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COMPILATION OF SUBMISSIONS BY PARTIES, GOVERNMENTS, INTERNATIONAL ORGANIZATIONS, INDIGENOUS AND LOCAL COMMUNITIES AND RELEVANT STAKEHOLDERS IN RESPECT OF THE MAIN COMPONENTS OF THE INTERNATIONAL REGIME ON ACCESS AND BENEFIT-SHARING LISTED IN DECISION IX/12, ANNEX I

Note by the Executive Secretary

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INTRODUCTION

1. In decision IX/12, paragraph 9, the Conference of the Parties invited Parties, other Governments, international organizations and indigenous and local communities, and relevant stakeholders to submit, for further elaboration and negotiation of the international regime on access and benefit-sharing, views and proposals including operational text, where relevant, in respect of the main components listed in the annex I to decision IX/12, preferably with supporting rationale.

2. In paragraph 10, the Executive Secretary is requested to compile the submissions received and to collate in three separate documents:

(a) Any operative text submitted;

(b) Operative text including related explanations and rationale;

(c) Any other views and information;

by subject matter, in accordance with the annex I to decision IX/12 and as indicated in the submissions, and to identify in the collation the respective sources. It further requested the Executive Secretary to make the compilation and these documents available to Parties sixty days prior to the seventh meeting of the Working Group on Access and Benefit-sharing.

3. In accordance with the above, notification 2008-120 of 19 September 2008 was sent to Parties, Governments, international organizations, indigenous and local communities and relevant stakeholders inviting them to provide their submissions by 15 December 2008.

4. As requested by the Conference of the Parties, the present document provides a compilation of the full submissions provided by Parties, Governments, international organizations, indigenous and local communities and relevant stakeholders. The contributions have been reproduced in the form and language in which they were received. In addition, contributions provided in a language other than English have been translated into English.

I. SUBMISSIONS FROM PARTIES

CAMBODIA

Views on ABS

I-Introduction

Cambodia is a tropical country located in Southeast Area covering land area of 181,035 km^2. Biogeographically, the country is dominated by low land along the Mekong River and Tonlé Sap Lake, where agriculture activities are concentrated, and three mountain regions in the Southwest, North and Northeast.

Genetic Resources: Due to lack of research very little is known about the genetic diversity within species and there is serious lack of information on distribution and occurrence of wild species and wild relatives of crops in the country. Nevertheless, over 2,000 varieties of rice and several wild rice species have been identified and/or used in the country. A mix of wild and domesticated animal genetic resources has been reported (NBSAP, 2002).

Crop cultivation in the country is largely dependent on traditional cultivars, old varieties, and native landraces evolved over thousands of years within the country. Almost 80% of cultivated areas are used for local unimproved crop varieties. This traditional agriculture relies on a diversity of rice strains and a diversity of associated rice ecosystem species to provide food and stable production. It is estimated that for every 400 ha, there existed a traditional cultivar in the past. Rich diversity has built up in rice and other crops including maize, soybean, sesame, sweet potato, peanut, and vegetables.

Small farmers who maintain crop genetic diversity in the form of local cultivars are inclined to change to improved hybrids to increase production. Since PAs are the repository of genetic resources of untapped agricultural potential, encroachment, overuse and degradation in protected areas and remaining natural ecosystems also results in the erosion or genetic resources. The country agricultural system are unusually diverse and networks, thus encroachment and land claim, particularly on traditional agricultural practices could result in erosion of agricultural genetic resources that may, otherwise, a source of in situ of agricultural genetic materials.

Species diversity: Knowledge at the species levels for plants and animals of Cambodia remains very limited. Recent surveys and studies, particularly from the end of 1990s have generated some information of species diversity and to certain extent the abundance of and geographic distribution of fauna, particularly for mammals and birds and to the lesser extent for other classes of faunal and floral species in the country. According to IUCN Redlist, 39 mammal, 36 bird, 15 reptile, 38 plant species are listed as critically endangered, endangered, vulnerable, near-threatened or data deficient (SoE, 2004). Surveys and studies in the country on the other hand listed 28 mammal, 21 bird, 7 fish, and 30 plant species as critically endangered, endangered, and vulnerable. Known species for reptile 114 (1992-2003) and amphibian 8 (1992-2003). There is limited information on invertebrates. Four species, including 2 mammal and 2 bird species, are believed to have been extinct from Cambodia since 1990 (SoE, 2004, p. 130-136). The complete dataset from which Known Species of Mammals, Birds, Plants, Reptiles, and Amphibians were extracted represents only about 2% of the total species of the world. As a result, the numbers reported here are vast underestimates of the actual species worldwide. Mammals and birds are better known and represented than other taxonomic groups. Invertebrates in the kingdom Animalia, the kingdom Protista, and the kingdom Monera are not included in these country profiles. Data on known Species of Mammals, Birds, Plants, Reptiles, and Amphibians are based on a compilation of available data from a large variety of sources. They are not based on species checklists, (UNEP-WCMC/WRI).

II- Different ways of Understanding biological and genetic resources:
Cambodia recognizes the need to conserve and foster the sustainable use of biodiversity (both wild and cultivated) resources. To this end Cambodia is party to various conventions (at the international and regional levels) that contribute to the conservation of biodiversity. Cambodia ratified the CBD in 1995.

In Cambodia Botanic Gardens have not been established. Most resource uses are traditional botanical medicine (traditional healers) that the majority of users are insufficiently informed about the CBD and its associated legal framework regarding the use of genetic resources. Most users do not know whether CBD regulations are relevant to them or not.
The main public institutions which use genetic resources for research are in the area of agriculture such as IRI ( ) and Institute of Fishery research under the Ministry of Agriculture, Forestry and Fishery which are only party concerned with the CBD regulations and they are also non-commercial users.

III- Different forms of utilization of genetic resources in relation to sectoral and subsectoral activities in the context of Article 15, paragraph 7, of the convention:
As mentioned above there are no significant commercial use of genetic resource in Cambodia
The sector of traditional medicine is the considerable user of genetic resources in which most of the users receive their material from their partners rather than collect or produce it themselves while collecting is reported significantly more often than the reproduction of genetic material. Providers from the rural or forest area constitute the most important supply sources for this sector. Ornamental plants are mostly imported from other countries because the biotechnology for ornamental plant breeding has not been developed. However existing law on Plant breeding stipulate the protection of the right of plant breeders for plant variety invention. According to Cambodia Breeding law (art. 40) the existing plant varieties can be registered as national plant variety, however the law does not clearly regulate how shall the property right of national plant variety be protected and what are obligation of the users of these resources. The poor regulation on ABS in Cambodia lead to the weak awareness on CBD regulation especially the implementation of article 15, paragraph 7 of the CBD Convention. Event the Cambodian Government passed a series of the laws and the regulatory framework to protect IPRs these regulations did not respond good enough to the requirement of ABS regime. Cambodia IPRs regulatory framework is dealing with copyright and related rights which protects the type of works as follows :

1. Works of authors who are Cambodian nationals or who have habitual residence in Cambodia. Works first publishing in Cambodia, including works first published abroad which were brought to publish in Cambodia within 30 days of the first communication to the public.

2. Computer programs and design encyclopedia documents relevant to those programs, etc.

Second related law is the “Law on the Patents, Utility Model Certificates and Industrial Design” which was promulgated on January 22, 2003 and provides the protection for granted patents, utility model certificates and registered industrial designs in Cambodia. *PATENT*:

According to Cambodia Patent Law, “Patent” means the title to be granted to protect an invention and “Invention” means an idea of an inventor that permits in practice the solution to a specific problem in the field of technology. An invention may be, or may relate to, a product or a process (Article 4). An invention is patentable if it is new, involves an inventive step and is industrially applicable (Article 5).The right to a patent shall belong to the inventor (Article 10) and the application for a patent shall be filed with the Ministry in charge of industry (the Ministry of Industry, Mines and Energy: MIME), which shall be subject to the payment of the application fee (Article 16).

The paragraph 7 of the article 15 of CBD requires each contracting party, whether developed or developing, to take legislative, administrative or policy measures whose goal is the fair and equitable sharing of benefits with the contracting party providing genetic resources. The benefits to be shared are :

- research and development results; and
- the commercial or other benefits derive from utilizing the genetic resource provided

Sharing is to be on mutually agreed term.

There is no clear information on research for commercial purpose in Cambodia. Most research institutes are governmental sectors. Three existing governmental research institute are: - (i)Cambodian Agricultural Research Development Institute (CARDI) which mostly focus on rice variety research- (ii) Fishery Research Institute- (iii) Forest and Wildlife Research Institute. The research of the first two institutes is for the development of agricultural production and the later is for conservative purpose. The limits of the bio-prospecting are stated in Cambodian Law on Protected Areas which requires the research activities in the core zone of the protected areas shall be subject to prior approval from the Ministry of Environment. However no legal requirement concerning research agreement, especially there is no specific regulation on bio-prospecting.

Article 58 of Cambodia Constitution state that natural resource is the property of the State, the control, use and management of state property shall be determined by law. Actually many natural resource use related laws were passed which regulate the criteria and control of the use of the biodiversity, they reflect only the right of the State to manage the biodiversity resource but these laws have not addressed the sharing of benefits arising from the utilization of traditional biodiversity-related knowledge.

Finally, Cambodia needs more capacity to implement the requirement of CBD regarding ABS regime and especially the ability in developing ABS regulation.

EUROPEAN COMMUNITY AND ITS MEMBER STATES

EU SUBMISSION to ABS WG7 in response to notification 2008-120

CBD Decision IX/12 paragraph 9 invites Parties, other governments, international organisations and indigenous and local communities and relevant stakeholders to submit, for further elaboration and negotiation of the international regime on access and benefit-sharing, views and proposals including operational text, where relevant, in respect of the main components listed in Annex I to Decision IX/12, preferably with supporting rationale.

The EU submits the views below and examples of operational text with supporting rationale in respect to some of the main components listed in Section III, Annex I to Decision IX/12.

The EU recalls its position as contained in the Conclusions of the Council of the European Union in preparation for the ninth ordinary meeting of the Conference of the Parties (COP 9) to the Convention on Biological Diversity (CBD) of 3 March 2008 that "the international ABS regime could include some binding components, if it also includes international standards on national access law and practice, linked to compliance support measures". Therefore, wherever the word "should" appears within square brackets throughout this submission, it should be understood that it will be subject to further assessment by the EU prior to discussions on nature at ABS WG8. The EU reserves its right to submit further views and examples of operational text, including examples of a binding nature, as well as to amend or modify the views and examples of operational text included in this submission in response to other submissions made and to the course of negotiations.

Section III.A. - Fair and equitable benefit-sharing

1. Components for further elaboration with the aim of incorporating them in the IR

1) Linkage of access to fair and equitable sharing of benefits

Example of Operational Text

Recognising that the fair and equitable sharing of benefits can only be realised after access to genetic resources has been granted. [Preambular paragraph]

Recalling that Article 15(5) of the Convention provides that access to genetic resources shall be subject to prior informed consent of the Contracting Party providing genetic resources, unless otherwise determined by that Contracting Party. [Preambular paragraph]

Further Recalling that Article 15(4) of the Convention provides that Contracting Parties shall take measures to ensure that access, where granted, is on mutually agreed terms. [Preambular paragraph]

1. Parties requiring prior informed consent for access to their genetic resources [should] take measures to encourage providers and users to provide in their mutually agreed terms, as appropriate, for the fair and equitable sharing of benefits arising from the utilisation of genetic resources, whilst recognising that the fair and equitable sharing of benefits can only be realised after access to genetic resources has been granted.

Explanations and rationale

The first preambular paragraph clarifies that benefits from the utilisation of genetic resources can only be realised after access has been granted. The second and third preambular paragraphs recall relevant provisions in Article 15 CBD.

The operational paragraph picks up on the fundamental notion in Article 15.7 that specific benefit-sharing arrangements will be established on mutually agreed terms between the provider and the user of genetic resources. Parties should take measures to encourage providers and users of genetic resources to provide in their mutually agreed terms, as appropriate, for the fair and equitable sharing of benefits arising from the utilisation of genetic resources.

The same operational paragraph also appears in III.A.1.2) operational paragraph 1.

The same component appears in the section on Access under III.B.1.2).

2) Benefits to be shared on mutually agreed terms

Example of Operational Text

Further Recalling that Article 15(4) of the Convention provides that Contracting Parties shall take measures to ensure that access, where granted, is on mutually agreed terms. [Preambular paragraph]

Further recalling that in accordance with Article 15.7 of the CBD, the fair and equitable sharing of benefits arising from the commercial and other utilisation of genetic resources shall be upon mutually agreed terms as decided between the provider and user. [Preambular paragraph]

Recognising that benefit-sharing on mutually agreed terms may include monetary and/or non-monetary benefits [Preambular paragraph]

1. Parties requiring prior informed consent for access to their genetic resources [should] take measures to encourage providers and users to provide in their mutually agreed terms, as appropriate, for the fair and equitable sharing of benefits arising from the utilisation of genetic resources, whilst recognising that the fair and equitable sharing of benefits can only be realised after access to genetic resources has been granted.

2. Parties requiring prior informed consent for access to their genetic resources [should] take measures to encourage providers and users of genetic resources, when establishing mutually agreed terms, to consider:

i. including in these terms model clauses and using relevant inventories/catalogues of typical utilisations of genetic resources and related monetary or non-monetary benefits developed in accordance with [Operational Text developed under III.A.2.5)];

ii. sharing of results of research and development;

iii. access to and transfer of technology which makes use of those resources;

iv. the effective participation of providers of the genetic resources in research activities and/or to facilitate the joint development of research activities between the provider and the user;

v. the Bonn Guidelines.

Explanations and rationale

The first and second preambular paragraphs recall the relevance given to mutually agreed terms in the context of Article 15 CBD for both access to genetic resources and the fair and equitable sharing of benefits arising from their commercial and other utilisation. The third preambular paragraph recalls the relevance of monetary and/or non-monetary benefits as already acknowledged in the Bonn Guidelines and shows the close relationship of this operational text to operational text III.A.1.3).

The operational provision in paragraph 1 is the same as provided in paragraph 1 of Operational Text III.A.1.1) and once again shows the close relationship between these two bricks.

The operational paragraph 2 lists specific aspects/issues that providers and users of genetic resources should be encouraged to consider when establishing mutually agreed terms. i) on model clauses is a component under consideration in this section as well as in Section III.C. on compliance.

ii) to v) bring together further components that Parties have agreed to further elaborate or consider in this section of the International Regime-Annex.

3) Monetary and/or non-monetary benefits

Example of Operational Text

Recognising that benefit-sharing on mutually agreed terms may include monetary and/or non-monetary benefits [Preambular language]

Mutually agreed terms may identify the types of monetary and/or non-monetary benefits to be shared for the utilisation of genetic resources and associated traditional knowledge, innovations and practices

Explanations and rationale

Provider and user of genetic resources will identify in mutually agreed terms the type of benefits to be shared. Examples of monetary and non-monetary benefits are provided in Appendix II of the Bonn Guidelines. The mix between non-monetary and monetary benefits identified in mutually agreed terms will likely vary between different sectoral uses of genetic resources. Particularly in the case of non-commercial research on genetic resources, non-monetary benefits will be more readily available.

4) Access to and transfer of technology

Example of Operational Text

See above III.A.1.2)

Explanations and rationale

Access to and transfer of technology is addressed in Operational Text III.A.1.2) paragraph 2 iii).

5) Sharing of results of research and development on mutually agreed terms

Example of Operational Text

See above III.A.1.2)

Explanations and rationale

The sharing of results of research and development on mutually agreed terms is addressed in Operational Text III.A.1.2) paragraph 2 ii).

6) Effective participation in research activities, and/or joint development in research activities

Example of Operational Text

See above III.A.1.2)

Explanations and rationale

The effective participation in research activities, and/or joint development in research activities is addressed in Operational Text III.A.1.2) paragraph 2 iv).

7) Mechanisms to promote equality in negotiations

Example of Operational Text

Recognising the importance of promoting equality in negotiations of mutually agreed terms between providers and users of genetic resources, Parties should take measures such as

(i) making information available to users and providers through the designated ABS focal point in a timely manner, including the model clauses and relevant inventories developed in accordance with [OT III.A.2.5)];

(ii) developing consultative arrangements with relevant stakeholders and indigenous and local communities holding traditional knowledge associated with genetic resources.

(iii) supporting the capacity of providers and users of genetic resources to negotiate mutually agreed terms and contractual arrangements.

Explanations and rationale

Negotiations of mutually agreed terms will be more successful if both sides to an agreement are well informed about its practical and legal implications. The availability of model clauses and relevant inventories/catalogues of typical utilisations of genetic resources as well as related benefits will strengthen particularly the "weaker" party in such negotiations. Further support could be given through national ABS focal points in both provider and user countries.

The provisions will furthermore strengthen the ability of indigenous and local communities to successfully engage in negotiations of mutually agreed terms. These provisions are linked to Section III.D on Traditional Knowledge and Section III.E on Capacity, respectively.

8) Awareness-raising

Example of Operational Text

Parties [should] take measures to raise awareness of ABS issues. Such measures could include:

i. making available up to date information about their domestic ABS framework, 1/ in particular national laws, policies and procedures;

ii. steps to promote the CBD international regime on access and benefit sharing ;

iii. organisation of stakeholder meetings;

iv. promotion of codes of conduct;

v. promotion of regional exchange of experiences related to ABS.

Explanations and rationale

Awareness about access and benefit-sharing issues is critical for the successful establishment of mutually agreed terms and the further development and effective implementation of ABS frameworks at domestic level. It will be important to raise awareness amongst users, providers, indigenous and local communities and other groups. Awareness-raising activities also appear in section on Compliance - III.C.1.1) a).

9) Measures to ensure participation and involvement of indigenous and local communities in mutually agreed terms and sharing of benefits with traditional knowledge holders

View

Measures to ensure participation and involvement of indigenous and local communities holding traditional knowledge associated with genetic resources must be an important component of the international regime. However, this "brick" is closely linked to Sections D and E of the International Regime Annex. These sections will only be discussed at the Eighth Meeting of the ABS Working Group, in light of the deliberations of the Technical Expert Group on Traditional Knowledge. The EU welcomes the opportunity to further discuss this issue and intends to submit an example of operational text and underlying rationale prior to ABS WG8. The EU will continue to discuss its views with representatives of indigenous and local communities prior to this submission.

10) Mechanisms to encourage benefits to be directed toward conservation and sustainable use of biodiversity and socio-economic development, in particular the Millennium Development Goals (MDGs) in accordance with national legislation

Example of Operational Text

Recognising that the conservation and sustainable use of biodiversity will contribute to socio-economic development, Parties should take measures to encourage users and providers, in their mutually agreed terms, to direct benefits arising from the utilisation of genetic resources towards the conservation and sustainable use of biological diversity in accordance with the objectives set out in Article 1 of the CBD as a contribution towards socio-economic development, in accordance with national legislation.

1/ The term "domestic ABS framework" in this and other Operational Texts submitted refers to the substantive and procedural rules applicable to access to genetic resources and the fair and equitable sharing of the benefits arising out of their utilization, within the scope of the international regime.

Explanations and rationale

An important element of the international ABS regime will be that it also supports the other two objectives of the Convention in order to enhance socio-economic development, in particular, in the run up to 2015, the Millennium Development Goals.

2. Components for further consideration

5) Development of menus of model clauses for potential inclusion in material transfer agreements

Example of Operational Text

Emphasising that both providers and users of genetic resources benefit from the availability of model clauses for potential inclusion in material transfer agreements and inventories/catalogues of typical utilisations of genetic resources since the use of such clauses and inventories will raise legal certainty, may lower transaction costs and will contribute to creating a level playing field between provider and user when negotiating mutually agreed terms. [Preambular Paragraph]

1. Parties [should] take measures to encourage providers and users of genetic resources, when establishing mutually agreed terms, to consider

- including in these terms model clauses developed in accordance with paragraphs 2 and 3 below,
- relevant inventories/catalogues of typical utilisations of genetic resources and related monetary and non-monetary benefits.

2. In order to enhance legal certainty, lower transaction costs and promote equality in negotiations of mutually agreed terms the Parties will establish a procedure for the development of sectoral model clauses and inventories/catalogues of typical utilisations of genetic resources and related monetary or non-monetary benefits. The procedure should:

i. identify sectors for which model clauses and inventories/catalogues of typical utilisations of genetic resources and related benefits should be developed,

ii. identify issues that should be addressed in model clauses,

iii. include clear and transparent rules to facilitate the involvement of stakeholders.

3. The Parties will collectively consider and, where appropriate, adopt recommendations for model clauses and inventories/catalogues of typical uses of genetic resources. They will regularly review and, where appropriate, update such model clauses and inventories/catalogues of typical uses of genetic resources.

Explanations and rationale

The availability of model clauses for potential inclusion in material transfer agreements and inventories/catalogues of typical utilisations of genetic resources and related benefits will raise legal certainty, may lower transaction costs and will contribute to creating a level playing field between provider and user when negotiating mutually agreed terms.

The Preambular paragraph underlines the multiple benefits of model clauses.

According to operational paragraph 1 providers and users of genetic resources should be encouraged to consider using such model clauses and relevant inventories/catalogues of typical utilisations of genetic resources when establishing mutually agreed terms, reflecting that this component refers to menus of model clauses for potential inclusion in material transfer agreements.

Operational paragraphs 2 and 3 establish a procedure through which Parties collectively initiate the development of as well as the eventual consideration, adoption and review of model clauses and inventories/catalogues of typical utilisations of genetic resources and related benefits.

The same component appears in Section III.C.2.1)b) under Development of tools to encourage compliance.

6) Enhanced utilization of Bonn Guidelines

Example of Operational Text

Recalling Decision VI/24 of the Conference of the Parties to the Convention on Biodiversity adopting the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization. [Preambular Paragraph]

Explanations and rationale

The Bonn Guidelines set out a best practice "baseline" for the international regime on access and benefit-sharing and as such provide an important source of inspiration in the development and implementation of the international ABS regime. Operational provisions of the international ABS regime should make reference to the Bonn Guidelines or parts thereof whenever relevant and appropriate.

Section III.B. - Access to genetic resources

1. Components for further elaboration with the aim of incorporating them in the IR

1) Recognition of the sovereign rights and the authority of Parties to determine access

Example of Operational Text

Recalling the sovereign rights of States over their natural resources and that the authority to determine access to genetic resources rests with the national governments and is subject to national legislation. [Preambular Paragraph]

Further recalling that each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not impose restrictions that run counter to the objectives of the Convention. [Preambular Paragraph]

Further recalling that access to genetic resources shall be subject to the prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party; and in this context recognising that each Contracting Party may determine that access to its genetic resources will not be subject to prior informed consent in the context of Article 15 CBD. [Preambular Paragraph]

Explanations and rationale

Article 15.1 CBD recognises the sovereign rights of States over their natural resources and in this context, that the authority to determine access to genetic resources rests with the national governments and is subject to national legislation. For Contracting Parties, the authority of national governments to determine access to genetic resources is qualified by Article 15.2: Contracting Parties are obliged to

endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of the CBD.

Preambular paragraph 3 recalls that Contracting Parties may, in exercising their sovereign rights over genetic resources, determine that access to their genetic resources will not be subject to prior informed consent (Article 15.5 CBD, "unless otherwise determined").

2) Linkage of access to fair and equitable sharing of benefits

Example of Operational Text

Recognising that the fair and equitable sharing of benefits can only be realised after access to genetic resources has been granted. [Preambular paragraph]

Recalling that Article 15(5) of the Convention provides that access to genetic resources shall be subject to prior informed consent of the Contracting Party providing genetic resources, unless otherwise determined by that Contracting Party. [Preambular paragraph]

Further Recalling that Article 15(4) of the Convention provides that Contracting Parties shall take measures to ensure that access, where granted, is on mutually agreed terms. [Preambular paragraph]

1. Parties requiring prior informed consent for access to their genetic resources [should] take measures to encourage providers and users to provide in their mutually agreed terms, as appropriate, for the fair and equitable sharing of benefits arising from the utilisation of genetic resources, whilst recognising that the fair and equitable sharing of benefits can only be realised after access to genetic resources has been granted.

Explanations and rationale

The first preambular paragraph clarifies that benefits from the utilisation of genetic resources can only be realised after access has been granted. The second and third preambular paragraphs recall relevant provisions in Article 15 CBD.

The operational paragraph picks up on the fundamental notion in Article 15.7 that specific benefit-sharing arrangements will be established on mutually agreed terms between the provider and the user of genetic resources. Parties should take measures to encourage providers and users of genetic resources to provide in their mutually agreed terms as appropriate for the fair and equitable sharing of benefits arising from the utilisation of genetic resources.

The same operational paragraph also appears in III.A.1.2) operational paragraph 1.

The same component appears in section III.A.1.1).

3) Legal certainty, clarity and transparency of access rules

Example of Operational Text

To create conditions to facilitate access to genetic resources and to support compliance with access and benefit-sharing related obligations across jurisdictions, Parties requiring prior informed consent [should] take the necessary legislative, policy or administrative measures to provide for legal certainty, clarity and transparency of their domestic ABS frameworks. (*The measures referred to in this operational text are those referred to in operational text III.B.2.2).*

Explanations and rationale

According to Article 15.2 CBD Parties shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Parties and not to impose restrictions that run counter to the objective of the CBD. Legal certainty, clarity and transparency of national access frameworks are general principles concretising this obligation of Parties under Article 15.2 CBD. The international regime should include guidance on specific measures to give effect to these general principles. An example of relevant operational text is provided below under III.B.2.2).

2. Components for further consideration

1) Non-discrimination of access rules

Example of Operational Text

Each Party, when applying its domestic ABS framework, [should] not discriminate between users from other Contracting Parties.

Explanations and rationale

Non-discrimination between users of genetic resources from other Contracting Parties is an important concept adding to the predictability and legal certainty of national access decisions.

2) International access standards (that do not require harmonization of domestic access legislation) to support compliance across jurisdictions

Example of Operational Text

Recalling the sovereign rights of States over their natural resources and that the authority to determine access to genetic resources rests with the national governments and is subject to national legislation. [Preambular Paragraph]

Further recalling that each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not impose restrictions that run counter to the objectives of the Convention. [Preambular Paragraph]

Recognising that each Contracting Party may determine that access to its genetic resources will not be subject to prior informed consent in the context of Article 15 CBD. [Preambular Paragraph]

Further recognising that the fair and equitable sharing of benefits can only be realised after access to genetic resources has been granted. [Preambular paragraph]

1. To create conditions to facilitate access to genetic resources and to support compliance with access and benefit-sharing related obligations across jurisdictions, Parties requiring prior informed consent [should] take the necessary legislative, policy or administrative measures to provide for legal certainty, clarity and transparency of their domestic ABS frameworks. These should include:

(General issues)

a) clear rules on accessing genetic resources existing in *in situ* and *ex situ* conditions that do not discriminate between users from other Contracting Parties;

b) a clear procedure for applying for prior informed consent from a competent authority and, where applicable, from indigenous and local communities;

c) a simplified procedure for access to genetic resources for non-commercial research in accordance with [Operational Text provided under III.B.2.5)].

d) making available and easily accessible information on their domestic ABS frameworks, in particular on how to apply for prior informed consent;

e) providing and regularly updating the information generated under subparagraph (d) to the CBD Clearing House Mechanism, including information on ABS focal points;

f) requiring the competent authority to register its decision to grant prior informed consent in the CBD Clearing House Mechanism;

g) Appropriate administrative or judicial appeals procedures in respect of PIC, including for failure to act and discriminatory access practices;

(Specific aspects for obtaining decisions on prior informed consent from the competent authority)

h) requiring that decisions by competent authorities granting or refusing prior informed consent are reasoned, set out in writing, and notified to the applicant;

i) identifying in the domestic ABS framework the grounds upon which prior informed consent may be denied;

j) requiring competent authorities to take decisions on prior informed consent within a reasonable period of time as specified in the domestic ABS framework;

k) ensuring that the costs for obtaining decisions on prior informed consent do not exceed the actual costs of processing the application;

l) requiring the competent authority to include in its decision to grant prior informed consent available passport data as well as a reference code of the genetic resource(s) covered by this decision;

(Specific aspects related to mutually agreed terms (normally set out in contracts)):

m) clear rules, in domestic ABS frameworks, for establishing mutually agreed terms;

n) requiring the establishment of mutually agreed terms;

o) requiring that mutually agreed terms be set out in writing;

p) requiring that mutually agreed terms include a clause on the settlement of disputes;

q) requiring that mutually agreed terms reflect that consideration has been given to benefit-sharing;

r) reference to the model clauses and inventories/catalogues of utilisations of genetic resources and related benefits developed in accordance with OT III.A.2.5).

2. The additional measures set out in [Operational Text III.C.2.3)] to support compliance in cases of misappropriation will be applicable if the domestic ABS framework of a Contracting Party providing a genetic resource is in conformity with paragraph 1 of this Operational Text.

Explanations and rationale

The first and second Preambular paragraphs recall Article 15.1 and 15.2 CBD and are the same as in Operational Text III.B.1.1).

The third Preambular paragraph acknowledges that Contracting Parties may, in exercising their sovereign rights over genetic resources, determine that access to their genetic resources will not be subject to prior informed consent (Article 15.5 CBD, "unless otherwise determined"). The text is the same as in Operational Text III.B.1.1).

The fourth Preambular paragraph clarifies that benefits from the utilisation of genetic resources can only be realised after access has been granted. The text is the same as in Operational Text III.A.1.1).

Operational paragraph 1 concretises the obligation of Contracting Parties to endeavour to create conditions to facilitate access to genetic resources. The first sentence of this paragraph is the same as the operative paragraph submitted for component III.B.1.3) on legal certainty, clarity and transparency of access rules. The second sentence of this paragraph and sub-paragraphs a) to r) translate the general principles of legal certainty, clarity and transparency into specific issues and measures that should be reflected in national access frameworks.

Operational paragraph 2 establishes the link between implementation of the essential elements listed in paragraph 1 a) to r) and additional measures to support compliance: The additional measures set out in [Operational Text III.C.2.3)] to support compliance in cases of misappropriation will be applicable if the domestic ABS framework of a Contracting Party providing a genetic resource is in conformity with operational paragraph 1. – The EU has consistently underscored the relevance of the link between access and compliance. The operational text suggests how this link between access-related decisions in the jurisdiction of Parties providing genetic resources and measures to support compliance in jurisdictions where these genetic resources are utilised could be addressed through operational text.

3) Internationally developed model domestic legislation

Example of Operational Text

The Parties will, as soon as practicable, adopt examples of model provisions for domestic legislation and exemplary frameworks for administrative decision making that are consistent with the international access standards set out in [Operational Text III.B.2.2)].

Explanations and rationale

The ABS-related provisions of the Convention and the future International ABS Regime need to be implemented at national level to be effective. Recent studies indicate that so far only few CBD Parties have developed national legislation on access and benefit-sharing. Internationally developed model domestic legislation would have an important role in strengthening national capacity for developing national legislation and for implementing the international ABS regime.

The operational text suggests that model domestic legislation is developed internationally after negotiations on the international ABS regime have been concluded and the specific content of the international ABS regime is known.

5) Simplified access rules for non-commercial research

Example of Operational Text

1. Parties requiring prior informed consent [should] provide for a simplified administrative procedure for access to genetic resources for non-commercial research.

2. The classification of research as "non-commercial" may be determined based on its nature, form and objective, particularly on the non-commercial intent at the time of access.

3. To preserve the integrity of the simplified procedure, Contracting Parties [should] take measures aimed at

a) ensuring that obligations in relation to access and benefit-sharing are passed on to subsequent users;

b) addressing potential changes in intent by non-commercial users, including through identification of clear reference points for such changes;

c) ensuring the renegotiation of mutually agreed terms with the provider of the genetic resource in cases of changes in intent by non-commercial users where appropriate

d) avoiding that users of genetic resources without obligations vis a vis the provider make use of generated information if such use is restricted, for example, through publication policies.

e) giving recognition to the commitment of users of genetic resources to ABS best practice codes of conduct applicable to the research community.

