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CONVENTION ON BIOLOGICAL DIVERSITY

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Item 4.1 of the provisional agenda*

**WRITTEN SUBMISSIONS BY PARTIES AND OBSERVERS RELATED TO THE MAIN
COMPONENTS OF THE INTERNATIONAL REGIME ON ACCESS AND BENEFIT-SHARING
MADE AT THE SIXTH MEETING OF THE AD HOC OPEN-ENDED WORKING GROUP ON
ACCESS AND BENEFIT-SHARING**

Note by the Executive Secretary

INTRODUCTION

1. At the sixth meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing, held in Geneva, from 21 to 25 January 2008, it was agreed that the written submissions provided by Parties and observers would be compiled and made available at the ninth meeting of the Conference of the Parties. The compilation is contained in the annex to the present document.
2. The submissions have been reproduced as they were given to the Secretariat during the meeting. It should be noted that only the submissions on the “main components” of the international regime have been included. Submissions on “nature and scope” are included as options in the annex to the report of the Working Group on its sixth meeting (UNEP/CBD/COP/9/6). With regard to “objectives”, proposals made during the meeting were introduced in the contact group and subsequently consolidated into the negotiating text, which is also included in the annex to the report.

* UNEP/CBD/COP/9/1.

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POSITION OF THE AFRICAN GROUP REGARDING THE MAIN COMPONENTS

Fair and Equitable Sharing of Benefits

Conditions to promote and safeguard benefit sharing:

The IR on ABS shall ensure that measures and conditions are taken at the international level to promote and safeguard the fair and equitable sharing of benefits arising from the use of biological resources (BR), genetic resources (GR), their derivatives, products and associated TK

- a) Fair and equitable sharing of benefits arising from use of BR, GR, derivatives, products and associated TK
- b) Minimum conditions and standards in IR for sharing of benefits
- c) Access shall be linked to minimum benefit sharing arrangements
- d) Benefit sharing for derivatives and products must be covered by IR
- e) Multilateral benefit sharing options for BR and GR whose origin is not clear or transboundary BR and GR
- f) Monetary and non monetary benefits for every use, in line with elements listed under appendix 2 of the Bonn Guidelines
- g) Facilitating access to and transfer of appropriate technology by parties/ private sector on concessional and preferential terms
- h) MAT must stipulate benefit sharing arrangements on derivatives and products
- i) Benefits should be directed towards conservation and sustainable use of biodiversity and socio-economic development in countries of origin
- j) Establish trust funds for trans-boundary genetic resources and associated TK
- k) Ensure effective participation, involvement and inclusion of indigenous and local communities through PIC, MAT and benefit sharing processes

Access:

The IR shall ensure that access to BR and GR, their derivatives, products and associated TK be conditional on fair and equitable benefit sharing arrangements, contributing towards socio-economic development of the country of origin/legal provenance, sustainable use of biological resources, transfer of appropriate technology associated with BR and GR, their derivatives, products and associated TK being accessed and shall be subject to:

- a) National sovereignty
- b) National competent authority
- c) National legislation/requirement (Art 15.1 and 15.5)
- d) Environmentally sound uses
- e) PIC and MAT from contracting party or as otherwise provided by national law/regulations/requirements
- f) Sharing results of R and D and results commercialization and other utilization with provider countries
- g) Transfer of appropriate technology associated with BR, GR, their derivatives, products and associated TK being accessed
- h) Protection and enforcement of associated traditional knowledge and practices

Compliance:

The compliance mechanism of the international regime shall ensure that access to BR, GR, their derivatives, products and associated TK and benefit sharing mechanisms shall be mutually enforceable both in provider, user countries and other parties in conformity with CBD obligations and national law/regulations/requirements of provider country regarding access and benefit-sharing.

