives of indigenous communities and organizations and in all relevant jurisdictions to ensure coherence and understanding of national ABS policies and community-level ABS policies, whether existing or proposed. National dialogues on ABS policies will contribute to a better understanding of all the interests at play and how to best accommodate the various concerns. Once the importance of this dialogue is recognized, all that remains in order to develop and apply such models is capacity-building from all concerned Parties. Because of the legal, social, and political complexities involved, the biggest challenge will be the time, financial and human resources constraints faced by both governments and indigenous communities

It is Canada's view that, because of the role they will play in the functioning of an ABS system, Indigenous communities and organizations should be encouraged by Parties to express their concrete

[1] Canada uses the term "indigenous" here to refer to all indigenous groups and organizations. In Canada the term indigenous is used interchangeably with the term "Aboriginal". The term "Aboriginal peoples of Canada" is used in the *Constitution Act*, 1982, includes Indian, Inuit and Metis.

views about how to respect, preserve and promote their traditional knowledge as it relates to genetic resources found in their areas.

Considerations on Facilitated Access

The international regime must fully and appropriately address access to genetic resources, as without access, there will be no benefit-sharing. That access is a key part of our negotiations is illustrated in our mandate from COP-7: "to elaborate and negotiate an international regime on access to genetic resources and benefit-sharing with the aim of adopting an instrument/instruments to effectively implement the provisions in Article 15 and 8 (j) of the Convention and the three objectives of the Convention."

Article 1 of the Convention provides as its third objective the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources.

Article 15.1 of the CBD recognizes the sovereign rights of States over their natural resources, and confirms that the authority to determine access to genetic resources rests with national governments and is subject to national legislation. Further, access to genetic resources shall be subject to the prior informed consent of the Party providing such resources, unless otherwise determined by that Party (Art. 15.5).

However, Article 15.2 requires each Party to endeavour to create conditions to facilitate access to genetic resources for environmentally sound purposes by other Parties, and not to impose restrictions that run counter to the objectives of the Convention. Under Article 15.4, where access is granted, it is to be on mutually agreed terms and subject to the provisions of Article 15.

Similarly, one of the objectives of the Bonn Guidelines is to provide guidance to Parties in the development of access and benefit-sharing regimes at the national level. To this end, the Guidelines can help guide our deliberations on access. As well, the Guidelines quite rightly point out that Parties and stakeholders may be both users and providers.

Some of the Guidelines are procedural in nature, such as the need to designate a national focal point to provide information to applicants for access on procedures for acquiring prior informed consent (PIC) and mutually agreed terms, and establish competent national authorities to be responsible for granting access and advising on various matters related to the access and benefit-sharing process. The Bonn Guidelines also outline a number of key pieces of information that could be required on applications for access, which should be adapted to national circumstances.

The Guidelines recommend that national PIC systems be based on legal certainty and clarity; facilitating access at minimum cost; ensuring that restrictions on access are transparent, based on legal grounds, and do not run counter to the objectives of the Convention. The Guidelines note in particular that permission to access genetic resources does not necessarily imply permission to use associated knowledge and vice versa.

The Guidelines recommend that providers of genetic resources should strive to avoid the imposition of arbitrary restrictions on access to genetic resources. Equally, Canada is of the view that access should be facilitated in a non-discriminatory fashion as between domestic and foreign applicants for access.

Considerations related to Benefit-Sharing

Canada believes the Bonn Guidelines provides a good approach to the question of benefit-sharing. Providers of genetic resources could do well to take note of the types, timing and distribution of benefits the Guidelines contain.

Parties should also remember that there are many possible benefit sharing models that could involve two or more actors from the public or private sectors (private/private arrangements, private/public arrangements, or public/public arrangements for instance). However, the majority of them will at some point in the process involve contracts.

National governments have at their disposal a number of ways to influence the form that ABS-related contracts may take and the kinds of benefits they include, including making available model contracts or stipulating in law what ABS contracts must contain. In this respect, the Guidelines rightly note that the balance among near-term, medium-term and longer-term benefits (as well as the balance between monetary and non-monetary benefits) should be considered on a case-by-case basis. Before developing national measures designed to capture the benefits from genetic resource use, each Party could usefully undertake an analysis of the likely mix of the type and timing of benefits with a view to creating realistic and practical ways to influence ABS contracts. To support such an exercise, the Working Group could suggest that Parties submit to the CBD (as well as other relevant international bodies such as WIPO) model ABS contracts. This would be consistent with the international elements of the Action Plan on Capacity-Building for Access to Genetic Resources and Benefit-Sharing contained in the Annex to COP Decision VII/19.

Canada also recognizes the role that financial and technical assistance must play in supporting the efforts of countries both to develop national ABS measures and to support the creation of national policy environments that facilitate benefit-sharing. For financial assistance to be used most effectively in support of national capacity-building measures, countries must identify their priorities and ensure there is strategic coherence across the range of issues for which increased capacity is required. Such an approach is consistent with a key lesson identified from Biosafety capacity-building efforts, namely, the need to determine the direction of a national policy in advance of planning what specific capacity (scientific/technical/ human resource/informatics) will be required to implement it.

The GEF is one of the largest sources of funding for capacity-building related to the conservation and sustainable use of biodiversity at the local, national and regional level and should be the main source of funds relating to Article 20 of the Convention. Canada is pleased to note that Revised Programming Document prepared in advance of the GEF 4th replenishment emphasizes capacity building for ABS as a key emerging issue. This is consistent with recent CBD decisions, which have requested the GEF to provide support for countries to implement the Bonn Guidelines. The ABS WG could encourage developing countries to take advantage of such funding if and when it becomes available and urge the COP to request that developed country Parties contribute appropriately to the 4th replenishment.

In order to ensure that efforts to implement the Action Plan on Capacity-Building for Access to Genetic Resources and Benefit-Sharing make efficient use of existing resources for capacity-building and avoid duplication of efforts, the Working Group could consider requesting the GEF prepare a report on the Strategic Approach to Capacity Building in the biodiversity portfolio to ensure that the GEF is prioritizing activities critical to the crosscutting capacity building needs of Least Developed Countries (LDCs) and Small Island Developing States.

Concessionary aid is not the only way to support the creation of benefit-sharing models. Canada believes that effective public policy, including market-based incentives such as intellectual property rights or preferential tax treatment, can go a long way in supporting measures likely to attract investments in biodiversity-based innovation. Given that many of these public policy changes could have effects beyond facilitating benefit-sharing under ABS arrangements, the Working Group should also encourage countries

to make progress on these kinds of capacity-building efforts without prejudice to the negotiations on an international ABS regime.

Many of the benefits outlined in the Bonn Guidelines could accrue to indigenous and local communities. Canada has stated in the past and continues to believe that capacity-building for indigenous and local communities should be prioritized within national jurisdictions so that they will be in a position to negotiate for and receive a fair and equitable share of benefits. With this in mind, the Working Group could request that the Working Group on Article 8(j) discuss this capacity-building issue with indigenous groups and order to determine the most appropriate process for elaborating more fully the capacity-building priorities of indigenous and local communities.

Compliance Measures

1. General Considerations around the Proposed Compliance measures:

A series of measures are under discussion with a view to ensuring compliance with access and benefit-sharing principles. Without prejudice to the nature, scope and elements of a regime regulating this area, Canada submits the following observations relating to some of the compliance measures proposed in the terms of reference set out in Decision VII/19 D of the Conference of the Parties and Annex 1 of document UNEP/CBD/WG-ABS/3/7. The following analysis is guided principally by the question of practicality in implementation.

Compliance measures can be grouped under four main categories:

- **a.** Measures to ensure Prior Informed Consent (PIC)
- **b.** Measures to ensure the negotiation of Mutually-agreed Terms (MAT)
- **c.** Documentation, including certificates of origin/source/legal provenance
- **d.** Disclosure mechanisms, such as disclosure of origin of genetic resources (GR) and associated traditional knowledge (TK) in patent applications, international/ national/regional databases, clearing-house mechanism

Canada believes that the above mentioned measures are interrelated. Each set of measures must be in place in order to ensure that both users and providers of genetic resources and traditional knowledge are in a position to comply with ABS measures. Moreover, certain measures, such as those designed to ensure PIC and MAT, must have been properly developed by national authorities in a manner respectful of the interests of all concerned stakeholders and local and Indigenous communities, if the Convention's objectives are to be met.

2. Specific observations on the above mentioned compliances measures can be found in the following papers from Canada

- Submission by Canada : Specific Considerations relating to PIC
- Submission by Canada : Specific Considerations relating to MAT
- Submission by Canada : Specific Considerations relating to Documentation: certificates of origin/source/legal provenance
- Submission by Canada : Specific Considerations relating to Disclosure of origin/source/legal provenance of genetic resources (GR) and associated traditional knowledge (TK)

Specific Considerations relating to Measures to Ensure PIC

Compliance with national ABS measures will be more likely if there are in place transparent, non-discriminatory, and practical measures within relevant national and sub-national jurisdictions. Furthermore, given the differences in national contexts and the potential differences in national

legislation, these measures should have "common requirements" which incorporate the fundamental elements and objectives of ABS.

In the case of PIC, the concept should apply to both providers and users of GR and TK. Compliance with a PIC requirement can only be ensured through a transparent, efficient and timely administrative process. As a central component of an ABS regime, a PIC system centred in national legislation, consistent with the Bonn Guidelines, would be essential to facilitate access to genetic resources and traditional knowledge in a fashion respectful of cultural and legal circumstances at the national, sub-national and local levels.

PIC is crucial to the credibility and legitimacy of an ABS regime. Its efficiency will be measured on the basis of whether there is continued access to GR and associated TK and whether users of genetic resources can obtain PIC without undue delays or excessive administrative burdens.

Canada therefore believes that it will be important for all providers to develop a transparent, timely, efficient and nationally appropriate system for giving and obtaining such prior informed consent. This is consistent with the basic principles of a prior informed consent system contained in the Bonn Guidelines, which stipulates:

(a) Legal certainty and clarity;
(b) Access to genetic resources should be facilitated at minimum cost;
(c) Restrictions on access to genetic resources should be transparent, based on legal grounds, and not run counter to the objectives of the Convention
(d) Consent of the relevant competent national authority (ies) in the provider country. The consent of relevant stakeholders, such as indigenous and local communities, as appropriate to the circumstances and subject to domestic law, should also be obtained.

In multi-jurisdictional countries, where the management of GR and the development of policies for the protection and promotion of traditional knowledge are shared by different government agencies, developing a transparent yet credible and efficient mechanism for PIC will be challenging. Determining which national entity or entities are appropriate for granting consent will be a key challenge that all countries endorsing the PIC requirement will have to face. While it appears that the various questions relating to PIC will be resolved nationally, it remains clear that the functioning of an international ABS regime could greatly depend on the capacity of provider countries to establish an efficient PIC system which will be transparent enough to allow users to easily comply with it.

Canada strongly encourages the elaboration of national codes of ethics/codes of conduct/Models of prior informed consent as well as and the implementation of the provisions of the Bonn Guidelines relating to PIC. While the term PIC is being commonly used, a complete understanding of how it should be granted, by whom and under which conditions must still be discussed. While most researchers are generally willing to work in a spirit of "good governance", they expect certainty and clarity when it comes to policies or regulations which will affect their work.

Developing a PIC system respectful of the social organization of Indigenous communities and their spiritual and cultural values is crucial. This is particularly challenging in countries which multiple jurisdictions and pluralistic legal systems where there are communities with varying legal situations, cultural traditions and customary practices.

Developing a PIC system which can accommodate traditional knowledge associated to genetic resources must start from three key considerations:

- The need to ensure the proper identification of the knowledge holder(s) (i.e. community, family, individual, etc.),

- Respect for the various decision-making processes of Indigenous communities.
- The importance of clarity, fairness and a common understanding of the implications of granting PIC both for the providers and users of the TK.

Specific Considerations relating to Mutually-agreed Terms (MAT)

One of the elements to be considered for inclusion in the international regime set out in section 4 of Annex 1 of document UNEP/CBD/WG-ABS/3/7 is: Measures to ensure compliance with the mutually agreed terms on which genetic resources were granted and to prevent unauthorized access and use of genetic resources consistent with the Convention on Biological Diversity (xi);

The determination of which elements are to be negotiated under contractual agreements between the users and providers of genetic resources and associated TK should be done by the appropriate national authorities. Based on the basic requirements for mutually agreed terms contained in the Bonn Guidelines, but subject to national determinations regarding their content and purpose, Mutually-Agreed Terms (MAT) should:

(a) Ensure legal certainty and clarity;

(b) Minimize transaction costs;

(c) Include provisions on user and provider obligations;

(d) Allow for the development of different contractual arrangements for different resources and for different uses and for the development of model arrangements;

(e) Cover different uses, including, *inter alia*, taxonomy, collection, research, commercialization;

(f) Be negotiated efficiently and within reasonable period of time;

(g) Be set out in a written agreement.

Canada would like to underline the fact that the negotiation of MAT will greatly depend on the capacity of users and providers of genetic resources and associated TK to identify and defend their respective interests. The determination of which elements are to be negotiated under contractual agreements between the users and providers of genetic resources and associated traditional knowledge should be done by the appropriate national authorities, bearing in mind the various elements set out in the Bonn Guidelines. National authorities could also have an important role to play in support of negotiations over MAT in order to ensure the fair and equitable sharing of benefits.

Finally, legal certainty and clarity in the context of MAT could also be ensured by an appropriate awareness raising efforts of the legal requirements (at all the various stages of ABS) in provider and user countries. Transparency and efficiency could also be maximized through the creation of model MAT and benefit-sharing arrangements. In this regard, existing international and national MAT models might provide a useful point of departure.

Specific Considerations relating to
Documentation: certificates of origin/source/legal provenance

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

> Any certificate of origin scheme would need to protect the interests of resource providers without being so restrictive as to prevent desired flows of genetic resources for scientific purposes linked to the conservation objectives of the CBD. Access to genetic resources is also important for food security and to create commercial opportunities from which benefits may flow. Furthermore, any system must not be so bureaucratic or costly that the transaction costs effectively consume potential benefits.[2]

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

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

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

Specific Considerations relating to
Disclosure of origin/source/legal provenance of genetic resources (GR) and associated traditional knowledge (TK)

One proposal designed to help track the origin of genetic resources and associated TK is a requirement to disclose of origin/source/legal provenance of genetic resources (GR) and associated traditional knowledge (TK) in patent applications. This issue has been the subject of intense debate both at WIPO and WTO TRIPS-Council.

In this context, further assessment of the impacts of such a requirement is needed, both on the existing national and international IP systems as well as on the users of genetic resources and associated TK. Canada has taken seriously the views expressed by many countries in their proposals to WIPO and WTO TRIPS-Council and supports the continuation of discussions in these fora as well as the CBD, as appropriate.