4. Parties [should] take measures to encourage providers and users of genetic resources, when establishing mutually agreed terms, to consider including in these terms model clauses and relevant inventories/catalogues of typical utilisations of genetic resources developed in accordance with [OT developed under III.A.2.5)].

5. Parties will collaborate in the exchange of experience in the use of and the development of electronic tools for the tracking of genetic resources.

6. Parties will exchange information on best practices in the application of simplified administrative procedures for access to genetic resources for non-commercial research.

Explanations and rationale

Biodiversity-research makes an important contribution to the implementation of the CBD. Simplified access is particularly important for non-commercial research, such as taxonomic work.

Operative paragraph 1 establishes that each Party requiring prior informed consent should provide for a simplified procedure for access to genetic resources for non-commercial research. Operative paragraphs 2 and 3 provide guidance on how Parties may identify the non-commercial intent of those seeking simplified access and the steps that may be taken to ensure that the simplified access rules for non-commercial are not abused.

Operative paragraph 4 repeats operational text provided under component III.A.2.5).

Operative paragraphs 5 and 6 establish an exchange of experience and information that will support Parties in building the necessary confidence in the effective functioning of and integrity of their simplified access procedures for non-commercial research.

Section III.C. - Compliance

1. Components to be further elaborated with the aim of incorporating them in the international regime

1) Development of tools to encourage compliance:

(a) Awareness-raising activities

Example of Operational Text

Parties [should] take measures to raise awareness of ABS issues. Such measures could include:

i. making available up to date information about their domestic ABS framework, in particular national laws, policies and procedures;

ii. steps to promote the CBD international regime on access and benefit sharing;

iii. organisation of stakeholder meetings;

iv. promotion of codes of conduct in consultation with stakeholders;

v. Promotion or regional exchange of experiences related to ABS.

Explanations and rationale

Awareness about access and benefit-sharing issues is critical for the successful establishment of mutually agreed terms and the further development and effective implementation of ABS frameworks at national level. It will be important to raise awareness amongst users, providers, indigenous and local communities, and other groups. Awareness-raising activities also appear in section on Fair and equitable benefit-sharing - III.A.1.8).

2) Development of tools to monitor compliance:

(a) Mechanisms for information exchange

Example of Operational Text

1. Parties will collaborate to facilitate information exchange on access and benefit-sharing between Parties, providers and users of genetic resources, including through the CBD's clearing house mechanism, and, where appropriate, between national ABS focal points with a view to:

i. supporting potential users of genetic resources in accessing relevant information;

ii. helping providers of genetic resources to obtain relevant information, including in specific cases of alleged infringements of provider country requirements in relation to prior informed consent and mutually agreed terms.

2. Parties will collaborate in the exchange of experience in the use of and the development of electronic tools for the tracking of genetic resources.

3. Parties will exchange information on best practices in the application of simplified administrative procedures for access to genetic resources for non-commercial research.

Explanations and rationale

Information-exchange under the international ABS regime should support Parties, providers and users in obtaining information relevant to them. Furthermore, information-sharing between ABS focal points could provide (case-) specific information.

b) Internationally recognized certificate issued by a domestic competent authority

Views

The EU suggests focussing further elaborations on an internationally recognised certificate of compliance. Such certificate could provide legal credibility across different jurisdictions that a specific genetic resource has been obtained in accordance with national access rules in the country issuing the certificate. It could thereby add to legal certainty for users and providers of genetic resources.

The EU considers that an internationally recognised certificate of compliance could essentially be the written decision of a national competent authority granting prior informed consent that is registered in the CBD's clearing-house mechanism. Registration should be required for Parties implementing the international access standards set out in Operational Text III.B.2.2).

An internationally recognised certificate of compliance could provide legal credibility across jurisdictions that a specific genetic resource has been obtained in accordance with national access rules in the country issuing the certificate. The EU considers that it would raise legal certainty for users of genetic resources if internationally recognised certificates of compliance were to be available and reliable. Such certificates could potentially be a reliable tool to demonstrate that genetic resources have been acquired in accordance with national rules. More detailed considerations on the scope, nature, content and governance of an internationally recognised certificate of compliance are needed, including its interaction with potential further elements of the international ABS regime.

2. Components for further consideration

1) Development of tools to encourage compliance:

(a) International understanding of misappropriation/misuse

Views

The EU recalls its expressed willingness to engage in a substantive discussion on further measures to support compliance with prior informed consent and mutually agreed terms not excluding legally binding ones and that this discussion could also include work on an international definition of misappropriation and a related international obligation to prohibit the use of misappropriated genetic resources.

The EU continues to see merit in further discussing the issue of misappropriation. An international understanding of "misappropriation" of genetic resources must focus on (1) acquisition of a genetic resource in circumvention of national PIC requirements that meet international access standards (purposeful or negligent); (2) the acquisition of a genetic resource without setting up MAT (purposeful or negligent). Breaches of contract must be left outside the scope of any international understanding of "misappropriation", since breaches of contracts can be pursued through a well established set of national and international level rules.

A key challenge to developing an international understanding of misappropriation is how to approach the link between national access legislation of provider countries and eventual user countries measures to pursue instances of misappropriation so that fundamental legal principles of clarity, predictability, proportionality and reciprocity are respected and practical implementation issues such as the burden of proof in national court proceedings or the distinction between genetic resources within and outside the scope of the international ABS regime are addressed. The development of international access standards that are linked to the application of any provisions on misappropriation is central in this regard.

(b) Sectoral menus of model clauses for material transfer agreements

Example of Operational Text

Emphasising that both providers and users of genetic resources benefit from the availability of model clauses for potential inclusion in material transfer agreements and inventories/catalogues of typical utilisations of genetic resources since the use of such clauses and inventories will raise legal certainty, may lower transaction costs and will contribute to creating a level playing field between provider and user when negotiating mutually agreed terms. [Preambular Paragraph]

1. Parties [should] take measures to encourage providers and users of genetic resources, when establishing mutually agreed terms, to consider

- including in these terms model clauses developed in accordance with paragraphs 2 and 3 below,
- relevant inventories/catalogues of typical utilisations of genetic resources and related monetary and non-monetary benefits.

2. In order to enhance legal certainty, lower transaction costs and promote equality in negotiations of mutually agreed terms the Parties will establish a procedure for the development of sectoral model clauses and inventories/catalogues of typical utilisations of genetic resources and related monetary or non-monetary benefits. The procedure should:

i. identify sectors for which model clauses and inventories/catalogues of typical utilisations of genetic resources and related benefits should be developed,

ii. identify issues that should be addressed in model clauses,

iii. include clear and transparent rules to facilitate the involvement of stakeholders.

3. The Parties will collectively consider and, where appropriate, adopt recommendations for model clauses and inventories/catalogues of typical uses of genetic resources. They will regularly review and, where appropriate, update such model clauses and inventories/catalogues of typical uses of genetic resources.

Explanations and rationale

The availability of model clauses for potential inclusion in material transfer agreements and inventories/catalogues of typical utilisations of genetic resources and related benefits will raise legal certainty, may lower transaction costs and will contribute to creating a level playing field between provider and user when negotiating mutually agreed terms.

The Preambular paragraph underlines the multiple benefits of model clauses.

According to operational paragraph 1 providers and users of genetic resources should be encouraged to consider using such model clauses and relevant inventories/catalogues of typical utilisations of genetic resources when establishing mutually agreed terms, reflecting that this component refers to menus of model clauses for potential inclusion in material transfer agreements.

Operational paragraphs 2 and 3 establish a procedure through which Parties collectively initiate the development of as well as the eventual consideration, adoption and review of model clauses and inventories/catalogues of typical utilisations of genetic resources and related benefits.

The same component appears in Section III.A.2.5).

(c) Codes of conduct for important groups of users

Example of Operational Text

Recognising the existence of a range of national and international, sectoral or company specific codes of conduct and best practice guidelines on access and benefit-sharing and their importance in achieving the third objective of the Convention. [Preambular Paragraph]

1. Parties will support, as appropriate, the development, review and eventual update of access and benefit-sharing related codes of conduct for important groups of users of genetic resources.

Explanations and rationale

The adoption of the CBD and the Bonn Guidelines has resulted in the development of a range of codes of conduct and best practice guidelines on access and benefit-sharing. Codes of conduct and best practice guidelines contribute to and enhance the effective implementation of domestic regulatory frameworks. It is therefore important that Parties appreciate codes of conduct and best practice guidelines as potential building blocks of the international regime on access and benefit-sharing.

(d) Identification of best-practice codes of conduct

Example of Operational Text

Recognising the existence of a range of national and international, sectoral or company specific codes of conduct and best practice guidelines on access and benefit-sharing and their importance in achieving the third objective of the Convention. [Preambular Paragraph]

1. Parties will collectively establish a procedure for identifying and regularly reviewing access and benefit-sharing related codes of conduct and guidelines that constitute best-practice.

Explanations and rationale

Codes of conduct and best practice guidelines contribute to and enhance the effective implementation of domestic regulatory frameworks. It is therefore important that Parties appreciate codes of conduct and best practice guidelines as potential building blocks of the international regime on access and benefit-sharing. This should be supported by collective efforts of Parties to identify those codes and guidelines that constitute best-practice.

(e) Research funding agencies to oblige users receiving research funds to comply with specific access and benefit sharing requirements

Views

The EU welcomes the opportunity to further discuss this issue with a view to submitting an example of operational text and underlying rationale prior to ABS WG8.

(f) Unilateral declaration by users

Views

The EU welcomes the opportunity to further discuss the potential role of unilateral declarations by users in supporting compliance (particularly with PIC) by demonstrating that genetic resources have been legally obtained, with a view to submitting an example of operational text and underlying rationale prior to ABS WG8.

(g) International access standards (that do not require harmonization of domestic access legislation) to support compliance across jurisdictions

Example of Operational Text

1. The additional measures set out in [Operational Text III.C.2.3] to support compliance in cases of misappropriation will be applicable if the domestic ABS framework of a Contracting Party providing a genetic resource is in conformity with paragraph 1 of [OT III.B.2.2]

Explanations and Rationale

The EU considers that international access standards should be a key component of the international ABS regime, including a simplified access procedure for cases of non-commercial research. The establishment of international access standards is, in our view, also a pre-requisite for potential additional measures to support compliance in cases of misappropriation of genetic resources. As identified in Operational Text III.B.2.2) paragraph 2, the additional measures to support compliance in cases of misappropriation will only be applicable if the domestic ABS framework of a Contracting Party providing a genetic resource is in conformity with paragraph 1 of Operational Text III.B.2.2).

2) Development of tools to monitor compliance:

(b) Information technology for tracking

Views

The EU welcomes the opportunity to further discuss steps that allow tracking of genetic resources in cases of doubt on the fulfilment of ABS requirements by users, with a view to submitting an example of operational text and underlying rationale prior to ABS WG8. The EU also stresses the need to ensure that the international regime is crafted in a way that maximises the utility of modern IT tools to ABS governance. The EU envisages an international regime that is practical, and minimises costs and administrative burden for both providers and users.

(c) Disclosure requirements

Views

The EU recalls its proposal to the World Intellectual Property Organization (WIPO) of December 2004 that sets out a balanced and effective way to include in international patent law a binding requirement to disclose the origin or source of genetic resources and associated traditional knowledge in patent applications. The disclosure requirement as proposed by the EU would, if adopted, allow States to keep track, at global level, of all patent applications with regard to genetic resources and thereby enhance transparency about uses of genetic resources that have left the providing country.

In the context of the ongoing WTO negotiations of the Doha Development Agenda the EU has agreed to amend the WTO Agreement on Trade-Related Aspects of Intellectual Property rights (TRIPS) to include a mandatory requirement for the disclosure of the country providing/source of genetic resources, and/or associated traditional knowledge for which a definition would be agreed, in patent applications. Patent applications would not be processed without completion of the disclosure requirement. On substance the EU would not go beyond its above-mentioned proposal in WIPO.

3) Development of tools to enforce compliance:

Views

The EU looks forward to the deliberations of the Group of Legal and Technical Experts on ABS compliance issues that will take place in Tokyo, 27-30 January 2009. The EU expects to benefit from the advice of this group and intends to submit examples of operational text and underlying rationale prior to ABS WG8.

(a) Measures to ensure access to justice with the aim of enforcing ABS arrangements

(b) Dispute settlement mechanisms:

(i) Inter-State

(ii) Private international law

(iii) Alternative dispute resolution

(c) Enforcement of judgments and arbitral awards across jurisdictions

(d) Information exchange procedures between national focal points for access and benefit sharing to help providers obtain relevant information in specific cases of alleged infringements of prior-informed-consent requirements

(e) Remedies and sanctions

4) Measures to ensure compliance with customary law and local systems of protection

INDIA

India's Views for Seventh Meeting of Ad hoc Open-ended Working Group on Access and Benefit sharing (ABSWG-7)

The International Regime

1. Objective

1. Effectively implement the provisions in Articles 15, 8(j), 1, 16 and 19.2 of the Convention specifically by:

- regulating access to genetic resources, their derivatives and associated traditional knowledge in a transparent manner;

- Ensuring fair and equitable sharing of benefits arising out of the utilization of genetic resources, their derivatives and associated traditional knowledge and to prevent their misappropriation and misuse;

- Securing compliance in user countries with national laws and requirements, including PIC and MAT, of the country of origin providing those resources or of the Party that has acquired those resources in accordance with the Convention on Biological Diversity.

2. Scope

1. The international regime on access and benefit-sharing applies to genetic resources, and their derivatives, as well as associated traditional knowledge, and derivatives of traditional knowledge associated with genetic resources, innovations and practices.

2. The international regime on access and benefit-sharing does not apply to:

- Human genetic resources;

- Species listed in Annex I of the International Treaty on Plant Genetic Resources for Food and Agriculture unless they are used beyond the purpose of the said treaty;

- Genetic resources, including marine genetic resources found in areas beyond national jurisdiction.

3. Main components

A. Fair and equitable benefit sharing

1. Parties shall take measures and establish minimum conditions and standards for ensuring fair and equitable sharing of results of research, and of benefits arising from every commercial and other forms of utilization of genetic resources, derivatives and associated traditional knowledge, upon mutually agreed terms.

2. The benefits shared shall be monetary and/or non-monetary. Monetary benefits may include:

- Access fees/fee per sample;
- Up-front payments;
- Milestone payments;
- Payment of royalties;
- Licence fees in case of commercialization;
- Research funding; and
- Investment in joint ventures.

Non-monetary benefits may include:

- Sharing of research and development results;
- Participation in product development;
- Collaboration, cooperation and contribution in education and training;
- Transfer to the provider of the genetic resources, their derivatives and/or associated traditional knowledge, the technology developed using such resources and knowledge, including biotechnology, or the technology which is relevant to the conservation and sustainable use of biological diversity, on fair and most favourable terms, including on concessional and preferential terms where mutually agreed.
- Strengthening capacities to enable effective technology transfer to user developing country Parties and to Parties that are countries with economies in transition and technology development in the country of origin that provides genetic resources. Also to facilitate abilities of indigenous and local communities to conserve and sustainably use their genetic resources;
- Institutional capacity-building;
- Human and material resources to strengthen the capacities for the administration and enforcement of access regulations;
- Training related to genetic resources with the full participation of providing Parties, and where possible, in such Parties;
- Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;
- Contributions to the local economy;
- Food and livelihood security benefits; and
- Joint ownership of relevant intellectual property rights.

B. Access to genetic resources

1. States have sovereign rights over their own genetic resources, and the authority to determine access to genetic resources, their derivatives and associated traditional knowledge rests with the national governments and is subject to national legislation.

2. Parties shall take measures, which are clear and transparent, to facilitate access for environmentally sound uses, on mutually agreed terms and subject to prior informed consent of country providing such resources, so as to ensure fair and equitable sharing of benefits arising from such use to the country providing the resource including by using certificate of compliance with national legislations.

C. Compliance

1. Compliance to the international regime shall be ensured through a mandatory internationally recognized certificate of compliance issued by a national competent authority.

2. Parties shall establish other effective supporting mechanisms for compliance at border check points, IPR offices, entities funding research, etc., including by using certificate of compliance with national legislations, so as to prevent misappropriation of resources.

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

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

D. Traditional knowledge associated with genetic resources

1. Parties shall take measures to ensure fair and equitable sharing of benefits arising from the use of traditional knowledge associated with genetic resources in consultation with the holders of such knowledge.

E. Capacity building

1. The international regime shall provide for capacity building of developing country Parties, for development of national legislation, participation in negotiations, information and communication technology, development and use of valuation methods, monitoring and enforcing compliance, technology transfer and cooperation, etc.

4. Nature

1. The international regime shall be composed of a single legally binding instrument containing a set of principles, norms, rules and compliance and enforcement measures.

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MEXICO

Annex I Decision IX/12 CBD

OPINIÓN DE MÉXICO

THE INTERNATIONAL REGIME

I. OBJECTIVE /

Effectively implement the provisions [in Articles 15, 8(j), 1, 16 and 19.2] of the Convention [and its three objectives], specifically by:

Opinión:

Eliminar del texto en el preámbulo, los primeros corchetes, conservando los artículos 15, 8j), 1, 16 y 19.2, en particular es importante conservar el Artículo 19.2, a fin de que la redacción no sea limitativa de los aspectos que tratará el régimen internacional. En los últimos corchetes, modificar la redacción para que se refiera únicamente al tercer objetivo del CBD.

~~[Facilitating]~~[Regulate] access to genetic resources, [their derivatives] [and products] [and associated traditional knowledge];]

Opinión:

El término regular es el adecuado para un régimen, Se considera que el régimen debe ser vinculante y contener elementos no vinculantes, se sugiere eliminar el término facilitar pues ya es parte del CBD, conjuntamente con la aplicación de las Directrices de Bonn. En dado caso que se quisiera conservar dicho término, la redacción debe señalar que el objeto del Régimen es regular el acceso a los recursos genéticos y facilitar la implementación de las disposiciones del CBD.

Un régimen internacional es transparente *per se*, por la forma en que se lleva a cabo el proceso en que se construye.

En el primer párrafo se propone la inclusión del término "derivados". Este término está aún en debate, de hecho aún no se ha determinado que definición – de las varias disponibles – sería la que se utilizaría en el régimen, será pertinente esperar a la publicación de los resultados de la reunión del Grupo de Expertos realizado en Namibia. Lo que hay que tener muy claro es que el argumento de que su inclusión va más allá del propio Convenio, no viene se sustenta, pues el RI se aprobaría en la COP 10, que es un equivalente a órgano legislativo y, por tanto, bien puede hacer esa extensión del Convenio.

Ensuring the effective, fair and equitable sharing of benefits arising out of their utilization, [their derivatives] [and associated traditional knowledge] [and to prevent their misappropriation and misuse];

Opinión:

Se propone incluir derivados, conocimiento tradicional asociado. Se sugiere eliminar el texto del último corchete, ya que es redundante y es una connotación negativa que no debería formar parte del objetivo.

Se propone eliminar también productos, porque su inclusión depende de la definición de derivados. Nuestra posición es que una definición medianamente amplia de derivados no requeriría la inclusión de productos en el texto.

[Securing compliance in user countries with national laws and requirements, including PIC and MAT, of the country providing those resources or of the Party that has acquired those resources in accordance with the Convention on Biological Diversity].

Opinión:

Se sugiere eliminar los corchetes. Se sugiere eliminar la palabra origen.

Se considera pertinente que se refiera al país proveedor del recurso, no país origen, en términos biológicos.

[taking into account all rights over those resources, including the rights of indigenous and local communities, and ensuring compliance with PIC.]

Opinión:

Eliminar redacción última que se refiere a las comunidades indígenas, esta sección puede quedar en el proemio y en el ámbito, no en los objetivos.

II. SCOPE 21/

Option 1 (Consolidated text of submissions made at WG-ABS 6)

1. The international regime on access and benefit-sharing applies to [biological resources,] genetic resources, [derivatives,] as well as [to their] [associated] traditional knowledge, innovations and practices ~~[in accordance with Article 8(j)]within national jurisdiction and of a transboundary nature][in accordance with the relevant provisions of the CBD]~~

Opinión:

El ámbito debe determinar el alcance del instrumento legal. Partiendo de la CBD parecería bastante claro cuál puede ser este. Sin embargo, el tema, ya se ha mencionado, es muy complejo y toca aspectos de vanguardia tecnológica en los que el derecho, bajo el que se deben enmarcar las actividades realizadas con estas nuevas tecnologías, está en etapa de gestación. Ello da pie al debate de hasta donde puede y debe llegar un RI como el que se está elaborando. A la pregunta ¿Que debe cubrir el RI? se está contestando de la siguiente forma:

Se sugiere eliminar la última parte le aplica el artículo 4 del CBD que se refiere al ámbito jurisdiccional del Convenio. El ámbito debería comprender, al menos, los aspectos:

Material: Los recursos genéticos y sus derivados, los conocimientos tradicionales asociados, los beneficios derivados del acceso.

Temporal: Sólo cubrirá los materiales después de la entrada en vigor del CBD el 29 de diciembre de 1993.

Tratándose de recursos biológicos y genéticos, a los que se haya tenido acceso en el territorio de las Partes, después de la entrada en vigor del Convenio.

Espacial: El régimen aplicará a las Partes.

Jurisdiccional: En términos del artículo 4 del CBD, las zonas situadas dentro de los límites de la jurisdicción nacional.

[2. Subject to paragraph 1, the international regime on access and benefit-sharing applies to:

(a) [Benefits arising from commercial and other utilization] [from] [genetic resources acquired after] the entry into force of the ~~[internacional regime]~~ [Convention on Biological Diversity];

Consideramos que la vigencia debe ser a partir de la entrada en vigor del Convenio, se sugiere eliminar por tanto lo que se refiere al régimen internacional y eliminar corchetes del resto de la oración.

[(b) Continuing benefits arising from commercial and other utilization taken prior to the coming into force of the Convention on Biological Diversity.]]

De acuerdo, eliminar corchetes

3. The international regime on access and benefit-sharing does not apply to:

(a) [Human genetic resources;]

De acuerdo, eliminar corchetes

(b) [Genetic resources that were acquired before the entry into force of the Convention on Biological Diversity on 29 December 1993 [or before the entry into force for a Party];] [Genetic material acquired prior to the national ratification of the Convention on Biological Diversity [and since then cultivated *ex situ]*;]

De acuerdo, eliminar los primeros y los segundos corchetes.

Es necesario aclarar lo referente a las colecciones ex situ, para definir opinión de México.

(c) [Genetic material already made freely available by the country of origin;]

(d) [[Species] [listed in Annex I of] [genetic resources covered under] the International Treaty on Plant Genetic Resources for Food and Agriculture [unless they are used beyond the purpose of the said treaty];]

México no ha ratificado este Tratado, pero no debe excluirlos, sino que aquel tratado debe ser considerado como un régimen específico dentro de este RI. Las mismas especies son consideradas para la alimentación o no, por lo que sí deben ser parte de este RI, aunque el tratado les de un trato excepcional bajo ciertos usos.

(e) [Genetic resources, including marine genetic resources found in areas beyond national jurisdiction;]

De acuerdo, eliminar corchetes

(f) [Genetic resources located in the Antarctic Treaty Area.]

De acuerdo, eliminar corchetes

Option 2

The international regime applies to all genetic resources and associated traditional knowledge, innovations and practices covered by the Convention on Biological Diversity, subject to other international obligations, with the exclusion of human genetic resources and genetic resources beyond national jurisdiction.

Esta es la mejor opción para el ámbito, consideramos a las demás En nuestra opinión el ámbito del régimen debe ser:

(b) Los recursos genéticos y los derivados

(c) El conocimiento tradicional asociado a los recursos genéticos y sus derivados.

(a) Los beneficios derivados de la utilización de los recursos genéticos, los derivados y productos.

Option 3

1. Will cover:

Access to genetic resources and promotion and safeguarding of fair and equitable sharing of the benefits arising out of the utilization of genetic resources in accordance with relevant provisions of the Convention on Biological Diversity;

Traditional knowledge, innovations and practices in accordance with Article 8(j).

2. Outside the scope will be:

Genetic resources that were acquired before the entry into force of the Convention on Biological Diversity on 29 December 1993;

Human genetic resources.

3. The international regime on access and benefit-sharing established in the framework of the Convention on Biological Diversity should provide flexibility to respect existing and allow for the implementation and potential and further development of other, more specialized international access and benefit-sharing systems.

4. Special consideration will be given to:

Genetic resources covered by the FAO International Treaty on Plant Genetic Resources for Food and Agriculture when these are accessed for research, breeding or training for the purpose for food and agriculture;

The relationship with the International Convention for the Protection of New Varieties of Plants (UPOV);

Marine genetic resources found in areas beyond national jurisdiction;

Genetic resources located in the Antarctic Treaty area;

Animal genetic resources for food and agriculture;

Work within the WIPO Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore;

Genetic resources within the remit of the FAO Commission on Genetic Resources for Food and Agriculture.

III. Main Components

A. Fair and equitable benefit-sharing

1. Components to be further elaborated with the aim of incorporating them in the international regime

1) Linkage of access to the fair and equitable sharing of benefits

2) Benefits to be shared on mutually agreed terms

3) Monetary and/or non-monetary benefits

4) Access to and transfer of technology

5) Sharing of results of research and development on mutually agreed terms

6) Effective participation in research activities, and/or joint development in research activities

7) Mechanisms to promote equality in negotiations

8) Awareness-raising

9) Measures to ensure participation and involvement of indigenous and local communities in mutually agreed terms and sharing of benefits with traditional knowledge holders

10) Mechanisms to encourage benefits to be directed toward conservation and sustainable use of biodiversity and socio-economic development, in particular the Millennium Development Goals (MDGs) in accordance with national legislation

2. Components for further consideration

1) Development of international minimum conditions and standards

2) Benefit-sharing for every use

La participación de los beneficios en todo tipo de utilización ha generado confusión pues hay varios países que proponen que la utilización con fines científicos tenga otro tratamiento. No obstante, al referirse exclusivamente a "los beneficios", no debería haber duda de que si la actividad científica genera beneficios, estos deben entrar al ámbito del RI. Pueden ser no monetarios, como es la transferencia de tecnología y la creación de capacidades.

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

3) Multilateral benefit-sharing options when origin is not clear or in transboundary situations

Es necesario especificar el contenido de esta opción, suponemos se refiere a que habrá casos en donde no se sepa exactamente de donde vino el material cuando se comparte un mismo ecosistema por varios países parte, ya que la participación de beneficios multilateral cuando el origen de los recursos no sea claro da pié para contenciosos aún cuando trata de evitarlos.. Es clara la razón para que se incluya, los recursos biológicos y, por tanto, los genéticos, no saben de fronteras políticas, por lo que se dan muchos casos que entran en este supuesto. Esta incertidumbre no debe ser utilizada como pretexto para que no haya distribución de los beneficios, la creación de un fondo o bolsa multilateral podría sería complemento del punto anterior.

4) Establishment of trust funds to address transboundary situations

Es necesario aclarar puntos de vista entre las Partes, ya que este elemento, no es objeto del régimen.

5) Development of menus of model clauses for potential inclusion in material transfer agreements

De acuerdo.

6) Enhanced utilization of Bonn Guidelines

B. Access to genetic resources 22/

1. Components to be further elaborated with the aim of incorporating them in the international regime

1) Recognition of the sovereign rights and the authority of Parties to determine access

2) Linkage of access to fair and equitable sharing of benefits

3) Legal certainty, clarity and transparency of access rules

2. Components for further consideration

1) Non-discrimination of access rules

La no discriminación en las reglas de acceso es una solicitud por parte de los países potencialmente usuarios que prevén ciertos comportamientos proteccionistas. Es una demanda que coincide y es coherente con la mayoría de los compromisos internacionales de comercio e inversión entre naciones.

2) International access standards (that do not require harmonization of domestic access legislation) to support compliance across jurisdictions

Aún no se ha definido adecuadamente. Consideramos que esta propuesta consiste en tener bien definido qué componente del acceso y bajo qué criterios debe ser respetado transfronterizamente. El propósito es conocer qué acto legal se debe dar como cumplido y digno de recibir protección legal

3) Internationally developed model domestic legislation

Los modelos de legislación nacional desarrollados internacionalmente deben quedar como un componente voluntario.

4) Minimization of administration and transaction costs

La reducción al mínimo de los costos es un deseo generalizado, al combatirse a la biopiratería – es decir la ilegalidad – este componente se convierte en algo ineludible. No obstante, el fraseo no es afortunado y pareciera que debe sacrificarse la regulación ante la eficiencia. En este sentido, el componente deberá ser redactado con mayor claridad.

5) Simplified access rules for non-commercial research

El tema de las reglas de acceso simplificadas para la investigación no comercial, debe ser evaluado en profundidad. En principio, no parece haber razón para diferenciar acceso comercial del científico en un régimen de distribución equitativa de beneficios; si hay beneficios estos deben ser distribuidos. Si bien es cierto que la investigación científica actual se traduce en que una muestra puede transitar diversas fronteras en un lapso muy breve de tiempo, con las complicaciones de monitoreo que ello implica para un régimen como el que se diseña, también es cierto que el tema del RI es la distribución de beneficios – monetarios y no monetarios – por lo que el régimen debe cumplir de cualquier manera con el CPI y los TMA, que son sus pilares y los componentes más complejos. En todo caso las reglas simplificadas son de responsabilidad sobre las muestras, independientemente de los intercambios de material genético que efectúen los laboratorios.

C. Compliance

La creación de sistemas de seguimiento y presentación de informes es clave en una materia en la que los productos al final de la cadena productiva requieren de varios años dentro del proceso de producción. Sin duda, para el mejor funcionamiento de estos sistemas se requiere de la utilización de la mejor y más actual tecnología de la información para el seguimiento.

1. Components to be further elaborated with the aim of incorporating them in the international regime

1) Development of tools to encourage compliance:

(a) Awareness-raising activities

2) Development of tools to monitor compliance:

(a) Mechanisms for information exchange

b) Internationally recognized certificate issued by a domestic competent authority

3) Development of tools to enforce compliance

2. Components for further consideration

1) Development of tools to encourage compliance:

(a) International understanding of misappropriation/misuse

De acuerdo, es fundamental para el RI

(b) Sectoral menus of model clauses for material transfer agreements

De acuerdo, sin embargo consideramos más conveniente que dichas cláusulas se desarrollen en función del uso de los recursos genéticos en lugar de por sector.

(c) Codes of conduct for important groups of users

(d) Identification of best-practice codes of conduct

De acuerdo, es fundamental para el RI

(e) Research funding agencies to oblige users receiving research funds to comply with specific access and benefitsharing requirements

(f) Unilateral declaration by users

(g) International access standards (that do not require harmonization of domestic access legislation) to support compliance across jurisdictions

2) Development of tools to monitor compliance:

(a) Tracking and reporting systems

(b) Information technology for tracking

(c) Disclosure requirements

(d) Identification of check points

Opinión

Se requiere de un trabajo mayor en la búsqueda e identificación de puntos de verificación. Esta labor no conlleva ningún compromiso, por lo que no se entiende, más que por motivos de estrategia de negociación, su no inclusión como componente aceptado y por discutirse. Este es el mismo caso para la propuesta de utilización de tecnologías de la información.

3) Development of tools to enforce compliance:

(a) Measures to ensure access to justice with the aim of enforcing ABS arrangements

(b) Dispute settlement mechanisms:

(i) Inter-State

(ii) Private international law

(iii) Alternative dispute resolution

(c) Enforcement of judgments and arbitral awards across jurisdictions

(d) Information exchange procedures between national focal points for access and benefitsharing to help providers obtain relevant information in specific cases of alleged infringements of prior-informed-consent requirements

(e) Remedies and sanctions

4) Measures to ensure compliance with customary law and local systems of protection

Una vez observada alguna conducta que aparentemente viole algún contrato de bioprospección, el RI deberá actuar, para ello se deben desarrollar instrumentos para la observancia el cumplimiento. Entre los que se encuentran las medidas para asegurar el acceso a la justicia con miras a aplicar los acuerdos sobre acceso y participación en los beneficios. Aparentemente, hay cierta confusión pues este componente aparece duplicado, pues ya fue aceptado en la sección de justa y equitativa distribución de beneficios.
También se proponen componentes normales para un régimen jurídicamente vinculantes, que tendrán que esperar hasta que exista consenso sobre la naturaleza del régimen. El mecanismo de solución de controversias podrá ahorrar costosos y largos juicios que podrían darse de acuerdo con el derecho internacional privado, que sin duda debe tener un papel importante en la aplicación del régimen, simplemente ante la presentación de pruebas de incumplimiento de algún contrato.