Measures to ensure compliance shall include but not limited to the following:

- Reporting systems
- Tracking systems
- Speedy and effective enforcement of contracts in case of breach
- ABS related judgments passed in one party should be mutually enforceable in all other parties (liability and redress)
- Certificate of origin/source/legal provenance
- Certificate of compliance with national laws/ regulations/requirements and CBD obligations
- Disclosure of origin of genetic resources, derivatives, products and associated TK in IPR applications in all relevant fora
- Transfer of technology
- Sanctions for non-compliance

Capacity-Building:

Capacity-building measures shall be undertaken at all relevant levels in both user and provider countries to ensure effective implementation of the IR. Capacity-building measures shall include but not limited to:

- a) Establishment of a financial mechanism to address the issue of capacity-building.
- b) Development of capacity for legislation on ABS issues.
- c) Enhancement of capacity of negotiators and stakeholders
- d) Building of capacity for information and communications technology on ABS at all national focal points.
- e) Building of capacity to prevent misappropriation, misuse and bio-piracy
- f) Building of capacity of local and indigenous communities
- g) Building of capacity of national focal points
- h) Ensuring that national capacity self assessment will be the guideline for minimum capacity-building requirements
- i) Capacity-building should include, but not limited to valuation of genetic and other natural resources, valuation of TK and Innovations, negotiations of legal contracts, bio prospecting/associated research methods and relevant equipment for such research and taxonomic studies. Conservation and sustainable use of natural resources and inventorying/documentation of genetic resources and technologies for monitoring and tracking of genetic material.

Traditional Knowledge:

The IR shall include measures to ensure the full and effective participation and involvement of indigenous and local communities in decision making, PIC and MAT and the sharing of benefits arising from the use of their GR, innovations, practices and associated TK.

- a) The IR shall ensure a declaration to be made on the certificate of origin/source/legal provenance as to whether there is any associated TK and who the owners of the TK are
- b) The IR should recognise the rights of communities to control use including future use of GR and associated traditional knowledge in the context of benefit sharing agreements
- c) The IR shall ensure that measures for capacity-building shall be undertaken among ILCs to ensure their effective participation in ABS related issues.

AUSTRALIA'S STATEMENT ON BULLET POINTS UNDER "MAIN COMPONENTS"

Before I begin on our suggestions of bullet points under components of an IR, I'd like to express concern about the process and our understanding of it.

Our understanding is that we have not started negotiating protocol or treaty text, we are simply contributing bullet points to ideas on the main components of an international regime.

There are some areas of consensus, which as we have stated previously, could be a useful basis to move forward. There still exists vast areas of disagreement between parties, and these differences are best served by identifying further work to help parties come to agreement.

Nor do we have any agreement on the meaning of the term "international regime" and we haven't begun contact group discussions on scope/nature, and we are still in disagreement on the objective of an IR.

As I did in plenary, I indicate our willingness to look at how the concerns of all parties can be met with further investigation

Beginning to negotiate operational text will end in failure, as it has in the past.

Here are our bullet points under each subheading. It is not a comprehensive list of what we believe the components should be, and it is without prejudice to further development of other ideas and work.

I'll now set out our bullet points under each component subheading

Benefit sharing

- the development of non-binding guidelines on benefit sharing, possibly on sectoral approaches
- reference to the CBD's central provisions and the Bonn Guidelines as primary source of advice for guiding national implementation

Access

- reference to the CBD's central provisions and the Bonn Guidelines as primary source of advice for guiding national implementation

Compliance

We have a bullet point on certificates which is in large agreement with Europe, but I'll set it out in any case

- voluntary certificate of compliance with domestic regulations issued by national authority covering genetic resources taken in accordance with the CBD
- elaboration of model contracts and/or model contract clauses, noting contracts are primary mechanism to ensure compliance with the CBD's ABS provisions.