Should there be a requirement to disclose the origin of a genetic resource in a patent application or other database, accurate information on the origin of the resource will be needed all along the genetic resource "use chain", from *in situ* collection to research to, where applicable, commercialization. The burden of such a system would likely have to be carried even by those who may not be obtaining a direct financial benefit. The burden of responsibility for ensuring proper disclosure should be shared by all actors along the "use chain", including, and most importantly, the country of origin of the resource. How that burden should be divided is a question that remains little explored. Evaluating the practicality of the obligation

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

would require a preliminary two-tier approach; the nature of the information that would need to be disclosed and the consequences that would follow from non-compliance. For instance, different burdens would likely be entailed depending on whether disclosure was of country of origin or of source. In the context of a patent application, the former would require that the resource was tracked from where it was first discovered while the latter would require that the resource was tracked only from where it was most recently accessed. Likewise, sanctions could vary between cases of insufficient, wrongful or lack of disclosure.

The selection of the appropriate mechanism regarding compliance with an ABS system presents a challenge as it may entail consideration of issues such as organization, monitoring, administrative costs, effectiveness and jurisdiction. Then would follow the determination of whether disclosure of origin/source of genetic resources is the optimal solution for ensuring benefit-sharing and complying with an ABS system. Indeed, other solutions have been put forward both nationally and internationally in order to achieve such compliance. Continued further analysis of such options in the appropriate contexts would make a useful contribution in considering optimal policy choices.

Nevertheless, until other key elements for compliance with an ABS system –i.e. PIC and MAT systems-- are in place, the practicality of disclosure, whether mandatory or voluntary, remains unclear.

COSTA RICA

Régimen Internacional sobre acceso y participación en los beneficios

Atendiendo la invitación del Grupo de trabajo especial de composición abierta para enviar al Secretario Ejecutivo del CDB comentarios y propuestas sobre los temas que figuran en el anexo 1 del documento UNEP/CBD/WG-ABS/3/7 se anotan seguidamente los siguientes comentarios:

1. **Naturaleza** :

El régimen internacional debe ser jurídicamente vinculante.

2. **Ambito:** Se apoya la redacción de la Opción 1.

3. **Objetivos potenciales**: La opción 5 reúne los temas que han estado en discusión en las diferentes reuniones del WG/ABS , por lo que creemos es la opción mejor.

4. Elementos cuya inclusión en el régimen internacional ha de considerarse agrupados por temas :

*Acceso***:** Las medidas para el acceso deben establecer procedimientos claros y expeditos, con la definición de una Autoridad Competente, las medidas deben ser orientadoras para la definición de leyes o normativas nacionales.

Garantizar la participación en los beneficios:

Las medidas deben garantizar la distribución equitativa de beneficios económicos, sociales, ambientales, científicos o espirituales , incluyendo posibles ganancias comerciales a corto, mediano y largo plazo.
Las medidas deben orientar a las Partes a la redacción de normativas o leyes nacionales que contemplen todas las opciones posibles en el tema de participación de beneficios.

Promover la participación en los beneficios :

Las medidas deben contemplar obligatoriedad de los países desarrollados para la generación de investigaciones conjuntas principalmente en países proveedores . Las medidas deben contemplar términos sobre el tipo de transferencia de tecnología o de generación de la información derivada de la investigación y dirigida a la creación de capacidades nacionales.

Reconocimiento y protección de los derechos de las comunidades indígenas y locales :

Las medidas del Régimen internacional deben orientar a los Estados para que bajo sus legislaciones se tutelen y se reconozcan expresamente el conocimiento tradicional , asimismo las prácticas e innovaciones de los pueblos indígenas y las comunidades locales relacionadas con el empleo de elementos de la biodiversidad y el conocimiento asociado. La distribución de beneficios por el uso del conocimiento tradicional debe ser una parte obligada a cumplir en el consentimiento fundamentado previo por parte de quien hace uso de este conocimiento.

Derivados:

Por ser el acceso a los derivados la forma más frecuente del uso de los recursos genéticos y atendiendo el principio de soberanía de los Estados sobre el manejo de sus recursos genéticos, los derivados deben ser

objeto de regulación nacional y el Régimen internacional debe contemplar medidas para su acceso y deben estar sometidos al consentimiento fundamentado previo y a la distribución de beneficios por su uso.

Fomento y mecanismos de imposición del régimen internacional y cumplimiento de lo relativo al consentimiento fundamentado previo y de las condiciones mutuamente convenidas

Las medidas que debe contemplar el Régimen internacional deben garantizar a las Partes establecer medidas de monitoreo y control, medidas para establecer restricciones, cancelaciones de solicitudes de acceso y establecer medidas de sanciones para el acceso no autorizado o por el no cumplimiento de términos en los que fue otorgado un permiso de acceso a recursos genéticos , incluyendo el cumplimiento de las condiciones mutuamente acordadas entre el interesado y el proveedor del recurso genético

Funcionamiento del Régimen Internacional:

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

En cuanto al certificado internacionalmente reconocido es un tema aun en discusión en el WG/ABS y debe procurarse porque las Partes contemplen en sus legislaciones nacionales este tema, a su vez el Grupo de Trabajo de Composición Abierta debe hacer un esfuerzo en recomendar a la Conferencia de las Partes en su próxima reunión el reconocimiento a nivel internacional de los certificados de origen/legal procedencia que estén avalados por una legislación nacional. Es decir si una Parte Contratante tiene estipulado en su legislación el tema de los certificados de origen/legal procedencia éstos sean reconocidos internacionalmente. Costa Rica es de la opinión de que los certificados de origen/legal procedencia deben ser revisados fundamentalmente, pero no exclusivamente, en solicitudes de patentes o en diferentes casos de protección del conocimiento cuando estén involucrados recursos genéticos.

Erradicación de la pobreza

El Régimen internacional debe contemplar medidas en concordancia con otros procesos o grupos de trabajo en el marco del CDB que contemplan acciones para erradicar la pobreza ubicados principalmente en el tema de conservación y uso sostenible de la bioiversidad.. Las medidas deben ser contempladas en el tema de distribución justa y equitativa de beneficios derivados del uso de los recursos genéticos.

5. Posibles elementos adicionales observados

Elementos adicionales

De la lista propuesta se puede observar que varios de los elementos adicionales ya son parte de la propuesta original de elementos del Régimen Internacional , sin embargo existen algunos elementos adicionales importantes que rescatar: Las medidas que se establezcan en el Régimen Internacional deben servir de guía para el desarrollo de legislaciones nacionales y de medidas administrativas para el acceso a los recursos genéticos . Debe contemplar también el establecimiento de medidas mínimas sancionatorias o de observancia. Debe rescatarse también el establecimiento de medidas para garantizar las comunicaciones, información y sensibilización al público en el tema. Las medidas del Régimen internacional deben promover el apoyo recíproco del CDB con otros marcos jurídicos internacionales que tratan el tema de derechos de propiedad intelectual. Igualmente el Régimen debe contemplar medidas de promoción de la investigación conjunta principalmente a ser desarrolladas en los países proveedores de recursos genéticos y medidas para garantizar el suministro de asistencia técnica y transferencia de tecnología.

ETHIOPIA

The Protocol on Access and Benefit-sharing to the Convention on Biological Diversity.

Preamble

The Parties to this Protocol,

Being Parties to the Convention on Biological Diversity, hereafter referred to as "the Convention",

Recalling Articles 1, 15, 16, 17, 18 and 19 of the Convention,

Recalling the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization,

Recalling also decisions VII/19 of the Convention

Have agreed as follows

Article 1

Objectives

The objectives of this Protocol are the facilitated access to, and the fair and equitable sharing of the benefits arising from, the use of biological resources and community knowledge and technologies for improving human life and for the conservation and sustainable use of biological diversity.

Article 2

Use of Terms

For the purposes of this Protocol

"Access"

"Access" means collecting or in any other way obtaining or using an object.

"Biological resources"

"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.

"Biotechnology"

"Biotechnology" means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

"Commercial"

"Commercial" means the use of an object or part or component or derivative thereof directly or indirectly for sale, agricultural production, manufacturing or any other industrial application, or for providing a service to a third party.

"Country of origin"

"Country of origin" means the country which possesses a biological resource *in-situ.*

"Ecosystem"

"Ecosystem" means a dynamic complex of plant, animal and micro-organism communities and their non-living environment interacting as a functional unit.

"*Ex-situ* conservation"

"*Ex-situ* conservation" means the conservation of components of biological diversity outside their natural habitats.

"Genetic material"

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

"Genetic resource"

"Genetic resource" means genetic material of actual or potential value.

"Local Community"

"Local Community" means a human population in a distinct geographical area within a country or in two or more countries with its biological resources, innovations, practices, knowledge, or technologies managed partially or completely under its own customs, traditions or laws.

"Object"

"Object" means a specimen of a specified biological resource or any modification thereof, or any parts or genetic or biochemical components derived therefrom, whether incorporated into any other organisms or not. "Object" also means a specified component of the knowledge or technology of a local community, whether that specified knowledge or technology is imbedded in a specimen of a biological, including genetic, resource or not.

"Person"

"Person" includes a natural or juridical person.

"Prior Informed Consent (PIC)"

"Prior Informed Consent (PIC)" means the consent given by the provider and/or concerned local community or local communities, as the case may be, to the recipient's or a third party's access application that shall contain complete and accurate information regarding the aim of, anticipated activities on, and expected results from, the object and the anticipated impacts of the results.

"Provider"

"Provider" means the Competent National Authority, who has legal and/or administrative authority of the country providing the object to grant access to that object.

"**Recepient**"

"Recepient" means the natural or legal person who seeks, or who has been granted, access to an object or objects.

"Result"

"Result" means the product, process or item of information that the recipient obtains from using the accessed object.

"Technology"

"Technology" includes biotiotechnologh

Article 3

Scope

1. This Protocol shall apply to the facilitation for users of access to objects and the fair and equitable sharing by the providers and users of the benefits that accrue from the commercial and other applications by the users of the accessed objects.

2. This Protocol shall also apply to cooperation between providers and users in accessing biological resources for conservation, research and teaching.

3. Any use of accessed objects for any purpose not covered by the provisions of this Protocol is prohibited unless it is covered by an agreement based on a prior informed consent between the country of origin and the user.

4. This Protocol shall not affect the customary access, exchange or use of any object among local communities.

Article 4

Ownership

1. Any biological resource, including any modifications thereof or any parts or genetic or biochemical components derived therefrom, whether incorporated into any other organism or not, whether located within the country of origin's territory or not, shall, at all times, be the property of the people of the country of origin and shall not be used by, or transferred to, third parties without the written prior informed consent of the provider and the concerned local community or communities of the country of origin.

2. Any community knowledge or technology, whether imbedded in a biological resource or not, belongs to the concerned local community or communities, and shall not be used by any person in another country without the written prior informed consent of the concerned local community or communities, as the case my be.

Article 5

Conditions Governing the Use of the Accessed Objects

1. Any accessed object shall be used only for the purposes specified in a written prior informed consent. Uses not foreseen during the first written prior informed consent shall be covered by subsequent written prior informed consents. If subsequent negotiations aimed at updates or new versions of written prior informed consent fail, then the recepient shall refrain from any use of the object in question for purposes other than those covered in an existing written prior informed consent.

2. No accessed object shall be used by, or be transferred to, any third party without the provider signing a prior informed consent with that third party.

3. The recipient shall be responsible for the scientists or other persons, whether employed by the recipient or not, who may handle or know of the accessed object, and the recepient shall ensure that the accessed object is always used only as provided for by the terms of the written prior informed consent.

Article 7

Rights and Obligations of the Provider and the Recipient

1. Both the provider and the recipient shall use every reasonable means to protect each other's interests that have been specified in the written prior informed consent. Failure by either side do so shall be fully compensated for by the failing side.

2. Both the provider and the recipient shall have joint and equal rights over the results arising from the use by the recipient of any object supplied by the provider and accessed by the recipient through a written prior informed consent.

3. Both the provider and the recipient shall jointly and equally own any intellectual property rights over new varieties, modifications, products or process arising from the use by the recipient of any object supplied by the provider and accessed by the recipient.

4. Either the provider or the recipient may, if he so wishes, prevent the obtaining, or forgo his own inclusion as a co-owner, of any intellectual property right, provided, however, that this is not done in violation of a written prior informed consent.

Article 8

Rights and Obligations of the Prividor

1. The Provider shall have the following rights:

   a) On behalf of the State or the local community or communities, as appropriate, to maintain ownership of the object provided;

   b) to act on behalf of the State and/or the local community or communities, as a appropriate, in exercising the ownership provided under subparagraph 1 (a) and other rights over the object accessed;

   c) to grant third parties access to the object specified in the written prior informed consent for uses other than those specified in the written prior informed consent;

   d) to grant third parties access to the object specified in the written prior informed consent for the same uses as those specified in the written prior informed consent or for other uses in areas of the world not covered by that written prior informed consent.

2. The provider shall have the following obligations:

   a) to give to the recipient the object specified in the written prior informed consent;

   b) when the object in the written prior informed consent is a biological material, upon the submission of the recipient's research proposals related to its use, to inform the recipient of any existing relevant community knowledge or technology, as well as propose a new written prior informed consent for providing that relevant community knowledge or technology so as to avoid any possible confusion between that item of existing community knowledge or technology and the recipient's research innovations.

Article 9

Rights and Obligations of the Recipient

1. The recipient shall have the following rights:

   a) to use the object he has accessed from the provider according to the terms of the written prior informed consent;

   b) to use the object he has accessed from the provider for purposes other than those specified in an existing written prior informed consent only based upon a new written prior informed consent.

2. The recipient shall have the following obligations:

   a) to refrain from using of, or claiming any rights over, the accessed object other than what is specified in the written prior informed consent;

b) to acknowledge in any publication or package that the accessed object belongs to the country of origin;

c) to assist in identifying or in bringing to court infringes upon the rights of the country of origin over the accessed object;

d) to refrain from any claims for intellectual property rights that exclude the provider over any innovations which involve the accessed object;

e) to keep the provider fully informed of any improvements or new developments arising from the use of the accessed object;

f) to keep as well as promptly communicate to the provider any data regarding the use of the accessed object;

g) to seek and obtain a written prior informed consent before accessing any additional object from the country of origin of the already accessed object in conformity with the relevant laws of that country of origin and international agreements to which that country of origin is a party.

Article 10

Assignability

1. All rights and obligations in a written prior informed consent are personal to the respective provider and recipient and cannot be assigned, transferred, pledged or otherwise disposed of by either one of them without a new written prior informed consent by the other.

2. Rights or obligations under a written prior informed consent may be assigned to a third party when both the provider and the recipient are parties to the agreement of assignment.