Se debe definir más claramente a qué se refiere cuando se define:"resolución de disputas alternativa". Cualquier instrumento en esa dirección, a priori, parecería aceptable.

La aplicación de sentencias y laudos arbitrales entre las jurisdicciones debe ser evaluada más a fondo. Si se piensa como un componente obligatorio, habría que señalar lo difícil que sería sin la generación de protocolos particulares o específicos y más bien bilaterales entre las Partes con lo cual el RI estaría sujeto a arreglos posteriores y, sería en cierta manera, inválido.

Otro componente que es ineludible para que exista un buen RI es la generación de "procedimientos de intercambio de información entre centros de coordinación nacionales de acceso y participación en los beneficios para ayudar a los proveedores a obtener la información pertinente en casos específicos de supuestas infracciones de los requisitos de consentimiento fundamentado previo". Es, más bien, un componente de apoyo al seguimiento.

D. Traditional knowledge associated with genetic resources 23/

1. Components to be further elaborated with the aim of incorporating them in the international regime

1) Measures to ensure the fair and equitable sharing with traditionalknowledge holders of benefits arising out of the utilization of traditional knowledge in accordance with Article 8(j) of the Convention on Biological Diversity

2) Measures to ensure that access to traditional knowledge takes place in accordance with community level procedures

3) Measures to address the use of traditional knowledge in the context of benefit-sharing arrangements

4) Identification of best practices to ensure respect for traditional knowledge in ABS related research

5) Incorporation of traditional knowledge in development of model clauses for material transfer agreements

6) Identification of individual or authority to grant access in accordance with community level procedures

7) Access with approval of traditionalknowledge holders

8) No engineered or coerced access to traditional knowledge

2. Components for further consideration

1) Prior informed consent of, and mutually agreed terms with, holders of traditional knowledge, including indigenous and local communities, when traditional knowledge is accessed

2) Internationally developed guidelines to assist Parties in the development of their domestic legislation and policies

3) Declaration to be made on the internationally recognized certificate as to whether there is any associated traditional knowledge and who owners of traditional knowledge are

4) Community-level distribution of benefits arising out of traditional knowledge

E. Capacity

1. Components to be further elaborated with the aim of incorporating them in the international regime

1) Capacity-building measures at all relevant levels for:

(a) Development of national legislation

(b) Participation in negotiations, including contract negotiations

(c) Information and communication technology

(d) Development and use of valuation methods

(e) Bioprospecting, associated research and taxonomic studies

(f) Monitoring and enforcing compliance

(g) Use of access and benefit-sharing for sustainable development

2) National capacity self-assessments to be used as a guideline for minimum capacity-building requirements

3) Measures for technology transfer and cooperation

4) Special capacity-building measures for indigenous and local communities

5)Development of menus of model clauses for potential inclusion in material transfer agreements

2. Components for further consideration

1) Establishment of a financial mechanism

IV. NATURE

Compilation of proposals on nature 24/

1. Recommendation of Co-Chairs of the Working Group

Options

1. One legally binding instrument

2. A combination of legally binding and non-binding instruments

3. A non-binding instrument

2. Submissions

Option 1

The international regime should be legally binding. In addition, it should stress more cooperative enforcement between parties and *not* refer conflicts primarily to private international law, which is not only expensive, but also a strain on resource poor countries.

Option 2

1. One legally binding instrument

2. A combination of legally binding and/***or*** non-binding instruments

3. A non-binding instrument

Se sugiere la Opción 2, ya que los elementos no vinculantes se agregarán como anexos al Régimen Internacional

Option 3

The international regime shall be composed of a single legally binding instrument containing a set of principles, norms, rules and compliance and enforcement measures.

Option 4

The nature should be discussed after deliberations of the substance of an international regime are completed. For the time being, Japan suggests the following: the international regime could be composed of one or more non-binding instruments within a set of principles, norms, rules and decision-making procedures.

Option 5

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

ENGLISH TRANSLATION

Annex I Decision IX/12 CBD

OPINIÓN DE MÉXICO

THE INTERNATIONAL REGIME

I. OBJECTIVE /

Effectively implement the provisions [in Articles 15, 8(j), 1, 16 and 19.2] of the Convention [and its three objectives], specifically by:

Opinion:

Remove the first set of brackets from the preamble, and keep the reference to Articles 15, 8j), 1, 16 and 19.2. It is particularly important to keep Article 19.2, so that the wording is not restrictive with regard to what the international regime will cover. In the last set of brackets, change the wording so as to refer only to the CBD's third objective.

~~[Facilitating]~~[Regulate] access to genetic resources, [their derivatives] [and products] [and associated traditional knowledge];]

Opinion:

The term 'regulate' is appropriate for a regime. In our view, the regime should be binding, with non-binding elements. We suggest that the term 'facilitating' be removed, seeing as it is already in the CBD with regard to implementation of the Bonn Guidelines. If this term is not removed, the wording should indicate that the purpose of the Regime is to regulate access to genetic resources, and facilitate the implementation of CBD provisions.

An international Regime is transparent *per se*, given the process undertaken to build such a regime.

The term 'derivatives' is proposed for inclusion in the first paragraph. That term is still under debate. No decision has been made regarding which of many possible definitions will be used for the Regime. It is therefore relevant to await the report of the Expert Group meeting in Namibia. It is very important to keep in mind that the argument that including derivatives goes beyond the scope of the Convention is unfounded, seeing as the IR was approved at COP 10, which is the equivalent of a legislative body, and can therefore extend the Convention in this manner.

Ensuring the effective, fair and equitable sharing of benefits arising out of their utilization, [their derivatives] [and associated traditional knowledge] [and to prevent their misappropriation and misuse];

Opinion:

We propose to include derivatives and associated traditional knowledge. We suggest that the text in the final bracket be deleted because it is redundant and has a negative connotation that should not be part of the objective.

The word 'productos' (products) in the Spanish text should also be removed, because the definition of derivatives will determine whether or not it should be included. In our view, a moderately broad definition of derivatives would not require the addition of the word 'productos' in the Spanish text.

[Securing compliance in user countries with national laws and requirements, including PIC and MAT, of the country providing those resources or of the Party that has acquired those resources in accordance with the Convention on Biological Diversity].

Opinion:

The brackets should be removed. The Word 'orígen' (origin) should also be deleted from the Spanish text.

In our view, in biological terms, it is relevant to refer to the country providing the resource, rather than the country of origin.

[taking into account all rights over those resources, including the rights of indigenous and local communities, and ensuring compliance with PIC.]

Opinion:

Delete the wording about indigenous communities. This section could go in the preamble or scope, but not in the objectives.

II. SCOPE 21/

Option 1 (Consolidated text of submissions made at WG-ABS 6)

1. The international regime on access and benefit-sharing applies to [biological resources,] genetic resources, [derivatives,] as well as [to their] [associated] traditional knowledge, innovations and practices ~~[in accordance with Article 8(j)]within national jurisdiction and of a transboundary nature][in accordance with the relevant provisions of the CBD]~~

Opinion:

The Scope should determine the legal instrument's reach. The CBD seems to give a fairly clear indication of said reach. However, as it has already been mentioned, this issue is very complex, and touches on aspects of cutting-edge technology for which governing legal provisions are at an embryonic stage. This begs the question of how far the reach of an IR like the one we are creating should be. Here is the answer to the question "what should the IR cover?":

We suggest deleting the last part that applies to Article 4 of the CBD referring to the jurisdictional scope of the Convention. The scope of the IR should at least cover the following aspects:

Material: Genetic resources and derivatives, associated traditional knowledge, benefits arising from access.

Time: It will only cover material after the date of the CBD's entry into force on December 29, 1993.

This means biological and genetic resources accessed within the territory of the Parties, following the Convention's entry into force.

Space: The Regime will apply to the Parties.

Jurisdiction: According to Article 4 of the CBD, the areas located within the limits of national jurisdiction.

[2. Subject to paragraph 1, the international regime on access and benefit-sharing applies to:

(a) [Benefits arising from commercial and other utilization] [from] [genetic resources acquired after] the entry into force of the ~~[internacional regime]~~ [Convention on Biological Diversity];

We believe that it should be in effect from the time of the Convention's entry into force. We therefore suggest that the reference to the international regime be deleted, and that the brackets be removed from the rest of the sentence.

[(b) Continuing benefits arising from commercial and other utilization taken prior to the coming into force of the Convention on Biological Diversity.]]

We agree, remove brackets

3. The international regime on access and benefit-sharing does not apply to:

(a) [Human genetic resources;]

We agree, remove brackets

(b) [Genetic resources that were acquired before the entry into force of the Convention on Biological Diversity on 29 December 1993 [or before the entry into force for a Party];] [Genetic material acquired prior to the national ratification of the Convention on Biological Diversity [and since then cultivated *ex situ]*;]

We agree, remove the first and second brackets.

Mexico requires further clarification regarding ex situ collections, in order to specify its opinion.

(c) [Genetic material already made freely available by the country of origin;]

(d) [[Species] [listed in Annex I of] [genetic resources covered under] the International Treaty on Plant Genetic Resources for Food and Agriculture [unless they are used beyond the purpose of the said treaty];]

Mexico has not ratified this Treaty, but such resources should not be excluded. Rather, the Treaty should be considered as a specific regime within this IR. The same species are considered, regardless of whether they are used for food, which means that they must be covered by this IR, though the Treaty grants them exceptional treatment for certain uses.

(e) [Genetic resources, including marine genetic resources found in areas beyond national jurisdiction;]

We agree, remove brackets

(f) [Genetic resources located in the Antarctic Treaty Area.]

We agree, remove brackets

Option 2

The international regime applies to all genetic resources and associated traditional knowledge, innovations and practices covered by the Convention on Biological Diversity, subject to other international obligations, with the exclusion of human genetic resources and genetic resources beyond national jurisdiction.

We consider that this is the best option for the scope. In our opinion, the regime should cover:

(b) Genetic resources and derivatives.

(c) Traditional knowledge associated with genetic resources and derivatives.

(a) Benefits arising from the use of genetic resources, derivatives and products.

Option 3

1. Will cover:

Access to genetic resources and promotion and safeguarding of fair and equitable sharing of the benefits arising out of the utilization of genetic resources in accordance with relevant provisions of the Convention on Biological Diversity;

Traditional knowledge, innovations and practices in accordance with Article 8(j).

2. Outside the scope will be:

Genetic resources that were acquired before the entry into force of the Convention on Biological Diversity on 29 December 1993;

Human genetic resources.

3. The international regime on access and benefit-sharing established in the framework of the Convention on Biological Diversity should provide flexibility to respect existing and allow for the implementation and potential and further development of other, more specialized international access and benefit-sharing systems.

4. Special consideration will be given to:

Genetic resources covered by the FAO International Treaty on Plant Genetic Resources for Food and Agriculture when these are accessed for research, breeding or training for the purpose for food and agriculture;

The relationship with the International Convention for the Protection of New Varieties of Plants (UPOV);

Marine genetic resources found in areas beyond national jurisdiction;

Genetic resources located in the Antarctic Treaty area;

Animal genetic resources for food and agriculture;

Work within the WIPO Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore;

Genetic resources within the remit of the FAO Commission on Genetic Resources for Food and Agriculture.

III. Main Components

A. Fair and equitable benefit-sharing

1. Components to be further elaborated with the aim of incorporating them in the international regime

1) Linkage of access to the fair and equitable sharing of benefits

2) Benefits to be shared on mutually agreed terms

3) Monetary and/or non-monetary benefits

4) Access to and transfer of technology

5) Sharing of results of research and development on mutually agreed terms

6) Effective participation in research activities, and/or joint development in research activities

7) Mechanisms to promote equality in negotiations

8) Awareness-raising

9) Measures to ensure participation and involvement of indigenous and local communities in mutually agreed terms and sharing of benefits with traditional knowledge holders

10) Mechanisms to encourage benefits to be directed toward conservation and sustainable use of biodiversity and socio-economic development, in particular the Millennium Development Goals (MDGs) in accordance with national legislation

2. Components for further consideration

1) Development of international minimum conditions and standards

2) Benefit-sharing for every use

Benefit-sharing for every use has created confusion, seeing as various countries propose that use for scientific purposes be treated differently. However, by referring exclusively to "benefits", there should be no doubt that if the scientific activity generates benefits, said benefits should be covered by the IR. Said benefits may be non-monetary, such as technology transfer and capacity building.

We propose and hope that benefits ultimately be used for the conservation and sustainable use of biodiversity, in accordance with the Convention. However, some have rightfully pointed out that benefits will be used according to the providers' priorities, mainly in accordance with the PIC and MAT.

3) Multilateral benefit-sharing options when origin is not clear or in transboundary situations

The content of this option must be clarified. We assume that it refers to the fact that there will be cases in which it is not known exactly where the material came from, when a single ecosystem is shared by various Parties. Multilateral benefit sharing can give rise to disputes, even when efforts are made to avoid them. The reason for including this is clear, seeing as biological and genetic resources are oblivious of political boundaries, giving rise to a number of cases in this situation. This uncertainty should not be used as a pretext not to share benefits. The establishment of a multilateral fund or account might help complement the above point.

4) Establishment of trust funds to address transboundary situations

The Parties must clarify their points of view, seeing as this element is not covered by the regime.

5) Development of menus of model clauses for potential inclusion in material transfer agreements

We agree.

6) Enhanced utilization of Bonn Guidelines

B. Access to genetic resources 22/

1. Components to be further elaborated with the aim of incorporating them in the international regime

1) Recognition of the sovereign rights and the authority of Parties to determine access

2) Linkage of access to fair and equitable sharing of benefits

3) Legal certainty, clarity and transparency of access rules

2. Components for further consideration

1) Non-discrimination of access rules

Non-discrimination of access rules has been requested by potential user countries that foresee some protectionist behaviour. This request is consistent with most international trade and investment commitments among countries.

2) International access standards (that do not require harmonization of domestic access legislation) to support compliance across jurisdictions

This has not yet been properly defined. We think this proposal involves properly defining which element of access should be complied with across jurisdictions, and according to which criteria. The purpose is to know what legal procedure should be carried out and deemed worthy of legal protection.

3) Internationally developed model domestic legislation

Internationally developed model domestic legislation should be a voluntary element.

4) Minimization of administration and transaction costs

Cost minimization is a general aspiration, and this aspect becomes inevitable in combating biopiracy, or illegal activity. However, the wording is unfortunate, and it would seem to indicate that regulation must be sacrificed to efficiency. This element must therefore be drafted more clearly.

5) Simplified access rules for non-commercial research

The issue of simplified access rules for non-commercial research must undergo in-depth examination. In principle, there seems to be no reason to differentiate between commercial and scientific access within a regime for fair benefit-sharing; if there are benefits, they must be shared. While it is true that current scientific research means that a sample may cross various borders over a short period, which creates monitoring headaches for a regime like the one being designed, it is also true that the IR deals with the sharing of benefits – be they monetary or non-monetary – which is why the regime must comply with the PIC and MAT, which are the pillars and most complex elements of the regime. In any event, the simplified rules have to do with responsibility for the samples, irrespective of the exchanges of genetic material carried out by laboratories.

C. Compliance

The establishment of monitoring and reporting systems is key in an area where the products at the outcome of the production chain spend a number of years within the production process. Without a doubt, the best and most up-to-date information technology is required for monitoring, to ensure optimum functioning of said systems.

1. Components to be further elaborated with the aim of incorporating them in the international regime

1) Development of tools to encourage compliance:

(a) Awareness-raising activities

2) Development of tools to monitor compliance:

(a) Mechanisms for information exchange

b) Internationally recognized certificate issued by a domestic competent authority

3) Development of tools to enforce compliance

2. Components for further consideration

1) Development of tools to encourage compliance:

(a) International understanding of misappropriation/misuse

We agree, this is essential for the IR

(b) Sectoral menus of model clauses for material transfer agreements

We agree, however, we think that it would be more appropriate for said clauses to be developed according to use of the genetic resources, rather than according to sector.

(c) Codes of conduct for important groups of users

(d) Identification of best-practice codes of conduct

We agree, this is essential for the IR

(e) Research funding agencies to oblige users receiving research funds to comply with specific access and benefit sharing requirements

(f) Unilateral declaration by users

(g) International access standards (that do not require harmonization of domestic access legislation) to support compliance across jurisdictions

2) Development of tools to monitor compliance:

(a) Tracking and reporting systems

(b) Information technology for tracking

(c) Disclosure requirements

(d) Identification of check points

Opinion

Further work is required to search for and identify check points. This work does not entail any commitment. We therefore do not understand why it has not been included as an agreed element for discussion, unless there are negotiation-strategy reasons for this. The same applies to the proposal to use information technology.

3) Development of tools to enforce compliance:

(a) Measures to ensure access to justice with the aim of enforcing ABS arrangements

(b) Dispute settlement mechanisms:

(i) Inter-State

(ii) Private international law

(iii) Alternative dispute resolution

(c) Enforcement of judgments and arbitral awards across jurisdictions

(d) Information exchange procedures between national focal points for access and benefitsharing to help providers obtain relevant information in specific cases of alleged infringements of prior-informed-consent requirements

(e) Remedies and sanctions

4) Measures to ensure compliance with customary law and local systems of protection

Once behaviour that seems to violate a bioprospecting contract has been detected, the IR must swing into action, which is why measures to ensure compliance must be developed. These include measures to ensure access to justice, in order to apply agreements on access and benefit sharing. There is seemingly some confusion, seeing as this element appears twice, and was accepted in the section on fair and equitable sharing of benefits.

The proposed measures include elements that are par-for-the-course in legally binding regimes, and a decision on those measures will have to await consensus on the nature of the regime. The dispute resolution mechanism could prevent long and costly trials that might take place under international private law, and must, without a doubt, play an

important role in the regime's implementation, simply upon presentation of evidence of non-compliance with a given contract.

The meaning of "alternative dispute resolution" must be defined more clearly. Any instrument for this purpose would seem acceptable in principle.

The enforcement of judgments and arbitral awards across jurisdictions must be considered more closely. If this is considered a mandatory element, it should be pointed out that it would be very difficult to do so without particular or specific protocols established bilaterally between Parties, making the IR subject to subsequent arrangements and, to a certain extent, invalid.

Another essential element for a good IR is the generation of "information exchange procedures between national focal points for access and benefit sharing to help providers obtain relevant information in specific cases of alleged infringements of prior-informed-consent requirements." This is, in fact, an element that supports monitoring.

D. Traditional knowledge associated with genetic resources 23/

1. Components to be further elaborated with the aim of incorporating them in the international regime

1) Measures to ensure the fair and equitable sharing with traditionalknowledge holders of benefits arising out of the utilization of traditional knowledge in accordance with Article 8(j) of the Convention on Biological Diversity

2) Measures to ensure that access to traditional knowledge takes place in accordance with community level procedures

3) Measures to address the use of traditional knowledge in the context of benefit-sharing arrangements

4) Identification of best practices to ensure respect for traditional knowledge in ABS related research

5) Incorporation of traditional knowledge in development of model clauses for material transfer agreements

6) Identification of individual or authority to grant access in accordance with community level procedures

7) Access with approval of traditional knowledge holders

8) No engineered or coerced access to traditional knowledge

2. Components for further consideration

1) Prior informed consent of, and mutually agreed terms with, holders of traditional knowledge, including indigenous and local communities, when traditional knowledge is accessed

2) Internationally developed guidelines to assist Parties in the development of their domestic legislation and policies

3) Declaration to be made on the internationally recognized certificate as to whether there is any associated traditional knowledge and who owners of traditional knowledge are

4) Community-level distribution of benefits arising out of traditional knowledge

E. Capacity

1. Components to be further elaborated with the aim of incorporating them in the international regime

1) Capacity-building measures at all relevant levels for:

(a) Development of national legislation

(b) Participation in negotiations, including contract negotiations

(c) Information and communication technology

(d) Development and use of valuation methods

(e) Bioprospecting, associated research and taxonomic studies

(f) Monitoring and enforcing compliance

(g) Use of access and benefit-sharing for sustainable development

2) National capacity self-assessments to be used as a guideline for minimum capacity-building requirements

3) Measures for technology transfer and cooperation

4) Special capacity-building measures for indigenous and local communities

5) Development of menus of model clauses for potential inclusion in material transfer agreements

2. Components for further consideration

1) Establishment of a financial mechanism

IV. NATURE

Compilation of proposals on nature 24/

1. Recommendation of Co-Chairs of the Working Group

Options

1. One legally binding instrument

2. A combination of legally binding and non-binding instruments

3. A non-binding instrument

2. Submissions

Option 1

The international regime should be legally binding. In addition, it should stress more cooperative enforcement between parties and *not* refer conflicts primarily to private international law, which is not only expensive, but also a strain on resource poor countries.

Option 2

1. One legally binding instrument

2. A combination of legally binding and/***or*** non-binding instruments

3. A non-binding instrument

We recommend option 2, seeing as non-binding elements will appear as annexes to the International Regime

Option 3

The international regime shall be composed of a single legally binding instrument containing a set of principles, norms, rules and compliance and enforcement measures.

Option 4

The nature should be discussed after deliberations of the substance of an international regime are completed. For the time being, Japan suggests the following: the international regime could be composed of one or more non-binding instruments within a set of principles, norms, rules and decision-making procedures.

Option 5

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

Annex II

TERMS OF REFERENCE OF THE EXPERT GROUPS ESTABLISHED IN PARAGRAPH 11 OF DECISION IX/12

A. Expert group on compliance

1. A group of technical and legal experts on compliance is established to further examine the issue of compliance in order to assist the Working Group on Access and Benefit sharing. The expert group shall provide legal and, as appropriate, technical advice, including, where appropriate, options and/or scenarios. The expert group will address the following questions:

(a) What kind of measures are available, or could be developed, in public and private international law to:

(i) Facilitate, with particular consideration to fairness and equity, and taking into account cost and effectiveness:

a) Access to justice, including alternative dispute resolution;

b) Access to courts by foreign plaintiffs;

(ii) Support mutual recognition and enforcement of judgments across jurisdictions; and

(iii) Provide remedies and sanctions in civil, commercial and criminal matters;

in order to ensure compliance with national access and benefit-sharing legislation and requirements, including prior informed consent, and mutually agreed terms;

(b) What kind of voluntary measures are available to enhance compliance of users of foreign genetic resources;

(c) Consider how internationally agreed definitions of misappropriation and misuse of genetic resources and associated traditional knowledge could support compliance where genetic resources have been accessed or used in circumvention of national legislation or without setting up of mutually agreed terms;

(d) How could compliance measures take account of the customary law of indigenous and local communities?

(e) Analyse whether particular compliance measures are needed for research with non-commercial intent, and if so, how these measures could address challenges arising from changes in intent and/or users, particularly considering the challenge arising from a lack of compliance with relevant access and benefit-sharing legislation and/or mutually agreed terms.

2. The expert group shall be regionally balanced and composed of thirty experts nominated by Parties and ten observers, including three observers from indigenous and local communities nominated by them, and remaining observers from, *inter alia*, international organizations and agreements, industry, research institutions/academia and non-governmental organizations.

B. Expert group on concepts, terms, working definitions and sectoral approaches

1. A group of technical and legal experts on concepts, terms, working definitions and sectoral approaches is established to further examine the issue of concepts, terms, working definitions and sectoral approaches in order to assist the Working Group on Access and Benefitsharing. The expert group shall provide legal and technical advice, including, where appropriate, options and/or scenarios. The expert group will address the following questions:

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

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

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

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

2.The expert group shall be regionally balanced and composed of thirty experts nominated by Parties and a total of fifteen observers from:

(a) Different sectors including, *inter alia,* industry, research institutions/academia, botanical gardens and other *ex situ* collection holders;

(b) International organizations and agreements, non-governmental organizations; and

(c) Including three representatives from indigenous and local communities nominated by them.

C. Expert Group on traditional knowledge associated with genetic resources

1. A group of technical and legal experts on traditional knowledge associated with genetic resources is established to further examine the issue of traditional knowledge associated with genetic resources in order to assist the Working Group on Access and Benefitsharing. The expert group shall provide legal and technical advice, including, where appropriate, options and/or scenarios. The expert group will address the following questions:

(a) What is the relationship between access and use of genetic resources and associated traditional knowledge?

(b) What practical impacts should the negotiations of the international regime take into account based on the range of community level procedures and customary systems of indigenous and local communities for regulating access to traditional knowledge associated with genetic resources at the community level?

(c) Identify the range of community level procedures and determine to what extent customary laws of indigenous and local communities regulate access to genetic resources and associated traditional knowledge at the community level and its relevance to the international regime;

(d) To what extent measures to ensure compliance with prior informed consent and mutually agreed terms under Article 15 also support the prior informed consent of indigenous and local communities for the use of their associated traditional knowledge?

(e) Identify elements and procedural aspects for the prior informed consent of holders of associated traditional knowledge when traditional knowledge associated with genetic resources is accessed also taking into account potential transboundary contexts of such associated traditional knowledge and identifying best practice examples;

(f) Is there a basis for prior informed consent for indigenous and local communities relative to traditional knowledge associated to genetic resources in international law? If so, how can it be reflected in the international regime?

(g) Assess options, considering the practical difficulties and distinct implementation challenges, for including traditional knowledge associated with genetic resources in a potential internationally recognized certificate issued by the competent domestic authority also by considering the possibility of a declaration on such certificate as to whether there is any associated traditional knowledge and who the relevant holders of traditional knowledge are;

(h) How to define traditional knowledge associated to genetic resources in the context of access and benefit-sharing?

2. The expert group shall be regionally balanced and composed of thirty experts nominated by Parties and fifteen observers, including seven observers from indigenous and local communities nominated by them, and remaining observers from, *inter alia*, international organizations and agreements, industry, research institutions/academia and non-governmental organizations.

3. Parties are also encouraged to nominate experts from indigenous and local communities where possible.

NAMIBIA ON BEHALF OF THE AFRICAN GROUP

THE INTERNATIONAL REGIME ON ACCESS AND BENEFIT SHARING- AFRICAN OPERATIVE TEXT AND EXPLANATIONS:

OBJECTIVE: (Operative Text)

To effectively implement the provisions in Art 1, 15, 16, 17, 18, 19 and 20 of the CBD through ensuring:

a) Appropriate and facilitated access to research and technology that is linked to conservation and sustainable use of biological diversity in accordance with Art 16.1, 16.2, 16.4, 16.5, 17, 18.4 and 18.5

b) Access to research and technology relevant to the genetic resources (GR) that is accessed in accordance with Art 15.6, 15.7, 16.3, 16.4, 16.5 and 19.1

c) Access to appropriate funding for developing countries to implement the CBD in accordance with Art 20.2

d) Appropriate and regulated access to GR only for environmentally sound uses based on PIC and MAT in accordance with Art 15.2, 15.4 and 15.5

e) Access to support for education and training in measures for the identification, conservation and sustainable use of biological diversity and its components for developing countries in accordance with Art 12 a

f) Fair and equitable sharing of benefits resulting from the use of GR in accordance with Art 1, 15.7, 19.2

g) Fair and equitable sharing of benefits resulting from the use of knowledge, innovations and practices (hereinafter referred to as 'associated TK') of indigenous and local communities (ILCs) in accordance with Art 8j

h) Relevant patents and other intellectual property rights are supportive of and do not run counter to the objectives of the CBD in accordance with Art 16.3. 16.4 and 16.5

Note:

i. The term 'appropriate access' is based on the wording of Art 1 of the CBD
ii. The term 'genetic resources' is explained under 'definitions'.

EXPLANATION

Rethinking Access- Gaining Clarity on the principle of 'Access' within the CBD:

Much of the discussion in the ABS WG around the objective of the IR in Annex 1 of COP decision IX/12 relates to facilitating or regulating access to genetic resources (GR) and associated traditional knowledge (TK) by provider countries in exchange for the fair and equitable sharing of benefits resulting from the commercial use of such GR and associated TK. We submit that notions of access and benefit sharing in the CBD are far wider than how it has been conceptualized so far.

Kinds of Access:

There are three kinds of access listed within Article 1 (Objectives) of the CBD. This is an inclusive definition that speaks of 1) appropriate access to GR 2) appropriate access to transfer of relevant technologies and 3) appropriate funding. Art 1 seems to indicate that fair and equitable benefit sharing can occur only in the context of access of this nature. The question before us now is what does "appropriate access" mean and the answer has to lie in understanding the 'appropriateness' of access in the context of the other provisions of the CBD.

Appropriate Access to Technology:

There are two kinds of access to technology in the CBD.
1) Access to technology that is relevant to conservation and sustainable use of biodiversity and
2) Access to technology that is related to the GR that is accessed.

1) Access to technology that is relevant to conservation and sustainable use:

Art 16 (1)(2) refers to access to and transfer of technology that is useful for conservation and sustainable use of biological diversity and such access shall be provided to developing countries on favorable, concessional and preferential terms. Art 16(4) makes it incumbent on contracting parties to ensure that the private sector also facilitates such an access to joint development and transfer of technology. Art 16 (5) states that intellectual property rights related to such technology must be supportive of the CBD and not run counter to its objectives. Art 17 (2) speaks of free exchange of different kinds of technologies and knowledge that is relevant for conservation and sustainable use of biological diversity from publicly available sources. Finally Art 18 addresses technical and scientific cooperation in the field of conservation and sustainable use of biological diversity between contracting parties.

2) Access to technology that is related to the GR that is accessed:

Art 15 (6) (7), Art 16 (3) and Art 19 (1) emphasize that there must be access in the form of transfer of technology and joint development with the provider country regarding any new scientific activities which relate to the GR from the provider country. The full

participation of the provider country in the development of the GR would also involve where possible the scientific research taking place in the provider country itself (Art 15(6)).

Appropriate access to technology in the context of Art 1 of the CBD must then be interpreted as not merely access to technology in exchange for the use of genetic resources but facilitated, concessional and preferential access to all technology that is related to conservation and sustainable use of biological diversity to all contracting parties irrespective of whether or not any GR is being accessed. So access to technology in this case should not be understood as a benefit that will be shared with developing countries only in exchange for complementary access to their GR. It is only access to technology that is related to the GR being used that can be understood in the form of benefit sharing where the technological advances that relate to the GR being accessed will be shared by the user country with the country providing the GR.

The importance of such an understanding for developing countries is that merely because a country does not have any GR that may be of commercial interest does not mean that it must not be entitled to any access to technology. The IR on ABS must ensure in its objectives that it is addresses such a universal access to technology which is exclusive of any benefit sharing agreement that may be reached between user and provider countries.

Access to Appropriate Funding:

Art 20 of the CBD addresses the importance of appropriate funding for developing countries in order to meet their commitments under the CBD. Art 20 (4) is unequivocal when it says that abilities of developing countries to implement the CBD is intrinsically linked to access to appropriate funding.

Here too it is important for developing countries to understand that access to funding for conservation and sustainable use of biological diversity is not a benefit that will be shared in exchange for providing access to their genetic resources but an independent right in itself under the CBD. The IR on ABS within its objectives must also highlight this aspect of access that isn't often highlighted in the ABSWG negotiations except under voluntary efforts towards capacity building.

Appropriate Access to GR:

Appropriate access to GR in the context of the CBD can be understood through a reading of Art 15 (2) which says that access to GR will be facilitated by provider countries only for environmentally sound uses and provider countries will not impose any restrictions that run counter to the objectives of the CBD- these objectives being conservation, sustainable use and benefit sharing.

There has been a lot of debate in ABSWG 6 and in the Informal Consultative Group (ICG) at COP 9 about the nature of such an access to GR. While developed countries have tended to focus on Art 15 (2) which speaks of facilitating access to GR, developing countries have instead focused on Art 15 (1) which refers to States having sovereign rights over their GR. The crux of this debate has been whether developed countries have a right to access GR under the CBD or whether this right is subject to the discretion of provider countries.

