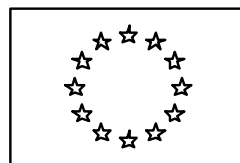


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EUROPEAN COMMISSION

Dr. Ahmed Djoghlaif
Executive Secretary
Convention on Biological Diversity
413, Saint Jacques Street, Suite 800
Montreal, Quebec, Canada
H2Y 1N9

Brussels / Lisboa, 28 November 2007

Subject: EU submission in reply to Notification 2007-132 – Concrete options for the further negotiation of substantive items on the agenda of the fifth and sixth meetings of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing

Dear Dr. Djoghlaif,

Please find attached a submission of the European Community and its Member States in response to notification 2007-132 inviting Parties to submit concrete options for the further negotiation of substantive items on the agenda of the Fifth and Sixth Meetings of the Ad-Hoc Open-Ended Working Group on Access and Benefit-sharing.

During ABS WG-5, the EU already expressed its views on items discussed during this meeting, based on Conclusions adopted by the Council of the European Union on 28 June 2007. The attached submission further explains these views.

The EU is currently developing its position for items on the agenda of ABS WG-6, particularly regarding discussions on nature, scope and objectives of the international ABS regime.

Sincerely yours,

[signed]
Maria Elisa Oliveira

CBD Focal Point
Institute for Nature Conservation and Biodiversity
Ministry of the Environment, Spatial
Planning and Regional Development
Portugal

[signed]
Hugo-Maria Schally

Head of Unit – CBD Focal Point
Environment Directorate-General
European Commission

**Submission by the European Community and its Member States of
28 November 2007 in response to CBD Notification 2007-132**

**CONCRETE OPTIONS FOR THE FURTHER NEGOTIATION OF
SUBSTANTIVE ITEMS ON THE AGENDA OF THE FIFTH AND SIXTH
MEETINGS OF THE AD HOC OPEN-ENDED WORKING GROUP ON
ACCESS AND BENEFIT-SHARING**

The European Community and its Member States are committed to completing the elaboration and negotiation of an international regime on Access and Benefit-sharing (ABS regime) at the earliest possible time before the tenth meeting of the Conference of the Parties as agreed at COP8 in Decision VIII/4.

The EU therefore regards it as essential that CBD COP9 in May 2008 will identify the main elements of the international ABS regime and determine the inter-sessional process between COP9 and COP10 for completing the negotiation of the international ABS regime.

The Ad Hoc Open-ended Working Group on Access and Benefit-sharing at its fifth meeting held in Montreal, from 8 to 12 October 2007 invited Parties, Governments, indigenous and local communities and stakeholders to submit to the Secretariat by 30 November 2007 concrete options on the substantive items on the agenda of the fifth and sixth meetings of the Working Group.

Responding to this invitation, the EU submits the following concrete options and elements on substantive items on the agenda of the fifth and sixth meetings of the Working Group, convinced that consideration and inclusion of these options and elements in the further negotiation of the international ABS regime will facilitate and expedite progress.

**ADDRESSING THE LINK BETWEEN ACCESS TO GENETIC RESOURCES
AND ADDITIONAL MEASURES TO SUPPORT COMPLIANCE**

Explicitly addressing the link between national frameworks on access to genetic resources and additional measures to support compliance is essential for a successful conclusion of this negotiation.

In response to the demand for potentially binding international commitments to support compliance with ABS requirements through clearly specified measures, the EU has identified the need for developing international standards on national access law and practice as part of the ABS negotiations.