Article 11

Publications

1. The recipient shall provide the provider with every manuscript resulting from any research using the accessed object at least 45 days prior to submission for publication or presentation

2. The provider reserves the right to review any such manuscript and to require that any part of it be kept as confidential in order to protect his proprietary rights and interests.

3. The provider shall notify the recipient in writing within 30 days identifying the information in the manuscript, if any, he wants kept confidential and suggesting editorial modifications, if any.

4. The recipient shall keep as confidential any information identified by the provider under subarticles 2 and 3 of this article except what is required by the law of the country where the recipient is operating.

Article 12

Guarantee

Each contracting party to this Protocol shall ensure that the commitments entered into by its citizens in written prior informed consents as providers or recipients fulfil his obligations.

Article 13

Principle of Benefit-sharing

The benefits that shall accrue to the provider from the use by the recipient of the accessed object shall have both monetary and non-monetary components.

Article 14

Monetary Benefits

1. Any costs borne by the provider in collecting or compiling the object accessed shall be charged to the recipient at the time of access or at any other time that the provider and the recipient mutually agree to.

2. The provider may require a specified up-front payment from the recipient. The amount will be mutually agreed.

3. When commercialisation starts, a royalty equal to half of the net profit from the monetary benefits that accrue from the object accessed shall be paid each year to the provider.

4. The provider shall pay directly to the local community or communities concerned at least half of the royalties earned under Sub article 3. If the local community or communities concerned so desire, this money shall be used to implement programmes that they determine; otherwise, it will be made available to them as cash.

Article 15

Non-monetary Benefits

Non-monetary benefits shall accrue to the country of origin of the accessed object and shall include:

a) Complete access to all research and development results;

b) Capacity building in research and development through the recipient carrying out all research and development activities wished by the country of origin of the accessed object in that country with the participation of those of its citizens its government specifies;

c) Participation in product development, including the establishment and running of joint ventures that the government of the country of origin wishes to join in or wishes any of its citizens to join in;

d) Transfer of any technology used on the accessed object to the country of origin of that accessed object.

Article 16

Confidential Information

1. Neither the provider nor the recipient shall directly or indirectly divulge to unauthorized persons any information which has been identified as confidential and mutually agreed by both parties, except when otherwise required by the laws of their respective countries.

2. Information identified by either the provider or the recipient as confidential shall be notified to the other side and agreed to in writing within 30 days except when national law prevents such recognition, in which case the situation shall be explained by the recipient or the provider, as the case may be, in writing within 30 days after receipt of notification.

3. The provisions of Sub articles 1 and 2 shall not apply to any:

   a) confidential information which has become part of the public domain independently of the recipient or the provider as the case may be:

   b) information of which either side was in prior possession independently of the other side's identification of that information as confidential;

   c) situation where either side obtains such information from a third side as a matter of right; or

d) situation where such information is generated by either side independently of any disclosure made by the other side under the written prior informed consent, as evidenced by written records. In the case of the provider, the evidence shall include oral traditions of local communities.

Article 17

Disclosure of Confidential Information to a Third Party

1. Either side may disclose information classified as confidential only to its representatives, including employees, director, agents, consultants or advisors for the purpose of evaluation.

2. any of the representatives to whom such information is disclosed shall:

a. be informed about the proprietary nature of the information;

b. agree to hold such information in confidence.

3. Either side shall be responsible for any breach of confidence by his respective representatives.

Article 18

Use of Confidential Information

Neither side shall:

a. use confidential information received from the other side for any purpose except for evaluation, testing, research and related activities;

b. disclose such information to any one except its representatives as provided in Article 17 of this Protocol unless a written prior informed consent has been obtained from the other side or it is required by law.

Article 19

Handling of Confidential Information

Both the provider and the recipient shall exercise all reasonable precaution to protect the confidentiality of the information identified as such by either side according to article 16 of this Protocol.

Article 20

Settlement of Disputes

1. Any written prior informed consent shall be interpreted in accordance with, and the performance of both the recepient and provider as well as the enforcement of their respective rights and obligations thereunder shall be governed in all respects by the laws of the country of origin of the accessed object and, where applicable, treaties to which that country is a party.

2. Any dispute between the provider and the recepient arising out of, or relating to, their written prior informed consent or the breach or termination thereof, which is not settled by negotiation or other agreed mode of settlement, shall be submitted, at the request of either side, to arbitration or judicial settlement in accordance with the laws of the country of origin of the accessed object.

Article 21

Notice

All notice, requests and other communications needed in the implementation of the written prior informed consent shall be made in writing and shall be deemed given if delivered or sent by fax or registered mail.

Article 22

Waiver

No failure by either the provider or the recipient to enforce any provision of their written prior informed consent shall constitute a waiver of any of that provision or of the rights of that provider or recipient thereafter to enforce each and every term and condition of the written prior informed consent.

Article 23

Termination of a Written Prior Informed Consent

1. Either the provider or the recipient may terminate a written prior informed consent at any time:
    a. Where performance becomes impossible for reasons beyond his control.
    b. Where an order has been made or resolution passed for the winding up or liquidation of the recipient's establishment.
2. In the event of the termination of a written prior informed consent by either side, the terminating side shall notify the other side in writing within 30 days.
3. Where notification within the time limit set under sub article 2 of this article is prevented by force majeure, the terminating side shall, immediately after the cessation of the occurrence of the force majeure, notify the other side of the event and his intention of terminating the written prior informed consent, including a statement describing the force majeure.
4. Upon the termination of a written prior informed consent, the recipient shall
    a. cease to make use of the accessed object or deal with any of the results related to it;
    b. refrain from transferring to third parties the accessed object.;
    c. refrain from disclosing any information relating to the accessed object not already in the public domain.

Article 24

Monitoring and Evaluation

1. The recipient shall submit to the provider regular research and financial reports.
2. The provider has the right to monitor and evaluate at any moment, through an independent consultant if he so wishes, the recipient's bookkeeping as well as relevant administrative details regarding the items covered by the written prior informed consent.

Article 25

Conference of the Parties Serving as the Meeting of the Parties

1. The Conference of the Parties shall serve as the meeting of the Parties to this Protocol.

2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, decisions under this Protocol shall be taken only by those that are Parties to it.

3. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, any member of the bureau of the Conference of the Parties representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

4. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall keep under regular review the implementation of this Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Protocol and shall:

   (a) Make recommendations on any matters necessary for the implementation of this Protocol;

   (b) Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;

   (c) Seek and utilize, where appropriate, the services and cooperation of, and information provided by, competent international organizations and intergovernmental and non-governmental bodies;

   (d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 29 of this Protocol and consider such information as well as reports submitted by any subsidiary body;

   (e) Consider and adopt, as required, amendments to this Protocol and its annexes, as well as any additional annexes to this Protocol, that are deemed necessary for the implementation of this Protocol; and

   (f) Exercise such other functions as may be required for the implementation of this Protocol.

5. The rules of procedure of the Conference of the Parties and financial rules of the Convention shall be applied, *mutatis mutandis*, under this Protocol, except as may be otherwise decided by consensus by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

6. The first meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be convened by the Secretariat in conjunction with the first meeting of the Conference of the Parties that is scheduled after the date of the entry into force of this Protocol. Subsequent ordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held in conjunction with ordinary meetings of the Conference of the Parties, unless otherwise decided by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

7. Extraordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held at such other times as may be deemed necessary by the Conference of the Parties serving as the meeting of the Parties to this Protocol, or at the written request of any Party, provided that, within six months of the request being communicated to the Parties by the Secretariat, it is supported by at least one third of the Parties.

8. The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State member thereof or observers thereto not party to the Convention, may be represented as observers at meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any body or agency, whether national or international, governmental or nongovernmental,

that is qualified in matters covered by this Protocol and that has informed the Secretariat of its wish to be represented at a meeting of the Conference of the Parties serving as a meeting of the Parties to this Protocol as an observer, may be so admitted, unless at least one third of the Parties present object. Except as otherwise provided in this Article, the admission and participation of observers shall be subject to the rules of procedure, as referred to in sub article 5 of this article.

Article 26

SUBSIDIARY BODIES

1. Any subsidiary body established by or under the Convention may, upon a decision by the Conference of the Parties serving as the meeting of the Parties to this Protocol, serve the Protocol, in which case the meeting of the Parties shall specify which functions that body shall exercise.
2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of any such subsidiary bodies. When a subsidiary body of the Convention serves as a subsidiary body to this Protocol, decisions under the Protocol shall be taken only by the Parties to the Protocol.
3. When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to the Protocol, shall be substituted by a member to be elected by and from among the Parties to the Protocol.

Article 27

SECRETARIAT

1. The Secretariat established by Article 24 of the Convention shall serve as the secretariat to this Protocol.
2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply, *mutatis mutandis*, to this Protocol.
3. To the extent that they are distinct, the costs of the secretariat services for this Protocol shall be met by the Parties hereto. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, decide on the necessary budgetary arrangements to this end.

Article 28

RELATIONSHIP WITH THE CONVENTION

Except as otherwise provided in this Protocol, the provisions of the Convention relating to its protocols shall apply to this Protocol.

Article 29

MONITORING AND REPORTING

Each Party shall monitor the implementation of its obligations under this Protocol, and shall, at intervals to be determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, report to the Conference of the Parties serving as the meeting of the Parties to this Protocol on measures that it has taken to implement the Protocol.

Article 30

COMPLIANCE

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, consider and approve cooperative procedures and institutional mechanisms to promote compliance with the provisions of this Protocol and to address cases of non-compliance. These procedures and mechanisms shall include provisions to offer advice or assistance, where appropriate. They shall be separate from, and without prejudice to, the dispute settlement procedures and mechanisms established by Article 27 of the Convention.

Article 31

SIGNATURE

This Protocol shall be open for signature at the United Nations Office at Nairobi by States and regional economic integration organizations from _____, and at United Nations Headquarters in New York from _____.

Article 32

ENTRY INTO FORCE

1. This Protocol shall enter into force on the ninetieth day after the date of deposit of the thirtieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention.
2. This Protocol shall enter into force for a State or regional economic integration organization that ratifies, accepts or approves this Protocol or accedes thereto after its entry into force pursuant to paragraph 1 above, on the ninetieth day after the date on which that State or regional economic integration organization deposits its instrument of ratification, acceptance, approval or accession, or on the date on which the Convention enters into force for that State or regional economic integration organization, whichever shall be the later.
3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.

Article 33

RESERVATIONS

No reservations may be made to this Protocol.

Article 34

WITHDRAWAL

1. At any time after two years from the date on which this Protocol has entered into
2. force for a Party, that Party may withdraw from the Protocol by giving written notification to the Depositary.
3. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.

EUROPEAN UNION

EU comments and proposals on Annex A – Potential elements of an International Regime on Access and Benefit-sharing

The European Union welcomes the progress achieved at the Third Meeting of the Open-Ended Working Group on Access and Benefit-sharing. The EU is concerned, however, about the number of additional options and elements that have been added to an already long list of potential options and elements of the international regime. It seems to us that further discussions should focus on those aspects that – following an analysis of gaps in existing national, regional and international legal and other instruments - are fundamental to achieving a practicable, transparent, and efficient international regime to promote and safeguard the facilitated access to genetic resources and the fair and equitable sharing of benefits arising out of their utilization.
In this context, the EU wishes to record that it supports the following options and elements listed in Annex A:

As regards Annex A, No. 2 on scope, the EU supports Option 6, as this is the closest to Decision VII/19, as copied above in italics before the new options.

With respect to Annex A, No. 3 on potential objectives, the EU supports Option 5.

As regards Annex A, No. 4 on elements to be considered for inclusion in the international regime, the EU notes that this section follows the same structure as the matrix contained in Annex B. The EU's comprehensive views on these elements are included in the information provided in the matrix.

With respect to Annex A, No. 5 on potential additional elements and options identified, the EU does not support the addition of the further options and elements identified by the Third Opened-Ended Working Group, since the mandate given by COP-7 is sufficiently comprehensive.

The EU believes that the main emphasis should now be focussed on the gap analysis.

INDIA

Nature, scope, potential objectives and potential additional elements (Annex A of Notification)

India has already submitted to the CBD Secretariat during the ABS WG-3 meeting held in Bangkok in February 2005, its position on nature, scope, potential objectives and potential additional elements, as the common position of the Group of Like Minded Megadiverse Countries (LMCCs).

JAPAN

Comments and proposals on Annex 1

If providing countries are too strict in regulating access to genetic resources, this will lead to user companies being reluctant to access such resources. This would mean that commercial benefits would not be generated. There would be few benefits to share with providing countries. This outcome would be unfortunate for users, providers, and all other stakeholders.
Facilitating access to genetic resources will build a win-win situation among providers and users through the use of these resources.

1. Nature

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

2. Scope

The legally binding and/or non-binding instrument(s) should apply to:

(a) Facilitated access to genetic resources in a non-discriminatory fashion.

(b) Fair and equitable sharing of the benefits arising out of the utilization of genetic resources in the context of mutually agreed terms.

(c) Protection of traditional knowledge, innovations and practices associated with genetic resources.

3. Potential objectives

(i) To prevent the unauthorized access and use of genetic resources, to ensure that fair and equitable sharing of benefits flow to the providers of the genetic resources and to reinforce national legislations.

(ii) To provide effective protection for the traditional knowledge of indigenous and local communities associated with genetic resources, subject to the national legislation of the countries where these communities are located.

(iii) To create conditions to facilitate access to genetic resources for environmentally sound uses.

(iv) To ensure compliance with prior informed consent of providers and of indigenous and local communities, as well as mutually agreed terms, and support the implementation of and compliance with national legislation.

4. Elements to be considered for inclusion in the international regime, clustered by subject matter

Access

Measures to promote facilitated access to genetic resources for environmentally sound uses according to Article 15, paragraph 2, of the Convention on Biological Diversity

Functioning of the international regime

Means to support the implementation of the international regime within the framework of the Convention.

Poverty eradication

Measures to promote access and benefit-sharing arrangements that contribute to the achievement of the Millennium Development Goals, in particular on poverty eradication and environmental sustainability.

5. Potential additional elements and options identified

Measures that support the development of national administrative, legislative and regulatory regimes.

Measures to establish international minimum standards for compliance with national legislations.

Promotion of the establishment of appropriate measures by Parties with users under their jurisdiction.

Measures to ensure recognition and protection of the rights of indigenous women as holders and protectors of traditional knowledge and genetic resources.

Measures to clarify national access laws.

Measures to ensure communication, information and awareness raising.

Measures to ensure access to information on regulating access and benefit-sharing of genetic resources and associated traditional knowledge.

Measures to ensure access to justice.

Measures to ensure mutual support between the Convention on Biological Diversity and intellectual property rights-related treaties.

Measures to build relationships with other international legal instruments.