We submit that such a debate may be counter productive since the objective of the CBD is the conservation and sustainable use of biological diversity coupled with the sharing of benefits that arise from the use of such biological diversity. Art 15 (1) and (2) of the CBD is explicit that countries have sovereign rights over their resources but the exercise of the sovereign right to exclude access to GR can only be done if such an access would not be environmentally sound. Restrictions on any other ground would run counter to the objectives of the CBD whose foundation seems to be that GR can be accessed for environmentally sound reasons. However Art 15 (4) (5) speak of such access being subject to MAT (mutually agreed terms) and PIC (prior informed consent) of the provider country and such an access must involve the fair and equitable sharing of benefits resulting from the use of such GR with the provider country.

Conclusion:

Appropriate access then in the context of the CBD and for the purposes of the IR on ABS should involve:
a) Universal access to research and technology that is linked to conservation and sustainable use of biological diversity irrespective of any reciprocal access to GR.
b) Access to research and technology relevant to the GR in question in exchange for the use of such GR
b) Access to appropriate funding for developing countries to implement the CBD irrespective of any reciprocal access to GR
c) Appropriate access to GR only for environmentally sound uses based on MAT with and PIC of the provider country and the fair and equitable sharing of benefits resulting from the use of the GR.

SCOPE: (Operative Text)

The International Regime (IR) on ABS in accordance with the relevant provisions of the CBD applies to:

a) Access to GR, their derivatives and products based on environmentally sound uses

b) Access to research and technology linked to conservation and sustainable use of biological diversity

c) Access to research and technology relevant to the GR accessed and the derivatives and products of these GR including biotechnology related to use, identification and tracking of such resources.

d) Access to funding for developing countries to implement those provisions of the CBD relevant to ABS

e) Fair and equitable sharing of all benefits arising from the commercial and other use of GR , their derivatives and products acquired pre and post CBD in *insitu* and *exsitu* conditions excluding those species covered by annex 1 of the ITPGRFA when used within the purposes of the said treaty

f) Fair and equitable sharing of all benefits arising from the commercial and other use of associated TK of ILCs in accordance with Art 8j acquired pre and post CBD

g) Fair and equitable sharing of all benefits arising from the commercial and other use of GR, their derivatives, products and associated TK of ILCs that are of a transboundary nature

h) All intellectual property rights associated with research and technology arising from the use of GR, their derivatives, products and associated TK of ILCs shall be subject to the IR on ABS

The IR on ABS shall not affect:

i. The traditional systems of access, use or exchange of GR , their derivatives and products

ii. Access, use and exchange of knowledge and innovations by and between ILCs

iii. The sharing of benefits based upon the customary practices of the concerned ILCs, provided that the provisions of (i) and (ii) shall not be taken to apply to any person or persons not living in the traditional and customary way of life relevant to the conservation and sustainable use of biological diversity.

iv. All species listed in Annex 1 of the ITPGRFA unless they are used beyond the explicit purpose of the said treaty

v. Human genetic resources excluded from the framework of the CBD in accordance with Decision II/11 of COP 2

EXPLANATION:

Pre-CBD Collections

The African position is that genetic resources that were acquired before the CBD's entry into force on 29 December 1993 should be included within the scope of the international regime.

The Nairobi Final Act that adopted the text of the CBD viewed the access to plant genetic resources within the Global System for the Conservation and Sustainable Use of Plant Genetic Resources for Food and Sustainable Agriculture held in ex-situ collections and not acquired in accordance with the CBD as an unresolved matter and in Resolution 3 asked the FAO to look into the matter. This led to the development of the ITPGRFA . The ownership over GRs not covered by the ITPGRFA is therefore still controversial. It is for this reason that the Andean Pact countries disregard the common interpretation of Art. 15.3 of the CBD as stating that Arts.15, 16 and 19 apply only to GR acquired after the CBD came into force. The Andean common regime on access applies to all GR originating from Andean Pact countries whether they were acquired pre or post CBD. The Andean Pact's access regime has not been challenged yet.

African countries feel that the exclusion of pre-CBD ex-situ collections from the IR would significantly weaken the benefits of the CBD for developing countries. This is because most of the GR that have been documented are pre-CBD and in ex-situ collections and therefore most likely to have commercial use in the near future. To argue that the scope of the IR is restricted only to post-CBD GR would limit the IR only to new GR that have been discovered since 1994 and are still being researched and unlikely to be commercialized in the next few decades.

African countries acknowledge that the origins of a large amount of GR in ex-situ collections would be hard if not impossible to trace. Many of them would be of transboundary nature. In cases such as this African countries feel that a fund should be set up to receive the benefits from the commercial and other utilization of pre-CBD GR and the monies of such a fund will be used to aid in conservation and sustainable use of biodiversity in developing countries and to support their socio-economic development.

NATURE: (Operative Text)

The International Regime should be composed of a single legally binding instrument containing among others a set of principles, norms, rules and compliance and enforcement measures

DEFINITIONS:

Fair and Equitable Benefit Sharing: (Operative Text)

The definition of 'fair and equitable benefit sharing' is non-exhaustive and inclusive.[1] It must however encompass the following minimum conditions. Fair and equitable benefit sharing:

i. Should contribute to strengthening the situation of the less powerful party/parties at all levels in the sharing relation, including by enabling:
   - ✓ equal access to information,
   - ✓ effective participation by all relevant stakeholders,
   - ✓ capacity building,
   - ✓ preferential access to markets, new technology and products.

ii. Should contribute toward, or as a minimum not counteract, the two other objectives of the Convention: conservation of biological diversity and the sustainable use of its components.

iii. Must not interfere with existing forms of fair and equitable benefit sharing, including customary benefit sharing mechanisms

iv. Must respect value and legal systems across cultural borders, including customary laws and practices and indigenous intellectual property systems.

v. Must allow democratic and meaningful participation in policy decisions and contract negotiation by all stakeholders, including stakeholders at the local level.

vi. Must be transparent enough that all parties understand the process equally well, especially ILCs, and have time and opportunity to make informed decisions (effective Prior Informed Consent, PIC)

vii. Must, include provisions for independent third party review to ensure that all transactions are on mutually agreed terms (MAT) and preceded by effective prior informed consent (PIC).

viii. Must provide for identification of the origin of genetic resources and related traditional knowledge.

ix. Must, make information about agreed terms publicly available.

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[1] *"Fair and Equitable- Sharing the benefits from use of genetic resources and traditional knowledge" report by the Swedish Scientific Council on Biological Diversity, September 1999 by Marie Byström et.al*

Genetic Resources:

To aid in distinguishing genetic resources from biological resources for the purposes of the IR on ABS, genetic resources should be understood in the context of their utilization rather than merely as 'functional units of heredity'[2].

Genetic resources are the product of any human activity with nature that involves:

i. the micro/physical component (extracting, multiplying and studying genetic or biochemical material);

ii. the information (synthesis or other development, or processes to do so); and

iii. the intangible and tangible being used together (i.e., where a molecule or sequence cannot be synthesized or multiplied, but must be continuously collected from wild sources).

Utilization of Genetic Resources:

a) the following is a list of activities[3] that constitute "utilization of genetic resources" for purposes of this law:

List 1- Utilization of GR under List 1 can be categorized either:

By sector:
Agriculture, aquaculture, pharmaceutical, neutraceutical (agro-pharmaceuticals), cosmetics, forestry, aromatherapy, fisheries, ex-situ collections, basic scientific research, etc.; or

By objective:
Food and food security; health and medicine; commerce; conservation; sustainable use; etc. or

By specific genetic-related activity:
Breeding, cultivation/variety development, extraction and identification of characteristics or properties, taxonomic characterization, genetic manipulation, synthesis of sequence or formula, nanotechnological activities, etc. or

By developmental stage and/or type:
It may also be possible to set a dividing line between genetic resource

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[2] *Tvedt, Morten Walloe and Young, Tomme, 'Beyond Access: Exploring Implementation of the Fair and Equitable Sharing Commitment in the CBD' IUCN Environmental Policy and Law Paper No.67/2.*
[3] *Ibid*

utilization and other activities based upon the position of that activity in the spectrum from collection to product development.

Some activities that are typically undertaken in the source country may be "utilization" as well as those in the user country:

Activities that are most often done in source country:
biodiversity inventory, specimen collection; initial taxonomic or biochemical analysis.
Activities that are sometimes done in source country, but often taken "beyond access":
exportation or transport of specimens; taxonomic or biochemical analysis; laboratory extraction; research; finalization/publication of research results; transfer of specimens or results to other potential users; application for intellectual property right protections; development of commercial and scientific applications (of the discovered characteristic, gene or formula); production; sale.

b) In addition to the items listed in (a), any activity that meets the following criteria shall be considered to be "utilization of genetic resources" for purposes of this law: [List 2].

Derivatives and Products:

The use of a dynamic definition of GR based on its utilization solves the problem of trying to define derivatives and products since every use, whether direct or through another interim product, would be separately evaluated as a possible "utilization of genetic resources". This is also the approach that is taken by the ITPGRFA.

Benefits arising from the utilization of GR:

Benefits arise when the 'actual or potential value' of the genetic material is realized. In terms of commercial development benefits arise when a commercially valuable commodity is created. This includes situations when the commodity is put on the market or when a certain development milestone is reached or when a patent is applied for. In terms of non-commercial development, arising of benefits includes situations when the research or data or any such activity is ready for publication.

MAIN COMPONENTS OF THE TEXT

A. FAIR AND EQUITABLE BENEFIT SHARING: (Operative Text)

1. Sharing of benefits arising from the use of knowledge, innovations and practices of ILCs:

Contracting Parties shall in accordance with Art 8j of the CBD ensure fair and equitable sharing of benefits arising from the utilization of knowledge, innovations and practices of ILCs. The benefits referred to here are benefits to humanity in general and benefits to ILCs in particular:

a) Benefits to humanity:

All Contracting Parties shall:

i) Promote the wider application of knowledge, innovations and practices of ILCs with their voluntary approval and involvement in accordance with Art 8j of the CBD

ii) Further the customary use of biological resources in line with traditional customary practices that are compatible with conservation and sustainable use of biological diversity in accordance with Art 10c of the CBD

iii) Encourage and develop methods of cooperation for the development and use of indigenous and traditional technologies in furtherance of the objectives of the CBD by the training of personnel and provision of expertise by representatives of ILCs in accordance with Art 18.4 of the CBD

b) Benefits to ILCs:

Contracting Parties shall ensure the fair and equitable sharing of benefits with ILCs arising from the utilization of their knowledge, innovations and practices. These benefits will based on MAT with the ILCs and may include but not be limited to monetary and non-monetary benefits listed in Appendix II of the Bonn Guidelines

2. Sharing of benefits arising from the use of GR, their derivatives and products:

Contracting Parties shall in accordance with Art 15.7 take measures to ensure the fair and equitable sharing of benefits arising from the commercial and other utilization of GR, their derivatives and products with the Country of Origin, on MAT. The benefits may include but not be limited to:

i. Monetary and non-monetary benefits listed in Appendix II of the Bonn Guidelines

ii. Non monetary benefits in accordance with Art 15.6, 16.3, 16.4 and 19.1, including providing Provider Countries with the R&D for commercialization.

3. GR accessed pre-CBD:

GR accessed pre-CBD, their derivatives and products shall be subject to ABS agreements with provider countries and all continuing benefits arising from these GR, their derivatives and products will be fairly and equitably shared with their Countries of Origin. In cases where the origin of the GR is unclear, a multilateral system of exchange should be developed.

4. Knowledge, innovations and practices of ILCs accessed pre-CBD:

Knowledge, innovations and practices of ILCs accessed pre-CBD shall be subject to ABS agreements with the ILCs concerned and all continuing benefits arising from such knowledge, innovations and practices will be fairly and equitably shared with the relevant ILCs. In cases where the origin of the knowledge, innovations and practices are unclear, a fund will be established which will be administered by representatives of ILCs who will ensure that it is used to further the rights of ILCs.

5. Sharing of benefits when GR is shared across national boundaries:

Contracting Parties who share GR shall enter into bilateral or multilateral agreements based on MAT to ensure the fair and equitable sharing of benefits arising from the utilization of transboundary GR

6. Sharing of benefits when the knowledge, innovations and practices are shared between ILCs:

Contracting Parties shall facilitate the inclusion of the different ILCs, within and across their boundaries that share a particular knowledge, innovation or practice in the negotiation of relevant ABS agreements and support the fair and equitable sharing amongst these ILCs of the benefits arising from such agreements

EXPLANATION:

Rethinking Benefit Sharing:

There are two kinds of sharing of benefits under the CBD:
1) Sharing of benefits arising from the use of GR (Art 1)
2) Sharing of benefits arising from the use of knowledge, innovations and practices of indigenous and local communities (Art 8j)

We will discuss both these types of benefit sharing in turn:

1) Sharing of benefits arising from the use of GR (Art 1):

In the case of provider countries, the reason the sharing of benefits from the use of GR is emphasized is because of the increasing enclosure of such benefits through the use

intellectual property systems (e.g. patents on food and medicines). Knowledge enclosure systems like patents are sets of relations that exclude some groups from accessing the benefits of the use of GR while providing others with a monopoly over such benefits.

We submit that the goal of developing countries that are providers of GR should not be focused on legitimating such enclosures in exchange of monetary and non-monetary benefits (agreeing to GR related patents by users in ABS agreements) but must instead insist for the inclusion in their benefits, free access to knowledge resulting from the use of GR. This is the only way that developing countries can ensure that they collectively benefit from the use of GR. Otherwise it will only be countries that provide GR that benefit from their use while other countries are still excluded from accessing such benefits.

Developing countries must focus on Articles 15, 16 and 19 of the CBD through which they begin to participate effectively in the development of research and technology related to the use of GR. Where possible they must ensure that such research and technology takes place within provider countries itself. These benefits could focus on skills upgrading, job creation, improving quality of education etc. all of which make certain that developing countries no longer remain as mere providers of raw GR but meaningfully participate in ensuring that their people benefit from the new uses of GR.

It is such an approach that would be in line with the first two objectives of the CBD which is conservation and sustainable use of biodiversity. Communities generally do not have an incentive to conserve and sustainably use biological diversity unless their lives are integrally linked to the ecosystem. To legitimize enclosures of new uses of GR in exchange for monetary and non monetary benefits would narrowly benefit only the country that provides the GR but in the long run prevent its people from benefiting from the new uses of the GR. Also enclosures while incentivizing its beneficiaries disincentivizes those who are excluded from the benefits. For e.g. while a provider country may monetarily gain from allowing access which includes patenting some of the new uses of the GR, other countries in the region that may have the same GR will be excluded from the new uses of the GR and will not be compensated monetarily thereby disincentivizing them from conserving and sustainably using the GR.

The impact of intellectual property rights (IPRs) on GR was addressed in COP Decision VI/24 C(3a) which requested the Executive Secretary to undertake further information gathering and analysis with regard to the impact of IP regimes on access to and use of GR and scientific research. The paper that was prepared was presented to ABSWG 2 which identified access related problems in reference to IPRs. These were:

- *Tensions between IPRs and achievement of their wider social objectives, particularly those related to the needs of poor producers*
- *Impediments to the effective development of science due to restricted flow and exchange of information (also referred to as the 'tragedy of the anti-commons'*

where resources are under-utilized due to the high transaction costs)

- *Increased product development costs (that translates to high prices for consumers)*

It is to prevent situations like this that Art 12 (3) (d) of the ITPGRFA states that "Recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral system"

It is important for developing countries that are providers of GR to ensure that IPRs will not restrict access to the uses of the GR by other developing countries. Developing countries must interpret 'appropriate access' in Art 1 and 'facilitated access' in Art 15 (2) of the CBD to mean that no IPRs can be granted for the original organism, it's isolated components as well as for modified organisms and modified genetic material. This will ensure that the first two objectives of the CBD can be upheld and we submit that this is the way to understand 'appropriate access for environmentally sound uses' under Art 15(2).

2) Sharing of benefits arising from the use of knowledge, innovations and practices of indigenous and local communities (Art 8j)

The sharing of benefits arising from the use of knowledge, innovations and practices (TK) of ILCs is established in Art 8j. It is however important to understand the scope and therefore the real essence of Art 8j to overcome common misunderstandings of it. Art 8j has the following components:

a) The obligation of Art 8j is not only limited to the Contracting Parties where the specific ILCs live but extends to all Contracting Parties. This despite the fact that Art 8j speaks of in-situ conservation since the TK of ILCs can be promoted and widely applied in any country irrespective of their presence there, thus aiding in-situ conservation in different regions.

b) Art 8j makes it incumbent on Contracting Parties to not just respect, preserve and maintain TK of ILCs but to also promote their wider application with the approval and involvement of the holders of such TK (our emphasis).

c) There will be an equitable sharing of benefits arising from the use of such TK.

To sum up, Art 8j makes it mandatory on all Contracting Parties to respect, preserve and maintain TK of ILCs embodying traditional lifestyles and also promote their wider application with the approval and involvement of the holders of such TK. The underlying reason this provision falls under the head 'in-situ conservation' is because of an acknowledgement by the CBD that the traditional lifestyles of ILCs has conserved biological diversity. This is also the reason why Art 8j doesn't speak of all TK of ILCs but

only of those embodying traditional lifestyles where such TK have relevance for the conservation and sustainable use of biological diversity. The critical link here is that the use or application of TK must ensure conservation and sustainable use of biodiversity.

Conclusion:

While fair and equitable benefit sharing for the use of GR and associated TK must be ensured by developing countries, what constitutes fair and equitable benefit sharing is as much about process as it is about outcomes. Outcomes can be measured in terms of the monetary and non-monetary benefits that providers are able to negotiate from users. Fair and equitable process on the other hand is about ensuring that certain ethical principles are not compromised upon and the long term implications of an agreement on conservation and sustainable use of biological diversity and protection of traditional lifestyles is seriously considered.

In an African context the ethical principles are derived from African Charter on Human and Peoples' Rights (OAU Charter) as interpreted by the 2005 report of the African Commission's Working Group of Experts on Indigenous Populations/Communities which makes a case for collective rights of indigenous and local communities. This is also evidenced by the OAU's African Model Law for 'The Protection of the Rights of Local Communities, Farmers and Breeders and for the Regulation of Access to Biological Resources'. It is crucial for African countries to use these ethical principles to define what they mean by 'fair and equitable benefit sharing' in the context of ABS. This will ensure values that are most important for Africa are not traded away in exchange for short term monetary rewards.

***Note:** It is important for Parties to clearly distinguish between benefit sharing as provided for in article 15 and incentive measures under article 11. Under article 11, parties are encouraged to adopt economically and socially sound measures that act as incentives for the conservation and sustainable use of components of biological diversity. These measures are meant to satisfy the first two objectives of the CBD, but not the third.*

B. ACCESS TO GENETIC RESOURCES (Operative Text)

1. Contracting Parties have sovereign rights over their natural resources and the authority to determine access to GR rests with the national governments. Where access to GR has an impact on the knowledge, innovations and practices of ILCs embodying traditional lifestyles, the ILCs concerned shall have a say in determining access.

2. Contracting Parties shall create conditions of legal certainty, clarity and transparency to facilitate access to GR and not impose any restrictions that run counter to objectives of the CBD in accordance with Art 1 of the Convention.

Access can however be denied if it is required for uses that are not environmentally sound. Countries of Origin have the authority to determine the environmental soundness of a particular use. The notion of 'use' shall be understood as including restrictions to use by third parties and Countries of Origin have the authority to determine whether the restriction of the use of GR through patents and other intellectual property rights are environmentally sound and whether such restrictions negatively impact the conservation and sustainable use of biological diversity.

3. Contracting Parties shall ensure that access to GR shall be subject to the PIC of the Country of Origin and be based on MAT with fair and equitable sharing of benefits arising from the utilization of the GR. Where the access to the GR and their derivatives is linked to the use of any knowledge, innovations and practices of ILCs, it shall where necessary be subject to the PIC and MAT of the concerned ILCs with fair and equitable sharing of benefits in accordance with Para 31 of the Bonn Guidelines.

4. New uses of GR beyond the scope what has been consented to under MAT shall require new PIC and MAT from the Country of Origin and/or the ILCs concerned in accordance with Para 34 of the Bonn Guidelines.

5. Access to GR can be revoked by the Country of Origin if any of the MAT are violated by the user and if the continuing use of the GR has negative environmental implications.

EXPLANATION:

Art 15.1 of the CBD which recognizes the sovereign rights of States over their natural resources has to be read with Art 8j. The knowledge, innovations and practices of ILCs embodying traditional lifestyles is integrally linked to the GR within their ecosystems. Any impact on these GR would affect the traditional lifestyles/relationships within these communities thereby having consequences on their knowledge, innovations and practices. Therefore it is important to harmonise both the rights of States over GR under Art 15.1 and the rights of communities to have their knowledge, innovations and practices respected, preserved and maintained under Art 8j. The only way to do this under the International Regime on ABS is by ensuring that where access to a particular GR in terms of how it will be collected and used has an effect on the knowledge, innovations and practices of particular ILCs, these ILCs will be involved in the decision making process. It is important to remember that while Art 8j begins with 'subject to national legislation', this must be understood not as 'the rights of ILCs being at the discretion of the State' but rather that States are bound to respect these rights but have the discretion to enact locally suited laws to uphold these rights. It is also pertinent to remind ourselves of Para 37 of the Bonn Guidelines which states that "Permission to access GR does not necessarily imply permission to use associated TK and vice versa".

While access to GR cannot be arbitrarily denied under Art 15.2 of the CBD, they can be regulated based on the environmental soundness of the use to which the GR will be put to. Environmentally sound use need not be understood only in a negative sense where the use of a particular GR will directly harm the environment- it can also be understood positively whereby preventing the use of a particular GR through use restriction strategies such as patents could also harm biological diversity. This has been referred to by some environmentalists as the 'tragedy of the anti-commons' where legal enclosures such as IPRs tend to make the use of certain innovations so expensive that they are under-utilized by people who need it the most. Studies have shown that biological diversity can be nurtured and increased not by restricting the free flow of GR but rather by facilitating its access to primary users such as farmers, plant breeders etc- thus any restriction on such free flows can be understood as environmentally unsound. It is for this reason that Art 12.3.d of the ITPGRFA under the heading 'Facilitated Access' states that "Recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral system". It is also important to bear in mind that the scope of facilitated access under Art 12.3.a which states that "Access is to be provided only for the purposes of utilization and conservation for research and breeding and training for food and agriculture" thereby emphasizing the importance of free flow of GR for primary users and researchers.

It is hard to separate the knowledge, innovations and practices of ILCs from the GR (which include whole ecosystems) on which this knowledge, innovations and practices are based. For example Company A, a user of a GR, the use of which is linked to TK, would need to get PIC from the Country of Origin to access the GR and PIC from the ILC concerned for the use of the associated TK. But within the supply chain, there would be users of the GR involved in activities not directly linked to the associated TK. For example Company B which acquires the GR so as to process it into the form that the Company A requires. While the ultimate product of Company A is based both on the GR and associated TK, Company B which merely processes the GR is also indirectly reliant on the associated TK without which there would be no commercial use for the GR. This means that Company B must also acquire PIC from the ILC on whose TK, the use of the GR by Company A is based, even though technically speaking Company B is using only the GR and not the associated TK. This ensures that anyone who commercially profits from the knowledge, innovations and practices of ILCs must require their PIC.

C. COMPLIANCE: (Operative Text)

<u>In Country Measures to Ensure Compliance:</u>

(a) Contracting Parties shall take the necessary policy, administrative and legislative to ensure that users of GR and/or associated TK within their jurisdiction comply with the necessary ABS laws of the Countries of Origin

(b) Contracting Parties shall undertake the necessary steps to ensure equity in contract negotiations

(c) Contracting Parties shall develop tracking and monitoring systems that identify breaches of contractual obligations or misappropriation of GR and/or associated TK and bring such breaches to the attention of the rights holders and stakeholders

(d) Contracting Parties shall develop effective, cost efficient systems to initiate and sustain actions to prevent, mitigate or seek redress in cases of breach of contractual obligations or misappropriation and where necessary provide support for claimants in actions for breach of contract or misappropriation

(e) Contracting Parties shall ensure that their courts will enforce the decisions of the courts of the Country of Origin against unlawful users under the former's jurisdiction subject to basic principles underlying enforcement of foreign judgments under comity in international law

(f) Contracting Parties shall ensure that no IPRs based on the utilization of GR and/or associated TK will be granted unless the application for the IPR establishes that it has complied with the ABS requirements of the Country of Origin.

Dispute Resolution Mechanism[4]:

a. The IR on ABS shall establish a Dispute Resolution Mechanism accessible to both countries and also other aggrieved parties who include ILCs, NGOs, research and commercial interests, and other providers and users of GR and/or associated TK

b. The Dispute Resolution Mechanism shall also have regional offices that uses local languages and has personnel conversant with the cultural, social, economic and environmental realities of the region

c. The Dispute Resolution Mechanism will be guided in its work by principles of equity drawn from a wide range of legal sources including customary law and practices of ILCs

International Ombudsman to Ensure Access to Justice[5]:

[4] *UNU Certificates of Clarity or Confusion -IAS report-*

The IR on ABS shall establish an international ABS ombudsman's office. The ombudsman's office shall be responsible for provider countries, ILCs to identify breaches of their rights and to provide aid in seeking fair and equitable resolution of disputes. The ombudsman's office shall be empowered to take action on behalf of ILCs through the binding Dispute Resolution Mechanism. The ombudsman's office shall also where necessary represent ILCs in proceedings in foreign jurisdiction, take depositions from ILCs and provide evidence of customary law and practice as and where appropriate.

Internationally Recognized Certificate[6]:

The IR on ABS shall establish a system of certification which will certify the compliance of a user of GR and/or associated TK with the relevant laws of the provider country. The certificate will be a public document to be issued by a competent national authority appointed in accordance with national law and would be required to be presented at specific checkpoints in user and provider countries established to monitor compliance in relation to a range of possible uses.

a. The Certificate shall include the following minimum information:

(i) Issuing national authority
(ii) Details of the provider
(iii) A codified unique alpha numeric identifier
(iv) Details of the rights holders of associated TK, as appropriate
(v) Details of the user
(vi) Subject matter (GR and/or TK) covered by the certificate
(vii) Geographic location of the access activity
(viii) MAT
(ix) Uses permitted and restrictions of use
(x) Conditions of transfer to third parties
(xi) Date of issuance

b. Contracting Parties shall establish checkpoints for the Certificate for commercial and non- commercial uses. Checkpoints for commercial uses may include customs controls, intellectual property offices and registration points for other commercial applications not covered by IPRs. Checkpoints for non- commercial uses may include publishing houses of scientific journals, grants making bodies

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[5] *Barber, C.V, et al, 2003, User Measures: Options for Developing Measures in User Countries to Implement ABS Provisions of the CBD*
[6] *2007 report of Group of Technical Experts on the Certificate*

and ex-situ collections.[7]

c. Contracting Parties shall facilitate an efficient, easy to use certification process through the use of new technology which may include: [8]

(i) Cost efficient publicly searchable certificate databases providing evidence of PIC and MAT
(ii) Recording of progressive compliance on such databases as conditions of PIC and MAT are met
(iii) Searchable patent application and registration databases
(iv) Integration of genomic and morphological taxonomy to create species certainty
(v) Low cost, portable, gene based bar-coding technology to create rapid attack taxonomy
(vi) Linking unique identifiers to gene based bar-coding

d. Contracting Parties where viable shall:

(i) Use existing tracking procedures by innovatively reconceptualising them to track GR and associated TK
(ii) Minimize the creation of new levels of bureaucracy
(iii) Promote automatic issuing of certificates upon compliance with specific criteria, such as completion of MTA or ABS agreement
(iv) Promote consolidation of existing permitting requirements with any new certification system
(v) Promote paperless systems
(vi) Establish minimum standards for recording of collections, to ensure a link between incoming and outgoing resources, without requiring harmonization of internal recording procedures
(vii) Provide economic support to developing countries to develop online systems to support an international documentation system

e. Contracting parties shall ensure that no IPRs based on the utilisation of GR and/or associated TK will be granted unless the applications for such IPRs include the disclosure of an Internationally Recognized Certificate of Compliance with the ABS legislation of the provider country.

EXPLANATION:

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[7] *Cunningham, D et al, 2004, Background paper for Smithsonian/UNU-IAS Roundtable on Certificates of Origin*
[8] *Brendan Tobin et al, Certificates of Clarity or Confusion, UNU-IAS 2008 report*

Determining what to call any certificate system prior to defining its component elements and procedures for its implementation is considered a distraction and potentially counter-productive. Terms may easily prove interchangeable. Compliance with the national ABS laws of provider countries would, for instance, raise the presumption of legal provenance of resources. Provider countries as defined under the CBD will have to be countries of origin or countries which have obtained resources in accordance with the CBD, i.e. from countries of origin. A certificate of origin would therefore imply both compliance and legal provenance. A legitimate source for resources would, in order to be compliant with the CBD, so have to be a country of origin or country which had obtained resources in accordance with the CBD. Although the actual provider of genetic resources may be an ex-situ collection or indigenous people, landowner, etc., to be a legitimate source they must still be providing resources for which that country is considered a provider country. Although each proposal has provided differing interpretations of the scope of any certification system, it is clear that to be CBD compliant they must fall within the same defined parameters regarding who can provide resources and under what terms, including PIC and MAT. Furthermore, all of the proposals could be applied in either a voluntary or mandatory system, making distinctions in nomenclature even less significant. Deciding what any certificate system is to be called is very much secondary to defining what a certificate system is meant to do and how it is to do it. Pressure to adopt a specific term to designate a future certification system may inhibit full and informed debate of all options. That way the name will describe the system rather than having a system defined to fit the name. In the long run it's not what a certificate is called that will matter but rather how - and if - it does what it is supposed to do.[9]

D. TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES: (Operative Text)

Contracting Parties shall:

a. With the full and effective participation of the ILCs concerned support and facilitate local, national and/or regional community protocols regulating access to TK taking into consideration the relevant customary laws and ecological values of ILCs in order to prevent the misappropriation of their associated TK and to ensure the fair and equitable sharing of benefits arising from the utilization of such associated TK.

b. Ensure that any acquisition, appropriation or utilization of TK in contravention of the relevant community protocols constitutes an act of misappropriation.

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[9] *Ibid*

c. Ensure that the application, interpretation and enforcement of protection against misappropriation of TK, including determination of equitable sharing and distribution of benefits, should be guided, as far as possible and appropriate, by respect for the ecological values, customary norms, laws and understandings of the holders of the knowledge

d. Encourage and support the development of community protocols that will provide potential users of TK with clear and transparent rules for access to TK where associated TK is shared between: (i) ILCs spread across national boundaries and (ii) between ILCs with different values, customary norms, laws and understandings

e. Where such community protocols are developed with the full and effective participation of ILCs, give effect to such community protocols through an appropriate legal framework

f. Community protocols in their efforts to prevent misappropriation of associated TK and ensure fair and equitable benefit sharing must also make efforts to respect, preserve and maintain relations within and between ILCs that generate and sustain the TK by ensuring the continued availability of TK for the customary practice, use and transmission.

EXPLANATION:

Community Protocols

The knowledge, innovations and practices of ILCs emerge at the intersection of their lands and culture. Art 8 j states that that ILCs embodying traditional lifestyles have conserved and sustainably used biological diversity and aspects of those lifestyles relevant to the conservation and sustainable use of biological diversity must be protected and promoted by Contracting Parties. Art 8 j also recognizes the rights of ILCs over their traditional knowledge, innovations and practices and obliges Contracting Parties to ensure that benefits arising from the use of such knowledge, innovations and practices are fairly and equitable shared with the ILCs in question.

The dominant interpretation of Art 8 j in the current negotiations towards the IR on ABS seems to focus on the protection of the TK of ILCs and ensuring the fair and equitable sharing of benefits arising from the use of such TK with the ILCs from whom it was taken.