Traditional Knowledge

- a set of non-binding guidelines to assist parties, through their domestic legislation and policies on access and benefit sharing or genetic resources and in accordance with Articles 8(j) and Article 15 of the Convention to:
 - o encourage the equitable sharing of benefits arising from the utilization of traditional knowledge, innovations, and practices related to the utilization of genetic resources; and
 - o ensure that access to genetic resources under the ownership or control of indigenous and local communities is undertaken with the approval of the community which owns or controls such resources under domestic law, and to ensure the sharing of benefits in such circumstances with indigenous and local communities through mutually agreed terms

CANADA

Additions to Fair and Equitable Sharing of Benefits

- Development of model contract terms
- Awareness raising
- Mechanisms to promote equality in negotiation
- Enhanced utilization of Bonn Guidelines

Additions to Access to Genetic Resources

- Legal certainty and clarity
- Foreign and domestic users should be subject to the same requirements
- Internationally developed model domestic legislation
- Minimize administration and transaction costs

Additions to Compliance

- Existing rules on Private International Law
- Existing International and domestic dispute resolution mechanisms
- Mechanisms for exchange of information
- Codes of conduct
- Utilization of information technology to enhance compliance

Additions to Traditional Knowledge

- Access to TK in accordance with community level procedures
- Facilitated Access does not apply to TK
- Benefits to be distributed at the community level

Additions to Capacity

- Capacity-building targeted at enhancing legal systems related to ABS
- Enhanced capacity to use genetic resources for sustainable development

EU PROPOSALS FOR MAIN COMPONENTS

Fair and equitable benefit-sharing

Further measures taken to support compliance with PIC and MAT will ensure fair and equitable benefit-sharing

- Development of menus of model clauses for potential inclusion in MTAs
- Development of IT tools to create transparency of obligations and to facilitate transactions
- Role of Private International Law to ensure compliance with MAT set out in contracts
- Involvement of ILCs in setting up MAT and in establishing PIC when TK associated with GR is accessed.
- Awareness raising activities
- In the context of the development of international standards on access rules and practices, a discussion on misappropriation to address obligation to acquire PIC and to set up MAT in accordance with national legislation

Access to genetic resources

International access standards that would facilitate access and raise transparency and predictability when supporting compliance with ABS requirements across jurisdictions, but that do not require a harmonization of national access legislation

International access standards should include

- international guidance on national access legislation (eg, model legislation);
- elements that are regarded as essential for national access regimes to be considered in accordance with Article 15.2 CBD:
(i) specific rules on PIC requirements or existence of other norms for obtaining PIC; (ii) clear legal status and the rules on ownership of GR found in situ and ex situ; (iii) availability and accessibility of information on how to obtain PIC; (iv) limitations on time and costs for obtaining PIC decisions; (v) existence of a procedure for simplified access for non-commercial research.)
- commitment of parties to notify up-to-date information on national provisions and administrative contacts relevant for access to GR and, if relevant, associated TK to an international information sharing mechanism;
- international commitment to ensure that national access rules apply in a non-discriminatory way.
- the establishment of an international assessment function

Compliance

It is difficult to consider additional and more specific international commitments to support compliance with ABS requirements if there is uncertainty about and a broad variety of what exactly is to be enforced in countries with users under their jurisdiction. International access standards will facilitate access and raise predictability when supporting compliance with ABS requirements across jurisdictions. All Parties could commit to further non-binding measures to support compliance with PIC and MAT without the need to link such commitments to the development of international access standards

- Internationally recognized certificate of compliance with national access rules

- International definition of misappropriation of GR that includes the acquisition of GR in circumvention of national PIC requirements that meet international access standards as well as the acquisition of GR without setting up of MAT;
- Disclosure of origin or source of GR and associated TK in patent applications to be further discussed in WIPO
- Sectoral work to develop menus of model clauses for potential inclusion in MATs
- development of information exchange procedures between national ABS focal points to help providers of GR obtain relevant information in specific cases of alleged infringements of PIC requirements;
- role of research funding agencies in obliging users of genetic resources receiving research funds to comply with specific ABS requirements
- steps to promote codes of conduct for important groups of users and to identify/ establish a mechanism for identifying those codes that are regarded as best practice;
- unilateral declarations by users that genetic resources have been legally obtained.
- Role of Private International Law to ensure compliance with MAT set out in contracts