MEXICO

Régimen internacional sobre acceso y distribución de beneficios

Naturaleza

1. Un régimen puede ser definido como la red de medidas legales, políticas y administrativas referentes a un tema (Young 2004), el cual incluye tratados internacionales, leyes, regulaciones, normas, instrumentos de política y estrategias, entre otros.

2. En el caso de los recursos genéticos, existe un régimen internacional conformado por el CDB y tratados relacionados, distintas disposiciones nacionales relativas a los recursos genéticos, así como las medidas adoptadas por diversos organismos privados como: empresas, instituciones académicas, jardines botánicos, comunidades indígenas y locales, etc.

3. No obstante, el régimen o sistema actual no sólo no funciona, sino que seguirá siendo más disfuncional en la medida que no se adopten diversas medidas de carácter interno y multilateral. Los modelos de leyes existentes sobre recursos genéticos no han logrado promover una distribución justa y equitativa de los beneficios, más aun, ni siquiera han podido tener una identificación clara de los beneficiarios y han enfrentado diversos problemas de implementación[i].

4. No es posible resolver los problemas de regulación de los recursos genéticos de manera unilateral: se requiere adoptar un modelo de regulación de los recursos genéticos a través de políticas coordinadas aunque diferenciadas, que permitan incorporar aspectos específicos según las prioridades nacionales.

5. Es por eso que México, junto con los países Megadiversos, impulsó la decisión del Plan de implementación de la Cumbre Mundial Sobre el Desarrollo Sostenible (CMDS) para negociar, dentro del CDB, un régimen internacional sobre distribución de beneficios. Es necesario *rediseñar* el marco normativo internacional actual para hacerlo más eficiente y efectivo, así como trabajar en el marco normativo nacional de acuerdo con lo anterior.

6. Existe un marco general que está dado por el Convenio sobre Diversidad Biológica y que es legalmente vinculante, mismo que no requiere ser modificado. Lo que se negociará en el marco del Régimen Internacional son medidas que permitan implementar las disposiciones ya existentes en el CDB de una manera efectiva y eficiente.

7. Para lo anterior, serán necesarios varios instrumentos, a saber:

    a. Un conjunto de medidas legalmente vinculantes, negociado dentro del CDB, cuyos elementos se elaboran más adelante

b. Un conjunto de medidas a ser tomadas en otros foros internacionales, a fin de habilitar y/o hacer obligatorias las medidas nacionales necesarias para el buen funcionamiento del régimen.

8. Para cumplir con las obligaciones emanadas de los instrumentos anteriores, los países deberán a su vez realizar algunos cambios en sus marcos normativos nacionales, algunos de manera obligatoria.

9. Si bien resulta claro que el instrumento propuesto en el párrafo 8 (a) deberá ser legalmente vinculante, se considera que será necesario analizar cuál es el formato legal más adecuado (e.g. Protocolo, Anexo al Convenio, etc.). Dentro de los criterios que deberán usarse para la decisión está la facilidad de instrumentarlo, así como la capacidad de hacer exigible su cumplimiento. Este instrumento representa el componente central del Régimen Internacional a ser negociado en el marco del CDB.

10. En lo relativo a los instrumentos referidos en 8 (b), estos tienen que ver con áreas que están relacionadas y que requieren ser modificadas en diferentes grados. Es en este conjunto en el que deben de incluirse medidas relacionadas con los derechos de propiedad intelectual, algunos relacionados con el conocimiento tradicional y con los recursos genéticos situados fuera de las jurisdicciones nacionales.

Ámbito

11. La utilización de recursos genéticos, se refiere al empleo directo de material genético o indirecto a través de la información derivada o de materiales expresados por el material genético original con fines comerciales. Esto quiere decir también que la colecta de material para otros fines cae fuera del ámbito del Régimen internacional. Si existiera un cambio de intención de uso sobre materiales colectados originalmente con propósitos científicos, a un uso con propósitos comerciales, esta modificación también será sujeta al régimen.

12. El ámbito del Régimen Internacional incluye como temas generales:
    a. El Acceso y el reparto de beneficios derivados de la utilización de los recursos genéticos
    b. Los conocimientos, innovaciones y prácticas tradicionales asociados con los recursos genéticos.

Regulación

13. En términos de las necesidades normativas, se deben considerar los siguientes elementos:
    a. El acceso y la utilización de los recursos genéticos, así como los diferentes procesos intermedios, incluyendo los derivados y los derechos de propiedad intelectual
    b. Los recursos genéticos dentro y fuera de la jurisdicción nacional
    c. El acceso y la utilización de los conocimientos, innovaciones y prácticas tradicionales asociadas a los recursos genéticos, incluidos los derechos de propiedad intelectual sobre los mismos
    d. El reparto de beneficios

14. En muchas ocasiones, la utilización de los recursos genéticos se lleva a cabo de manera indirecta, es decir, a través de un bien que en algún momento empleó al recurso genético o la información derivada del mismo, pero que no necesariamente contiene al recurso genético como material biológico. En este sentido, consideramos de la mayor relevancia avanzar en el desarrollo de un entendimiento internacional sobre lo que significa *utilizar* un recurso genético, esto es: ¿en qué situaciones podemos afirmar que hay utilización directa o indirecta de un recurso genético y que por tanto hay una obligación de distribuir beneficios en el marco del CDB? A nuestro juicio, esta es la pregunta de fondo en lo que en el debate que se ha dado sobre el concepto de derivados, que más que ser un concepto nuevo, se refiere al vínculo entre el material que es "accesado", y lo que es finalmente utilizado del mismo con propósitos de desarrollo biotecnológico y de lucro.

Objetivos potenciales

15. A partir de las disposiciones del Convenio es posible identificar tres grandes objetivos específicos para el Régimen internacional:
    a. Distribuir de manera justa y equitativa los beneficios derivados de la utilización de los recursos genéticos a través de condiciones más favorables para negociar términos de distribución de beneficios así como de otros enfoques cuando sea necesario
    b. Ampliar la capacidad de utilizar los recursos genéticos a través de la investigación y desarrollo y la transferencia de tecnología, en particular en y hacia países en desarrollo
    c. Facilitar el acceso a los recursos genéticos a través de medidas que den certeza y protección jurídica tanto a usuarios como a proveedores

16. En cuanto al primer objetivo – 16(a) y ante la incertidumbre de la obtención de los beneficios, ya que la investigación y desarrollo de productos toma mucho tiempo, se considera que la distribución de beneficios mediante enfoques contractuales puede ser complementada con otros mecanismos, incluyendo fondos multilaterales, como lo establece en propio Convenio en sus Art. 15 y 16 al referir que se distribuirán beneficios "cuando sea necesario, a través de lo dispuesto en Art. 20 y 21", referentes a recursos financieros y al mecanismo financiero.

17. Diversos países han argumentado que el costo del Régimen internacional puede superar sus beneficios. México, al igual que ellos, considera que hay que asegurar que se diseñen e implementen las medidas más costo-efectivas, tomando en cuenta que el argumento de costo no exime del cumplimiento con las disposiciones del Convenio.

18. El objetivo 16(b) propuesto arriba, incorpora una amplia gama de disposiciones del Convenio, todas ellas encaminadas a lograr no sólo mayor equidad en la capacidad para emplear los recursos genéticos para resolver las necesidades de desarrollo de todos los países sino también, que contribuyan aún más a la valorización los recursos genéticos. Es claro que en la biotecnología, contar con el acceso a las herramientas de exploración e investigación es tan importante como contar con el acceso a los recursos genéticos.

19. Finalmente, el último objetivo – 16(c) – se fundamenta en un hecho muy simple: si no hay acceso, no hay beneficios. Debemos buscar maximizar el valor de los recursos genéticos, y esto requiere de promover su uso más amplio en investigación y desarrollo. Para lograr esto, los usuarios requieren de procedimientos claros y sencillos para acceder a recursos genéticos y los proveedores requieren de suficientes herramientas para monitorear y hacer valer sus derechos, aún fuera de su jurisdicción, para poder relajar las condiciones al momento de acceso.

20. Notamos que varias opciones presentadas en el documento hacen referencia a prevenir la apropiación indebida de los recursos genéticos y del conocimiento tradicional como un objetivo del Régimen. Este es un tema de particular relevancia, ya que la viabilidad y aceptación de cualquier Régimen que sea negociado dependerá de que, como resultado de su aplicación, se evite la apropiación indebida. Esto está implícito en el tercer objetivo propuesto – 16(c) – como parte de la certeza jurídica que es necesario tenga el proveedor sobre los recursos y en su caso, conocimientos, a los cuales se esté facilitando el acceso.

Elementos del Régimen Internacional

21. Siguiendo el orden propuesto dentro del documento enviado por el Secretariado, y sin prejuzgar el orden o importancia de cada uno de los elementos, a continuación incluimos un listado de los elementos que debieran formar parte, *inter alia*, del Régimen internacional

Acceso

a. La creación de un certificado de legal procedencia que sea revisable en diversos puntos y al final de la cadena de investigación y desarrollo así como al momento de comercializar productos biotecnológicos para dar certidumbre a proveedores y usuarios, y que identifique y reconozca las aportaciones de los conocimientos tradicionales que eventualmente estén siendo utilizados. (ver también nota más adelante)

b. Explorar opciones prácticas, que sin menoscabo a la soberanía nacional, pudieran facilitar el acceso legal a los recursos genéticos a fin de promover su utilización amplia y dar certidumbre a los participantes.

Asegurar la distribución de beneficios

c. La consideración y en su caso, el desarrollo de enfoques complementarios para operar en casos en donde el enfoque contractual resulte limitado, para cumplir las obligaciones de distribución de beneficios. Esto podría incluir un mecanismo financiero internacional que tenga contribuciones ligadas a los beneficios monetarios derivados de la utilización de recursos genéticos.

d. En particular, el posible desarrollo de "disposiciones de base" que operen cuando no existan términos legales mutuamente acordados para distribución de beneficios o cuando no sea posible demostrar el cumplimiento con disposiciones del CDB (vía el Certificado)" que aseguren que el usuario

distribuya beneficios mínimos tales como una tasa de regalías, pagos únicos, etc. Es posible identificar diversos casos en los que aplicarían estas disposiciones, tales como:

i. Cuando los beneficios provengan de zonas más allá de la jurisdicción nacional
ii. Cuando el origen no es conocido
iii. Cuando el número de recursos genéticos haga imposible negociar términos de manera individual
iv. Otros

Fomento a la distribución de beneficios

e. Un paquete de medidas en países usuarios que fomenten el cumplimiento con las disposiciones del CDB así como las disposiciones nacionales de acceso. Esto debiera incluir incentivos a nivel nacional para que los usuarios de recursos genéticos cumplan con dichas disposiciones. A pesar de su potencial, este componente es a menudo olvidado en los análisis sobre el tema[iii]. Este apartado incluye, un conjunto amplio de medidas a nivel nacional, tales como: beneficios fiscales, criterios para asignación de fondos públicos de investigación, criterios de financiamiento de instituciones públicas, inversión directa en el marco de acuerdos de colaboración, etc.

f. Relacionado con el punto anterior, un paquete de incentivos, incluyendo los económicos, para fomentar la transferencia de tecnología y la investigación en países proveedores de recursos genéticos, así como el compartir los resultados de investigación.

Mecanismos para promover y asegurar el cumplimiento con el consentimiento informado previo y términos mutuamente acordados

g. Un paquete de medidas en países usuarios que fomenten el cumplimiento con las disposiciones de acceso.

Derivados

h. Aclarar y tomar medidas sobre la situación de los *derivados* así como llegar a un entendimiento sobre la noción de *utilización* a fin de identificar los límites de la obligación de distribución de beneficios y de cumplimiento con las disposiciones de acceso.

Regulación consistente para los diversos tipos de recursos genéticos

i. Aclarar la situación jurídica de las colecciones *ex situ*, y tomar medidas buscando su incorporación con algún tipo de obligación en cuanto a retribuir el valor del servicio ambiental global.

j. Un acuerdo internacional sobre la situación jurídica de recursos genéticos que están fuera de la jurisdicción nacional, como aguas internacionales, los fondos marinos y la Antártica y tomar medidas buscando su incorporación con algún tipo de obligación en cuanto a retribuir el valor del servicio ambiental global.

Coordinación regulatoria con otros foro, instrumentos y procesos internacionales

k. Desarrollar medidas, en colaboración con los foros pertinentes, a fin de garantizar contar con puntos de regulación clave. Específicamente, en lo relativo a las disposiciones asociadas a derechos de propiedad intelectual, en donde debiera de incluirse el Certificado de Legal Procedencia como un requisito en las solicitudes de derechos de propiedad intelectual que utilicen o hayan utilizado recursos genéticos como elemento clave de su desarrollo.

Notas

[i] Algunos países han argumentado que esta falta de resultados se debe al poco avance en el desarrollo de su legislación de acceso y que lo que necesitamos es simplemente acelerar el proceso legislativo nacional. Si bien esto pareciera ser cierto a primera vista, tomando en cuenta que a la fecha el Secretariado del CDB cuenta a la fecha con tan solo 26 legislaciones nacionales (Ogolla, 2005), al analizar las experiencias en la aplicación de la ley en aquellos países que cuentan con legislación específica se han encontrado pocos casos de aplicación efectiva de dichas disposiciones (Cabrera, J. 2004) asociados a limitaciones inherentes al modelo legislativo. La evidencia encontrada en un estudio de países de la cuenca del Océano Pacífico, en donde en los 9 países que contaban con algún tipo de legislación de acceso, sólo se habían logrado aprobar 29 solicitudes de acceso entre 1992 y 2004 (Carrizosa, S. 2004) apunta a serios problemas de implementación.

[ii] Con el fin de aclarar este elemento, considérese como ejemplo las diversas disposiciones que existen en materia de derechos de autor, en donde, en ausencia de un contrato específico, la legislación *asume* que existe un acuerdo básico entre las partes. En este caso, se promovería que, aun en ausencia de legislación nacional, el usuario tuviera obligaciones básicas relativas a la distribución de beneficios.

[iii] Un magnífico ejemplo de este tipo de medidas se encuentra en el programa ICBG en los Estados Unidos, ya que de manera unilateral, el programa obliga a sus proyectos a cumplir con los principios del CDB *independientemente de la legislación nacional tanto en Estados Unidos como en el país de origen*, alentándoles a ir más allá de lo mínimo obligatorio. El cuidado en la formulación de las propuestas, así como los resultados del programa son evidencia de lo poderoso que puede ser un instrumento de esta naturaleza.

International Regime on Access to Genetic Resources and Benefit sharing

Nature

1. A regime can be defined as a range of legal and administrative measures, and policies referred to ABS issues (Young 2004), all of which includes Laws and international treaties, regulations, standards, policy instrument strategies, among others.

2. In the case of genetic resources, there exists an international regime formed by the CBD and other related treaties, various national provisions related to genetic resources as well as measures adopted by diverse private organisms such as: coorporations, academic institutions, botanical gardens, indigenous and local communities, etc.