Art 8 j however is far wider in its reach and should be read in the broader context of the CBD, particularly its aims of conserving and sustainably using biodiversity. Article 8 j is clear that the conservation and sustainable use of biological diversity in the context of ILCs is dependent on aspects of their TK which is rooted in their 'ecological values'. This is the reason why Art 8 j does not refer to the protection and promotion of all the TK of all

ILCs but specifically the TK of ILCs embodying traditional lifestyles relevant to the conservation and sustainable use of biodiversity. Such ecologically integral TK is based on a value framework that regulates the relationship between the cultures of ILCs and their lands. Thus TK relevant for the conservation and sustainable use of biodiversity rests on 'ecological values' which in turn rests on secure rights to land and culture. The truth of the matter is that ILCs have conserved and sustainably used biological diversity for thousands of years not because they have been able to trade in their TK but because they have been able to live on their traditional lands in accordance with their 'ecological values'.

ABS in the context of ILCs focuses inordinately on an agenda of TK protection that perceives TK outside of the relationships which generate it, divorcing it from the ecological values that lead to its formation. The relations that the ILCs have with nature is one of a perpetual dialogue between land and culture each constituting and reconstituting the other. Ecological values are therefore rooted in an experience of relatedness between community and nature. Current IPR systems perceive TK in a manner that is quite similar to conventional property systems where land for example is viewed as a commodity separate from the network of relations within which it operates. TK is also viewed as an object separate from the cultural and spiritual relationships with the land within which it is embedded.

TK in reality is the manifestation of a particular kind of relationship with nature. TK is not just information but a set of relations that is embodied in traditional lifestyles of ILCs which ensure conservation and sustainable use of biodiversity. Currently there are no internationally agreed definitions of traditional knowledge and all efforts towards defining it tend to treat it as a product rather than as a process.

Efforts to protect traditional knowledge should be oriented less towards protection of knowledge as information and more towards sustaining the relationships based on ecological values that produce the knowledge. It is the ecological values that have sustained indigenous peoples within natural habitats, and the erosion of these values through the dispossession of indigenous lands and consequent annihilation of their cultures has seriously threatened biological diversity. To treat TK as a commodity and to assume that protecting this commodity will ensure conservation and sustainable use of biological diversity is akin to thinking that the sale of ivory will necessarily lead to the conservation of elephants and their habitats.

Community Approaches to Art 8 j:

The real extent of Art 8 j mandates Contracting Parties to go beyond creating databases of TK and ensuring benefit sharing when TK is utilized. The process and the outcome of ABS negotiations must uphold the spirit of Art 8 j and to do so the emphasis should not just be on the sale of TK but focus equally on the conservation and sustainable use of biological diversity and protection and promotion of traditional lifestyles including rights

to land and culture. This implies ensuring that the ecological values of the ILCs in question are central to all stages of the ABS negotiation i.e. at the stage of 'PIC', 'MAT' and 'benefit sharing'.

While the overarching framework of ecological values within which ABS agreements must be negotiated does not preclude monetary and non-monetary benefits to ILCs in exchange for the use of their TK, these benefits should not be the sole aim of ABS agreements. The process and the outcome of an ABS agreement between ILCs and the relevant stakeholders must affirm aspects of their traditional lifestyles that conserve and sustainably use biological diversity.

Contracting Parties are also bound by Art 8 j to ensure the wider application of the TK and by inference the ecological ethics of ILCs. This implies that ILCs must be integrally involved in Research and Training (Art 12) and Public Education and Awareness (Art 13). Art 12 and 13 must be read with Art 8 j where the research and training and public education is not only done by scientists, technical experts and ecologists but also by ILC representatives, elders and healers who have ensured the conservation and sustainable use of biodiversity by virtue of their lifestyles. ILCs have much to teach the world about their 'ecological values' and how they can be applied in non-traditional contexts - an application that would lead to genuine in situ conservation by challenging contemporary consumption patterns and lifestyle choices. Art 10c and 18 (4) already point us in this direction and we would do well to pay heed to them.

Conclusion- Working towards Community Protocols:

In order for ILCs to realise the full extent of their rights under Art 8 j it is crucial for them to develop community protocols based on their 'ecological values' that will inform all future ABS negotiations between them and other stakeholders who want access to their TK. While the ILCs themselves may be aware of their 'ecological values' on which their traditional lifestyles are based, setting them out in the form of community protocols would give parties interested in accessing the TK of ILCs clear guidelines as to the ethical preconditions and terms of potential ABS agreements. Community protocols amongst ILCs that are spread across national boundaries and/or between ILCs that share the same TK but belong to different cultural and ethnic groups would also be the only way in which to provide potential non community users of TK transparent instructions as to how and from whom to secure PIC, negotiate MAT and share benefits with.

States can at best insist that any access to TK must be based on ABS agreements with communities to whom the TK belongs, but neither national nor international law can go any further than this. It is communities to whom the TK belongs that must through community protocols guide parties interested in using TK on how to secure legitimate use rights. If this is not done than every potential user of TK despite having negotiated an ABS agreement risks being accused of misappropriation by: (i) either the community members who feel that the community representative who negotiated the agreement

had no authority to do so or (ii) by other communities that share the same TK who feel that they were wrongfully excluded from the ABS agreement.

The process of developing community protocols would involve communities developing ethical guidelines for ABS negotiations and agreements involving their TK that include but go beyond highlighting best practice standards for obtaining PIC and MAT. A community protocol is an outlining of ecological values on which PIC, MAT and benefit sharing would be based. A useful analogy for a community protocol would be the 'bill of rights' in the Constitution of a country that lists the core values of a people. It enunciates a community's core values and while it remains a flexible instrument, it provides community members and outside interests a level of certainty about the principles upon which any ABS agreement will be negotiated.

Community protocols are perhaps the best chance for ILCs to ensure that their ways of life and values are respected and promoted. Merely relying on the benefits of ABS agreements without affirming their 'ecological values' would reduce ILCs to sellers of TK who warm themselves on the embers of a lifestyle that is fast dying out.

E. CAPACITY: (Operative Text)

1. Contracting Parties shall ensure that capacity building measures in accordance with Art 8 j and 10 c of the CBD will promote the wider application of indigenous knowledge, innovations and practices by actively involving ILCs with their consent in the planning and implementation of 'Research and Training' (Art 12), 'Public Education and Awareness' (Art 13), 'Exchange of Information' (Art 17.2) and 'Technical and Scientific Cooperation' (Art 18.4).

2. Contracting Parties shall undertake capacity building measures at all relevant levels for:

(a) Development of national legislation
(b) Participation in negotiations, including contract negotiations
(c) Information and communication technology
(d) Development and use of valuation methods
(e) Bioprospecting, associated research and taxonomic studies
(f) Monitoring and enforcing compliance
(g) Use of access and benefit-sharing for sustainable development

3. Contracting Parties shall undertake national capacity self-assessments to be used as a guideline for minimum capacity-building requirements

4. Contracting Parties shall undertake capacity building measures for technology transfer and cooperation

5. Contracting Parties shall undertake special capacity-building measures for ILCs

6. Contracting Parties shall where required provide support for the development of menus of model clauses for potential inclusion in material transfer agreements

NORWAY

Development of an international regime on access to genetic resources and benefit-sharing under the CBD

Proposal for operational texts (notification 2008-120)

Submission from Norway

I. Objective

Operational text:

The objective of the international regime on access to genetic resources and benefit-sharing is to effectively implement the provisions in Articles 1, 8(j), 15, 16 and 19.2 of the Convention, specifically by:

- facilitating appropriate access to genetic resources
- ensuring the fair and equitable sharing of benefits arising out of the commercial and other utilization of genetic resources
- ensuring that Parties have legal provisions that support compliance with national regulations on access and benefit-sharing in provider countries
- enabling appropriate access to and transfer of technology relevant to genetic resources

taking into account all rights over these resources, including the rights of indigenous peoples and local communities.

II. Scope

Operational text:

The international regime on access and benefit-sharing applies to genetic resources and associated traditional knowledge, innovations and practices covered by the Convention on Biological Diversity, as well as to benefits arising from the commercial and other utilization of such resources.

Comment:
We may need to come back to the scope in relation to other multilateral agreements.

III. Main components

A. Fair and Equitable Benefit-sharing

Operational text:

Each Contracting Party shall take appropriate legislative, administrative, or policy measures with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilisation of genetic resources and their derivatives with the Contracting

Party providing such resources. Such sharing shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party and on mutually agreed terms. The elements of paragraph 44 of the Bonn Guidelines should be considered in the development of mutually agreed terms. Comment: Alternatively, relevant elements of the Bonn Guidelines could be included in an Annex to a protocol under the CBD.

Each Contracting Party shall take the following measures:

a) establish mechanisms to provide information to potential users concerning their obligations regarding access to genetic resources;
b) introduce rules requiring that users of genetic resources comply with national legislation in the providing country/Country of origin and the Mutually Agreed Terms on which access was granted, including requirements to equitably share the benefits arising from the utilisation of such resources, and their derivatives
c) The benefits to be shared may include, but are not limited to:
i)monetary and non-monetary benefits listed in Appendix II of the Bonn Guidelines, and
ii)non-monetary benefits in accordance with Art. 15.6, 16.3, 16.4 and 19.
d) introduce rules and measures aiming at ensuring that users disclose the country providing the resources/country of origin and prior informed consent as well as the origin of traditional knowledge, innovations and practices of indigenous peoples and local communities in applications for intellectual property rights;
Comment: A reference to "the agreed multilateral system" should be considered in order to cover plant genetic resources accessed through the multilateral system under the ITPGRFA.
e) introduce rules requiring that the importation of genetic resources from a country which requires prior informed consent for utilization or for the export of this resource, only takes place in compliance with such prior informed consent;
f) Measures aimed at preventing the use of misappropriated genetic resources and traditional knowledge.
g) Require that when genetic resources are used for research and commercial purposes within its jurisdiction, documentation with regard to the country of origin/providing country/agreed multilateral system providing these resources should accompany the material.
If national legislation in the country providing the genetic resources requires Prior Informed Consent for access to the material, the documentation should also specify whether such consent has been sought. If the providing country is different from the Country of origin, the country of origin or, if applicable, the agreed multilateral system shall also be disclosed. If some of the information referred to in this subparagraph does not exist, this should be stated in the documentation accompanying the material.
h) Require that genetic resources are only used for purposes consistent with the terms and conditions under which they were acquired.
i) Endeavour to direct benefits accruing to them towards conservation measures and measures promoting the sustainable use of biodiversity
j) introduce rules requiring that when genetic resources covered by the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) are used for research and commercial purposes, they should be accompanied by information confirming that these resources are accessed in accordance with the Standard Material Transfer Agreement under the Treaty.
k) introduce measures to facilitate cooperation between Contracting Parties to address alleged infringements of access and benefit-sharing agreements and misappropriation of genetic resources, such as access to justice and support for claimants in actions of breach of contract or misappropriation;
l) Other measures requiring users to comply with the provisions in the CBD and this Protocol.

Comment:
This section including measures to be taken by Contracting Parties may be developed in more detail at a later stage. There could be a need for an Annex specifying various types of utilisation of genetic resources and trigger points for benefit-sharing.

B. Access to genetic resources

Operational text:

As stated in Article 15 of the Convention on Biological Diversity, States have 'sovereign rights' over their natural resources and the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.

National focal point and competent national authorities

Each Party shall designate one *national focal point* for access and benefit-sharing which shall be responsible on its behalf for liaison with the Secretariat. The national focal point should inform applicants for access to genetic resources on applicable procedures, including procedures for prior informed consent, mutually agreed terms and benefit-sharing. It shall also inform applicants of any rights pertaining to indigenous peoples and local communities and relevant stakeholders.

Each Party should also, as appropriate, designate *one or more competent national authorities*, which should be responsible for handling and processing of access applications, including mutually agreed terms and benefit-sharing arrangements. A Party may designate a single entity to perform the functions of both Focal Point and competent national authority.

Each Party shall no later than the date of entry into force of this Protocol for it, notify the Secretariat of the names and addresses of the focal point and competent authority or authorities.

Access provisions

Operational text:

Contracting Parties which are countries of origin of genetic resources, or other Parties which have acquired the genetic resources in accordance with the Convention, shall:

a) Endeavour to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties. In accordance with Article 15, paragraph 5, of the Convention on Biological Diversity, access to genetic resources shall be subject to prior informed consent of the contracting Party providing such resources, unless otherwise determined by that Party.
b) Review their policy, administrative and legislative measures to ensure they are fully complying with Article 15 of the Convention in order to ensure clarity, legal certainty and transparency;
c) Require that, upon granting access, a certificate of compliance (or documentary evidence) is issued, with information on the country providing the resources and information on whether national legislation on access and benefit-sharing has been complied with.
d) The Contracting Parties should use elements of an access application referred to in paragraph 36 of the Bonn Guidelines, while bearing in mind that the list is indicative and may be adapted to national circumstances.
e) Report on access applications through the clearing-house mechanism;

f) Seek to ensure that the commercialization and any other use of genetic resources should not prevent traditional use of genetic resources;
g) Require providers only to supply genetic resources and/or traditional knowledge when they are entitled to do so;
h) Take measures to ensure appropriate participation by relevant indigenous peoples and local communities in access procedures when their rights are associated with the genetic resources being accessed or where traditional knowledge associated with these genetic resources is being accessed
i) Establish mechanisms to ensure that decisions are made available to relevant indigenous peoples and local communities and relevant stakeholders;
j) Consider simplified access rules to biological resources to be used for taxonomy purposes

Comment to subpara j): It is important to notice that the term *genetic resource* is defined from its utilisation. What is a genetic resource may therefore depend on the intended or the actual use of the genetic material. It can only be characterized as a genetic resource when the intended or actual use is based on the genetic information in the biological material. We do not consider use of a biological resource solely for taxonomy purposes to be a genetic resource and therefore simplified or no access procedures should be considered for this category.

k) Require that substantially new or changed uses of a genetic resource beyond the scope of what has been consented to under MAT, shall be subject to new prior informed consent and mutually agreed terms from the providing country and/or the indigenous peoples and local communities concerned.

C. Compliance

Comment:

We need to develop an understanding of what constitutes "misappropriation" of genetic resources and a related international obligation to prohibit the use of misappropriated genetic resources (see text on this at the end of this document).

Under Section A we have already identified some measures to monitor compliance. In addition, we support the introduction of an internationally recognized format for certificates of compliance which should serve to provide evidence of compliance with national access and benefit-sharing legislation, as may be required at specific checkpoints to be established in user countries. The certificate could contain, inter alia, the following information: codified unique identifier (for example code certificate NO 2008 A XXXX); issuing national authority, details of the provider, details of the right holders of associated traditional knowledge, as appropriate; details of the user; links to mutually agreed terms; conditions for transfer to third parties etc.

Countries that cannot provide for the mandatory issuance of certificates may wish to consider its issuance on a discretionary basis in light of the benefits for both providers and users. The issuance of such certificates in the provider country could be triggered automatically by the granting of access or at the request of a user.

These criteria and rules should not be open to arbitrary interpretation. Commercial users should be met with a clear and stable set of rules that they can trust in.

The Clearing House Mechanism (CHM) could have a role as receiver of notifications of disclosure of origin in patent applications and unique identifiers of genetic resources under a system for international certificates of origin/compliance.

Settlement of disputes

Comment:

Any dispute concerning the interpretation and application of Article 15 would be a matter of public international law and settled in accordance with Article 27 of the CBD. Article 15 regulates access to genetic resources, which is subject to prior informed consent and Mutually Agreed Terms (MAT). Where such a dispute arises between Parties to the CBD Article 27 provides Parties with a means to resolve disputes by first negotiation, then mediation and finally recourse to the arbitration procedures set out in Part I of the Annex II or to the International Court of Justice (ICJ). This is, however, optional since it requires Parties to accept either arbitration of submission to the ICJ, or both, as compulsory. Parties should therefore in the regime be encouraged to accept these dispute settlement procedures as compulsory means.

MATs are often concluded through a contract between private or public entities. Since most obligations arising under Mutually Agreed Terms will be between providers and users, disputes arising in these arrangements should be solved in accordance with the relevant contractual arrangements on access and benefit-sharing and the applicable law and practices.

Alternative dispute resolution (ADR) covers a range of mechanisms which allow parties to resolve differences without recourse to national courts. In an ABS context, many MATs already include settlement of dispute clauses based on arbitration, for example the Standard Material Transfer Agreement of the ITPGRFA. Standard clauses to be included in MATs could be developed under the international regime.

In cases where the access and benefit-sharing agreements consistent with the Convention on Biological Diversity and national legal instruments of the country of origin of genetic resources have not been complied with, the use of sanctions could be considered, such as penalty fees set out in contractual agreements.

Remedies

Operational text:

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

D. Traditional knowledge associated with genetic resources (Participation by indigenous peoples and local communities)

Operational text:

Indigenous peoples and local communities shall be consulted by the appropriate national authorities, and their views taken into consideration, when their rights are associated with the genetic resources being

accessed or where traditional knowledge associated with these genetic resources is being accessed, including:

a) When determining access, prior informed consent, and when negotiating and implementing mutually agreed terms, and in the sharing of benefits;

b) In the development of a national strategy, policies or regimes on access and benefit-sharing.

c) Appropriate consultative arrangements, such as national consultative committees, comprising relevant stakeholder representatives, should be established.

d)Providing information in order for them to be able to participate effectively;

e) Prior informed consent of indigenous peoples and local communities and the approval and involvement of the holders of traditional knowledge, innovations and practices, in accordance with their traditional practices, national access policies and subject to national legislation.

f) Documentation of traditional knowledge, innovations and practices, should be subject to the prior informed consent of indigenous peoples and local communities;

g) Providing support for capacity-building, in order for them to be actively engaged in various stages of access and benefit-sharing arrangements, such as in the development and implementation of mutually agreed terms and contractual arrangements.

E. Capacity

Operational Text:

Parties shall take measures to contribute to fulfilment of the Action Plan for Capacity-Building for Access to Genetic resources and Benefit-sharing as laid down in COP Decision VII/19. The Action Plan should provide a framework for identifying country and stakeholder needs, priorities and mechanisms of implementation and sources of funding.

IV. Nature

The regime should be composed of, but not limited to, a single legally binding international agreement, namely a Protocol under the CBD. It should *inter alia* build upon and further develop the Bonn Guidelines.

Finally we would like to submit the following with regard to definitions/use of terms:

Definitions

Genetic resources

Comments:

The definitions of the terms *biological resources/genetic resources* in the international ABS regime should be the same as the definitions in the CBD. It is important to notice that the term *genetic resource* is to be defined from its utilisation. What is deemed to be a ‘genetic resource’ may therefore depend on the intended or actual use of the genetic material. It can only be characterized as a genetic resource when the intended or actual use is based on the genetic information in the biological material.

The same biological material may have a function both as a biological resource and as a genetic resource. The actual or potential utilisation of the biological material should decide which of these two categories the biological material is subsumed under. When the biological material, e.g. a variety of soya bean, is to

be used as a commodity and to be sold in bulk on an international market, it should be seen as a 'biological resource'. However, the same biological material may be treated as a 'genetic resource' when used in a plant breeding programme.

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

Derivatives and products

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

Derivates and products from a genetic resource will also differ between the different utilisations of the material. The use of a dynamic understanding of what constitutes a genetic resource based on its utilization would seem to solve the derivatives problem.

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

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

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

Misappropriation of genetic resources/traditional knowledge

Norway believes that a working understanding on what we mean with misappropriation of genetic resources and traditional knowledge could be helpful in developing the regime and also with regard to national implementation of the regime. This could be linked to an international obligation in the regime for all parties to prohibit the use of misappropriated genetic resources/traditional knowledge.

At least the following can be considered as acts or cases of misappropriation of genetic resources:

- Use of genetic resources that is not in compliance with CBD or the provisions of the international regime or national legislation
- Any acquisition or utilisation of genetic resources by illegal means
- Use of a genetic resource for purposes substantially different from those for which it was accessed

- Deriving commercial benefits from the acquisition, appropriation or utilisation of genetic resources when the person using the genetic resources, knows, or is negligent to know, that these were acquired or appropriated by illegal means.

Concerning traditional knowledge, Norway submitted a proposal to the WIPO dated 20 April 2006 (WIPO/GRTKF/IC/9/12) on protection against misappropriation and unfair use of Traditional Knowledge based on Article 10bis of the Paris Convention.

The legal standard in article 10bis is "what an honest person would consider an act of unfair competition within a commercial or industrial context". Transposed to the WIPO committee's work, the concept of "behaviour contrary to honest practices or amounting to inequitable conduct" could be developed to guide understanding of what constitutes an act of misappropriation or unfair use of TK. Acts that could clearly qualify as "unfair use" - would inter alia be exploitation of TK obtained by theft, bribery, coercion, fraud etc. while also other relevant acts would, depending on the circumstances in each case be covered.

It could be argued that it would be difficult for indigenous peoples to obtain a court decision in a foreign country. However, it can be argued that the mere possibility would serve as an incentive for users to obtain prior consent from TK -holders and to participate in benefit-sharing arrangements.

Norwegian proposal regarding protection against misappropriation and unfair use of Traditional Knowledge:

1. The members of the Paris Union for the Protection of Industrial Property and the World Intellectual Property Organization should assure nationals of member countries adequate and effective protection against misappropriation and unfair use of Traditional Knowledge (TK)

2. Any use of TK against honest practices in cultural, industrial or commercial matters should be considered as actions in breach of paragraph one.

3. TK holders should in particular be provided with effective means to ensure that:

(i) the principle of prior informed consent applies to access to TK,

(ii) benefits arising from certain uses of TK are fair and equitable shared,

(iii) all acts of such a nature as to create confusion by any means whatever with the origin of the TK are repressed, and

(iv) all acts of such a nature that would be offensive for the holder of the TK are repressed."

II. SUBMISSIONS FROM INTERNATIONAL ORGANIZATIONS, RESEARCH INSTITUTIONS, NON-GOVERNMENTAL ORGANIZATIONS AND STAKEHOLDERS

ACCESS AND BENEFIT-SHARING ALLIANCE (ABSA)

Access and Benefit Sharing Alliance

ABSA

December 15, 2008

Objectives, Scope, Compliance, Fair and Equitable Sharing of Benefits, and Access in the ABS International Regime

Members of the Access and Benefit Sharing Alliance (ABSA) appreciate the opportunity to submit our views in response to Convention on Biological Diversity (CBD) Notification Ref: SCBD/SEL/VN/GD/64971 requesting proposals in advance of the 7th meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-Sharing (ABS WG-7). This submission provides ABSA perspectives on issues under consideration by ABS WG-7 for drafting operational text in the areas of: **Objectives**, **Scope**, **Compliance**, **Fair and Equitable Sharing of Benefits** and **Access**.

Before reaching these issues, it may be helpful to recall the ABSA's ABS Negotiating Principles (attached as Annex 1). ABSA member companies support the development of an ABS International regime (IR) that provides an enabling environment needed to generate social and economic benefits and promotes equity, transparency, predictability, fairness and national treatment for all participants in the ABS IR.

By taking into account real-world needs of innovators the world over, CBD members now have an opportunity to deliver on promises to all ABS stakeholders, including small and medium enterprises (SMEs) and local and indigenous communities with the most to gain from the sustainable commercialization of Genetic Resources (GR), with or without traditional knowledge (TK). Highly bureaucratic ABS regimes in developing countries have failed to generate social and economic benefits in Africa, Asia and Latin America. Imposition of a similarly heavy regulatory framework through the ABS IR would represent a tragic lost opportunity. SMEs in developed and developing countries alike would be most likely to gain through transparent, predictable and nondiscriminatory rules facilitating access and thus the possibilities to generate sharable benefits. Of equal importance, developing countries may be adversely affected by a resource intensive, highly proscriptive ABS IR, particularly in times of increasing economic insecurity, and would stand to benefit more from a targeted, cost-effective ABS IR.

As outlined below, **Objectives** and **Scope** for the ABS IR should remain consistent with the definitions, terms and jurisdictional limitations of the Convention itself as interpreted by subsequent decisions of CBD Ministers, including the *Bonn Guidelines,* the only international ABS instrument with consensus support of CBD members.[1]

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[1] The *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization,* were adopted by COP Decision VI/24) to assist countries in the implementation of CBD ABS provisions, including Articles 8(j), 10(c), 15, 16 and 19, and are available online at www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf.

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Objectives
The objectives of the ABS IR should harken back to the words of the CBD Treaty itself, and accordingly should encompass the following:

1. Protect "the sovereign rights of States"[2] over the *in situ* "genetic resources being provided by a Contracting Party"[3] and "only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention."[4]
2. Identify mechanisms for ABS stakeholders to ensure "[a]ccess, where granted, shall be on mutually agreed terms,"[5] and "shall be subject to prior informed consent of the Party providing such resources, unless otherwise determined by that Party,"[6] and, finally, to establish terms of benefit sharing "upon mutually agreed terms."[7]
3. "Encourage the equitable sharing of the benefits arising from the utilization of" traditional "knowledge, innovations and practices."[8]
4. Endeavor "to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention."[9]

Scope
Consistent with the **Objectives** proposed above and with the terms of its mandate from Decision VII/19 D, the ABS IR should be limited to effective implementation of the relevant provisions in Article 15, Article 8(j) and the three objectives of the Convention.[10]

Based on the clear language of the CBD Treaty, CBD members should limit the scope of the ABS IR to "genetic resources being provided by a Contracting Party"[11] and "only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with

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[2] Convention on Biological Diversity, Article 15.1.

[3] Convention on Biological Diversity, Article 15.3.

[4] Ibid.

[5] Convention on Biological Diversity, Article 15.4.

[6] Convention on Biological Diversity, Article 15.5.

[7] Convention on Biological Diversity, Article 15.7.

[8] Convention on Biological Diversity, Article 8(j) (order of phrasing reversed).

[9] Convention on Biological Diversity, Article 15.2.

[10] Ideas such as "derivatives" or "products" have no mention in the CBD. Nonetheless, they should be addressed under the ABS IR via individual ABS agreements. For more discussion of derivatives and other downstream products in the ABS IR, see **Fair and Equitable Benefit Sharing**, pp.5 - 6.

[11] Convention on Biological Diversity, Article 15.3.

this Convention."[12], based on "mutually agreed terms" (MAT's) between the acquirer and the provider, and Prior Informed Consent, "unless otherwise determined by that Party,"[13]

In this context, CBD Parties should agree to exclude "biological resources" as defined in Article 2 of the CBD that would otherwise would bring under the IR all natural resources and other commodities currently traded by countries all over the world, such as ornamental and garden plants, timber, agricultural produce (like apples or rice), and even household pets.

In addition, the IR should exclude human genetic resources consistent with Article 2 of the CBD, subsequent decisions taken by CBD Ministers, and the *Bonn Guidelines*. Article 2 of the Convention, for example, first defines "Genetic Material" as "any material of plant, animal, microbial or other origin containing functional units of heredity", and subsequently defines "genetic resources" as "any material of plant, animal, microbial or other origin containing functional units of heredity." Further, as adopted by CBD Ministers at the 2nd Conference of the Parties, Decision II/11: Access to Genetic Resources, "Reaffirms that human genetic resources are not included within the framework of the Convention"[14] The intention to exclude human genetic resources is confirmed explicitly in defined scope of the *Bonn Guidelines:* "All genetic resources and associated traditional knowledge, innovations and practices covered by the Convention on Biological Diversity and benefits arising from the commercial and other utilization of such resources should be covered by the guidelines, *with the exclusion of human genetic resources*." (emphasis added)[15]

The IR should recognize existing international instruments and also exclude resources that are already the subject of agreements or negotiations in other fora such as the FAO International Treaty on Plant and Genetic Resources for Food and Agriculture (ITPGRFA), the International Technical Conference on Animal Genetic Resources for Food and Agriculture under FAO, and human, plant and animal pathogens currently the subject of unrelated benefit sharing negotiations in the World Health Organization (WHO).

The IR should apply to *in situ* GR with or without TK acquired after entry into force of the ABS IR in the provider country, and should form a prospective system with no retroactive effect.[16]

Compliance

ABSA members joins CBD Parties, research institutes, indigenous groups and local communities in seeking the development of an enforcement system in the ABS IR that

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[12] Ibid.

[13] Convention on Biological Diversity, Article 15.5.

[14] Decision II/11: Access to Genetic Resources, UNEP/CBD/COP/2/19, p. 22.

[15] See *Bonn Guidelines*, "C. Scope 9, p.7.

[16] The CBD does not apply to genetic resources beyond those "that are provided by Contracting Parties that are countries of origin of such resources." CBD Article 15.3. In that light, these resources should be excluded from the scope of the IR.

provides effective and proportionate redress for all parties in cases of illegal or inappropriate activities related to the IR. While there is currently no agreement on the appropriate mechanism to enforce the ABS IR, ABSA members believe that an existing mechanism or, more likely, a combination of mechanisms, can be identified to serve as a deterrent to illegal or inappropriate activities and to address the question of enforcement across borders that would ensure durable and meaningful benefits for CBD members and indigenous peoples without undermining the incentives that industry needs to undertake bio-prospecting.

ABSA members have long believed that mechanisms considered for inclusion in the ABS IR be measured against real world experience. In this context, all compliance mechanisms under consideration for inclusion in the ABS IR should be subject to two key tests:

1. Examination of real-world experience at the national level to see if they have been effective in domestic ABS regimes;
   and,
2. Benefit-cost analysis to ensure that their potential value to ABS stakeholders would not be outweighed by the cost either at the national level (particularly the cost to developing countries) and/or at the international level.

ABSA members also seek the legal certainty, consistency and equity, which would benefit all CBD stakeholders, through the inclusion of a requirement to provide Mutually Agreed Terms (MAT) in each ABS Agreement – the detailed, written terms and conditions required for legitimate bio-prospecting in those agreements governed by the ABS IR.

Japan's highly-regarded ABS regime does just that. Japan's domestic ABS regime is currently the single most effective national ABS system with proven benefit-generation, and operates through written agreements, i.e., contracts. One way to promote greater inclusion of MATs in written ABS agreements would be through development of model Material Transfer Agreements (MTAs) as in the International Treaty on Plant Genetic Resources (ITPGR).[17] Development of model MTAs also could help to avoid later disputes by promoting transparency and greater understanding on both sides.

There is also increasing awareness that the ABS IR should balance compliance mechanisms with incentives. CBD members understand the need to encourage responsible *in situ* bio-prospecting and to contribute to the increased conservation of *in situ* GR. Development of an ABS IR that encourages environmentally sustainable levels of *in situ* bio-prospecting, is needed both to identify promising areas of research for scientific and commercial development that will generate benefits for CBD members, as well as to provide a greater awareness of the resources found in CBD members. These incentives should encourage the continued cataloguing of the genetic inventory of the planet – a process that has not even approached a fifth of the genetic resources

[17] "UNU-IAS Report, Certificates of Clarity or Confusion: The search for a practical, feasible, and cost effective system for certifying compliance with PIC and MAT" (2008), where authors Brendan Tobin, Geoff Burton and Jose Carlos Fernandez-Ugalde note that MTAs may be helpful to address the absence of national ABS regimes. p. 8.

remaining *in situ* in CBD members. These goals are related, in that increased taxonomy and related bio-prospecting activities may provide greater incentives for conservation.

Compliance mechanisms that would create only a right to litigate in the national judicial system should be avoided. The current situation facing CBD members and indigenous peoples will not improve through the adoption of enforcement mechanisms that rely on far-flung civil litigation. Established forms of alternative dispute resolution include negotiation, mediation and arbitration based on previously agreed written agreements. Alternative dispute resolution may provide a cost-effective alternative to cross-border civil litigation given the international scope of arbitral decisions. For example, Article 8(4)(C) of the Food and Agriculture Organization (FAO) International Treaty for Plant and Genetic Resources for Food and Agriculture (ITPFGRA) Standard MTA provides for recourse to negotiation, mediation and binding arbitration under the auspices of the International Chamber of Commerce' International court of Arbitration.

Some of the international instruments currently under discussion in the area of compliance, such as certificates of origin, still lack clarity in their basic terms and concepts. While ABSA members conceptually understand the potential value of an international certificate as formal documentation of PIC and/or MAT, we have seen very little documentation relating to successful real-world experience with international certificates,[18] and so are not able to make informed decisions on the merits of various certificates proposals. Further, there has been little discussion at the expert level of the actual need for the various certificate systems, as balanced against their cost at the national and international level. As noted, this benefit-cost analysis is essential to the development of a successful ABS IR.