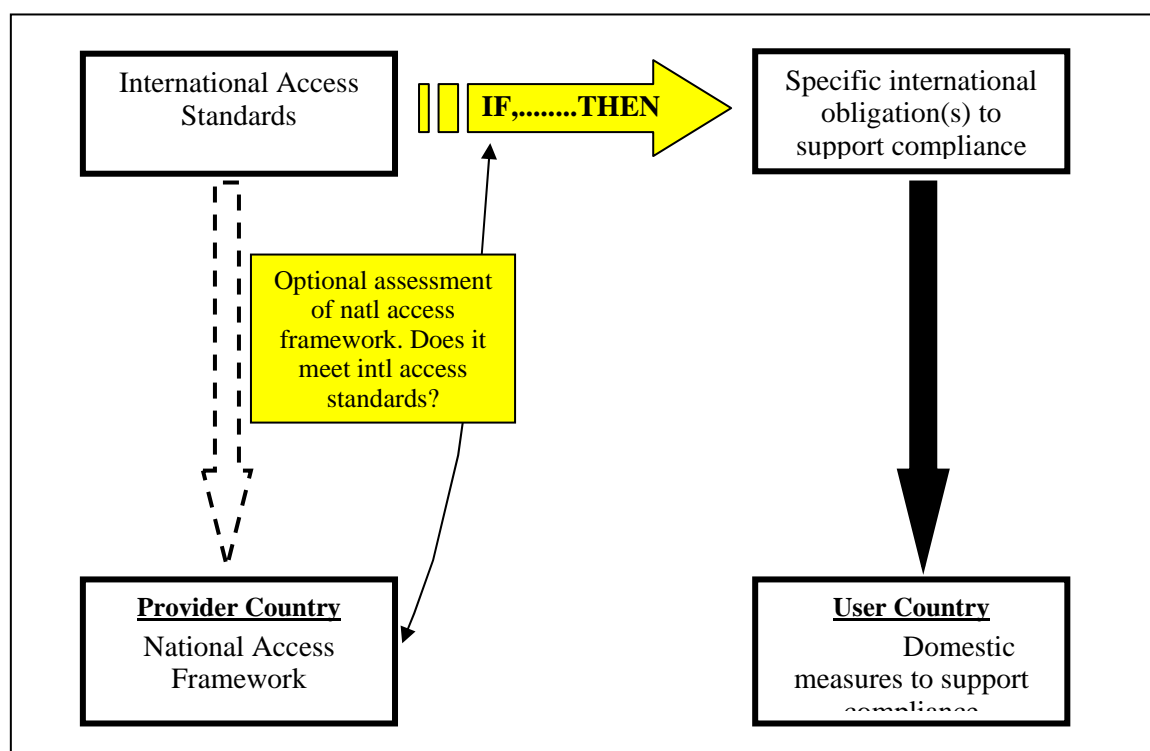
The EU believes that it is difficult to consider additional and more specific international commitments to support compliance with ABS requirements if there is uncertainty about and a broad variety of what exactly is to be enforced in countries with users under their jurisdiction.

Following from this argumentation the international ABS regime needs to include international standards on national access law and practice and an international mechanism/ process for assessing whether or not national access frameworks meet international standards.

In the EU's view, the international ABS regime could include international access standards as well as a commitment by all Parties to undertake additional enforcement activities vis a vis users of genetic resources which are provided by Parties whose national access framework meet international access standards. In this regard the EU envisages the following:

- Additional and more specific international obligations of all Parties to support compliance would be triggered vis a vis those Parties whose national access frameworks meet international access standards.
- To establish whether or not its national access framework meets international standards, each Party to the CBD could ask for an assessment of its national framework by an international mechanism/ process set-up under the ABS regime.
- Each Party to the CBD would decide whether or not to develop a national access framework that meets international access standards.
- Targeted capacity-building activities could support the development of national access frameworks that meet international access standards.

The following picture seeks to capture this description:



In addition, in the EU's view, all Parties could commit to further non-binding measures to support compliance with PIC and MAT without the need to develop international access standards.

Concrete options for the potential substance of international access standards and concrete options for additional and specific international obligations to support compliance are developed in the two subsequent sections of this submission.

DEVELOPING INTERNATIONAL STANDARDS ON NATIONAL ACCESS LAW AND PRACTICE

Article 15.1 CBD recognises the authority of national governments to determine access to genetic resources as part of the sovereign rights of states over their natural resources. Article 15.2 CBD obliges each Party to 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 CBD objectives. – In the EU's view, an international ABS regime must enable, promote and facilitate national implementation of the access-related obligations under the CBD.

The EU suggests developing international standards on national access law and practice as a key component of the international ABS regime. These standards must also address the urgent need for simplified access procedures in case of research undertaken with non-commercial intent. As explained above, the establishment of international access standards is also important to respond to the demand for potentially binding international commitments to support compliance with ABS requirements through clearly specified measures. – In suggesting the development of international access standards, the EU is fully conscious of the capacity-building challenges involved.