3. Nevertheless, the regime or system we have today is not only a non functional one, but it will continue to be even more disfunctional unless effective internal and multilateral measures are taken. Current legislations for genetic resources have not been able to promote real benefit sharing under fair and equitable terms, moreover these have not even been able to clearly identify the beneficiaries and they have faced various implementation problems[1].

4. It is not possible to overcome the problems associated to the regulation of genetic resources in a unilateral way; model of genetic resources regulation is required through coordinated, but differentiated policies which allow the incorporation of specific aspects according to the national priorities.

5. This is the reason why Mexico, together with the Group of Like-Minded Megadiverse Countries, promoted the decision under the Implementation Plan of the World Summit on Sustainable Development (WSSD) for negotiating, under the CBD, an international regime on benefit sharing. It is necessary to *redesign* the international regulatory framework in order to make it more efficient and effective, as well as working on a national legislative framework in accordance with the previous comment.

6. At present, we have a general framework given by the CBD which is legally binding, which does not need to be modified. What needs to be negotiated under the framework of the International Regime are the necessary measures that will allow to implement the existent dispositions within the Convention in an effective and efficient way.

7. To achieve this, several instruments will be needed:

    a. A group of legally binding measures, negotiated under the CBD, of which elements will be further elaborated ;

b. A set of measures taken in other international fora in order to enable and/or make obligatory the national measures necessary for the sound operation of the regime.

8. To comply with the obligations generated by these instruments, countries will be required, in turn, to make the necessary changes into their regulatory systems and frameworks

9. While it is clear that the instrument proposed in paragraph 8 (a) should be legally binding, it is considered that further analysis is required to decide on the most adequate legal format (i.e. Protocol, Covention Annex, etc.). The ease of implementation, as well as the capacity to enforce compliance should be some of the criteria that should be used to decide on the specific format for the legally binding instrument. This instrument represents the central component of the International Regime to be negotiated under the CBD.

10. With regard to the instruments referred in paragraph 8 (b), these have to do with areas that are interrelated and that require a certain degree of modification. Some of the issues to be addressed directly in other for a include measures related to intellectual property rights, traditional knowledge and genetic resources outside national jurisdictions

Scope

11. The use of genetic resources refers to the direct usage of genetic material or indirect usage through the information derived or from materials expressed by the original genetic material with commercial purposes. This also means that the recollection of material for other purposes falls out of the scope of the international Regime. If there would be a change in the intention of use of the collected material originally with scientific purposes to a use with commercial purposes, this modification would also be subject to the regime.

12. The scope of the International Regime includes as general subjects:
    a. The access and benefit sharing derived from the usage of the genetic resources
    b. The knowledge, innovations and traditional practices associated with genetic resources.

13. In terms of the regulation needs, to the following elements must be considered:
    a. The access and use of genetic resources, as well as the different intermediate processes, including the derivatives and the intellectual property rights.
    b. The genetic resources inside and outside the national jurisdiction.
    c. The access and utilization of knowledge, innovations and traditional practices associated to the genetic resources, including their own intellectual property rights.
    d. Benefit sharing

14. In several occasions, the use of genetic resources is carried out in an indirect way, that is to say, through the use of a good that at some moment used the genetic resource or the information derived from it, but that not necessarily contains the genetic resource as biological material. In this sense, we considered of great

relevance to advance in the development of an international understanding on what it means *to use* a genetic resource, this is: in what situations we can affirm that there is direct or indirect use of a genetic resource and that therefore is an obligation to distribute benefits under the CBD framework? In our opinion, this is the central question in the debate on the concept of derivatives, where more than being a new concept, it refers to the link between the material that is being "accessed", and what finally is used with the same purposes of biotechnological development and profit.

Principal Objectives

15. From the dispositions of the Agreement it is possible to identify three specific objectives for the international Regime
    a. The fair and equitable distribution of benefits derived from the utilization of genetic resources through more favorable conditions to negotiate terms of distribution of benefits as well as of other approaches when it is necessary
    b. To extend the capacity to use the genetic resources through research and development, the transfer of technology, in particular, in developing countries
    c. To facilitate the access to the genetic resources through measures that provide certainty to both suppliers and users

16. In terms of the first objective -1x6(a)- and in the face of uncertainty in the obtainment of benefits, given that research and development takes too long, it is considered that benefit sharing through contracts may be complemented with other mechanisms, including multilateral funds as it is established by the Convention in Art. 15 and 16 stating that distribution of benefits shall take place "when considered necessary", according to the provisions in Art. 20 and 21", which refer to the financial and resources mechanisms.

17. Several countries have argued that the costs of the international regime can exceed its benefits. Mexico considers that it is possible to design and implement cost-effective measures and that the argument of cost of compliance does not exempt countries from their obligations under the CBD.

18. The objective 16(b) proposed above, incorporates a wide range of provisions within the CBD, all of which aim to accomplish not only more equity among countries with regard to their ability to use genetic resources to address their development needs, but to contribute to enhance the value of genetic resources. It is clear that in biotechnology, having the acces to tools of exploration and research is as important as having access to the genetic resources themselves.

19. Finally, the last objective -16(c)- is based on a simple fact: if there is no access, there are no benefits. We should seek to maximize the value of the genetic resources through its wider use in research and development. In order to do this, users require clear and simple procedures to access genetic resources and providers require effective means to monitor and enforce their rights, even when genetic resources are used beyond their national jurisdiction, since this would enable them to have less elaborate conditions for access.

20. Many of the options presented in the document circulated by the Secretary make reference to prevent the illegal appropriation of genetic resources and traditional knowledge as an objective of the regimen. This is an issue of great relevance given that the viability and acceptability of any Regime will depend on its capacity to avoid misappropriation. We consider this objective to be implicit in the third objective -16(c)- as part of the provider's necessary legal certainty about the resources and, as appropriate, over the knowledge to which the provider is given access to.

Elements of the International Regime to be considered for inclusion in the international regime, clustered by subject matter

21. Following the structure proposed in the document circulated by the Secretariat, and without prejudging the relative importance of the elements, we provide a list of elements that should be part, *inter alia*, of the international regimen

Access

a. The creation of a certificate of legal precedence that can be verified at different check points and located at late stages of the research and development processes as well as at the moment of commercialization of biotechnological products with the view of providing certainty to users and providers.and which would identify and acknowledge the contribution of traditional knowledge which is eventually used. (see below).

b. To explore practical options that, without hindering national sovereignity, could facilitate the legal access to genetic resources with the aim to promote its wider use and provide certainty to relevant stakeholders.

Ensure benefit sharing

c. Consider and develop, as appropriate, complementary approaches for benefit sharing in cases where the contractual approach is limited in order to comply with benefit sharing obligations. This could include an international financial mechanism with contributions by Parties linked to monetary benefits derived from the use of genetic resources.

d. In particular the possible development of "baseline provisions" to apply in cases where there are no legal terms mutually agreed for benefit sharing or when it is not possible to demonstrate the compliance with the CBD provisions (via the Certificate) which ensure that the user distributes minimum benefits such as a rate of royalties, single payments, etc. It is possible to identify several cases for which the following provisions would apply, such as:

i. When benefits originated in areas beyond the national jurisdiction
ii. When the origin is unknown
iii. When the number of genetic resources makes it impossible to negotiate terms in an individual manner
iv. Other

Measures to promote benefit sharing

e. A package of measures in user countries to promote compliance with provisions of CBD regarding benefit sharing and support compliance with national access laws. This should include incentives at national level so the users of genetic resources. Despite its potential, this component is often overlooked in the analysis of the problem[11]. These measures could include a wide range of measures at national level, such as: fiscal benefits, criteria for allocation of public funds for research, criteria for financing public research institutions, direct investment within the framework of collaboration agreements, etc.

f. Related to the previous element, a package of incentives, including economic ones, in order to promote the transfer of technology and research in countries providing genetic resources, as well as to promote the sharing the results of research.

Mechanisms to promote and to ensure compliance with prior informed consent and mutually agreed terms

g. A package of measures in countries with users under their jurisdiction to promote compliance with access provisions.

Derivatives

h. To clarify and take measures regarding the notion of derivatives, as well as reaching an international understanding on the notion of *utilization*. These with a view to clarify and define the reach of benefit sharing obligations and access conditions.

Consistent regulation for the diverse types of genetic resources

i. To clarify to the legal situation of *ex situ* collections, and to take measures to incorporate them to the regime with a view that utilization of genetic resources form such sources has some basic obligation recognize the value of genetic resources as a global environmental service and share the benefits.

j. An international agreement on the legal situation of genetic resources that are outside the national jurisdiction, such as deep sea beds and Antarctica and seek to incorporate some kind of benefit sharing obligation on *uses* derived from such resources in recognition of the value of this global environmental service.

Regulatory coordination with other forums and international existing, instruments and processes

k. To develop measures, in collaboration with the relevant forums, in order to create check points at key stages of the R&D and commercialization of genetic resources. Specifically, with respect to the intellectual property right procedures, where the Certificate of Legal Provenance should be included as a requirement in applications for intellectual property rights that make use of had used genetic resources as a key element in its development.

Notas

[i] Some countries have argued that this lack of results is due to the little advance in the development of its legislation of access and which what we needed it is simply to accelerate the national legislative process. Although this at first sight seemed to be certain, taking into account that to the date the Secretary of the CDB counts to date with 26 national legislations (Ogolla, 2005), when analyzing the experiences in the application of the law in those countries that count on specific legislation have found few cases of effective application of these dispositions (Goatherd, J. 2004) associated to inherent limitations to the legislative model. The evidence found in a study of countries of the Pacific Basin, where 9 countries that counted on some type of access legislation, but they had been only approved 29 requests of access between 1992 and 2004 (Carrizosa, S. 2004) points at serious problems of implementation.

[ii] An excellent example of this type of measures is in program ICBG in the United States, since of unilateral way, the program forces its projects independently to fulfill the principles of the CBD of the national legislation as much in the United States as in the origin country, encouraging to them to go beyond the obligatory minimum. The care taken by applicants to those grants is evidences of the power of instruments of this nature.

NORWAY

Norway has the pleasure to submit the following comments and proposals on Annex 1 – Potential elements of an International Regime on Access and Benefit-sharing:

In general, Norway is of the opinion that the list of options and elements should be narrowed down. The negotiations of an international regime should focus on issues to be addressed at the international level.

We support the following options and elements listed in Annex 1:

Scope:

Norway supports option 6. With regard to elements to be covered Norway also supports the contents of option 5.

Potential objectives:

Norway supports option 5.

Elements:

Norway is of the opinion that the international regime should:

- promote facilitated access to genetic resources for environmentally sound uses

- promote and ensure benefit-sharing for example by developing standard provisions on benefit-sharing to be included in the context of mutually agreed terms.

- recognise and protect the rights of indigenous peoples and local communities over their traditional knowledge associated with genetic resources in relation to prior informed consent and mutually agreed terms

- the regime needs to address the issue of derivatives

- include measures to ensure compliance with national legislation on ABS and PIC and MAT (*inter alia* a legally binding commitment by the user to comply)

- include a monitoring mechanism

- include a system under the CBD for an internationally recognised certificate of origin/source/legal provenance of genetic resources. This is subject to further exploration of the modalities of such a certificate.

- the discussions on disclosure of origin/source/legal provenance/PIC needs to be further pursued at the multilateral level within the TRIPs Council and WIPO PCT.

- Capacity building, technology transfer and financial resources are necessary elements of an international regime

In the context of the list of relevants instruments and processes, Norway is of the opinion that there is a need to identify synergies amongst the various instruments/fora. (e.g. fora dealing with IPR issues (WIPO, TRIPs, Paris Convention etc.) as well as organisations dealing with genetic resouces (CBD, FAO), in order to create an international regime based on one or more instruments. Therefore, an element stating the mutually supportiveness and complementarity of an international regime and existing international legal instruments and processes (ITPGRFA, WIPO, TRIPs Council etc.). should be added.

Norway believes that most of the options are already included in section 4 of Annex 1. With regard to additional elements Norway agrees that the focus should primarily be on the elements listed in option 1 under section 5 A.

In addition, Norway refers to the matrix contained in Annex II for further views on gaps at the international level.

SWITZERLAND

To prepare our discussion in order to make progress, the ABS 4 session should focus on a limited number of priority issues and k-gaps which need to be fulfilled at international level. In this regard the issues of particular importance for the establishment of a coherent international regime on ABS are, from an international perspective, the possible concrete measures and approaches to implement the related articles of the CBD on ABS. In our view those include at first the international certificate of origin/ source / legal provenance. With regard to the disclosure of source, the ABS 4 session could analyze the WIPO's reply concerning the invitation by COP-7, and submit to the WIPO, if deemed necessary, further issues for clarification. With regard to the national level, the focus should be on the further implementation of national legislation on ABS and on the designation of the competent authorities, including the national focal points on ABS. Recognized and accepted Global standards that would define good practices based on the Bonn Guidelines should be also taken into due consideration.

II. SUBMISSIONS FROM RELEVANT ORGANIZATIONS AND STAKEHOLDERS

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS (FAO)

Introduction

1. This document responds to the invitation by the Third Meeting of the *Ad Hoc* Open-ended Working Group on Access and Benefit-sharing to comment on the items in *annex 1* to its recommendation 3/1, and thereby contribute to the preparatory work for its Fourth Meeting.

2. The Food and Agriculture Organization of the United Nations deals with all aspects of food and agriculture. The FAO Constitution makes clear that "the term, 'agriculture' and its derivatives include fisheries, marine products, forestry and primary forestry products".[3] Through its regular programme and, in particular, through the deliberations of its inter-governmental Commission on Genetic Resources for Food and Agriculture, its member states address all aspects of agricultural biodiversity (including questions of access and benefit-sharing) in a systematic manner. FAO has also collaborated closely with the CBD since its entry into force, and has been the major partner of the CBD in the development of its Programme of Work on Agricultural Biodiversity.

3. By its decision II/15, the Conference of the Parties to the CBD has recognized "*the special nature of agricultural biodiversity, its distinctive features and problems needing distinctive solutions*."