Traditional knowledge associated with genetic resources

Protect the rights of indigenous and local communities to their traditional knowledge related to genetic resources consistent with international human rights obligations

- ways to incorporate TK in PIC decisions;
- best practices to ensure respect for TK in ABS-related research
- establishment of a conducive environment when TK is accessed
- consideration of access to TK in the development of menus of model clauses for potential inclusion in MTAs
- Capacity-building to support TK-holders in negotiating MAT

Capacity

- capacity-building needs integral to the negotiation and any eventual ABS regime
- targeted capacity-building measures to support provider countries in developing national access frameworks that meet international access standards.

PROPOSAL BY THE LATIN AMERICAN AND CARRIBEAN GROUP (GRULAC)

Fair and equitable sharing of benefits

Fair and equitable sharing of benefits (monetary and non- monetary) can only be assured if there is:

- 1) Adoption of administrative, legislative and policy measures, including:
 - minimum conditions and standards, based upon mutually agreed terms and prior informed consent, to ensure the fair and equitable sharing of the benefits, from commercial and other utilization of genetic resources, its derivatives and associated traditional knowledge.
 - measures to ensure providers of genetic resources are granted access to joint development and facilitated transfer of those technologies and associated capacity-building resulting from the use of those resources
- 2) Facilitation of access to the results of research and development,
- 3) The establishment of activities that could *inter alia* consider tools to create transparency, involvement of indigenous and local communities and awareness by different stakeholders, including users.

Access to Genetic Resources

- 1) States have sovereign rights over their genetic resources and derivatives and the authority to determine access rests with the national governments and is subject to national legislations.

Compliance

The International Regime on Access and Benefit Sharing should contain the following measures:

- 1) Identification of a minimum of checkpoints that could be expanded as necessary.
- 2) Implementation of a Certificate of Compliance that demonstrate compliance with national legislation. Such information on certificates need to form part of an overall clearing house mechanism/international repository.
- 3) Implementation of adequate, transparent dispute settlement mechanisms and sanctions in order to prevent misuse and misappropriation of genetic resources, derivatives and associated TK according to national legislation
- 4) Legislative, administrative and policy measures in order to comply with the provisions of the international regime and ensure compliance with PIC and MAT from indigenous and local communities in relation to their associated traditional knowledge, innovations and associated practices
- 5) (5) Implementation of measures to ensure genetic resources, derivatives and associated TK are used for purposes consistent with the terms and conditions under which they were accessed
- 6) Implementation of a system to ensure access to justice and remedies in the user countries, in order to safeguard the rights over genetic resources, derivatives and associated traditional knowledge.

Traditional Knowledge associated with genetic resources

In order to ensure adequate consideration for the Traditional Knowledge associated with genetic resources the following recommendations are made:

- 1) Administrative, legislative and policy measures should be implemented to ensure Indigenous and local communities obtain a fair and equitable distribution of the benefits arising from the use and application of the traditional knowledge associated with GR and derivatives. Stakeholders interested in using those TKs and practices should obtain the PIC of the local and indigenous communities.

Capacity-Building

In order to ensure effective building of capacity related to the use of genetic resources and traditional knowledge:

There is need to ensure targeted capacity-building measures and in particular, technology transfer according to article 16 of the CBD, for the development of national access, protection and benefit sharing frameworks that meet the objectives of the International Regime.