International standards on national access law and practice should include:

- o Guidance on national access legislation, for example in the form of model legislation or technical protocols guiding administrative decision-making;
- o Essential procedural and substantive elements that need to be reflected in national access frameworks before national access frameworks can be regarded as meeting international standards. This should include
 1. specific rules on PIC requirements or the existence of other norms for obtaining PIC;
 2. clear legal status and rules on the acquisition of genetic resources found in situ and ex situ;
 3. availability and accessibility of information on how to obtain PIC;
 4. limitations on time and costs for obtaining PIC decisions;
 5. existence of a procedure for simplified access for non-commercial research.
- o An international commitment of parties to notify up-to-date information on national provisions and administrative contacts relevant for access to genetic resources and, if relevant, associated TK to an international information sharing mechanism such as the CBD's Clearing House Mechanism.

- o An international commitment of parties to ensure that their national access rules apply in a non-discriminatory way.

ADDITIONAL MEASURES TO SUPPORT COMPLIANCE WITH PIC AND MAT

There are specific and very practical challenges for providers of genetic resources to be sufficiently certain that users of genetic resources comply with their agreed ABS obligations, including contractually agreed ones. Such challenges arise mostly from the difficulty to be informed about transactions and subsequent uses of genetic resources. Further challenges arise from the fact that often providers and users of genetic resources are located in different jurisdictions.

The EU has identified a range of concrete options for additional measures to support compliance with PIC and MAT. Each of these options by itself could substantively support compliance with ABS requirements.

Concrete options to support compliance with access related obligations, in particular regarding PIC

- o Mandatory disclosure requirement in patent applications. 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 by WIPO, 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.
- o International definition of misappropriation of genetic resources. The EU suggests developing an international definition of what constitutes "misappropriation" of genetic resources. The outcome of this work could then be linked to an international obligation for all Parties to the Convention, to prohibit the use of misappropriated genetic resources.
- o Unilateral declarations by users: The EU suggests discussing the potential role of unilateral declarations by users that genetic resources have been legally obtained in supporting compliance particularly with PIC.
- o Internationally recognised certificate of compliance. The EU is ready to consider an internationally recognised "certificate of compliance" with national access rules. However, more detailed considerations on the scope, nature, content and governance of such certificate are needed, particularly, how it would relate to and interact with other potential elements of the international ABS regime.

- o *Promoting and building on ABS-related codes of conduct.* The EU regards it as important to explore how the international ABS regime can promote ABS-related codes of conducts for important groups of users and identify codes of conduct that are regarded as best practice.
- o *Engaging with public research funding agencies.* Many *in situ* bioprospecting activities are supported with public research funds. Public research funding agencies therefore have a possible role in obliging users of genetic resources receiving research funds to comply with specific ABS requirements. The EU suggests engaging with public research funding agencies and exploring how these can support compliance with PIC and MAT.

Concrete options to support compliance with MAT

Mutually agreed terms (MAT) are typically set out in contracts between providers and users of genetic resources; so called "Material Transfer Agreements" (MTAs).

Specific compliance challenges that result from the fact that parties to an ABS-contract reside in different jurisdictions are addressed in private international law relating to contracts. It is therefore essential that the ABS negotiations build upon existing rules of private international law relating to contracts in supporting compliance with MTAs to avoid duplication of efforts.

Significant support to compliance with MAT would also result

- o from work to improve the information base for ABS-related transactions, and
- o by offering providers and users of genetic resources menus of model clauses for potential inclusion in Material Transfer Agreements.

Both of these concrete options are further explained in the following sections of this submission.

DEVELOPING MENUS OF MODEL CLAUSES FOR POTENTIAL INCLUSION IN MATERIAL TRANSFER AGREEMENTS
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A concrete and practical option relevant to the fair and equitable sharing of benefits as well as to supporting compliance with ABS requirements is the development of menus of model clauses for potential inclusion in Material Transfer Agreements.¹

¹ Responding to discussions on its proposal to initiate work on "standardising choices in MTAs", the EU will in the future refer to "the development of menus of model clauses" to express more clearly the overall thrust and potential contents of such work.