4. FAO, therefore, welcomes the opportunity to contribute to this exercise. In doing so, FAO wishes first to acknowledge the strong support that the Conference of the Parties to the CBD has over the years given to the on-going work of its Commission on Genetic Resources for Food and Agriculture, particularly in the areas of plant and animal genetic resources for food and agriculture. In particular, the Conference of the Parties regularly gave its strong support to the negotiation of the International Treaty on Plant Genetic Resources for Food and Agriculture, and

> "*Recognize[d] the important role that the International Treaty on Plant Genetic Resources for Food and Agriculture will have, in harmony with the Convention on Biological Diversity, for the conservation and sustainable utilization of this important component of agricultural biological diversity, for facilitated access to plant genetic resources for food and agriculture, and for the fair and equitable sharing of the benefits arising out of their utilization*".[4]

5. In the area of farm animal genetic resources, in its Decision VI/5, the Conference of the Parties:

> "*Welcome[d] the process initiated by the Food and Agriculture Organization of the United Nations for the preparation of the first Report on the State of World's Animal Genetic Resources*", and "*invite[d] Parties, other Governments, the financial mechanism and funding organisations to … implement follow-up actions identified through the process that will contribute to conservation sustainable use, access and benefit-sharing of animal genetic resources for food and agriculture*".[5]

6. Against this background, FAO:

- recognizes the importance the Conference of the Parties attaches to the development of an international regime on access and benefit-sharing, and is willing to cooperate with the *Ad Hoc* Open-

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3/ Article 1.
4/ DecisionVI/6.

5/ DecisionVI/5. The *Report on the State of World's Animal Genetic Resources*, will be presented to the First International Technical Conference on Animal Genetic Resources, to be convened in Switzerland in 2007.

ended Working Group on Access and Benefit-sharing in its elaboration;

- notes that both the International Treaty on Plant Genetic Resources for Food and Agriculture and the Commission on Genetic Resources for Food and Agriculture are identified as possible elements of the international regime; and
- notes that the Conference of the Parties has also recognized the relevance of its work on animal genetic resources for access and benefit-sharing.

7. This document accordingly provides information on a number of matters that will need to be taken into account in the development of an international regime on access and benefit-sharing:

- the special nature of agricultural biological diversity;
- the mandate and activities of the FAO Commission on Genetic Resources for Food and Agriculture; and
- the International Treaty on Plant Genetic Resources for Food and Agriculture.

8. Comments are provided in each case, which should be reflected, as appropriate, in the development of the items in *annex 1* to recommendation 3/1.

The special nature of agricultural biological diversity

9. By its decision V/5, the Conference of the Parties to the CBD reiterated decision II/15, and further identified a number of the distinctive features of agricultural biodiversity, including that:

- agricultural biodiversity is essential to satisfy basic human needs for food and livelihood security, and that, as a consequence, their conservation is inherently linked to sustainable use;
- there is great interdependence between countries for these resources; and
- for crops and domestic animals, diversity within species is at least as important as diversity between species.

10. These are major factors that need to be taken into account in the development of policy on access and benefit-sharing.

Food Security

11. The conservation and sustainable utilization of genetic resources for food and agriculture, and the fair and equitable sharing of the benefits, are the *sine qua non* of food security and poverty alleviation. Hunger and malnutrition affect nearly 850 million people, and 15 million die as a result every year. FAO's prime commitment is to feeding the world's poor and hungry, and achieving the Millennium Development Goals.

12. The conservation of genetic resources for food and agriculture without utilization will not fill the mouths of our ever-increasing world population. Effective access to agricultural genetic resources, and their efficient use by farmers throughout the world to increase the range and quality of food products, and to face foreseen and unforeseen ecological changes, is imperative. This is the key objective that must guide policy formation in relation to agricultural genetic resources.

Interdependence

13. Regions and countries are substantially inter-dependent in regard to agricultural biodiversity—that is, they all rely for a large part of their food on crops and animals, and on genetic resources, that originated elsewhere. FAO has studied this inter-dependence. In terms of food energy from plants in national diets, countries depend on average for about 70% on genetic resources that originated outside

their region.[6] Two implications may be drawn. First, given that most countries require more agricultural genetic resources from others than they provide to others, a commercial approach to the transfer of such resources would result in substantially higher expenditure than income. Secondly, in order to meet the ethical imperative of feeding this and future generations, and to wisely deploy the portfolio of agricultural genetic resources built up by farmers world-wide over 10,000 years of agriculture, it is necessary to reduce to an absolute minimum the transaction costs involved in accessing and using them.[7]

Intra-specific Diversity

14. Intra-specific diversity results from the incremental improvement of crops and animal breeds, through repetitive crossing and selecting from a very wide range of sources, in order to create improved plant varieties and animal breeds. Characteristically, in plant breeding, some tens of parent varieties (which already share most of their genetic make-up through earlier crossings) are involved. In this context, individual samples of genetic resources infrequently provide large-scale appropriable benefits, and it is impossible, in retrospect, to identify with certainty the parent varieties and the origins of genes, as well as their relative value, in the finished variety.

15. The above analysis bears out the accuracy of the Conference of the Parties' recognition that agricultural biodiversity is of a special nature, and that it has distinctive features and problems that need distinctive solutions.[8] FAO accordingly has the following general observations:

- Different international institutions, instruments and processes either regulate some part of the matters being discussed in the process of developing an international regime of access and benefit-sharing, or have mandates in this respect. Therefore, in the construction of an international regime, it may well prove necessary to establish memoranda of understanding with such institutions, instruments and processes, in order to ensure synergy and mutual respect for competences.
- As the apex institution of the food and agriculture sector, Governments negotiate agreements within FAO and its Commission on Genetic Resources for Food and Agriculture on all aspects of genetic resources for food and agriculture.
- There are, to date, only two legally binding international instruments governing access and benefit-sharing for genetic resources, namely the CBD and the International Treaty on Plant Genetic Resources for Food and Agriculture. These are in harmony one with the other.[9]
- In negotiating the International Treaty, Governments recognised that agreeing multilateral provisions for access and benefit-sharing was the appropriate way of addressing plant genetic resources for food and agriculture. Many Governments have also expressed the view that a multilateral approach to access and benefit sharing is the appropriate way of addressing the special needs of agricultural biological diversity generally.

6/ Ximena Flores Palacios, C*ontribution to the estimation of countries' interdependence in the area of plant genetic resources*. Background Study Paper no. 7. FAO Commission on Genetic Resources for Food and Agriculture, Rome, 1997. ftp://ext-ftp.fao.org/ag/cgrfa/BSP/bsp7E.pdf.

7/ *Transaction costs of germplasm exchange under bilateral agreements*, Bert Visser (CGN / Plant Research International), Derek Eaton (Agricultural Economics Research Institute), Niels Louwaars, (Plant Research International), and Jan Engels, (Plant Genetic Resources Institute) (paper prepared for Global Forum on Agricultural Research (GFAR) meeting in Dresden, 21-23 May 2000. Background Study Paper no. 14. FAO Commission on Genetic Resources for Food and Agriculture, Rome, 2001. ftp://ext-ftp.fao.org/ag/cgrfa/BSP/bsp14e.pdf.

8/ Further discussion of the special nature of agricultural genetic resources is given in Stannard, Clive, Niek van der Graaff, Alan Randell, Peter Lallas and Peter Kenmore. *Agricultural biological diversity for food security: shaping international initiatives to help agriculture and the environment*. Howard Law Journal, vol. 48, 397-430 (2004).

9/ In Decision VI/24, the Conference of the Parties has also stated that the Bonn Guidelines "are without prejudice to the access and benefit-sharing provisions of the FAO International Treaty for Plant Genetic Resources for Food and Agriculture".

- Any international regime of access and benefit-sharing should clearly recognize, in relation to agricultural genetic resources, the ethical and practical dimensions arising from their crucial importance for world food security, and for the achievement of the Millennium Development Goals.

The FAO Commission on Genetic Resources for Food and Agriculture

16. The Commission on Genetic Resources for Food and Agriculture was the first permanent inter-governmental forum dealing with agricultural genetic resources, including in relation to access and benefit-sharing. At present, 167 Governments and the European Community are members. Its statutes provide that it shall:

> "*have a coordinating role and shall deal with policy, sectorial and cross-sectorial matters related to the conservation and sustainable use of genetic resources of relevance to food and agriculture" …*
>
> *"provide an intergovernmental forum for negotiations and […] oversee the development, upon the request of the FAO Governing Bodies, of other international agreements, undertakings, codes of conduct or other instruments relating to genetic resources of relevance to food and agriculture, and […] monitor the operation of such instruments …*
>
> *"facilitate and oversee cooperation between FAO and other international governmental and non-governmental bodies dealing with the conservation and sustainable use of genetic resources, in particular with the Conference of Parties to the Convention on Biological Diversity and the UN Commission on Sustainable Development, and […] seek to develop appropriate mechanisms for cooperation and coordination in consultation with such bodies".*

17. The Commission was established in 1983, as the Commission on Plant Genetic Resources, and, in 1995, its mandate was extended to cover all components of biodiversity of relevance to food and agriculture. This mandate is being implemented through a step-by-step approach, and work has so far focused largely on plant and animal genetic resources for food and agriculture. Major achievements of the Commission (those since the entry into force of the CBD have been welcomed by the Conference of the Parties) include:

- the adoption, in 1983, of International Undertaking on Plant Genetic Resources, a voluntary instrument that was the first international agreement dealing with the conservation and sustainable use of any component of genetic resources. Farmers' Rights were first recognized, in 1989, in the context of the International Undertaking;
- the establishment, in 1994, of the International Network of *Ex Situ* Collections of Plant Genetic Resources for Food and Agriculture under the Auspices of FAO. This currently provides the legal framework under which the most important collections for food security and sustainable development are held, in trust for the international community, and under the Commission's policy guidance;
- the adoption, in 1996, of the first *Report on the State of the World's Plant Genetic Resources for Food and Agriculture* and of the *Global Plan of Action for the Conservation and Sustainable Utilization of Plant Genetic Resources for Food and Agriculture*";
- the adoption, in 2001, of the International Treaty on Plant Genetic Resources for Food and Agriculture; and
- the launching of the process, to culminate in 2007, for the negotiation of the first *Report on the State of the World's Animal Genetic Resources.*

18. With the completion of the International Treaty, the Commission is to consider a draft Multi-year Programme of Work, at its Eleventh Regular Session, in late 2006 or early 2007. This will provide an opportunity to strengthen and plan more systematically FAO's cooperation with the CBD. In the context of the Multi-year Programme of Work, the last meeting of the Commission:

> *"recommended that FAO and the Commission contribute to further work on access and benefit-sharing, in order to ensure that it move in a direction supportive of the special needs of the agricultural sector, in regard to all components of biological diversity of interest to food and agriculture. It recognized the essential role of the International Treaty in this context."*

19. The development of an international regime on access and benefit-sharing should recognize the role of the Commission on Genetic Resources for Food and Agriculture in initiating, negotiating and monitoring the implementation of relevant instruments in relation to all components of biological diversity of relevance to food and agriculture.

The International Treaty on Plant Genetic Resources for Food and Agriculture

20. The International Treaty was negotiated through the Commission on Genetic Resources for Food and Agriculture, and adopted by the FAO Conference on 3 November 2001. It entered into force on 29 June 2003. At the time of preparing this note (September 2005), 72 states and the European Community had become Parties to the Treaty.[10] The Commission on Genetic Resources for Food and Agriculture acts as Interim Committee for the Treaty, until the Governing Body convenes, in Madrid, Spain, in June 2006.

21. The objectives of the Treaty are:

> *"the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security"*.

22. The Treaty's scope is "*plant genetic resources for food and agriculture*". It provides an agreed international framework for addressing these resources, including the fair and equitable sharing of the benefits. It includes articles on conservation and sustainable utilization; international commitments and international cooperation; technical assistance, in particular for developing countries and countries with economies in transition; and the realization of Farmers' Right. It establishes a Multilateral System of Access and Benefit-sharing, for an agreed list of crops crucial for food security and interdependence ("*annex 1* crops"). In establishing this system, Contracting Parties act in the exercise of their sovereign rights. Provision for benefit-sharing in the Multilateral System includes the exchange of information; access to and transfer of technology; capacity-building; and the sharing of monetary and other benefits of commercialization.[11] The benefits arising from plant genetic resources for food and agriculture in the Multilateral System "*should flow primarily, directly and indirectly, to farmers in all countries, especially in developing countries, who conserve and sustainably utilize plant genetic resources for food and agriculture*". The Treaty provides for a Funding Strategy to "*enhance the availability, transparency, efficiency and effectiveness of the provision of financial resources to implement activities under [the] Treaty*", with priority being given to "*The implementation of agreed plans and programmes for farmers in developing countries, especially in least developed countries, who conserve and sustainably utilize plant genetic resources for food and agriculture*". The Treaty also provides for the International Agricultural Research Centres of the Consultative Group on International Agricultural Research (CGIAR) and other international institutions holding *ex situ* collections of plant genetic resources for food and

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10/ http://www.fao.org/Legal/TREATIES/033s-e.htm provides an up-to-date list of Contracting Parties.

11/ A Standard Material Transfer Agreement will define the terms for facilitated access to the plant genetic resources for food and agriculture under the Multilateral System, including the arrangements for the sharing of monetary benefits arising from their use. A draft Standard Material Transfer Agreement is currently being prepared by a Contact Group established by the Interim Committee for the International Treaty. This Contact Group met for the first time on 18 – 22 July 2005, and significant progress was made. (document CGRFA/IC/CG-1/05/Rep, Report of the Contact Group for the Drafting of the Standard Material Transfer Agreement (http://www.fao.org/ag/cgrfa/cgmta1.htm). It proposed that a second meeting be held in order to finalize the draft for submission to the First Session of the Governing Body. The issue of non-monetary benefit-sharing will be considered by an Open-ended Working Group on the Rules of Procedure and Financial Rules of the Governing Body, Compliance and the Funding Strategy on 14 – 17 December 2005, in the context of the Funding Strategy.

agriculture to bring these into the Multilateral System.[12]

23. The Treaty and its Multilateral System—in the context of those plant genetic resources for food and agriculture specified—provides a framework for many of the elements identified as potential elements for the international regime, including measures:

- to promote and encourage collaborative research, as well as research for commercial purposes and commercialization;
- to ensure the fair and equitable sharing of benefits;
- for benefit-sharing, including, *inter alia*, monetary and non-monetary benefits, and effective technology transfer;
- to promote facilitated access to genetic resources for environmentally sound uses;
- to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources;
- to ensure the sharing of benefits arising from the commercial and other utilization of genetic resources and their derivatives and products, in the context of mutually agreed terms;
- to promote access and benefit-sharing arrangements that contribute to the achievement of the Millennium Development Goals, in particular on poverty eradication and environmental sustainability;
- to ensure compliance with national legislations on access and benefit-sharing, prior informed consent and mutually agreed terms, consistent with the Convention on Biological Diversity;
- for monitoring, compliance and enforcement; and
- for dispute settlement and arbitration, if and when necessary.