Capacity-building could consider, *inter alia*:

- Measures for the building and enhancement of capacity in developing countries, LDCs, SIDs as well as CEEs for implementation of the IR at national, regional and international levels.
- Measures for effective technology transfer and cooperation to support the generation of social, economic and environmental benefits.
- Measures for the building of human, institutional, scientific capacities, including for putting in place a legal mechanism, taking into account articles 18, 19 and 20.4 of the CBD
- Measures for capacity-building , for *inter alia*,
 - o Contract negotiation
 - o Assisting indigenous and local communities to implement their right to PIC and MAT

PROPOSALS BY THE LIKE MINDED MEGADIVERSE COUNTRIES (LMMC)

MAIN COMPONENTS AND ELEMENTS OF AN IR

1. FAIR AND EQUITABLE SHARING

- Measures to ensure the fair and equitable sharing of benefits including monetary and non monetary benefits:
 - arising out of the commercial and other utilization of GR, its derivatives and associated traditional knowledge
 - the results of research and development including through facilitating access to the results of such research and development
 - Providing access to and facilitated transfer of technology to developing countries under fair and most favorable terms including on concessional and preferential terms, including that which is IPR protected
 - Information, and,
 - Capacity-building
- Effective participation in research activities, and/or joint development in research activities for the benefit of developing countries
- MAT and PIC as reflecting fair and equitable sharing of benefits
- International standards for the sharing of benefits based on the commercial exploitation of IPR or products developed with or derived from GR, their derivatives and/or associated TK
- Measures to promote access and benefit-sharing arrangements that contribute to the achievement of the Millennium Development Goals, in particular on poverty eradication and environmental sustainability

2. ACCESS

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

3. COMPLIANCE

- Parties shall take legal, administrative or policy measures to support effective compliance with national legislation regarding PIC of the contracting party providing GR their derivatives and associated TK, and, MAT on which such access was granted.
- Measures to ensure collaboration between law enforcement agencies in both provider and user country
- Measures to prevent misappropriation and/or misuse of GR, their derivatives and/or their associated TK

International Certificate of Compliance

- Issued by national authority
- Internationally recognized
- Mandatory for both user and provider
- Public document
- To facilitate and ensure compliance with national law/requirements

- To facilitate, monitoring by national authority/ies in user/provider country that the use of GR, their derivatives and associated TK to ensure that the use is in compliance with national law
- Allows for tracking and monitoring through, inter alia, reporting to CHM, unique identifier
- As a confidence building measure between user and provider of GR, their derivatives and associated TK
- requires checkpoints in user and provider country, inter alia, at:
 - Borders;
 - IPR offices;
 - Registration points for commercial application for example product approval processes.

Disclosure Requirements for IPRs:

- Kind of GR or its derivatives
- Country of origin and/or the provider that acquired the GR in accordance with the Convention
- Associated TK used, if any,
- TK holder, if any,
- PIC
- MAT (fair and equitable sharing of benefits)

4. SANCTIONS

- General
 - Administrative, legal,
 - punitive-fines and/or jail, compensatory
 - seizure of samples
- IPR*
 - prevent future processing of application or grant
 - revocation of IPR granted
 - IPR rendered ineffective and unenforceable
 - compensatory including repayment of profits earned from IPR
 - return of resource forming subject matter of IPR

5. ACCESS TO JUSTICE

- Measures to ensure access to justice and redress
 - expeditious, effective and at a low cost
 - administrative and judicial remedies and alternative dispute resolution mechanism by provider and user
 - Cooperative procedures and institutional mechanisms to address infringement of national legislation and of agreements on ABS

* With reservation by Peru

6. DISPUTE SETTLEMENT MECHANISM

- Parties shall establish a dispute settlement mechanism for the IR

7. FINANCIAL MECHANISM

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

8. TRADITIONAL KNOWLEDGE (TK)

- Measures to ensure the recognition and protection of the rights of indigenous and local communities over their TK associated with GR and their derivatives
- Measures to ensure the fair and equitable sharing of benefits arising from the utilization of TK associated with GR and their derivatives, subject to national legislation
- Measures to ensure PIC of indigenous and local community where their TK associated to GR and their derivatives is involved, subject to national legislation