Finally, the ABS IR providing legally binding provisions requiring CBD member governments to provide focal points and transparency in decision-making regarding penalties, to avoid any adverse impact that subsequent changes in government policy may have on companies that had sought and received the appropriate permits in the ordinary course of business.

Fair and Equitable Benefit-Sharing

ABSA members understand the economic value and importance of derivatives and/or downstream products relating to GR with or without TK, and the concern of many developing country CBD members of their importance to **Fair and Equitable Benefit-Sharing.** However, to date it has proven impossible for the ABS WG to agree even upon workable definitions, and/or their inclusion in the ABS IR. Again, the *Bonn Guidelines* provide valuable guidance, and specifies that the parties should address this important issue through negotiation of Mutually Agreed Terms (MAT) in ABS

[18] ABSA members would appreciate an opportunity to review information on national experiences by commercial and noncommercial researchers certification systems implemented at the national level.

agreements.[19] ABSA supports this approach for use in the ABS IR so that the parties to individual ABS agreements can address the issue of derivatives and/or downstream products on a case by case basis, as appropriate given the specific issues raised by research that may differ from sector to sector.

Overall, ABSA members believe that Fair and Equitable Benefit Sharing can best be ensured through an ABS IR that stresses transparency, predictability, legal certainty, equity and provides national treatment to all ABS stakeholders. As noted in the ABSA ABS Principles, ABSA members remain committed to "respect the sovereign rights of CBD members over their *in situ* genetic resources (GR) and to the equitable sharing of the commercialization of GR and any related relevant traditional knowledge (TK) derived from indigenous and local communities, assuming a clear, internationally accepted definition of TK."[20]

Access

As noted by the Indian Minister for Environment and Forestry at the High-level Segment of the 9th Conference of the Parties (COP 9) at Bonn in May 2008: "So far, even after 16 years of adoption of CBD, only 18 countries have come up with legislation on Access and Benefit Sharing. A benefit sharing arrangement needs to be put in place with utmost speed to prevent provider countries from losing interest and diverting the scarce resources for their development needs."[21] Industry agrees with India's assessment that the issue of national regimes is an area in urgent need of assistance. It is a truism that without effective ABS regimes at the national level to facilitate access to GR and provide clean title to GR, businesses will remain reluctant to engage in high-risk commercial activities in developing countries.

An ABS IR should encourage adoption of national access provisions flexible enough to provide for the timely decision-making on ABS applications made by scientific and commercial researchers in different sectors. Procedures established to regulate bio-prospecting in a number of CBD members, including in Brazil and in India, have failed to provide for timely decisions, thus frustrating commercial and scientific activities. In addition, there should not be any discrimination between domestic and foreign bio-prospecting applications. There is evidence that the promulgation of restrictive laws in the Philippines and in a number of Latin American countries has chilled bio-prospecting and has not advanced CBD goals.

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[19] "(b) In the implementation of mutually agreed terms, users should . . . (v) Ensure that uses of genetic resources other than those for which they were acquired, only take place after new prior informed consent and mutually agreed terms are given;" and, further, "2. Indicative list of mutually agreed terms 44. (i) Provisions regarding the sharing of benefits arising from the commercial and other utilization of genetic resources and their derivatives and products." *Bonn Guidelines,* p. 6 and p.13.

[20] ABSA ABS Negotiating Principles, attached at Annex 1, and available online at: http://www.abs-alliance.org/version02/html/issue.html.

[21] Statement by Honorable Minister of State (Environment), India for the High-level Segment of the Ninth Conference of the Parties (COP-9) to the Convention on Biological Diversity (CBD), 28-30th May 2008, Bonn, Germany.

It is well understood that complicated requirements may drive academic scientists underground or result in worse documentation of research activities; in fact this could affect commercial bio-prospecting even more negatively. Few bio-prospecting agreements lead to commercialized discoveries, but nonetheless contribute to the goals of the Convention and the science-base of CBD members.[22] Non-commercial research ultimately may contribute to the commercial development of a product and commercial research may be licensed for public research purposes. The development of Golden Rice, for example, relied heavily on private-sector research. Given the need for research to move back and forth between non-commercial and commercial purposes, ABSA members fail to understand how different rules or standards for commercial versus noncommercial uses of GR, with or without TK, would be workable in real world conditions.

Fortunately, the clear text of the CBD Treaty recognizes the need for creation of "conditions to facilitate access to genetic resources for environmentally sounds uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of the Convention."[23] The ABS IR should encourage the further development and harmonization of national regimes in the spirit of the *Bonn Guidelines*, including establishment of national focal points and possible model provisions for access and benefit sharing critical to its successful implementation at the national level.

Conclusion

ABSA members hope that the foregoing is helpful to CBD members and other ABS stakeholders at the upcoming 7th Meeting of the Ad Hoc Open Ended Working Group on Access and Benefit Sharing to develop operational text to address the above areas. By focusing on areas of previous consensus found in the text of the CBD Treaty, prior Ministerial Decisions on ABS and the *Bonn Guidelines,* CBD members have the greatest likelihood of finding common ground on a combination of voluntary and legally binding provisions needed for an effective ABS IR.

Annex I: ABSA ABS Negotiating Principles

[22] Merck, a founding member of the ABSA, did not successfully commercialize any of the discoveries found during its multiyear collaborative bio-prospecting agreement with INBIO.

[23] Convention on Biological Diversity, Article 15.2.

Access and Benefit Sharing Alliance

ABSA

ABS Negotiating Principles

Introduction:

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

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

In that spirit, ABSA members provide the following principles.

Preamble:

ABSA members:

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

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

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

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

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PRINCIPLES:

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

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

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

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

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

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

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

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

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

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

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

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

AREAS OF CONTINUING DISAGREEMENT

- **New Additional Mandatory Disclosure Obligations**

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

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

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

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

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

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

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

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

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

BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO)

December 15, 2008

VIEWS AND PROPOSALS OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO) IN RESPECT OF THE MAIN COMPONENTS IN ANNEX I OF DECISION IX/12 OF THE CONFERENCE OF THE PARTIES (COP) OF THE CONVENTION ON BIOLOGICAL DIVERSITY (CBD)

General Comments:

The decisions of the Conference of the Parties (COP) of the Convention on Biological Diversity (CBD) define the work program for the Ad-hoc Working Group on Access and Benefit-Sharing (ABS Working Group). The Working Group has been tasked by the COP to "elaborate and negotiate an international regime on access to genetic resources and benefit-sharing" (Decision VII/19) at the earliest possible time before the tenth meeting of the COP in October 2010(Decision VIII/4).

Decision IX/12 of the Ninth Session of the Conference of the Parties (COP-9) of the Convention on Biological Diversity (CBD) "*[i]nvites* Parties, Governments, international organizations, indigenous and local communities and relevant stakeholders to submit, for further elaboration and negotiation of the international regime on access and benefit-sharing, views and proposals including operational text, where relevant, in respect of the main components listed in Annex I to the present decision, preferably with supporting rationale."

As requested by the COP, set forth below are the views and proposals of BIO regarding the components listed in Annex I to Decision IX/12 along with accompanying rationale in the form of comments.

The Biotechnology Industry Organization (BIO) is pleased to take this opportunity to submit such views and proposals on matters to be addressed by the ABS Working Group. BIO respectfully requests that the ABS Working Group Members take these comments into consideration during their deliberations.

Annex I [Annex to COP 9 Decision IX/12]

THE INTERNATIONAL REGIME

I. OBJECTIVE

General Comment on Objectives: The mandate of the ABS WG 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) of the Convention and the three objectives of the Convention" (COP Decision VII/19D, para. 1). As a general matter, the objectives of the International Regime (IR) must track the terms of reference of the ABS Working Group, which were dictated by the COP in Decision VII/19D and must also be consistent with the terms of the CBD itself. Efforts to further broaden or otherwise modify these governing principles are outside the scope of the ABS WG exercise and should be avoided.

The mandate of the ABS WG refers to the implementation of Article 15 and Article 8(j) of the CBD and "the three objectives of the Convention" (Decision VII/19D). The text of this paragraph should therefore be limited to CBD Articles 15 and 8(j). References that have been proposed to other articles, e.g., Articles 16 (transfer of technology) and 19.2 (access to benefits from "biotechnologies based on genetic resources") address different issues and should not be included.

The provisions of Article 15 regarding access and benefit-sharing are limited to "genetic resources." The IR should be limited as such and therefore should not include "derivatives" or "products." In addition, including such concepts may be inconsistent with the notion of obligations arising through "mutually agreed terms" in an ABS arrangement and would have potential to subject downstream actors to further uncertainties.

The ABS WG should proceed with care when addressing the topic of "traditional knowledge." For example, the term "associated traditional knowledge," which is presented as a textual option for the objectives, is not used in the CBD. Article 8(j) specifically recites that its scope is limited to such "knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity." In order to avoid confusion, a specific reference to Article 8(j) is warranted when addressing "traditional knowledge" issues. In addition, the terms "misappropriation" and "misuse" are not used or defined in the CBD. While these terms may be a useful tool for dialog, they should not be included as a potential definitional element relating to the objectives of the international regime.

II. SCOPE

General Comment on Scope: The IR should be within the scope of the CBD. In respect of access and benefit-sharing, the terms of the CBD are limited to "genetic resources." Thus, the IR should not apply to the broader term "biological resources" and should also not apply to "derivatives," "products" or other items, however defined, unless those items would also meet the definition of a genetic resource under the Convention, i.e., "genetic material of actual or potential value," where genetic material is defined as "any material of plant, animal, microbial or other origin containing functional units of heredity" (CBD Article 2). Thus, proposed references to "derivatives" and "products," should be deleted to be consistent with the scope of the CBD. In addition, reference to Article 8(j) is warranted when discussing "traditional knowledge" to link the concept of traditional knowledge to the context in which it is used in the CBD.

The Options: In respect of the three options presented, Option 1 is more comprehensive and would make the most appropriate basis for discussions. However, option 3 could be amended to be consistent with the views of BIO set forth herein. Option 2, however, appears to suggest an overly broad scope for the IR.

For example, it contains no exception for genetic resources made freely available (e.g., "commodities"), resources found beyond national jurisdictions or other excluded categories of genetic resources.

Excluded Subject Matter

The following subject matter should be excluded from the scope of the IR:

i. *Human genetic resources* – human genetic resources must be excluded consistent with COP Decision II/11, reaffirming that "human genetic resources are not included within the framework of the Convention;"

ii. *Genetic resources acquired prior to the entry into force of the IR* (i.e., no retroactive effect) - any effect should arise only after obligations are accepted by a particular Contracting Party;

iii. *Genetic material made freely available or that otherwise enters the public domain* (i.e., commodities or other genetic resources made available without restriction) - If the genetic resources are made freely available without restriction, they should not be covered by the IR;

iv. *Species listed in Annex I of the ITPGRFA*, unless the use is beyond the scope of that agreement;

v. *Genetic resources found in areas beyond national jurisdiction* - The CBD recognizes "the sovereign rights of States over their natural resources" (CBD Article 15.1). In that light, resources accessed beyond national jurisdictions should be excluded from the scope of the IR to avoid any doubt.

vi. *Genetic resources located in the Antarctic Treaty Area* - To the extent that such an exclusion would avoid competing "sovereignty" claims to resources located in the Antarctic Treaty Area, it would seem positive, so we suggested keeping this exclusion.

vii. *Human, plant and animal pathogens, including viruses* - Pathogens should be excluded from the IR. Inclusion of such resources does not appear consistent with the scope of the Convention and its objective of conservation of biological resources.

Effective Date

The effective date should be the date of the international regime and not the CBD in order to establish a prospective system that has no retroactive effect. The IR will likely add additional guidance or requirements relating to ABS regimes. Any acquisitions of genetic resources made prior to the IR will have been accessed pursuant to national laws and access and benefit-sharing terms that were agreed at that time. The IR should not contemplate the possibility of changing obligations relating to such acquisitions after the fact. In addition, applying the IR in a purely prospective manner will enhance enforcement by providing greater certainty to providers and recipients of the relevant genetic resources.

The proposed language referring to applying the IR to "continuing benefits" arising from utilization prior to the CBD or the IR itself as proposed in current paragraph II(2)(b) of the Annex is not appropriate as it would retroactively apply the IR to acts done prior to the entry into force of the CBD and the IR. This type of approach, attempting to regulate acts already agreed or to re-negotiate terms of access already granted under access and benefit-sharing laws in effect at that time, would be unworkable.

Relationship to Other International Organizations and Agreements

The scope section proposes negotiating instructions that provide for "flexibility" in respect of "specialized" ABS systems such as the Multilateral System established under the ITPGRFA, and for "special" consideration of particular matters. These provisions appear to be negotiating instructions, that may be helpful for the negotiation, but should not be incorporated into a final agreement.

This section also addresses relationship to UPOV, which deals with the protection of plant varieties, and discussions in the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (GRTKF). The IR should not interfere with protection of plant varieties under UPOV. To that extent, it is appropriate for the CBD to give special consideration to the relationship with that agreement. Similarly, the WIPO IGC is the appropriate body in WIPO for the consideration of matters relating to the relationship of intellectual property and CBD related issues. The work in the WIPO IGC should be given "special consideration" in the sense that the CBD should defer to WIPO on all intellectual property-related issues.

Genetic resources within the remit of the FAO Commission on Genetic Resources for Food and Agriculture may deserve special consideration, and at least some of these resources (e.g., species listed in Annex I of the Multilateral System of the ITPGRFA) should be excluded entirely. For example, animal genetic resources may justify special consideration in light the ongoing work of the Intergovernmental Technical Working Group on Animal Genetic Resources for Food and Agriculture in the FAO context.

As noted previously, genetic resources found in areas beyond national jurisdiction as well as resources located within the Antarctic Treaty Area should be excluded from the IR.

III. MAIN COMPONENTS

A. Fair and equitable benefit-sharing

General Comment on Fair and Equitable Benefit-Sharing: BIO supports fair and equitable benefit-sharing under the terms of the CBD. The CBD is clear that the benefit-sharing envisioned "shall be on mutually agreed terms" (see, e.g., Article 15.7). It should be understood that any of the potential components listed for further consideration are to be subject to reaching "mutually agreed terms" consistent with the CBD. Such terms will normally be embodied in a contract or other type of agreement that represents a meeting of the minds of the provider and the recipient of the genetic resources at issue. In addition, there needs to be transparency and typical contracting principles must apply. Therefore, attempting to establish a "multilateral benefit-sharing option" through the treaty mechanism or to otherwise mandate particular ABS terms would appear to be both inconsistent with CBD principles and unworkable. In order to maintain legal certainty for both the provider and the recipient, the mutually agreed terms must govern the transaction and ensure compliance.

Linkage of Access and Benefit-Sharing

BIO supports linking fair and equitable sharing of benefits to access to the genetic resources. In fact, benefit-sharing issues should be handled at the point of access through the mutually agreed terms embodied in an appropriate ABS agreement in order to reduce any uncertainties as to the status of genetic resources and benefits arising from their use.

BIO also supports further elaboration of different types of benefits, including monetary and non-monetary benefits, when included in mutually agreed terms. This work could draw on the elements articulated in respect of monetary and non-monetary benefits in Appendix II of the Bonn Guidelines. However, BIO does not support any "mandatory" benefits or a "fixed-basket of" benefits under the IR. To be consistent with the CBD, benefit-sharing must be based on mutually agreed terms. Access to and transfer of technology could be addressed as an issue of benefit-sharing arising from the use of genetic resources, if included in mutually agreed terms, consistent with CBD Articles 15 and 16.

Capacity Building and Awareness Raising

Exercises in capacity building for developing countries, as well as awareness raising activities for bio-prospectors may be helpful in ensuring better compliance with ABS systems. For example, BIO has voluntarily established detailed guidelines for bio-prospecting for its members with the goal of educating BIO members regarding relevant issues that may arise in the conduct of these activities. These guidelines

are publicly available and are attached to the comments that BIO submitted to the Technical Expert Group on Concepts, Terms and Working Definitions (those comments are attached to this document for consideration by the ABS Working Group).

It is important that both the participation of indigenous and local communities, as well as any sharing of the benefits with traditional knowledge holders be based on mutually agreed terms. In addition, any such measures must be part of a transparent national ABS regime and provide clear points of contact/approval for obtaining prior informed consent and agreement relating to mutually agreed terms.

Mechanisms to Encourage Benefits be Directed to Conservation and Sustainable Use

It is not clear what mechanisms are envisaged to encourage benefits to be "directed toward biodiversity and socio-economic development." The IR should not regulate specific terms of ABS relating to how the benefits should be "directed." However, internal to national systems, countries may choose to allocate benefits, once received. The recipient, however, should have no obligation other than to transfer benefits according to the ABS agreement.

Development of international minimum conditions and standards

This element should not be further elaborated. For example, it is not clear what "conditions" and "standards" are being referred to in the draft language of paragraph (1). To the extent that this is an attempt to regulate particular terms in ABS agreements, this should be avoided.

Benefit Sharing for Every Use

This concept appears to indicate mandatory benefit-sharing for "every use" of a genetic resource, even including uses that are not subject to mutually agreed terms (e.g., uses of a genetic resource made freely available). This is outside the scope of the CBD and should not be included in the International Regime.

Multilateral benefit-sharing options when origin is not clear or in transboundary situations.

This introduces uncertainties and may not be consistent with the concept of "mutually agreed terms" to the extent that this may envision rights of third countries to "claim" benefits even if they are not party to an ABS agreement. Permitting claims of third countries not party to an ABS agreement would add great uncertainties to the process. However, in cases where multiple countries hold resources in common, agreements between such countries could be arranged so that benefits received by one member in a group of countries or indigenous communities that holds a particular resource in common would share the benefits received with others from that group. Such agreement should be separate from the ABS agreement between provider and recipient and should not have any effect on the liabilities or obligations of a recipient of genetic resources that is not party to that agreement. It should be noted, however, that attempting to negotiate such an agreement would likely be highly complex and resource intensive. In addition, the wide diffusion of many resources would likely make such an exercise impracticable in at least a number of cases.

Establishment of trust funds to address transboundary situations.

It is not clear what such a "trust fund" would entail. If it is a fund for capacity building to address certain biodiversity sustainability issues, this may be further considered. However, the fund should not envision any type of international "claim" or "tribunal" under the CBD that would make findings as to potential wrongdoing or "rights" to share in benefits. Disputes should be handled pursuant to mutually agreed terms and appropriate dispute settlement mechanisms. In addition, if such a fund were to be established, funding sources would need to be identified. BIO does not support "taxing" transfers made under an ABS agreement pursuant to obligations of the IR.

Enhanced utilization of Bonn Guidelines and Development of Model Clauses for MTAs

BIO supports, in principle, enhanced utilization of the Bonn Guidelines. The Bonn Guidelines are particularly useful in respect of presenting options for Material Transfer Agreements, including monetary and non-monetary benefit options, etc. However, the Bonn Guidelines also discuss certain matters (e.g., consideration of patent disclosure requirements (see para. 16(d)(ii) of the Bonn Guidelines) that have been shown to have negative consequences. As such, enhanced utilization of the Guidelines must not be construed as an endorsement of all concepts presented therein, but rather as guidelines to assist in developing national ABS regimes.

The development of model clauses also may be helpful to guide ABS negotiations in certain cases. However, if established, any such clauses should not be binding as the IR should permit flexibility in achieving mutually agreed terms for material transfers. In addition, alternatives, such as a database of sample clauses from successful ABS agreements or capacity building programs relating to "best practices," may be preferable.

B. **Access to genetic resources**

General Comment on Access to Genetic Resources: BIO supports the concept of access to genetic resources being linked to fair and equitable sharing of benefits on the basis of mutually agreed terms, as envisioned in the CBD. However, national laws governing the terms of access, e.g., in national ABS regimes, should be non-discriminatory and should thereby treat domestic and foreign researchers on similar terms. In addition, access terms should be "facilitative" in nature and should not be overly regulatory or punitive in nature.

Recognition of the sovereign rights and the authority to determine access

This language must be consistent with the language used in CBD Article 15.1. In that light, it should refer to the recognition of "the sovereign rights of States over their natural resources," and "the authority to determine access to genetic resources rests with national governments and is subject to national legislation." The language used should not be susceptible of interpretation that may extend the "sovereignty" principle beyond that contained in the CBD.

Legal certainty, clarity and transparency of access rules

BIO strongly supports the legal certainty, clarity and transparency of access rules. Specific and detailed guidance should be incorporated into the IR with respect to access rules that, e.g., require identification of clear points of contact and give legal security to bioprospectors that access genetic resources in a particular CBD Member.

Non-discrimination of access rules

BIO supports non-discrimination of access rules. All researchers, regardless of their status within the CBD or their national origin, should be permitted to access resources under the facilitative mechanisms of the ABS regime. These researchers should also be subject to the benefit-sharing requirements implemented by national laws in provider countries, in order to provide benefits that may flow thereby consistent with the goals of the CBD.

International access standards and internationally developed model legislation or guidance

BIO can support detailed guidance in the IR as to certain access principles consistent with the CBD requirement to "facilitate" access in Article 15.2, including, e.g., standards that would help ensure transparency and clarity, including identification of clear authorities and points of contact to improve reliability in agreed terms of access.

However, while model legislation may be useful to standardize approaches between nations and thereby facilitate access by eliminating differences of law between jurisdictions, such an approach would be resource-intensive. It would be difficult for Parties to negotiate appropriate model legislation in light of different national circumstances and the general recognition that a "one-size fits all" approach will not be workable. It may also be inconsistent with the principle contained in CBD Article 15.5 that Parties may,

e.g., forego requirements for prior informed consent if they so choose. Resources would be better spent on developing specific guidance on certain access and other principles consistent with the CBD and providing needs-based capacity building for countries when implementing their national ABS regimes.

Simplified access rules for non-commercial research

It will be very difficult to define "non-commercial research" for purposes of providing a separate set of access rules. Generally speaking, a unitary system in which the agreements themselves would limit the research to non-commercial uses, commercial uses or a combination of the two, and would address benefit-sharing terms accordingly would be an better approach. To the extent that work on a split system is pursued, any system that envisions a differentiation between "non-commercial" and "commercial" research should provide for the ability to "convert" from non-commercial to commercial research. While not optimal, this approach may be workable if a clear definition for what is intended by "non-commercial" research and for how this may transition to "commercial" applications is developed.

C. **Compliance**

General Comment on Compliance: BIO supports effective compliance to ensure that the objectives of the CBD can be implemented in a fair and equitable manner that facilitates access. In that light, a contract-based approach envisions tools that are currently used effectively in many international business transactions, such as private international law mechanisms including voluntary international mediation, arbitration and civil law regarding enforcement of foreign judgments, used in manner that can provide effective enforcement. In respect of foreign enforcement of judgments, however, it should be noted that CBD Members in the past have been reluctant to recognize judgments from other jurisdictions. The delegation of Canada has explained the utility of private international law measures in their submission to the sixth session of the ABS Working Group (UNEP/CBD/WG-ABS/6/INF/3/Add.2).

Awareness-raising activities

BIO supports the use of tools to encourage compliance, including awareness-raising activities to assist potential commercial and non-commercial bioprospectors in understanding the objectives of the CBD and elements of national ABS laws.

Mechanisms for information exchange

BIO supports, in principle, mechanisms for information exchange relating to monitoring compliance with CBD requirements. However, more information is needed on specific proposals for information exchange for BIO to articulate a view. For example, recipient country officials should not be tasked with interpreting or enforcing foreign laws, whether or not in the context of alleged "infringements." Further, any such mechanisms must respect agreements regarding confidentiality of the relevant parties.

Internationally recognized certificate issued by a domestic competent authority

There are still many outstanding issues regarding the feasibility of establishing such an international certificate system (see, e.g., the Report of the Technical Experts Group in UNEP/CBD/WG-ABS/5/7 (Feb. 20, 2007)). In that light, such certificates should not be considered for the International Regime until a much more thorough discussion has taken place as to the actual use of such certificates. Further, these types certificates, if pursued, should not be tied to other laws, e.g., intellectual property laws.

Development of tools, including private international law mechanisms, to enforce compliance

Any enforcement system should build on existing systems. In cases involving violations of national access laws, appropriate, effective and proportionate measures (including civil and/or criminal measures) should be considered. However, extraterritorial "enforcement" mechanisms under the CBD itself, e.g., CBD tribunals, would be unworkable and should be avoided.

In the case of enforcing ABS systems, private international law offers many dispute settlement mechanisms that are currently used to enforce contracts relating to international business transactions around the world; see, e.g., paper by the delegation of Canada submitted to the sixth ABS WG meeting

(UNEP/CBD/WG-ABS/6/INF/3/Add. 2 (Jan. 15, 2008)). Measures such as negotiation, mediation, arbitration and consideration of enforcement of foreign judgments should be further elaborated.

Further consideration of existing frameworks established under private international law to improve cross-border enforcement of ABS agreements may be further studied, however, CBD Members in the past have been reluctant to recognize judgments from other jurisdictions. The voluntary use of existing mechanisms, such as the New York Convention on the Recognition and Enforcement of Foreign Arbitral Awards, in mutually agreed terms, could provide a good starting point for discussion.

International understanding of misappropriation/misuse

A further understanding of the concept of "misappropriation" or "misuse" may be helpful to the dialog among Members of the ABS Working Group. However, providing a definition in the IR of "misappropriation" or "misuse" may not be appropriate in that this would add a term that is not found in the CBD. A common understanding of these terms should include the notion of a link to compliance with national ABS laws. In other words, if there is no violation of national law, there is no misappropriation. Further, in order to reach a common understanding of the term, it will be necessary to better understand the intended context, e.g., the purpose for which the term will be used and any consequences of acts that may be deemed "misappropriation" or "misuse."

Sectoral MTA model clauses and access standards

A sectoral approach in the IR is needed as a general matter because a "one size fits all" approach would be unworkable given the vast differences in how genetic resources are utilized by different industries. Further, the development of model clauses may be helpful to guide ABS negotiations in certain cases. However, if established, any such clauses should not be binding as the IR should permit flexibility in achieving mutually agreed terms for material transfers. In addition, alternatives, such as a database of sample clauses from successful ABS agreements or capacity building programs relating to "best practices" may be preferable. BIO also supports providing guidance with respect to certain access principles consistent with the CBD requirement to "facilitate" access in Article 15.2. For example, guidelines that would help ensure transparency and clarity, including identification of clear authorities and points of contact to improve reliability in agreed terms of access.

Codes of conduct and identification of "best practices"

Voluntary "Codes of Conduct" for industry may be helpful. One current example in the biotechnology sector is the BIO Guidelines on Bioprospecting. Any such code should be established on a voluntary basis by an industry association with participation from industry actors. The industry group itself may monitor compliance. Mandatory "codes of conduct" would be counterproductive and would not be appropriate. In addition, to the extent that this language envisions a "mandated" code to be enforced through a CBD compliance-type mechanism, this would be very problematic and should be avoided. Identification of "best practices," however, could also take the form of guidelines or other instruments that would not be binding and would provide significant benefits in this area.

Unilateral declaration by users

It is not clear what is envisioned to be a "unilateral declaration" in this context. More information is needed on the nature of the declarations intended. If it is a voluntary, "good faith" declaration that, to the knowledge of the user, no resources were obtained in contravention of any national laws, it could be studied further. However, any declaration should be kept out of particular areas of law, such as intellectual property law. Further study of unilateral, voluntary declarations may be envisioned, e.g., on customs forms when bringing resources into recipient countries. A voluntary declaration may be feasible, depending on how it is designed. However, the potential for unintended consequences such as interruption of trade flows must be fully considered.

Tracking and reporting systems and identification of check-points.

Attempting to develop a centralized tracking and reporting system relating to any and all transfers of genetic resources would be a highly resource intensive exercise. In addition, the potential for unintended

consequences, such as interruption of voluminous trade in goods, must be fully considered. However, further study of tracking mechanisms may be appropriate.

The concept of identification of "check points" envisions a user-country approach to enforcement of foreign ABS laws. The IR should instead focus on implementation of effective national ABS regimes in provider countries. Nonetheless, certain check points in user countries, such as agencies responsible for border entry points, may be feasible. However, agencies involved in functions generally unrelated to transport or acquisition of materials, such as intellectual property offices, are not appropriate "check points." In addition, potential for unintended consequences, such as interruption of voluminous trade in goods, must be fully considered.

Disclosure requirements

BIO opposes proposals made regarding new patent disclosure requirements (e.g., regarding source/origin of genetic resources). BIO members are of the view that such requirements will be (a) ineffective in promoting the objectives sought (e.g., compliance with CBD principles) and (b) will introduce uncertainties into the patent system that will inhibit innovation in relevant technologies and will thereby decrease potential benefit-sharing from such efforts. Detailed and lengthy discussions in WIPO and WTO, have confirmed this view and further, have not led to any consensus on such proposals. These proposed requirements should not be included in the IR. Instead, promoting access and benefit-sharing through "mutually agreed terms" is the best approach. To the extent further discussion is necessary on these proposals, it should be done at WIPO.

Remedies and sanctions

This topic should be understood in the sense of exploring remedies and sanctions available through the dispute settlement mechanisms mentioned above and should not attempt to impose a type of international regulation with respect to bioprospecting or related activities.

Measures to ensure compliance with customary law and local systems of protection

Any measures to ensure compliance with customary law and local systems of protection should be developed at the national level, in light of the vast differences in customary law approaches. However, the IR should include provisions, such as the identification of clear points-of-contact, to ensure that legal certainty, clarity and transparency of the ABS regime are maintained as to the appropriate hierarchy and so the terms of ABS agreements will be respected.

D. Traditional knowledge associated with genetic resources

General Comment on Traditional Knowledge Associated with Genetic Resources: BIO supports use of traditional knowledge in accordance with the appropriate access and equitable benefit-sharing principles articulated in the Convention, including under Article 8(j). However, any such measures must be transparent in nature. In addition, the scope of what is envisioned by the term "traditional knowledge" is paramount. The scope in the IR should be limited to "knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity" consistent with CBD Article 8(j). In addition, any provision relating to traditional knowledge should not attempt to regulate or repatriate information that has entered, or may enter, the public domain. This could have significant ramifications beyond the CBD context and would provide great uncertainty.

Measures regarding use of TK in ABS context

BIO supports further consideration of measures to ensure the fair and equitable sharing of benefits with traditional knowledge holders. However, any such measures should be clear and transparent in order to ensure legal certainty regarding the access of traditional knowledge and benefit-sharing arising therefrom.

Similarly, any measures to ensure that access to TK takes place in accordance with community level procedures should be developed at the national level, in light of the vast differences in customary law approaches. However, the IR should include provisions, such as the identification of clear points-of-

contact to ensure that legal certainty, clarity and transparency of the ABS regime are maintained. Along these lines, BIO supports the identification of an individual or authority to grant access. This is an essential part of developing an access regime that is consistent with the principles of legal certainty and transparency and is thereby a crucial element of a workable regime.

In order to facilitate this work, further consideration of measures, such as the "identification of best practices" or establishment of model clauses for MTAs could be further elaborated as a non-binding set of guidelines with respect to those entities that may access traditional knowledge. As noted previously, BIO can support detailed guidance as to certain access principles consistent with the CBD requirement to "facilitate" access in Article 15.2. Similar principles may also be appropriate in the context of TK. However, it should be noted that CBD Article 15.2 only applies to genetic resources.

Access with approval of TK holders

When domestic procedures are implemented, the approval of TK holders should be part of "prior informed consent" process established at national level with appropriate input from TK holders in the relevant jurisdiction. Recipients should not be drawn into potential disputes between provider countries and TK holders.

Engineered or coerced access to TK without consent of the relevant TK holders would not be consistent with notions of prior informed consent. Appropriate legal authority to address this concern should be established at the national level. For example, many countries provide for protection against "contracts of adhesion" or other manifestly unfair arrangements. Similarly, contracts may be voided if entered into under duress. However, if there is a grievance that the access has been "coerced" because of dissatisfaction with the national ABS law, and the recipient has acted in good faith, this should be considered a domestic matter regarding the ABS regime and should not affect the researchers and the terms agreed by that party.