24. With the convening of the Governing Body, in 2006, Contracting Parties will be taking a large variety of decisions, and establishing various processes, for the effective implementation of the Treaty. FAO accordingly has the following observations:

- It is important, in the development of an international regime on access and benefit-sharing, that the International Treaty be appropriately handled, either by inclusion or exclusion, bearing in mind that decisions regarding the implementation of the International Treaty, and matters that it covers, are a prerogative exclusively of its Governing Body.
- The role in the Treaty in relation to *all* plant genetic resources for food and agriculture should be reflected.
- It should be noted that under the Treaty benefit-sharing does not relate only to *annex 1* crops, nor does it operate only in the context of the Multilateral System. Article 15 provides for the inclusion of a wide variety of resources of both *annex 1* and non-*annex 1* crops, which will be subject to the benefit-sharing provisions of the Treaty.[13]
- The interpretation of the scope of the Treaty, and the coverage of *annex 1* to the Treaty, at any one time, is the prerogative of the Contracting Parties to the Treaty.

12/ These provisions provide solutions, *inter alia*, as requested by Resolution 3 of the Nairobi Final Act for the Adoption of the Agreed Text of the Convention on Biological Diversity, for access to *ex situ* collections not acquired prior to the CBD, and for the realization of Farmers' Rights.

13/ For the CGIAR alone, this means some 600,000 accessions of the world's most important crops.

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

I have the pleasure in sending you hereafter the contribution of the International Union for the Protection of New Varieties of Plants (UPOV) to the work of the WG-ABS. UPOV's contribution is based on the 1991 Act of the UPOV Convention and the reply of UPOV to the Notification of June 26, 2003, "Access to Genetic Resources and Benefit-Sharing", adopted by the Council of UPOV on October 23, 2003, and sent to you under cover of a letter dated October 27, 2003. The reply is also placed on the UPOV website as follows:

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

UPOV's contribution is related to the following sections of the Notification:

International Regime on Access and Benefit-Sharing (pages 1 and 2 of the Notification):

Annex I to this letter contains UPOV's comments on Annex A of the Notification.

Information has not been provided on the basis of the matrix contained in Annex II of the recommendation (reproduced as Annex B to your notification of April 12, 2005) because that matrix concerns "analysis of gaps in existing national, regional and international legal and other instruments relating to access and benefit-sharing". As explained in the reply of UPOV to the Notification of June 26, 2003, the UPOV Convention is not an instrument relating to access and benefit-sharing. However, as explained more fully in the comments on Annex A (Annex I of this document), there are certain measures under consideration in the international regime, in particular concerning disclosure of origin in relation to applications for intellectual property rights, which could be contrary to the UPOV Convention. Therefore, in the same manner as CBD wishes to ensure that "intellectual property rights do not undermine the international regime",we would request that consideration is made that any measures pursued in the international regime do not undermine plant variety protection according to the UPOV Convention. For its part UPOV supports the view that the CBD and relevant international instruments dealing with intellectual property rights, including the UPOV Convention, should be mutually supportive.

Articles 5, 7 and 15 of the 1991 Act of the UPOV Convention are the most relevant provisions on which UPOV's comments are based. Those Articles are reproduced in Annex II to this letter.

ANNEX I

General comments on Annex A

The following is an extract from paragraph 17 of the reply of UPOV to the Notification of June 26, 2003, "Access to Genetic Resources and Benefit-Sharing".

"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."

Comments on specific parts of Annex A

Reference to the Notification:

(Page 11 of the Notification)

" Disclosure of origin/source/legal provenance of genetic resources and associated traditional knowledge in applications for intellectual property rights"

(Page 13 of the Notification)

"VI Disclosure of legal provenance of genetic resources and associated traditional knowledge in applications for intellectual property rights"

UPOV's comments:

With respect to the above, the Council of UPOV has commented as follows (paragraphs 7 to 10 of the Reply of UPOV to the Notification of June 26, 2003, "Access to Genetic Resources and Benefit-Sharing"):

"Disclosure of Origin

7. The requirement for "distinctness" in the UPOV Convention 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 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."

Reference to the Notification:

(page 15 of the Notification)

- "Measures to ensure that intellectual property rights do not undermine the international regime."
- "Measures to ensure mutual supportiveness between the Convention on Biological Diversity and intellectual property rights-related treaties."
- "Relationship with other international legal instruments."

UPOV's comments:

With respect to the above, the Council of UPOV has commented as follows (paragraphs 3, 11 and 16 of the Reply of UPOV to the Notification of June 26, 2003, "Access to Genetic Resources and Benefit-Sharing"):

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.

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.

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.

ANNEX II

Article 5

Conditions of Protection

(1) [*Criteria to be satisfied*] The breeder's right shall be granted where the variety is

(i) new,

(ii) distinct,

(iii) uniform and

(iv) stable.

(2) [*Other conditions*] The grant of the breeder's right shall not be subject to any further or different conditions, provided that the variety is designated by a denomination in accordance with the provisions of Article 20, that the applicant complies with the formalities provided for by the law of the Contracting Party with whose authority the application has been filed and that he pays the required fees.

Article 7

Distinctness

The variety shall be deemed to be distinct if it is clearly distinguishable from any other variety whose existence is a matter of common knowledge at the time of the filing of the application. In particular, the filing of an application for the granting of a breeder's right or for the entering of another variety in an official register of varieties, in any country, shall be deemed to render that other variety a matter of common knowledge from the date of the application, provided that the application leads to the granting of a breeder's right or to the entering of the said other variety in the official register of varieties, as the case may be.

Article 15

Exceptions to the Breeder's Right

(1) [*Compulsory exceptions*] The breeder's right shall not extend to

(i) acts done privately and for non-commercial purposes,

(ii) acts done for experimental purposes and

(iii) acts done for the purpose of breeding other varieties, and, except where the provisions of Article 14(5) apply, acts referred to in Article 14(1) to (4) in respect of such other varieties.

(2) [*Optional exception*] Notwithstanding Article 14, each Contracting Party may, within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, restrict the breeder's right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety or a variety covered by Article 14(5)*(a)*(i) or (ii).

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)

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 members1. 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

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.

Disclosure of Origin

7. The requirement for "distinctness" in the UPOV Convention2 means that protection shall only be granted after an examination to determine if the variety is clearly distinguishable from all other varieties, whose existence is a matter of common 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.

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* Openended 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.

AUSTRALIAN APEC RESEARCH CENTRE

Interim Comments on the subject matters of Decisions 3/1 and 3/3 of the Third Meeting of the Ad Hoc Open-Ended Working Group on Access and Benefit Sharing

Systems to provide access to genetic resources must encourage investment as well as protect national rights

Access to genetic resource, acquisition of benefits from that and distribution of those benefits requires a system that encourages bioprospecting and investment as well as generating income that can enable distribution of benefits.

Investment in bioprospecting requires secure property rights for the prospector and clear agreements with national authorities on how those rights are provided and how benefits from provisions of those rights are to be paid.

To encourage investment, the property right to a discovery, should be like any other and protected in law like any other.

No case exists for new legally binding regulation of access to and benefit sharing from genetic resources

Virtually no significant product has been developed from discoveries from bioprospecting. There is no significant incidence of "biopiracy".

The case for a new legally binding instrument is a case to regulate problem that does not exist.

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

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

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

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

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

A legal requirement to verify legality would also raise problems in international trade law when any product was traded. The Kimberley Accord which requires Governments to require that diamonds are certified as legally acquired before than be sold, required a formal waiver from the WTO that international trade rules would not

apply to trade in diamonds. The cost of such a waiver is loss of valuable rights to protect trade from political interference.

Equitable distribution of benefits from genetic resources is a matter for national governments

Achieving equitable distribution of rights within a prospected country is a matter for the national authorities of that country. Handing a sensitive responsibility like this to an international authority would significant restrict the capacity of a government to determine what is equitable among its own citizens.

Preservation and conservation of genetic resources is a matter for national governments

Preservation and conservation of any environmental value can only be efficiently achieved through effective national regulation. The biodiversity of every country is different. Applying standardized international approaches to the management of biodiversity, as is proposed in the idea of a legally binding international instruments, carries a significant risk. The capacity to apply policies tailored to the specific national characteristics of biodiversity will be constrained. The result could be counterproductive to environmental goals.

A legally binding international regime to regulate access to and benefit sharing from genetic resources is strongly opposed.

This constitutes onerous regulation which will be likely to stop bioprospecting altogether. It will deter general investment in biotechnology in the countries which adopt such a system.

Using a legally binding international instrument to set the terms of access to genetic resources and to stipulate how equitable sharing of resources is to be achieved will transfer responsibility for this from national governments to an international secretariat. This will reduce the capacity of governments to develop approaches which best suit the distinct characteristics of their biodiversity.

If a legally binding regime included rights to establish an international system of regulated certification of the legality of genetic resource materials, this would create a powerful disincentive for companies to explore naturally occurring genetic resources.

Proposals to include in such a regime a right for Governments to have a say over how any product, even patented, which was developed from a genetic resource was to be used, will undermine intellectual property law and undermine use of property rights to manage access to genetic resources.

Any party to such a regime will deny itself the opportunity to secure investment in development of biotechnology industries. It will deny itself the opportunity to secure royalties which can be used for more effective management of the nation's biodiversity.

ABS is most effectively achieved by a markets-based approach using property rights properly protected in law.

Where Governments have heavily regulated access and benefit sharing, like the Philippines and Peru, there is little interest in any development of genetic resources in those countries. These Governments also receive little funding to improve management of their biodiversity.

Where Governments have created a system of clear rights to prospect to secure access to genetic resources as well as clear payments of royalties for those rights, like Costa Rica, there has been investment and payment of royalties which Costa Rica put to good effect for environmental conservation.

Only a markets based system can meet the twin interests of careful use of genetic resources to secure benefits for the nation and support for an active program to manage the nation's biodiversity.

A legally binding international regime creates unnecessary and ineffective bureaucracy, deters investment and development of biodiversity and creates no capacity for improved management of biodiversity.

INTERNATIONAL FEDERATION OF ORGANIC AGRICULTURE MOVEMENT (IFOAM), RESEARCH FOUNDATION FOR SCIENCE, TECHNOLOGY AND ECOLOGY, THE GREENS / EUROPEAN FREE ALLIANCE IN THE EUROPEAN PARLIAMENT

The three organizations presenting this Submission were **joint Opponents in the first legal challenge to a Biopiracy patent.** We understand that the invitation to make this Submission was extended to us because our particular experience in prosecuting our legal action against Biopiracy, which spanned ten years, was deemed to have potential relevance for the Working Group's deliberations.

IFOAM, the International Federation of Organic Agriculture Movements, is the only worldwide umbrella body for the organic sector. Its membership consists of 800 organizations from more than 100 countries, representing organic farmers, processors, consumers, certifying bodies, research, educational, and consulting groups, etc.; it holds official consultative status with both the FAO and UNEP. The Research Foundation for Science, Technology and Ecology was founded by the renowned Indian environmental activist, Dr. Vandana Shiva. The Greens/EFA in the European Parliament is a political group within the structure of the European Parliament, consisting of all the Members of the European Parliament (MEPs) elected from Green and like-minded Parties of Member States of the European Union.

On June 14th,1995 we filed a Legal Opposition to a patent which had been granted by the European Patent Office (EPO) to the United States of America and a U.S.-based multinational corporation named W.R. Grace for a fungicide consisting of oil extracted from crushed seeds of the Neem tree. This tree is indigenous to the Indian subcontinent, and its fungicidal properties had been known and used there for thousands of years. As such, it was a clear example of a growing number of patents based on false claims to products and processes which have simply been stolen from countries of the South. We decided to mount a legal challenge to this patent within system which had granted it, and won our case on May 10th, 2000, when the Opposition Division of the EPO struck down the patent. However, the patentees appealed that decision; five years later their appeal was set aside by the EPO's Technical Board of Appeals and the patent definitively revoked.

We should point out that it was never our intention to acquire monopoly property rights for our Indian partner on the Neem oil claimed by the USA and Grace or to bargain with them for a percentage of the profits they were making from this patent. Our action was intended solely to destroy the patentee's claim to having invented it and the exclusive rights which ensued from that claim. We were neither competing for ownership of the patent, nor proposing to share in the money it generated. A Briefing which provides more detail about our experience with the Neem patent case is attached for your information, as well as a concise legal history of the case, and a selection of press articles. Here we shall limit ourselves to drawing out the lessons and implications of the case for an International Regime on Access and Benefit-sharing.

It is interesting to note that in our case the patentees themselves had acknowledged their debt to Indian traditional knowledge in their original application; however, even this explicit recognition failed to trigger an adequate examination of the impact of such traditional knowledge on their claims of novelty and inventive step. One probable reason is that the form in which community innovation is recorded and passed on throughout the centuries does not conform to the practice of the EPO, which searches for "prior art" essentially in published, scientific literature. Traditional knowledge of the fungicidal properties of Neem oil in its country of origin was, in effect, "invisible" or didn't count for the examiners.

We used both "unconventional" and conventional sources to justify our claims that the patent should never have been granted. The unconventional sources consisted of affidavits to record oral testimony from people in India who had experience in using Neem oil fungicides for plant protection. These affidavits were then notarized in India and submitted to the EPO. The Opposition Division based its decision to revoke the Neem patent on one of these affidavits, that given by Dr. Phadke, along with his testimony during the Oral Proceeding. We consider one of the primary and most innovative achievements of the case was to **validate the use of affidavits to record oral evidence**, which extended the standard

operating procedures of the EPO in ways which could be more applicable to traditional knowledge.

Another major achievement of the Neem case was the Opposition Division's ruling that **patents should not be granted for traditional knowledge** and that such knowledge may be used to establish "prior art" and thus destroy novelty and inventive step:

"Moreover, the opposition division agrees with the Opponents that no patents should be granted for anything which was known previously, for example as part of common traditional knowledge. However, under the EPC this is not a matter of Article 53(a) EPC, but is a question of novelty or prior public use."

The revocation of the Neem patent established jurisprudence and was greeted around the world as a landmark legal victory; however, the Opponents are only too aware of the limitations of what we won. Indeed, we are obliged to conclude that our experience cannot and should not serve as a model for seeking a remedy to Biopiracy. Why?

1. First and foremost, it was quite simply too expensive. The Opponents spent in the range of 20,000 Euro and ten years' work to obtain this victory. The major portion of the funding was supplied by a Dutch development foundation (HIVOS) and the Greens in the European Parliament; the rest was in the form of smaller NGO contributions and in-kind support, as well as significant volunteer labor. Given that there are thousands of biopiracy patents, it is completely unrealistic and unfair that the victims of the theft, primarily from poor countries, should be forced to mount burdensome legal challenges like ours to each such patent individually.

2. Furthermore, there is no way to recover our expenses for the case, even though we won. The offending party is not required to pay for the costs incurred by the "plaintiff." It is not as in civil or criminal law, where the loser must often reimburse the winner for court costs and damages; in this situation it is not the patentee, strictly speaking, which has committed the fault, but rather the Patent Office itself for having granted the patent on something which failed to meet the criteria of patentability. And there is certainly no provision within the EPO to accept financial responsibility for what it costs an injured party to correct a bad decision. Furthermore, if even the winners, such as in our case, are not able to recover the costs incurred in revoking an individual Biopiracy patent, how much more so for a poor country or organization which loses its case? They will have even less chance of seeing their expenses reimbursed. Thus, most will be discouraged from attempting such an initiative.