9. CAPACITY-BUILDING

- Ensure measures for the building and enhancement of capacity in developing countries, LDCs, SIDSs, as well as CEEs for implementation of the IR at national, regional and international levels
- Ensure measures for effective technology transfer and cooperation to support the generation of social, economic and environmental benefits
- Ensure measures for the building of human, institutional and scientific capacities including for putting in place a legal mechanism, taking into account Articles 18, 19 and 20.4 of the CBD
- Ensure capacity-building measures for, *inter alia*,
 - contract negotiation
 - assisting indigenous and local community to implement their right to free and PIC
 - PIC and MAT

NEW ZEALAND

- “The working group agreed that further work should be undertaken with the aim of making the protection of TK associated with genetic resources an integral part of the IR, in accordance with the following principles:
- In according with article 8(j) of the Convention, access to traditional knowledge should be only with the approval o f the knowledge holders;
- The individual or entity with the authority to grant access should be correctly identified in accordance with the practices of the community concerned
- Under no circumstances should the approval of knowledge holders be engineered or otherwise coerced
- All rights over genetic resources and associated traditional knowledge should be taken into account, in particular those of indigenous and local communities.

SUBMISSION BY SWITZERLAND ON MAIN COMPONENTS

Fair and equitable sharing of benefits:

The regime should facilitate the fair and equitable sharing of benefits by improving the use and enforcing existing instruments on national and international level.

The regime should draw on existing guidelines and contract laws to elaborate best practices which will include a list of various types of standardized benefits which could be used in a flexible way according to different circumstances. Those standardized benefits should enable to shape best practices to conclude and operate bilateral agreements “under mutually agreed terms”. The regime should facilitate the fair and equitable sharing of benefits by improving the use and enforcing existing instruments on national and international level.

- sectoral approach should be chosen to implement Benefit sharing agreements in the IR.

Access to genetic resources:

- The International regime should be based on the article 15 of the CBD which recognizes the national authority to determine the access to genetic resources as part of their sovereign rights (art 15.1 of the CBD) as well as on the art 15.2 of the CBD ,to promote and facilitate such access. To that aim the regime should build upon the Bonn guidelines and move beyond them in order to establish internationally agreed minimum standard requirements on access. Such procedures should also address the need for simplified access rules regarding research with non- commercial intent.
- To develop transparent procedures and rules on PIC requirements on clear information and on standards how to obtain PIC in a non discriminatory manner.

Compliance:

Measures to support compliance with PIC:

- The development of an Internationally recognized certificate of compliance with national access rules has to be further examined.
- The disclosure of source as a requirement in patent application to be negotiated within WIPO.

Measures to support compliance with MAT:

- The elaboration of indicative possible “standardizing choices” in Material Transfer Agreements (MTA) adapted to various sectors of genetic resources could offer a solution and needs to be further explored.

SUBMISSION BY IIFB ON MAIN COMPONENTS

Main components

Fair and equitable sharing of the benefits

- Conditions to promote and safeguard benefit-sharing, including appropriate transfer of relevant technologies, taking into account all rights over those resources and technologies.

Access to genetic resources

- Conditions to regulate access in accordance with national legislation and human rights law and other international obligations, ensuring respect for rights to genetic resources, including rights of indigenous and local communities, when applicable. [*language drawn from the Granada Text “Scope”, p. 1*]

Compliance

- International certificate of compliance with PIC and MAT
- Other measures of compliance with PIC and MAT
- Mechanisms for monitoring, enforcement and dispute settlement
- Customary law and local systems of protection [*language drawn from Decision 7/19, Annex D (xvi) “Elements”*]
- Disclosure of indigenous peoples names, their territory and country in IPR applications [*language drawn from Decision 7/19, Annex D (xiv) “Elements”*]

Traditional knowledge associated to genetic resources

- PIC and MAT of indigenous and local communities
- Benefit-sharing

Capacity

- Capacity-building
- Communication, education and public awareness
- Other ways and means