It would enhance legal certainty and compliance with ABS requirements and add to a supportive environment for the fair and equitable sharing of benefits if providers and users of genetic resources could turn to such menus of model clauses when negotiating "their" Material Transfer Agreement (MTA).

The availability of model MTA-clauses for specified uses of genetic resources would protect the weaker party in negotiations of mutually agreed terms by creating a level playing field. It also has significant potential for lowering transaction costs and for achieving legal certainty that obligations agreed between provider and users are enforceable in practice.

Such menus of model clauses should primarily be developed through sectoral processes in a bottom-up way with the involvement of stakeholders. Governments cooperating in the framework of the CBD should identify suitable sectors, spell out minimum process requirements and provide support as appropriate.

The international ABS negotiations need to address how the development of menus of model clauses for inclusion in MTAs would fit into and contribute to the international ABS regime. To facilitate a concrete and outcome-oriented discussion, the EU has made a submission on this specific issue in June 2007 (see pp. 49 ff. of Document UNEP/CBD/WG-ABS/5/INF/1).

MAXIMISING THE UTILITY OF MODERN IT-TOOLS TO IMPROVE THE INFORMATION BASE OF ABS-RELATED TRANSACTIONS

One of the greatest challenges to the effective implementation of access and benefit-sharing obligations are difficulties for both providers and users of genetic resources to be informed about transactions of genetic resources, changes in uses of genetic resources and ABS-related rights and obligations, including those from traditional knowledge associated with genetic resources.

It is therefore essential that the international ABS regime improves the information-base of ABS governance and thereby adds to enhanced transparency of and legal certainty in transactions of genetic resources. Practical and meaningful steps in this regard will also contribute to the ability of governments and stakeholders to take on further commitments to support compliance with PIC and MAT.

There is room for achieving significant improvements in the availability of ABS-related information at very low cost, if the advanced communication capacities of modern electronic networks were employed to support providers and users in obtaining a record of transactions of "their" GR and associated rights and obligations.

It is therefore essential that the ABS negotiations reflect and build on existing technological possibilities to ensure that rules and instruments of the international ABS regime are crafted in a way that maximises the utility of modern IT-tools to ABS governance.

CONSIDERING AND RESPONDING TO CAPACITY-BUILDING NEEDS

The EU regards capacity-building as a cross-cutting issue and relevant considerations as integral to the ABS negotiations and the international ABS regime.

However, specific capacity-building needs resulting from the international ABS regime and specific responses can only be discussed with negotiations further advanced. Nevertheless, the EU stresses its willingness to support capacity-building, as appropriate, to help eligible countries meet emerging requirements under the international ABS regime.

The EU also holds that GEF should play a major role in ABS-related capacity building over the coming years.

INTEGRATING TRADITIONAL KNOWLEDGE INTO THE ABS REGIME

The EU works to ensure that the international ABS regime contributes to the respect for and the preservation and maintenance of traditional knowledge associated with genetic resources as well as to the equitable sharing of benefits arising from the use of such knowledge in accordance with Article 8j CBD.

The EU is convinced that indigenous and local communities and their representatives could make important contributions to the ABS negotiations by providing well reflected, focused views on issues linked to traditional knowledge.

The EU has identified the following list of issues where work on the ABS regime could benefit from targeted, technical reflections by experts from indigenous and local communities.

- o Internationally Recognised Certificate of Compliance: How could the scope of such certificate also include traditional knowledge associated with GR?
- o Ethical code of conduct: How could the draft code contribute to the effective implementation of the CBD's ABS-related obligations?
- o TK and ABS-related research: best practices to ensure that ABS-related research respects existing TK? (e.g. publication policies, TK registries)
- o TK and PIC: ways to incorporate TK in PIC decisions. Options to address the balance between domestic flexibility and international minimum requirements on access. How to ensure that national PIC decisions respect transboundary indigenous communities?
- o TK and MAT: Options and examples for incorporating TK in efforts to standardise choices for MAT.
- o TK and Capacity-Building: Identification of current capacity-building needs, as well as potential capacity-building implications in the proposed international ABS regime context.