3. Far from having to reimburse their victims, the proprietors of the patent are even allowed to continue making money on the patent during the entire period of the Opposition and Appeal procedures. When the patentees filed their Appeal, it had the effect of suspending the revocation. Since the process took ten years (which is about standard), they were able to retain their monopoly property rights on the Neem fungicide for half the time they would have had anyway.

4. Although the first instance of the EPO, the Opposition Division, based their decision to revoke the patent on an affidavit and oral testimony, the case was finally decided by the Technical Board of Appeals on the basis of a scientific paper, peer-reviewed and published in a well-known scientific journal. And whereas the Opposition Division considered the affidavit/oral testimony the closest prior art, the Appeals Board preferred to look only at the scientific paper, because the patentee had not objected to it (which they did the oral testimony). Thus, the Appeals Board was able to conveniently skirt the issue of "traditional knowledge."

5. Finally, the revocation of this Neem patent does not call into question patents already granted on Neem products, whether in the EPO or anywhere else, and will have no effect on pending Neem patents in other regimes (such as the United States Patent and Trademark Office). Even the extent to which this jurisprudence will impact Neem and other Biopiracy patents currently in the examination phase in the EPO is unclear.

Although we were able to use the existing mechanisms of the EPO to overturn this Biopiracy patent, the problems enumerated above are an indication of the inadequacy of that system alone to provide a satisfactory remedy to Biopiracy. Already at the time of the first Oral Proceeding, we stated that a lasting resolution to this particular kind of injustice would require transposing our victory into an overarching international legal framework which would make this type of theft illegal throughout the world. The proposed "International Regime on Access and Benefit-sharing" could provide such a legal framework, and we would like to offer the following comments toward its elaboration in the light of our specific experience with the Neem patent Opposition.

We have reviewed the various options and wordings put forward in Annex A for consideration at the upcoming Working Group meeting, and will focus here on some of the basic questions which emerge from a comparison of the different formulations.

On the question of whether the International Regime should be legally-binding, we think that, in principle, it must be--although, in practice, that depends on the character of the instrument as finally agreed. We are convinced that we would never have obtained the justice we sought if the European Patent Convention had not been legally-binding. The patentees in our case fought to maintain their control over the Neem product they had claimed, and it is difficult to imagine that we would have emerged victorious in a system which was not legally-binding. It would be idealistic to expect those who stand to gain the most financially from Biopiracy patents to renounce them out of respect for a voluntary code of conduct. The International Regime will have to have teeth to acquire any relevance among already existing systems which ARE legally binding.

A striking example of this is the "Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization." This non-legally-binding set of guidelines was adopted by the European Commission with much fanfare, and yet this has in no way prevented the EU itself and some of its individual Member States from negotiating bilateral Free Trade Agreements which impose even more demanding patenting requirements on the poor country partners than TRIPs (which, in its present form, runs counter to the ABS approach).

On the question of scope: We would strongly urge the Working Group to retain the broadest possible formulations of the targeted resources. Although we understand that the term "genetic resources" is used for historical reasons, we would nonetheless like to take this opportunity to propose the broader term biological resources to replace it. "Biological resources" would include genetic resources, whereas "genetic resources" is a more restrictive term. For example, it would be more accurate to describe the subject of the patent we challenged as having been derived from a "biological resource," since the genetic (DNA, reproductive) aspects of the material were not relevant to the claimed innovation.

Furthermore, the term "genetic resource" would indicate that the scope is primarily intended to cover "inventions" based on genetic modification, manipulation, and engineering of the genetic material. We do not wish for the International Regime on ABS to become the new cover for patents on life, which we oppose.

The terms "derivatives and products," as in Option 3, should be retained.

The use of the term "protection," in association with "traditional knowledge, innovations and practices associated with genetic resources"—which has apparently garnered wide agreement, appearing in all six options as point (c)—is nonetheless questionable for us. We think it could lead to confusion, as the same term is used in connection with intellectual property rights. A different term such as safeguarding or conservation may be helpful in order to distinguish legal instruments developed specifically for traditional knowledge from those of conventional patent laws, which are based on exclusivity and ownership. However, as community innovation may be considered to be a form of collective intellectual property, it may be that the patent instrument could be successfully adapted to cover it. In this case, the word "protection" would be appropriate.

With regard to the Potential Objectives of the Regime: We disagree that a primary objective of this instrument should be to create conditions to facilitate access to genetic resources and traditional knowledge (although we understand the historic reasons for inclusion of the point). In our view, such facilitated access may naturally arise as a *result* of the correct functioning of the Regime, and as the confidence of the source communities is rebuilt; but this cannot be its *raison d'etre.* The objective of the International Regime should remain clearly focused on preventing the theft of biodiversity and traditional knowledge. We would therefore propose the formulation "**regulate** access to …resources" rather than "facilitate."

In any event, we would disagree with an objective of insuring access to genetic resources in a non-discriminatory fashion; on the contrary, conflicts regarding access should be resolved on the basis of a principle of positive discrimination which recognizes a priority in the utilization and exploitation of biological resources and traditional knowledge to be accorded to parties from the countries of origin.

The relationship of the International Regime to national legislation is mentioned in all the options under Potential Objectives, and is defined variously as "compliance," "reinforcing," or "subject to." Our view is that the International Regime must supercede existing national legislation in order to be effective at harmonizing these potentially conflicting systems—assuming, of course, that the Regime as finally agreed is an effective instrument for preventing Biopiracy . Furthermore, national authorities must be required to enact the necessary legal instruments to assure enforcement of their international obligations under the Regime. Should conflicts arise between national law and the Regime, a dispute settlement mechanism, as mentioned below, should be available to the parties.

Under Measures for implementing the International Regime, there should be exploration of a mechanism to suspend the effect of patents based on traditional knowledge or biological resources which are disputed according to the provisions of the Regime, during the period required to resolve the matter.

Our experience in the Neem case clearly indicates that relying on scientific literature is insufficient for establishing the source of biological resources and traditional knowledge. The International Regime will need to recognize other ways of documenting informal innovation and community resources. We recommend the use of notarized affidavits and oral testimony, which we employed successfully in the Neem case, log books, religious texts, and literature, as well as community biodiversity registers.

The Opponents in the Neem case would have appreciated reimbursement of the costs we incurred in the successful prosecution of our case, and we urge the members of the Working Group to explore a mechanism for financially assisting source communities which seek to exercise their rights under the Regime—irrespective of the ultimate outcome of their case—thus helping to guarantee equality of access to justice under this law.

We are concerned about *how* the benefits which arise from the application of the Regime will be distributed to the communities which should receive them. The principle of national sovereignty as the basis for regulating Access and Benefit-sharing introduces opportunities for new patterns of Biopiracy. Thus, we consider it a priority to elaborate measures aimed at forestalling the misappropriation of the Regime itself.

Under 4. Elements…Ensuring benefit-sharing, we note that assigning a monetary value to biodiversity and traditional knowledge is problematic, and agree with wording to provide options for non-monetary forms of compensation, which may be more appropriate or preferred by the communities concerned in some cases.

In order for such a regime to be effective at remedying the injustice of Biopiracy, the various existing international patent regimes such as TRIPS and regional and bilateral treaties, must be adapted to bring them into line with the aims and operation of the International Regime. As one step in this direction, we hope that the repeated request of the CBD Secretariat for observer status at the TRIPS Council will be quickly granted by the WTO.

Although the International Regime has been developed within the framework of the Convention on Biological Diversity, it is worth considering which intergovernmental agency is best equipped for effectively administering such an instrument, once in force. In our view, the administering body will need to be fitted out with a legally-binding dispute settlement mechanism similar to that exercised by the WTO, if it is to have the stature and means to enforce its rulings.

We would like to make one last comment, and that is on timing. These are admittedly extraordinarily complex issues to be worked out among parties with conflicting interests, and reaching agreement requires meticulous and skilled negotiation. But in the absence of such a regime—and notwithstanding major victories in specific cases such as the Neem fungicide patent—Biopiracy will continue unabated on one hand, while on the other, more and more holders of traditional knowledge will lock their doors, refusing to cooperate. From the documents we have reviewed, it appears that the essential elements for this International Regime are already on the table. Thus, we wish the members of the Working Group success in bringing the project for an International Regime on Access and Benefit-sharing to a rapid conclusion so that it may be quickly implemented, while it is still relevant to preventing Biopiracy.

The Submitters are grateful for this opportunity to provide input to your deliberations, based on our experience in the Neem patent challenge. We will follow your important work with interest and look forward to hearing the results of your upcoming meeting.

PHARMACEUTICALS RESEARCH AND PANUFACTURERS OF AMERICA (PhRMA)

PhRMA represents leading pharmaceutical research and biotechnology companies in the United States. Our member companies are dedicated to inventing and making available medicines that allow patients to live longer, healthier, and more productive lives. Genetic resources are sometimes used in the conduct of research leading to new medicines, but reliance by the pharmaceutical industry on bio-prospecting and on the genetic resources covered by the CBD has diminished over time. Those member companies that may still engage in bio-prospecting are committed to complying with applicable regulations regarding prior informed consent and access to genetic resources.

Goals

PhRMA members support the broad policy goals of the CBD to conserve diversity of genetic resources worldwide, to promote the sustainable use of those resources, and to equitably share benefits arising from that access. These goals are furthered when individuals and companies seeking access to genetic resources covered by the CBD obtain prior informed consent and reach agreement with the providers of genetic resources on the sharing of benefits resulting from such access. We also believe that

there should be simple, effective, and inexpensive methods for enforcing laws governing access.

Some elements in the suggested outline on an International Regime on Access and Benefit-sharing may be useful to ensure that those seeking access to genetic resources obtain prior informed consent and equitably provide benefits arising from that access. In our view, the objectives of the CBD will best be achieved through effective legal regimes at the national level that specify the authorities responsible for granting prior informed consent to genetic resources and for developing benefit-sharing terms. These regimes should be based on market principles that ensure tangible and reasonable benefit sharing for genetic resource providers. The *Bonn Guidelines* is a valuable resource relevant to this approach as it provides guidelines that have already been accepted by CBD members for such national regimes.

Disclosure Requirements

Proposed Element "xiv" of Item 4 of the outline is "Disclosure of origin/source/legal provenance of genetic resources and associated traditional knowledge in applications for intellectual property rights." In most cases, the intellectual property rights subject to this disclosure obligation would be patents or, perhaps, plant variety protection certificates. As such, this would amount to an additional disclosure requirement in patent applications that creates additional legal uncertainty.

PhRMA members do not support these additional disclosure requirements in patent applications. As currently understood, the suggested disclosure obligations would not help to achieve the broad policy objectives of the CBD, nor would they provide simple, effective, or inexpensive methods for obtaining prior informed consent or equitable benefit sharing arrangements. They would in practice, however, create greater uncertainty in patent enforceability and may create an environment that discourages doing this kind of research rather than the environment sought to be created by the CBD.

Requiring patent applicants to indicate the geographical origin will not be an effective substitute for national access and benefit-sharing legislation. This is, in our view, an unproductive and even counter-productive approach. Most researchers never establish a commercial use for genetic resources or for innovative materials based in some way on genetic resources. Often, they do not obtain patents for their innovations because of that reality. Others never intend to use accessed genetic resources to develop innovative commercial products and will not seek patents for that reason. Some researchers may indeed develop a commercial use for inventions based on genetic resources, but will protect their commercial processes or products through trade secrets protection, rather than patents.

Researchers in the situations described above obtain some value from use of the genetic resources, and the goals of the CBD would be furthered by sharing or providing benefits on appropriate agreed-upon terms. But inserting into the patent system a

requirement to indicate the source or origin of genetic resources for reasons unrelated to patentability will do little to promote benefit sharing in any of the situations described above. The lengthy time span between access to genetic resources and any resulting commercialization of an innovative product undermines the practical effectiveness of the proposed disclosure obligations. With regard to the pharmaceutical industry, in the rare event that a commercial product is developed, this time span between access and commercialization can often exceed a decade or more. In contrast, effective national laws that govern access and benefit-sharing can secure benefits immediately and can require such benefit-sharing whether or not a commercial product or process is ever developed.

In addition, the proposed requirements to indicate source or origin of a genetic resource create added legal uncertainty in the patent system while doing little to fulfill objectives of the patent system. In that way, the new obligation, as described in the Notice, would undermine the benefits of patents in encouraging investment in high risk technologies. Such requirements would not assist officials, applicants, or the public in determining whether inventions meet substantive requirements such as novelty, inventive step, and industrial application.

For these reasons, PhRMA opposes adoption of a single, binding international instrument that imposes special disclosure requirements in patent applications. As explained previously in this communication, PhRMA members believe that development of effective national access and benefit-sharing regimes developed on market-based principles will provide the best model for developed and developing countries to achieve the policy objectives of the CBD. This is said with recognition that enhanced international programs may be needed to help developing countries deploy effective legal regimes and conclude equitable agreements. International organizations can and should be involved in providing such programs in cooperation and collaboration with governments and private organizations to ensure continued national or local community sovereignty over genetic resources and their use.

Applicability of the Regime

While PhRMA believes that an international regime would be premature at this stage, any national or international regime that is ultimately developed needs to be within the framework of the CBD. The current outline does not specify which genetic resources would be encompassed by the proposed international regime on access and benefit-sharing. Any proposal should clarify that the regime relates only to "genetic resources" encompassed by the CBD. For instance, "genetic resource" means material of non-human animal, plant or microbial origin containing functional units of heredity. No regime under the CBD should purport to apply to materials obtained from humans or to materials that do not contain functional units of heredity. The metes and bounds of the CBD must be strictly adhered to in order to ensure legal certainty to those members of the scientific community worldwide that may wish to use genetic resources in their research.

Rights to, and benefits from, products derived from or based upon genetic resources are not within the framework of the CBD.

Most non-human genetic resources used in research today were acquired before entry into force of the CBD and may be found in various public and private collections. Many of these resources entered the collections many years ago, and the countries of origin are no longer known. Thus, it is often impossible for researchers – who have not acted inconsistently with the CBD - to identify the country of origin. Any proposed national or international regime should thus also be limited to genetic resources acquired from countries of origin after the entry into force of the CBD.

Conclusion

PhRMA hopes that these comments will be helpful to the fourth meeting of the Ad-Hoc Working Group on Access and Benefit-sharing and urges the participants in this meeting to engage in a constructive discussion of a Regime that is in accordance with the principles of the CBD. PhRMA members further hope that such a Regime will promote access to genetic resources, sustainable use of such genetic resources and equitable benefit-sharing with the providers of these resources.