E. Capacity

BIO members support capacity building measures as developed by CBD Parties under the terms of that agreement. This includes capacity building at levels for the various acts listed in item E(1) of the Annex. However, industry actors should not bear any mandatory obligation to provide resources for such activities. Instead, participation should be done on a voluntary, case-by-case basis involving mutually agreed terms.

IV. NATURE

General Comment on Nature: BIO supports the view that the international regime should be non-binding. This is based on a number of factors, including: (i) many countries have only recently implemented or have not yet implemented national ABS systems; (ii) until further experience is gained, maximum flexibility should be afforded under the CBD while still documenting best-practices and norms to enhance operability of the agreement; and (iii) further consideration of utility of existing mechanisms, i.e., ABS agreements, arbitration and other dispute settlement mechanisms, etc., need to be pursued prior to entering into a binding regime.

Options:

BIO favors Options 2 and 4 as presented in Decision IX/12. As noted above, BIO members continue to support the concept of a non-binding instrument. Therefore, to maintain all options without prejudice to the outcome of the negotiations, the recitation of a combination of "legally binding and/or non-binding instruments" (emphasis added, from Option 2) should be maintained. BIO can also agree with Option 4. The work should at least commence on the basis of creating one or more non-binding instruments and delineating best practices. Once the substantive provisions are worked out, then a more informed

discussion may take place regarding the nature of the agreement. It is very difficult to reach agreement on the binding nature of any such agreement if the content is unknown.

Options 1 and 3 are not appropriate as both mandate an entirely legally binding instrument and should be deleted. Further, with respect to Option 1, any successful IR must include a heavy reliance on private international law mechanisms, particularly with respect to cross-border disputes that may arise with respect to mutually agreed terms of access and benefit-sharing.

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

Introduction:

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

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

General Comments:

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

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

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

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

Specific Comments:

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

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

CBD Article 2 provides the following definitions:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

ANNEX I

Guidelines for BIO Members Engaging in Bioprospecting

Preamble

The Biotechnology Industry Organization,

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

hereby establishes the following Guidelines for bioprospecting.

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

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

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

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

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

B. Scope of the Guidelines:

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

II. Conduct of Bioprospecting

A. Steps to take before engaging in Bioprospecting.

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

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

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

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

III. **Prior Informed Consent**

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

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

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

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

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

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

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

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

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

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

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

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

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

ANNEX II

BIOTECHNOLOGY INDUSTRY ORGANIZATION
Suggested Model Material Transfer Agreement

Introduction

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

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

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

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

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

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

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

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

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

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

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

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

Preamble

Whereas:

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

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

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

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

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

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

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

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

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

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

Article 1. Definitions

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

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

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

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

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

Article 2. Materials

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

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

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

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

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

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

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

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

Article 3. Transfer

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

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

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

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

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

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

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

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

Article 4. Use of the Materials

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

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

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

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

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

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

Article 5. Sharing of Benefits

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

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

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

Alternative 3: **as described below.**

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

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

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

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

Article 6. Conservation and Sustainable Use of Biodiversity

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

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

Article 7. General Provisions

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

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

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

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

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

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

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

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

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

Signatures

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

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

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

COMMENTS OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION (BIO) AND THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA) ON ISSUES TO BE ADDRESSED BY THE TECHNICAL AND LEGAL EXPERTS GROUP ON COMPLIANCE

Introduction:

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

The Biotechnology Industry Organization (BIO) and the Pharmaceutical Researchers and Manufacturers of America (PhRMA) appreciate this opportunity to submit comments on matters to be addressed by the Technical and Legal Experts Group on Compliance ("Compliance TEG"). BIO and PhRMA respectfully request that the experts selected for the Compliance TEG take these comments into consideration during their deliberations.

General Comments:

BIO and PhRMA members firmly believe that the proposed international regime on access and benefit-sharing should be within the scope of the CBD. It is also our strong belief that a "one size fits all" approach is not workable for the International Regime. Suppliers and recipients of genetic resources will obtain optimum economic and social benefits through the negotiation of "mutually agreed terms" for access and benefit-sharing at the "point of access," rather than applying a fixed access scheme and a fixed "basket" of benefits mandated by a treaty. Negotiations at the point of access would allow suppliers and recipients to determine the appropriate balance between "up-front" and "back-end" benefits for the relevant transaction as well as to determine an appropriate level of benefits arising from the contemplated arrangement. Compliance measures envisioned under the International Regime should be consistent with this approach.

BIO and PhRMA members support providing for effective compliance measures under the International Regime to ensure that the objectives of the CBD can be implemented in a fair and equitable manner that facilitates access. In that light, the use of existing tools, including the use of private international law mechanisms, should be further considered. Some of these tools, including mediation, arbitration and other dispute settlement mechanisms, are currently used effectively in many international business transactions and provide a good foundation for facilitating transactions relating to genetic resources. The delegation of Canada has explained the utility of such measures in their submission to the sixth session of the ABS Working Group (UNEP/CBD/WG-ABS/6/INF/3/Add.2).

Note on compliance and intellectual property. Industry strongly opposes acceptance of proposals for new disclosure requirements in patent applications relating to genetic resources. Industry is of the view that such requirements will be (a) ineffective in promoting the objectives sought (e.g., compliance with CBD principles) and (b) will introduce uncertainties into the patent system that will inhibit innovation in relevant technologies and will thereby decrease potential benefit-sharing from such efforts. Detailed and lengthy discussions in the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) have confirmed this view. These requirements should not be included in the International Regime. Instead, promoting access and benefit-sharing through "mutually agreed terms" is the best approach. To the extent further discussion is necessary on these proposals, it should be done at WIPO, which has an intergovernmental committee (IGC) with a specific mandate to discuss matters regarding the relationship of intellectual property and genetic resources, traditional knowledge and folklore.

Specific Comments:

The terms of reference of the Compliance TEG provide that the experts group will consider and address the following questions. The questions are reproduced below and are followed by the comments of BIO and PhRMA.

(a) What kind of measures are available, or could be developed, in public and private international law to:

(i) Facilitate, with particular consideration to fairness and equity, and taking into account cost and effectiveness:

a) Access to justice, including alternative dispute resolution;

b) Access to courts by foreign plaintiffs;

(ii) Support mutual recognition and enforcement of judgments across jurisdictions; and

(iii) Provide remedies and sanctions in civil, commercial and criminal matters;

in order to ensure compliance with national access and benefit-sharing legislation and requirements, including prior informed consent, and mutually agreed terms;

Comment:

Facilitating access to justice and access to courts by foreign plaintiffs

Any enforcement measures considered by the Compliance TEG should build on existing systems.

In the case of enforcing ABS systems and facilitating access to justice, private international law offers many alternative dispute mechanisms that are currently used to enforce contractual agreements relating to international business transactions around the world.[1] Existing measures such as negotiation, mediation, arbitration and consideration of enforcement of foreign judgments should be further elaborated and adapted for use in this context. The New York Convention on the Recognition and Enforcement of Foreign Arbitral Awards (New York Convention) could provide a good starting point for discussion. The New York Convention currently has 143 members. It is truly a multilateral agreement and is an effective mechanism for settling disputes involving cross-border parties.

Mediation and arbitration offer many advantages as a model for compliance methods under the CBD. First, there are existing models for these programs. The International Chamber of Commerce (ICC) has highly developed programs in amicable dispute resolution processes, such as mediation, and has a well-recognized court of arbitration. The WIPO Arbitration and Mediation Center also provides for the resolution of international commercial disputes between private parties with highly developed procedures that are widely recognized as particularly appropriate for disputes involving intellectual property.[2]

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[1] *See, e.g., Compilation of Submissions Provided by Parties, Governments, Indigenous and Local Communities, and Stakeholders on Concrete Options on Substantive Items on the Agenda of the Fifth and Sixth Meetings of the Ad Hock Open-ended Working Group on Access and Benefit-Sharing: Submission from Canada*, UNEP/CBD/WG-ABS/6/INF/3/Add. 2 (Jan. 15, 2008).

[2] *See* description of WIPO Arbitration and Mediation Center, *available at* http://www.wipo.int/amc/en/.

It is also instructive that the text of the CBD itself provides for rules of dispute settlement between the Contracting Parties that follow a multi-step negotiation-mediation-arbitration model.[3] A similar approach is also included in the standard material transfer agreement (SMTA) concluded under the Food and Agriculture Organization (FAO) International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).

Supporting mutual recognition and enforcement of judgments across jurisdictions:

The potential to improve foreign enforcement of judgments should be studied further. However, CBD Members in the past have been reluctant to recognize judgments from other jurisdictions. Indeed, the relative failure of the 1971 Hague Convention on Recognition and Enforcement of Foreign Judgments in Civil and Commercial Matters stands in stark contrast to the wide membership of the New York Convention and is instructive as to the political difficulties of this issue.

Nonetheless, there are mechanisms in national laws that provide for the enforcement of foreign judgments in a number of CBD Parties when certain conditions are met. For example, according to the submission of Canada to the ABS Working Group,[4] the clear trend in Canadian courts is to recognize and enforce foreign judgments. In addition, the recent 2005 Hague Convention on Choice of Court Agreements may also provide a tool to be considered in this context.

Providing remedies and sanctions in civil, commercial and criminal matters:

This topic should be understood in the sense of exploring remedies and sanctions available through the dispute settlement mechanisms mentioned previously. The International Regime should not attempt to impose direct civil or criminal regulation with respect to bioprospecting or related activities at the international level. Any such specific regulation should be the domain of national laws.

Civil remedies for violation of contractual terms can include provision of damages, injunctions, or other mechanisms to address breaches of contractual terms.[5] In addition, the parties to agreement can include clauses in the mutually agreed terms providing for particular remedies if a breach occurs. The International Regime should not attempt to regulate long-held principles of contract law regarding available remedies in the various jurisdictions.

In respect of compliance with national laws on access to genetic resources, BIO and PhRMA members understand that there are significant concerns about perceived illicit bioprospecting activities and other acts that may raise concerns of "misappropriation" or "bio-piracy." In order to address these concerns, CBD Parties may provide fines or other sanctions for violation of ABS laws. Civil remedies also may be available in jurisdictions providing a cause of action for torts, such as conversion, that can address wrongful acts in respect of genetic resources.

In addition, more work should be done in respect of studying the scope of these perceived activities. Industry supports a fact-based consideration of this issue in order to identify the magnitude of any such perceived acts and any evident gaps in national ABS regimes that may result in particular problems. However, it appears that most perceived instances of misappropriation result either from the lack of appropriate national ABS regimes or lack of information to researchers working in-region. Punitive measures, therefore, will likely not address the perceived problems but may instead exert a significant chilling effect on legitimate researchers seeking to engage in activities in those countries. In that light,

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[3] CBD Article 27 provides that parties seek to resolve disputes first by negotiation, then mediation by a third party and, if those efforts fail, it provides for arbitration. CBD Article 27.3(b) also provides an option for submission of the dispute to the International Court of Justice. However, we do not view this as a workable model for disputes relating to ABS agreements concluded pursuant to the International Regime that may involve private parties.

[4] UNEP/CBD/WG-ABS/6/INF/3/Add.2, *supra* note 1.

[5] *See, e.g.*, E. ALLAN FARNSWORTH, FARNSWORTH ON CONTRACTS, Vol. III, §12.2, pp. 153-154 (1998).

overly punitive measures would be contrary to the requirements of the CBD to facilitate access and should be avoided.

The International Regime should focus instead on measures for increasing awareness of national ABS requirements by those engaging in bioprospecting activities, as well as capacity building efforts for countries developing effective ABS regimes.

(b) What kind of voluntary measures are available to enhance compliance of users of foreign genetic resources;

Comment:

Awareness-raising measures aimed at those engaging in bioprospecting activities, as well as capacity building efforts for countries developing effective ABS regimes are voluntary measures that would enhance compliance of users of foreign genetic resources. It is our belief that the vast majority of researchers and others seeking access to genetic resources are good-faith actors that intend to fully comply with local ABS laws. These methods would be highly effective at enhancing compliance of these actors.

In addition, there are currently voluntary industry guidelines that seek to formalize "best practices." BIO has published guidelines to educate and assist its members on access and benefit-sharing practices.[6] BIO has also published a model material transfer agreement (MMTA).[7] In addition, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) has also published guidelines for its members in this area.[8] While not intended to be standard agreements or mandatory codes of conduct, these guidelines help identify "best practices" in the industry and also are intended to be updated as practices change.

(c) Consider how internationally agreed definitions of misappropriation and misuse of genetic resources and associated traditional knowledge could support compliance where genetic resources have been accessed or used in circumvention of national legislation or without setting up of mutually agreed terms;

Comment:

BIO and PhRMA members are strongly of the view that the International Regime must be within the scope of the CBD. In that light, providing a definition of "misappropriation" or "misuse" in the International Regime itself may not be appropriate as these terms are not found in the CBD.

However, a further understanding of the concept of "misappropriation" or "misuse" or other terms might be helpful for discussion purposes in the ABS Working Group. In that light, greater convergence by CBD members regarding the meaning of these terms for purposes of discussion could be helpful. It is noted that, in certain jurisdictions, "misappropriation" and "misuse" have particular meanings within the context of unfair competition and anti-competition laws, respectively, which further adds to confusion and, perhaps, may indicate that different terminology should be used to capture notions of illicit acts undertaken in respect of genetic resources.

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[6] Guidelines for BIO Members Engaging in Bioprospecting, *available at* http://www.bio.org/ip/international/200507guide.asp

[7] BIO Model Material Transfer Agreement, *available at* http://www.bio.org/ip/international/BIO_Model_MTA.pdf

[8] Guidelines for IFPMA Members on Access to Genetic Resources and Equitable Sharing of Benefits Arising Out of Their Utilization, *available at* http://www.ifpma.org/Issues/fileadmin/templates/ifpmaissues/pdfs/2008_05_22_Guidelines_Genetic_Resources_EN.pdf

Any definition should be linked to compliance with national ABS laws. In other words, if there is no violation of national law, there can be no "misappropriation." This is a concept that has not reached a level of common understanding in the Working Group. As noted in the submission of ICC for the Concepts TEG,[9] the International Regime cannot remedy gaps in national legislation; failure of countries to fulfill CBD obligations in developing ABS regimes will directly lead to non-fulfillment of ABS objectives.

(d) How could compliance measures take account of the customary law of indigenous and local communities?

Comment:

Compliance measures that take into account the customary law of indigenous and local communities should be developed at the national level. The vast differences in customary law approaches within and among States make it impossible to design a "one size fits all" approach that would be functional at the international level. The International Regime should include provisions that articulate guidance for national ABS regimes, such as the identification of clear points-of-contact to ensure that legal certainty, clarity and transparency are maintained. In this manner, recipients of genetic resources will know what requirements apply to obtaining genetic resources, whether these requirements are derived from customary law or not.

If the national ABS regime does not fully comply with customary law principles, it is the State that should be held accountable and the laws changed. As noted, the International Regime cannot remedy gaps in national legislation, whether these gaps relate to customary law or other matters.

(e) Analyse whether particular compliance measures are needed for research with non-commercial intent, and if so, how these measures could address challenges arising from changes in intent and/or users, particularly considering the challenge arising from a lack of compliance with relevant access and benefit-sharing legislation and/or mutually agreed terms.

Comment:

It is not clear whether particular compliance measures under the International Regime would be needed for research with non-commercial intent. Generally speaking, the type of research envisioned will likely drive the terms that are to be mutually agreed between the relevant parties. For such cases, a specific set of rules under the International Regime would not be necessary. The agreements themselves would limit the research to non-commercial uses, commercial uses or a combination of the two, and would address benefit-sharing terms accordingly. BIO and PhRMA members view this as the optimal approach.

Nonetheless, there may be some CBD Parties that envision a split system with different rules of access for non-commercial research. It will be very difficult to specifically define this activity. If such an approach is considered by the Working Group, any such work should full address the ability to "convert" from non-commercial to commercial research. This is likely highly fact-specific and would be workable if, and only if, a clear definition for what is intended by "non-commercial" research is developed and how this may transition to "commercial" applications.

It should be noted that even where a country may pursue a bifurcated system, the compliance measures previously described would be applicable to all cases of unauthorized access. Countries may choose to apply only a particular subset of such measures to behavior that can objectively be determined to have

[9] *Good Business Practices and Case-Studies on Biodiversity: Report Submitted by the International Chamber of Commerce*, UNEP/CBD/ABS/GTLE/1/INF/1 (Oct. 31, 2008).

been in pursuit of "non-commercial" research objectives. In any case efforts should be made to ensure that the compliance measures in question are effective to enforce ABS requirements while facilitating access consistent with CBD and do not become barriers to access themselves.

EUROPEAN SEED ASSOCIATION (ESA)

Secretariat of the Convention on Biological Diversity

Montreal, Canada

Via e-mail: secretariat@cbd.org

Ref.: ESA_08.0832

Subject: ESA Submission to the Secretariat of the Convention on Biological Diversity for the seventh meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing

Brussels, 15.12.2008

ESA European Seed Association is the voice the European seed industry and represents the interests of those active in research, breeding, production and marketing of seed of agricultural, vegetable and ornamental plant varieties in Europe. Today, ESA's membership comprises 37 national seed associations from EU Member States and beyond, representing several hundreds of seed companies, as well as more than 45 direct company members, many of them small and medium sized enterprises.

The European seed industry attaches great importance to the discussions held on the issue of biodiversity, access to plant genetic resources and benefit sharing. ESA and its members are committed to the conservation and sustainable use of plant genetic resources, the lifeblood of plant breeders for developing new and better yielding varieties in a changing environment. Open access to genetic resources and interdependency of countries constitute the foundation of professional plant breeding. Access to plant genetic resources is therefore of key importance to the seed industry all around the world.

In view of the seventh meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing to be held in Paris on 2-8 April 2009, ESA is keen to share its position on some of the main components listed in the annex I to decision IX/12 and in particular on **objective (1)**, **scope (2)**, **fair and equitable benefit sharing (3)**, **downstream products (4)**, **access (5)**, and **compliance (6)**. In addition, ESA would like to express its support to the relevant submissions from ICC (International Chamber of Commerce) to the CBD Secretariat.

1) Objective of the IR

Access to genetic resources (GR) should be actively supported as it is a precondition for the generating of benefits and for the sharing of these benefits. An effective International Regime (IR) on Access and Benefit Sharing (ABS) should maintain and foster the diversity of uses of these resources as well as the commercial arrangements through which they are acquired. The IR should be a transparent, non-discriminatory, predictable, and facilitative structure

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narrowly targeted. The establishment of a workable system with regards to traditional knowledge (TK) should also be an essential part of the IR.

Accordingly, ESA suggests the following amended version of the Objective text as proposed in Annex I of Decision IX/12 adopted at COP 9:

Objective **(Annex I of Decision IX/12)**	***Objective*** **(ESA proposal for legal text)**
Effectively implement the provisions [in Articles 15, 8(j), 1, 16 and 19.2] of the Convention [and its three objectives], specifically by: • *[[Facilitating] [regulating transparent] access to genetic resources, [their derivatives] [and products] [and associated traditional knowledge];]* • *Ensuring [the conditions and measures for] the [effective,] fair and equitable sharing of benefits arising out of their utilization, [their derivatives] [and products] [and associated traditional knowledge] [and to prevent their misappropriation and misuse];* • *[Securing compliance in user countries with national laws and requirements, including PIC and MAT, of the country [of origin] providing those resources or of the Party that has acquired those resources in accordance with the Convention on Biological Diversity].* *[taking into account all rights over those resources, including the rights of indigenous and local communities, and ensuring compliance with PIC.]*	*Effectively implement the provisions in Articles 15, 8(j), 1, 16 and 19.2 of the Convention on Biological Diversity and its three objectives, specifically by:* • *Facilitating access to genetic resources and associated traditional knowledge;* • *Ensuring the conditions and measures for the effective, fair and equitable sharing of benefits arising out of their utilization and associated traditional knowledge*

2) Scope

The IR should not apply to biological resources, derivatives and products. This should be subject to agreement between the Provider and the Recipient. The IR should only apply to acquisitions of GR which take place after entry into force of the IR in the provider country, and be without prejudice to prior acquisitions carried out in good faith The IR should not provide the possibility of changing obligations relating to such acquisitions after they have been made.

Pathogens should be explicitly excluded from the IR. The IR approach on ABS is not suitable for pathogens as these do not appear to fit within the objectives of the CBD on conservation and sustainable use. With regards to plant genetic resources (PGR), the IR should not create overlaps with the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and species covered by the ITPGRFA should not fall under the scope of the IR.

Therefore, among the three options of the Scope text still to be negotiated, ESA favours the Option 1 in Annex I of Decision IX/12 amended as follows (additional provisions or wording proposed by ESA are underlined):

Scope **(Option 1, Annex I of Decision IX/12)**	***Scope*** **(ESA proposal for legal text)**
1. The international regime on access and benefit-sharing applies to [biological resources,] genetic resources, [derivatives,] [products] as well as [to their] [associated] traditional knowledge, [and derivatives of traditional knowledge associated with genetic resources,] innovations and practices [in accordance with Article 8(j)] [within national jurisdiction and of a transboundary nature] [in accordance with the relevant provisions of the CBD].	*1. The international regime on access and benefit-sharing applies to genetic resources as well as associated traditional knowledge, within national jurisdiction in accordance with the relevant provisions of the CBD <u>and subject to specific sectoral provisions set out in the International Regime.</u>*
[2. Subject to paragraph 1, the international regime on access and benefit-sharing applies to:	*2. Subject to paragraph 1, the international regime on access and benefit-sharing applies to benefits arising from commercial and other utilization from genetic resources acquired after the entry into force of the international regime;*
(a) [Benefits arising from commercial and other utilization] [from] [genetic resources acquired after] the entry into force of the [international regime] [Convention on Biological Diversity];	
[(b) Continuing benefits arising from commercial and other utilization taken prior to the coming into force of the Convention on Biological Diversity.]]	
3. The international regime on access and benefit-sharing does not apply to:	*3. The international regime on access and benefit-sharing does not apply to:*
(a) [Human genetic resources;]	*(a) Human genetic resources;*
(b) [Genetic resources that were acquired before the entry into force of the Convention on Biological Diversity on 29 December 1993 [or before the entry into force for a Party];] [Genetic material acquired prior to the national ratification of the Convention on Biological Diversity [and since then cultivated ex situ];]	*(b) Genetic resources that were acquired before the entry into force of the International Regime for a Party or according to national legislation already in place;*
(c) [Genetic material already made freely available by the country of origin;]	*(c) Genetic material already made freely available by the country of origin;*
(d) [[Species] [listed in Annex I of] [genetic resources covered under] the International Treaty on Plant Genetic Resources for Food and Agriculture [unless they are used beyond the purpose of the said treaty];]	*(d) Species covered under the International Treaty on Plant Genetic Resources for Food and Agriculture unless they are used beyond the purpose of the said treaty*
(e) [Genetic resources, including marine	*(e) Genetic resources, including marine genetic resources found in areas beyond*

genetic resources found in areas beyond national jurisdiction;]	*national jurisdiction;*
(f) [Genetic resources located in the Antarctic Treaty Area.]	*(f) Genetic resources located in the Antarctic Treaty Area.*
	(g) Human, animal and plant pathogens
[…]	*[…]*

3) **Benefit-sharing: the breeder's exemption**

For the plant breeding sector the Standard Material Transfer Agreement of the International Treaty on Plant Genetic resources for Food and Agriculture (ITPGRFA) is a workable system. Access and Benefit Sharing of genetic resources in this way can be done quick and efficient. The use of the contract could be extended for those crops that are not yet in Annex 1 of the ITPGRFA.

The UPOV convention has inherent benefit sharing principle in the form of the breeder's exemption and other exceptions, which authorise the free use of improved varieties and the genetic diversity for further breeding activities. The FAO ITPGRFA (Article 13(d)(ii)) recognises the concept of breeders' exemption, in that breeders, who commercialise a variety, that incorporates material accessed from the Treaty's Multilateral System (MLS), are exempted from mandatory financial benefit sharing whenever these products are available without restriction to others for further research and breeding.

4) **Downstream products**

The IR should only regulate the relationship between the provider and party gaining access to genetic resources and not seek to regulate downstream activities and/or derivatives or products being developed from them. An IR which tries to regulate downstream activities and products will be unworkable, unenforceable and extremely costly to implement by governments and users alike. Broadening the scope of the IR to downstream products would bring under the IR common household items such as wine, bread and wood products. Benefit-sharing arrangements in relation to derivatives and downstream products should instead be determined through MAT in the ABS contract between the providing and accessing parties, as provided for in Article 15(7).

5) **Access**

ESA recognizes the sovereign rights and the authority of Parties to determine access. However, it is important that legal certainty is provided through access rules. In addition those access rules should be non-discriminatory over nationalities.

In providing access, it is important that the administration and transaction costs are minimized to stimulate sustainable use of genetic resources.

6) **Compliance**

On this issue, ESA would like to recall that the business delegation, coordinated by the International Chamber of Commerce (ICC) has developed and submitted a position to the CBD Secretariat on "Access and Benefit Sharing; Priority issues for the Compliance TEG" from 28 November 2008 (Document n° 450/1042).

INTELLECTUAL PROPERTY OWNERS ASSOCIATION (IPO)

December 15, 2008

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

Re: IPO Submission to CBD ABS WG 7 (Notification no. 2008-120)

Dear Secretary Djoghlaf:

Intellectual Property Owners (IPO) welcomes the opportunity to submit comments in response to CBD Notification no. 2008-120, in preparation for the seventh Ad Hoc Open-ended Working Group on Access and Benefit-sharing, to be held from 2-8 April, 2009.

IPO is a trade association representing companies and individuals in all industries and fields of technology who own or are interested in intellectual property rights. IPO's membership includes more than 200 companies and more than 10,000 individuals who are involved in the association either through their companies or as IPO inventor, author, executive, law firm, or attorney members.

In this submission, IPO does not suggest operational text (which should be negotiated by the Parties). However, we strongly believe that these negotiations should be informed by the views of those individuals and entities that will be affected by the International Regime. Therefore, the attached detailed comments have been drafted to provide real-world examples of the need for clarity and certainty.

IPO recognizes the importance of establishing frameworks for access and benefit-sharing that will lead to increased international conservation, sustainable utilization of genetic resources and equitable benefit-sharing. Compliance measures occurring within the context of the patent system are not effective means to ensure proper access and benefit-sharing. Thus, the focus of the International Regime should be on facilitating mutually agreed terms between users and providers, which are best agreed at the time of acquisition.

Please feel free to contact me should you have any questions.

Sincerely,

Herbert C. Wamsley
Executive Director

Enclosure

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INTELLECTUAL PROPERTY OWNERS ASSOCIATION

IPO Submission to CBD ABS WG 7 (Notification no. 2008-120)
Detailed Comments

Objective

According to Decision IX/12 of the Conference of the Parties to the CBD, the Working Group's mandate is to elaborate and negotiate an International Regime with the purpose of implementing Articles 15 and 8(j), and the three objectives, of the Convention. This should occur in accordance with Decisions VII/19D and XIII/4A.

Therefore, IPO interprets these Decisions as limiting the objectives of the International Regime to the following: (1) to protect the sovereignty of states over their natural resources; (2) to facilitate access to Genetic Resources on the basis of mutually agreed terms and with the prior informed consent of the providing Party; and (3) to ensure sharing of the results of research and other benefits arising from the use of Genetic Resources on the basis of mutually agreed terms. Furthermore, the International Regime must do so in a manner that is consistent with the other two defined objectives of the CBD – namely, conservation and sustainable use.

IPO believes that the focus of the International Regime should be on facilitating mutually agreed terms between users and providers, which are best agreed at the time of acquisition. Focusing specifically on the point of acquisition will ensure not only that there is agreement between user and provider on the terms and conditions of access, but will also serve to guarantee prior informed consent, and in a manner that preserves the sovereign right of states over their *in situ* Genetic Resources.

Scope

If the International Regime is to be successfully negotiated and implemented, one of the most important aspects that will provide certainty to users and providers of Genetic Resources is a clear delineation of the scope of the Regime. IPO lists below certain elements for further consideration by the Parties:

- The International Regime should apply only to Genetic Resources, as defined in Article 2 of the CBD, so as not to extend beyond the objectives of Article 15. According to the definition of Genetic Resources, the Regime should apply only to "Genetic Material" (that is, material containing functional units of heredity) of actual or potential value. This necessarily requires that the Regime exclude those Biological Resources that do not contain functional units of heredity. This distinction can be seen in the following examples: (1) plant materials (such as sugar beets or sugarcane) contain functional units of heredity, but products developed

from these plants (such as sucrose or bagasse) do not; (2) the opium poppy plant contains functional units of heredity, but morphine (an extract used as an analgesic) does not; (3) Fungi such as *Penicillium* contain functional units of heredity, but penicillin (an anti-bacterial compound produced from the fungus) does not.

- Human Genetic Resources are exempt from the scope of the International Regime. This has already been decided by the Parties (Decision II/11, and Bonn Guidelines). Recent negotiations have appeared to contradict this earlier decision; therefore, in order to provide clarity, the Regime should specifically reiterate the exclusion of human Genetic Resources from its scope.

- To be most effective, the International Regime should apply only at the time of acquisition of a Genetic Resource, and as a result, should not encompass so-called "Derivatives" or derived "Products" that are downstream of the actual acquisition. Using the example of morphine described above, research on chemical analogs of morphine may be undertaken by scientists in an effort to create new compounds that may be useful as analgesics. Such research may involve pure synthetic chemistry and can easily take place without the need for access to a single opium poppy plant. Such research should not be encompassed under the access and benefit-sharing obligations of the Regime, which are specifically related to "bioprospecting" activities. If a particular situation exists in which benefit-sharing is appropriate and valid for downstream research activities, these decisions are best made through mutually agreed terms between the user and the provider, consistent with Articles 15(4) and 15(7).

- The above example also illustrates that many "Derivatives" may enter the public domain, for example, through publication in research literature or through availability of the "Derivative" in the open market. In those instances where "derivatives," including information about the genetic resource from which they are derived, enter the public domain, they should be excluded from the International Regime. This is necessary in order to promote clarity and to maintain a workable system.

- The International Regime should be prospective; therefore, it should apply only to the *in-situ* acquisition of Genetic Resources after entry into force of the Regime in the provider country, consistent with the provisions of Article 36 of the CBD.

- The International Regime should not apply to items readily available in trade. The CBD specifically addresses issues of access and benefit-sharing as related to "bioprospecting." The ready sale and availability of items in trade (also referred to as "biotrade") is not intended to be encompassed

under the more limited category of "bioprospecting." To apply the International Regime to items in trade would also contradict the principle of sovereignty found in Article 3 of the CBD, which gives member states the freedom to exploit their own resources (but with the obligation of doing so in an environmentally sustainable manner).

- The International Regime should not apply to pathogens. The purpose and objective of the CBD is to ensure conservation and sustainable use of biological diversity, and to minimize adverse effects on biological diversity. To broaden the scope of the Regime to include pathogens would contradict these goals.

- The International Regime should not apply to those Genetic Resources that are subject to other international agreements, such as plant genetic resources subject to the International Treaty on Plant Genetic Resources for Food and Agriculture, or animal genetic resources subject to the International Technical Conference on Animal Genetic Resources for Food and Agriculture, both under the Food and Agriculture Organization of the United Nations.

Access

- States should have sovereign control over their *in-situ* Genetic Resources, and an International Regime can assist states with creating access regulations based on model legislation that is consistent and accepted among member countries.

- States must determine how best to ensure that access, when granted, has the consent of all involved parties – indigenous groups, local community and local government. Parties that wish to acquire Genetic Resources should be able to approach a single entity and be assured access is consented to by all interested parties. Overly long, burdensome processes could simply result in lost interest in the research, or drive potential users to another provider country. In this respect, some members of IPO have attempted to use the focal point contacts established under the Convention on Biological Diversity, but encountered bureaucracy and non-responsiveness that ultimately discouraged access.

Compliance

- Compliance measures occurring within the context of the patent system are not effective means to ensure proper access and benefit-sharing. Most uses of Genetic Resources for scientific research will not result in a patent filing, and the mere act of a patent filing may not result in a commercial product or financial benefit to any party. Furthermore, compliance

measures that involve refusal to examine a patent application, or invalidation or revocation of a patent should not be part of the International Regime. Although there have been several often-cited examples of alleged "misappropriation" of Genetic Resources in patents, a more careful examination of these patents shows that patent disclosure mechanisms will fail to achieve the intended compliance goals. In some instances, the source and origin of the Genetic Resource was already clearly indicated in the patent, but with no effect on the examination of the application or the ultimate status of the patent. See, for example, U.S. patent no. 5,401,504 (turmeric) and EP patent no. 0973534 (hoodia). In other instances, the Genetic Resource is claimed by one country of origin, though the patent indicates that the Genetic Resource was readily obtained from another country of origin. For example, U.S. patent no. 6,136,316 makes use of a "winter weed [found] throughout the hotter parts of India," but that patent was claimed by Peru to be a potential example of "biopiracy" (see, WIPO/GRTKF/IC/8/12). Finally, some claims of "biopiracy" involve patents that merely list a Genetic Resource in the description of the patent, but which make no use of the actual Genetic Resource in the invention. See, for example, U.S. patent no. 6,569,488, which is claimed by Peru to be a potential case of "biopiracy." The Genetic Resource in question is listed in the description of the patent; however, there is no evidence that the Genetic Resource was accessed or used in the development of the invention (WIPO/GRTKF/IC/8/12). As these examples show, patents are too often improperly characterized as the source of and the solution for "biopiracy."

- The use of certificates is burdensome and will likely result in an unworkable bureaucracy.

- The preferred option is for the International Regime to provide a framework to enable users and providers to come to mutually agreed terms subject to the dispute resolution system of their choosing or as provided in an International Treaty. For example, the sMTA established under the Food and Agriculture Organization (FAO) International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGRFA) refers to the ICC Rules of Arbitration as a means of dispute resolution.

Benefit-sharing

- Benefit-sharing can take many forms – direct payments (up front, at various development milestones, or at the time of commercialization), technology transfer, and indirect benefits (employment opportunities, infrastructure development). Users and providers require flexibility in reaching mutually agreed terms in order to fully realize the proper type of benefit-sharing for a particular situation.

- Examples of successful access and benefit-sharing arrangements have been described in Cabrera Medaglia J., Bioprospecting Partnerships In Practice: A Decade of Experiences at INBio in Costa Rica. *IP Strategy Today* (2004) No. 11-2004,[1] p. 27-40. As noted in this publication, INBio has entered into numerous agreements in diverse fields, and many patent applications have been filed by the parties to the agreement as a result. However, the actual development and commercialization of products from these research efforts is minimal. Nonetheless, because INBio entered into mutually agreed terms with its collaboration partners, many benefits were still realized. As noted in the publication, these benefits were both monetary (direct payment of research budgets, payments for conservation, technology transfer) and non-monetary (improved negotiations expertise, improved legal infrastructure for conservation, training).

[1] Found at http://www.biodevelopments.org/ip/ipst11.pdf.

INTERNATIONAL CHAMBER OF COMMERCE (ICC)

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Objective, scope, fair and equitable benefit sharing, access and compliance

Submission to the Secretariat of the Convention on Biological Diversity for the 7th Ad Hoc Open Ended Working Group on Access and Benefit Sharing, Paris, France, 2-8 April 2009

Introduction

The business delegation – coordinated under the umbrella of ICC - remains committed to contributing constructively on substantive discussions in the access and benefit sharing (ABS) negotiations. It has made submissions to and participated in the Technical Expert Groups on Concepts, Terms, Working Definitions and Sectoral Approaches[1], and on Compliance[2], and intends to do so with respect to the Technical Expert Group on Traditional Knowledge. Business looks forward to continuing to play an active and helpful role in the negotiations on an ABS International Regime (IR).

A diverse range of industries[3] utilize genetic resources in their everyday business, and access, use and create value from these resources in different ways. These industries - many of which consist in large part of small and medium-sized enterprises (SMEs) - play an essential role in creating social and economic benefits from genetic resources. As the Convention on Biological Diversity (CBD) negotiations struggle with the challenge of increasingly complex issues and a call to move toward a more practical discussion based on established common terms and definitions, business can assist in clarifying exactly how genetic resources are accessed, developed and commercialised and methods to best ensure the sharing of benefits.

All businesses are engaged in a continuous evaluation of **risk and return on investment**. A high risk environment will discourage investment and reduce opportunities for creating benefits.

[1] "Access and Benefit Sharing: Sectoral Approaches, Concepts, Terms and Working Definitions" - 17 October 2008, http://www.iccwbo.org/uploadedFiles/ICC/policy/intellectual_property/Statements/Sectoral%20approaches%20final.pdf
[2] "Priority Issues for the CBD/ABS Compliance TEG" - 28 November 2008, http://www.iccwbo.org/uploadedFiles/ICC/policy/intellectual_property/Statements/ICC%20Compliance%20TEG%20Paper%20final%2028%20Nov%2008.pdf
[3] Including, in alphabetical order: agricultural biotechnology, animal breeding, cosmetics, farming, flavours and fragrances, foods and drinks, forestry, herbal medicines and supplements, industrial biotechnology, pets, pharmaceutical and biopharmaceutical products, and plant breeding.

Given the long time period and heavy investments required to commercialize inventions using genetic resources, businesses need national laws or guidelines which are transparent, practical, science-based, non-discriminatory, and provide legal certainty to justify their investments.

Business therefore supports the creation of a practical and workable IR which will facilitate the activities of the different sectors working with genetic resources today and take into account the future evolution of those activities.

This paper outlines **general principles** business believes to be **important to the success of an IR** and specifically provides input to the issues which the Ad Hoc Open-ended Working Group on Access and Benefit Sharing (AHOEWG) is mandated to negotiate at its 7th meeting: **objective, scope, fair and equitable benefit-sharing, access and compliance**.

General Principles

It is of critical importance that the IR should be a **precisely targeted, facilitative structure that promotes national ABS regimes that are transparent, non-discriminatory, predictable and coherent across borders**; national ABS regimes that are difficult to reconcile with each other should be avoided. The IR should not be a heavy regulatory framework that will stifle the creation of value from genetic resources, and their trade and sustainable uses. This approach will promote not only the efficient organization of access and benefit sharing, but also the other two pillars of the CBD: conservation and sustainable use of genetic resources. Lessons should be learnt from the experiences of national regimes which show that highly regulated and bureaucratic ABS systems have failed to generate social and economic benefits.

In order to ensure that the CBD's objectives are attained, business submits **that the IR should be based on the following principles**:

- An IR should include **clear definitions** consistent with the terms and jurisdictional limitations of the CBD itself.

- **Research, economic activity and freedom to innovate** using genetic resources should be encouraged rather than constrained. This will help promote the generation of benefits and will be the single most important basis for assessing the success of the Regime. Access conditions should respect the Article 15(2) directive to "facilitate access" to genetic resources. Benefit-sharing arrangements in relation to derivatives and downstream products should be determined through mutually agreed terms in the ABS contract between the providing and accessing parties, as provided for in Article 15(7)[4]. Concepts such as "derivatives" or "products", however they may be defined or understood, should be determined between contracting parties.

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

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- The IR should **not seek to restrict what can be mutually agreed** and should encourage the **systematic use of contracts**, in the form of Material Transfer Agreements (MTAs) or other forms of agreements, to the greatest extent possible. These agreements may include, as appropriate, in addition to the terms and conditions for access and benefit sharing, clauses addressing conditions for the use of the GR, commercial rights, transfer of the GR with or without traditional knowledge to third parties, short-term and long term non-commercial and commercial benefits, the agreed dispute settlement mechanism, choice of law, and/or conditions regulating the future termination of the agreement. **Contractual agreements**, common in the normal course of ethical international business, enforceable under the judicial systems of sovereign CBD member states, and respecting CBD standards (if implemented by the applicable national law), remain the best methods to manage ABS of genetic resources.
- The CBD specifies that national governments have sovereign rights over the regulation of genetic resources found in their territories. The IR should therefore leverage national law, enforcement, and regulatory structures rather than attempt to create new mechanisms and obligations that are yet to be proven effective in real world experience. The IR should therefore focus on the **further development and harmonization of national regimes** in the spirit of the **Bonn Guidelines**.
- Such national ABS regimes should identify a **national focal point** which is authorized to grant access and prior informed consent, and to facilitate the negotiation of mutually agreed terms – this is essential to provide legal certainty and transparency for all stakeholders. Any measures to ensure the participation and involvement of indigenous and local communities in mutually agreed terms, and the sharing of benefits with traditional knowledge holders, must be part of a transparent ABS regime.
- The IR should take a **sectoral approach** to address the unique aspects of how genetic resources are accessed and managed in the many business and science sectors using genetic resources. If the IR is to be effective in promoting business activities which support biodiversity, it should maintain and foster the diversity of uses of these resources as well as of the commercial arrangements through which they are acquired.
- The IR should draw a distinction according to the specialties of sectors rather than between **commercial/non-commercial uses**. In reality, it may prove extremely difficult if not impossible to differentiate between non-commercial and commercial research. Scientific research that starts out as non-commercial may ultimately contribute to the commercial development of a product, either by the same party or by others. Similarly, commercial research may be licensed for public research purposes, (as in the case of the development of Golden Rice which relied heavily on commercially funded research). It is important to recognize that very few collaborative bio-prospecting agreements result in successful products, even in the case

of multinational corporations. Business, especially SMEs[5], may be deterred by increases in expenses or bureaucratic red-tape as much as non-commercial research institutes. Complicated requirements for access and benefit-sharing may have the unintended effect of causing a significant decline in academic and commercial research alike.

- The IR should not promote ABS regimes characterized by the **stacking of multiple payments** for a single product. This should apply in cases where multiple countries have particular GRs in common as indigenous resources, but also in cases where a particular GR has multiple beneficial properties and/or becomes the subject of multiple research projects. The IR should provide for **mutual recognition** between countries of ABS agreements so that once a user has entered into an ABS agreement in good faith, no further demands will be made.
- When negotiating the IR, CBD Parties should consider the **implementation costs** of proposed elements for both countries providing genetic resources and users, as well as the bureaucratic challenges that could have significant negative impacts on SMEs and research, and on the generation of potential benefits. In particular, any lengthy processes or negotiations before the start of a research program should be avoided. Cost-benefit and regulatory impact assessments should be undertaken before introducing new untested mechanisms.
- The IR should be a **prospective** system with no retroactive effect. Provisions of the IR should only take effect after the entry into force of the IR and its ratification in the provider country consistent with the provisions of Article 36 of the CBD.

Objective

The objectives of the IR should be consistent with the terms of reference of the AHOEWG detailed by the Ninth Conference of the Parties (COP-9), Decision VII/19D, and with the terms of the CBD itself. The mandate of the AHOEWG is clear: "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) of the Convention and the three objectives of the Convention."

The **objectives** of the International Regime should therefore be **limited to the said mandate**, namely:

(1) to protect the sovereignty of states over their natural resources;
(2) to facilitate access to Genetic Resources on the basis of mutually agreed terms and with the prior informed consent of the providing Party; and
(3) to ensure sharing of the results of research and other benefits arising from the use of genetic resources on the basis of mutually agreed terms.

[5] Many sectors working with genetic resources, such as biotechnology, plant and animal breeders, traditional medicines, etc - and businesses working in this area in developing countries - consist mainly of SMEs.

Furthermore, the IR must be consistent with the other defined objectives of the CBD – namely, conservation and sustainable use. Efforts to further broaden or otherwise modify these governing principles are **outside the scope** of the working group and should be rejected.

In the view of business, the most effective way of achieving these objectives would be for the IR to establish international benchmarks and guidelines that would assist CBD Members in developing **consistent, predictable, non-discriminatory, transparent and effective national ABS systems which provide legal certainty**.

The IR should develop Article 15(7) of the Convention, by identifying those "legislative, administrative or policy measures" which can, through implementation by the contracting parties, facilitate the activities of interested parties in the identification of sustainable uses, the agreement of mutually-agreed terms and the sharing of benefits.

Scope

The scope of the IR will be key in determining the approach to other issues under discussion, such as compliance measures. It is therefore essential that the scope of the IR be clearly defined.

Business suggests that the IR's scope be determined along the following lines:

- In order to ensure legal certainty, the IR should only apply to **acquisitions of genetic resources** which take place **after entry into force of the IR in the provider country**, and be without prejudice to prior acquisitions carried out in good faith. The IR will likely add additional requirements relating to ABS regimes. Any acquisitions prior to the entry into force of the IR in the provider country will have been made pursuant to national laws in force at that time, and access and benefit-sharing terms agreed accordingly. The IR should not provide the possibility of changing obligations relating to such acquisitions after they have been made.
- The IR should only regulate the relationship between the provider and party gaining access to genetic resources and **not seek to regulate downstream activities**. An IR which tries to regulate downstream activities and products will be unworkable, unenforceable and extremely costly to implement by governments and users alike. Broadening the scope of the IR to downstream products would bring under the IR common household items such as wine, bread and wood products. Benefit-sharing arrangements in relation to derivatives and downstream products should instead be determined through MAT in the ABS contract between the providing and accessing parties, as provided for in Article 15(7). Concepts such as "derivatives" or "products", should not be part of the IR itself, but instead. should be determined in the **MAT** between parties to the individual ABS agreement. ABS stakeholders already rely heavily on mechanisms based on written agreements which are proven and feasible methods to address ABS concerns.

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

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

- **Certain genetic resources should be excluded**. When defining which genetic resources should be covered by the IR, Parties should consider the following points:

  - The IR should exclude **human genetic resources**, consistent with COP Decision II/11 and the Bonn Guidelines.

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

  - The IR should not include genetic resources that enter the **public domain** without any restriction by the provider country.

  - Genetic resources **not subject to the jurisdiction of any particular country** should be excluded from the scope of the IR. The CBD does not apply to such resources and only recognizes "the sovereign rights of States over their natural resources" (CBD Article 15.1).

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

- **Traditional knowledge** (TK) is a very difficult concept to define and is subject to different interpretations by different communities and peoples. To ensure legal certainty, it is essential that if TK associated with genetic resources is to be governed by the IR, it should be clearly defined based on a common understanding, and limited to "knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for

the conservation and sustainable use of biological diversity." As with other ABS measures, measures regarding traditional knowledge associated with genetic resources must be transparent.

Fair and equitable benefit sharing

Business supports fair and equitable benefit-sharing which, under the terms of the CBD, should be on "**mutually agreed terms**" (Article 15(7)). Such terms will normally be embodied in an agreement between the provider and the recipient of the genetic resource. Transparency and internationally accepted contracting principles must apply to such agreements in order to maintain legal certainty for the provider and the recipient of genetic resources.

The development of **model clauses** or menus of clauses may be helpful to guide ABS negotiations. Alternatives, such as a database of sample clauses from successful ABS agreements or capacity building programs relating to "best practices" are preferable. If established, any such clauses should not be binding as the IR should permit flexibility in achieving MAT for material transfers. However, the Standard Material Transfer Agreement of the International Treaty on Plant Genetic Resources for Food and Agriculture is a good workable system for the plant breeding sector where many transfers of genetic resources are constantly being made.

There is a long history of benefit-sharing in many sectors using genetic resources. The manner in which benefits are currently shared should be considered in the development of the IR. **Existing systems** should not be unnecessarily disturbed and should, on the contrary, be recognized and carefully considered for the development of the IR.

Benefits from ABS transactions are not necessarily monetary in nature, (such as payments upfront or during the development process; funding for research or joint ventures), but can also include: the exchange of knowledge, skills, and technology; the sharing of research data, the free access to the use of protected varieties for further research and breeding, and networks; and the collection and conservation of genetic resources through financing or specific support activities. ABS transactions also indirectly benefit society as a whole as they can lead to improved productivity of agricultural crops, the development of new health, food and other products, and the creation of new employment opportunities resulting from the economic stimulus of new innovative products. The **full range of benefit-sharing** should be taken into account on the negotiations on the IR.

The wide-spread availability of genetic resources has led to demands for **horizontal benefit-sharing among in-situ repository countries**. The resolution of such questions and any disputes that arise from them should lie outside the IR and above all should not prevent acquirers of genetic resources from holding clear title to acquired resources. Claims of third countries not party to an ABS agreement would add great uncertainties to the process and should not be permitted. However, in cases where multiple countries hold resources in common, agreements

between such countries could be arranged so that benefits received by one member in a group of countries or indigenous communities that holds a particular resource in common would share the benefits received with others from that group. Any such agreement would be between potential providers of the genetic resource in question, and therefore should not have any effect on the liabilities or obligations of the user under an ABS agreement. It should be noted, however, that attempting to negotiate such an agreement would likely be highly complex and resource intensive.

CBD Parties should address with caution certain IR instruments currently under discussion, such as **certificates**, which could engender bureaucratic approaches to ABS that preclude benefit generation. Burdensome measures introduce significant costs for governments, users and local communities, and may deter larger companies and price innovative small and medium-sized enterprises, and research institutions out of the market entirely.

Access

Business supports the concepts of access to genetic resources being linked to fair and equitable sharing of benefits on the basis of mutually agreed terms, as envisioned in the CBD. The IR should **facilitate responsible access** and **prevent illegal access** to genetic resources. Business therefore supports **access standards** consistent with the CBD requirement to "facilitate" access in Article 15(2), such as those that would help ensure transparency and clarity, including the identification of clear authorities and points of contact to improve reliability in agreed terms of access. All concerns should be handled at the point of access through ABS agreements in order to reduce any uncertainties as to the status of genetic resources and benefits arising from their use.

Certainty, clarity and transparency of access rules depend fundamentally on the identification of **national focal points**. Business strongly supports the identification of a national focal point - one single authority that is authorized to grant access and grant prior informed consent. This is an essential part of developing an access regime that is consistent with the principles of legal certainty and transparency and is thereby a crucial element of a workable IR.

Any national laws governing the terms of access, e.g. in national ABS regimes, should be **non-discriminatory** and should thereby treat domestic and foreign researchers on similar terms. It should be realized that all countries are interdependent in terms of genetic resources and that most countries, including developing countries with extensive biodiversity, depend heavily on genetic resources accessed from other countries. Non-discriminatory treatment would therefore be beneficial for all CBD parties.

All researchers, regardless of their national origin or their countries' standing in the CBD , should be permitted to access resources under the facilitative mechanisms of the ABS regime, but also

be subject to the benefit-sharing requirements implemented by national laws in provider countries; this will help maximize potential benefits consistent with the goals of the CBD.

Negotiations on the IR also need to move toward a much more informed discussion of the **realities of access to genetic resources today**, and specifically a better understanding of access to genetic resources through **ex-situ** collections. The model upon which CBD obligations were based was one of a linear flow of genetic resources beginning with "bioprospecting" of genetic resources from their in-situ state, negotiation of mutually agreed terms with the sovereign state, and consultation with the concerned indigenous and local communities. This model is not an accurate reflection of how genetic resources are accessed, utilized, or shared today. Many genetic resources have long since been extracted from their original natural environment. Many have become commodities or staple commercial products in the trading system. Ex-situ collections exist in many countries for different types of genetic resources and range from zoos and aquariums to herbaria, such as the various botanical gardens and the Consultative Group on International Agricultural Research (CGIAR) system. Although the in-situ case is more conceptually clear and manageable than ex-situ cases, access of genetic resources through ex-situ collections is considerably more common in today's context.

Compliance

When discussing compliance issues, it is helpful to distinguish between regulatory compliance (i.e. compliance with laws and regulations set by governments relating to ABS); and compliance with contractual provisions (i.e. compliance with terms in an agreement mutually agreed between two parties such as Material Transfer Agreements).

Mechanisms for enforcing compliance will differ according to the type of compliance that is being addressed. In both cases, business submits that any compliance system set up by the IR should build on **existing enforcement systems**.

Regulatory Compliance

- Business believes that that the great majority of users of genetic resources make their best efforts to comply with ABS requirements. Nevertheless business does recognize that many CBD Parties have serious concerns relating to **misuse and/or misappropriation of GR**, with or without related TK. As there is currently little empirical data on the scope or the significance of such misuse and/or misappropriation, business supports more research on this topic to provide a solid factual basis for the AHOEWG's efforts to address this issue. This would greatly assist in identification, where applicable, of any appropriate and proportionate measures, and contribute to the likelihood of success of the IR overall.

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- Business recognizes the importance that a number of CBD Members place on mutual recognition of and enforcement of **judgments across borders** to enforce domestic national ABS laws in cases involving allegations of misuse or misappropriation of GR with or without related TK. At the same time, business notes the historic reluctance of states to enter into multilateral obligations requiring mutual recognition. Business looks forward to a discussion of possible approaches to address this difficult issue.
- Any further consideration of "**disclosure requirements**"[6] should be made dependent on the outcome of discussions in the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) in WIPO which, because of its collective intellectual property (IP) expertise, as illustrated by its discussions and detailed documentation, is the appropriate body for the consideration of matters relating to the relationship between IP and CBD related issues.
- Business remains greatly concerned about the possible **introduction of new instruments** without proven effectiveness in real life[7]. It therefore strongly recommends that the further elaboration of an "internationally recognized certificate" should not begin before a feasibility study is first undertaken and carefully analysed. Business firmly believes that if many of the issues still outstanding are not addressed in detail, the feasibility of establishing such a certificate system will be called into question (see report of the Technical Experts Group in UNEP/CBD/WG-ABS/5/7 (Feb. 20, 2007)). To date, discussions in the negotiations concerning certificates have failed so far to clarify fundamental concepts.

  Key matters that remain unresolved are:
  - what would the system certify (compliance with the CBD or national laws)?
  - who would certify?
  - who would use the certification and why?
  - what would be the impact of not having a certificate?
  - when does a certificate have to be produced?
  - what would be the cost and benefit of such a system?

- Business believes that **raising awareness** among stakeholders about ABS requirements will play a key role in improving compliance with ABS regimes. CBD Parties should make positive efforts to educate stakeholders about ABS laws and to make these more transparent. Business is willing to support governments in these efforts with respect to its own constituency.

  In this respect, several sectors have put into place **voluntary guidelines** and "**best practices**" to help companies in those industries to understand and comply with ABS

[6] See ICC paper on "Access and benefit-sharing: special disclosure requirements in patent applications" - 25 May 2005 : http://www.iccwbo.org/uploadedFiles/ICC/policy/intellectual_property/Statements/ABS_%20Special%20Disclosure.pdf
[7] See ICC paper on "Issues for consideration by the CBD Group of Technical Experts concerning a Certificate relating to genetic resources" 15 September 2006 at http://www.iccwbo.org/uploadedFiles/ICC/policy/intellectual_property/Statements/CertificationSubmission_to_CBD.pdf

requirements. Among those are Biotechnology Industry Organization (BIO) Guidelines for BIO Members Engaging in Bioprospecting[8], the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Guidelines for IFPMA Members on ABS, and the BIO Model Material Transfer Agreement (MMTA)[9], EuropaBio Principles for Accessing Genetic Resources[10], International Standard for Wild Collection of Medicinal and Aromatic Plants[11].

Business believes that such voluntary guidelines contribute significantly to promoting awareness of, and compliance with, ABS regimes among the users of genetic resources, and should be taken into account by CBD Parties when considering a sectoral approach to the IR.

Contractual Compliance

- Private international law offers many opportunities that are currently used to enforce agreements relating to international business transactions around the world (see for example the paper by the delegation of Canada submitted to the sixth ABS WG meeting (UNEP/CBD/WG-ABS/6/INF/3/Add. 2 (Jan. 15, 2008)). No special "measures to ensure access to justice" need to be developed that are peculiar to the CBD context. Instead, **existing tools** such as negotiation, mediation, arbitration and legal instruments for the enforcement of foreign judgments should be further explored.
- Negotiation, mediation, arbitration and conciliation mechanisms are common in business and provide a concrete basis for discussions on **the resolution of disputes arising from ABS contracts**. An example of a dispute resolution process referenced in an international instrument is found in Article 8(4)(C) of the Food and Agriculture Organization (FAO) International Treaty for Plant and Genetic Resources for Food and Agriculture (ITPFGRA) Standard MTA. This article provides that if the dispute has not been settled by negotiation or mediation, any party to the sMTA can submit the dispute to arbitration using the rules of an international body agreed by the parties or, failing such agreement, the Rules of Arbitration of the International Chamber of Commerce's International Court of Arbitration. Although arbitration procedures are unlikely always to be appropriate for all relationships or sectors, a potential advantage of them is that they allow ABS stakeholders to gain cost effective legally-binding judgments. that are enforceable across borders in countries that adhere to the New York Convention on Recognition and Enforcement of Foreign Arbitral Awards.

Document n° 450/1043

15 December 2008

[8] http://www.bio.org/ip/international/200507guide.asp
[9] http://www.ifpma.org/issues/CBD and http://www.bio.org/ip/international/BIO_Model_MTA.pdf
[10] http://www.europabio.org/positions/Bioprospecting%20Principles_Final.pdf
[11] http://www.floraweb.de/proxy/floraweb/MAP-pro/Standard_Version1_0pdf

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

UPOV

INTERNATIONALER VERBAND ZUM SCHUTZ VON PFLANZENZÜCHTUNGEN
GENF SCHWEIZ

UNION INTERNATIONALE POUR LA PROTECTION DES OBTENTIONS VÉGÉTALES
GENÈVE, SUISSE

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

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

CBD

July 18, 2008

Dear Executive Secretary Djoghlaf,

Further to my letter of July 16, 2008, I should like to refer to the letter of April 17, 2008, of the Secretary-General of the International Union for the Protection of New Varieties of Plants (UPOV) (copy attached).

The Council of UPOV, at its twenty-fifth extraordinary session, held in Geneva on April 11, 2008, requested that COP-9 consider the inclusion of the elements set out in the above-mentioned letter, in a decision relating to the "Recommendation of the Working Group on Access and Benefit-Sharing at its Sixth Meeting on Possible Elements of a Decision on Access and Benefit-Sharing for the Consideration of the Conference of the Parties at its Ninth Meeting".

It would be appreciated if the above-mentioned letter could also be distributed to the participants of the seventh meeting of the *Ad Hoc* Open-ended Working Group on Access and Benefit-Sharing (WGABS-7) together with the UPOV's position paper sent to you in my letter of July 16, 2008.

Sincerely yours,

Rolf Jördens

Rolf Jördens
Vice Secretary-General

Mr. Ahmed Djoghlaf
Executive Secretary
Secretariat of the Convention on Biological Diversity
United Nations Environment Programme
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UPOV

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GINEBRA, SUIZA

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

April 17, 2008

Dear Executive Secretary Djoghlaf,

I have the pleasure to refer to the "Recommendation of the Working Group on Access and Benefit-Sharing at its Sixth Meeting on Possible Elements of a Decision on Access and Benefit-Sharing for the Consideration of the Conference of the Parties at its Ninth Meeting".

As of April 17, 2008, 65 members of the International Union for the Protection of New Varieties of Plants (UPOV) are signatories of the Convention on Biological Diversity (CBD) and 64 members of UPOV have already ratified or acceded to the CBD.

The reply of UPOV to the Notification of June 26, 2003, from the Executive Secretary of the CBD on UPOV's views on the process, nature, scope, elements and modalities of an international regime on access to genetic resources and benefit-sharing"[1] supported the view that the CBD and the UPOV Convention should be mutually supportive.

On that basis, the Council of UPOV, at its twenty-fifth extraordinary session, held in Geneva on April 11, 2008, decided to:

> "request the Conference of the Parties of the Convention on Biological Diversity (CBD), at its Ninth Meeting, to consider the inclusion of the following elements in a decision relating to the 'Recommendation of

/...

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[1] UPOV's reply of 2003 is included in document UNEP/CBD/WG-ABS/3/INF/1 and can be found at: http://www.upov.int/en/news/2003/intro_cbd.html

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the Working Group on Access and Benefit-Sharing at its Sixth Meeting on Possible Elements of a Decision on Access and Benefit-Sharing for the Consideration of the Conference of the Parties at its Ninth Meeting':

"1. In the first page (considerations):

Recognizing that UPOV supports the view that the Convention on Biological Diversity (CBD) and the UPOV Convention should be mutually supportive.[2]

"2. In the guidance for further negotiation of an international regime on access to genetic resources and benefit-sharing:

Further instructs the *Ad Hoc* Open-ended Working Group on Access and Benefit-Sharing that any provisions which it develops for an international regime on access to genetic resources and benefit-sharing should ensure mutual supportiveness with the UPOV Convention.[3]"

Sincerely yours,

Kamil Idris
Secretary-General

2 See paragraph 3 of UPOV's reply of 2003.
3 See paragraph 16 of UPOV's reply of 2003.

UPOV

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

CBD

July 16, 2008

Dear Executive Secretary Djoghlaf,

I have the pleasure to refer to paragraph 9 of Decision IX/12 Access and Benefit-Sharing which was adopted by the Ninth Meeting of the Conference of the Parties of the Convention on Biological Diversity(COP-9), held in Bonn, Germany, from May 19 to 30, 2008, in which the Conference of the Parties

> *"Invites Parties, other Governments, international organizations and indigenous and local communities, and relevant stakeholders to submit, for further elaboration and negotiation of the international regime on access and benefit-sharing, views and proposals including operational text, where relevant, in respect of the main components listed in the annex I to the present decision, preferably with supporting rationale".*

Views and proposals of the International Union for the Protection of New Varieties of Plants (UPOV) in relation to the elaboration and negotiation of the international regime on access and benefit-sharing were expressed in the reply of UPOV to the Notification of June 26, 2003, "Access to Genetic Resources and Benefit-Sharing", adopted by the Council of UPOV on October 23, 2003, and sent to the Secretariat of the Convention on Biological Diversity under cover of a letter dated October 27, 2003.

/...

Mr. Ahmed Djoghlaf
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Mr. Ahmed Djoghlaf, Montréal – July 16, 2008

I have the pleasure to send you herewith the reply of UPOV as mentioned above, and I would appreciate it if you could arrange for this document to be distributed to the participants of the seventh meeting of the *Ad Hoc* Open-ended Working Group on Access and Benefit-Sharing (WGABS-7).

Sincerely yours,

Rolf Jördens
Vice Secretary-General

UPOV

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

ACCESS TO GENETIC RESOURCES AND BENEFIT-SHARING

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

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

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Introduction

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

2. As of July 31, 2003, UPOV has 53 members[1]. Furthermore, 18 States and two intergovernmental organizations have initiated, with the Council of UPOV, the procedure for becoming members of the Union and 53 other States have been in contact with the Office of the Union for assistance in the development of legislation on plant variety protection. It is therefore anticipated that more than 100 States or intergovernmental organizations may be members of UPOV in the future.

3. UPOV supports the view that the Convention on Biological Diversity (CBD) and relevant international instruments dealing with intellectual property rights, including the UPOV Convention, should be mutually supportive.

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

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

Access to Genetic Resources

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

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

Disclosure of Origin

7. The requirement for "distinctness" in the UPOV Convention[2] means that protection shall only be granted after an examination to determine if the variety is clearly distinguishable from all other varieties, whose existence is a matter of common knowledge[3] at the date of filing of the application, regardless of the geographical origin. Furthermore, the UPOV Convention provides that, if it is discovered that a breeder's right has been granted for a variety that was not distinct, that right shall be declared null and void.

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

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

Prior Informed Consent

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

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

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

Summary

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

Benefit-Sharing

Breeder's Exemption

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

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

Subsistence Farmers

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

Farm-Saved Seed

15. The provision on "farm-saved seed" (also known as the "farmer's privilege") is an optional benefit-sharing mechanism provided by the UPOV Convention, under which UPOV members may permit farmers, on their own farms, to use part of their harvest of a protected variety for the planting of a further crop. Under this provision, members of UPOV are able to adopt solutions, which are specifically adapted to their agricultural circumstances. However, this provision is subject to reasonable limits and requires that the legitimate interests of the breeder are safeguarded, to ensure there is a continued incentive for the development of new varieties of

plants, for the benefit of society. For example, certain members of UPOV apply the provision on farm-saved seed only to certain species or limit its application using criteria such as the size of the farmer's holding or the level of production.

Summary

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

Conclusion

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

[End]
