



**Convention on  
Biological Diversity**

Distr.  
GENERAL

UNEP/CBD/WG-ABS/8/6/Add.4  
8 November 2009

ORIGINAL: ENGLISH

AD HOC OPEN-ENDED WORKING  
GROUP ON ACCESS AND BENEFIT-  
SHARING

Eighth meeting

Montreal, 9-15 November 2009

Items 3.4, 3.5 and 3.6 of the provisional agenda\*

**COLLATION OF CONTRIBUTIONS SUBMITTED BY PARTIES, GOVERNMENTS,  
INTERNATIONAL ORGANIZATIONS, INDIGENOUS AND LOCAL COMMUNITIES AND  
RELEVANT STAKEHOLDERS ON COMPLIANCE, FAIR AND EQUITABLE  
BENEFIT-SHARING AND ACCESS**

*Addendum*

**SUBMISSION BY THE EUROPEAN UNION**

*Note by the Executive Secretary*

1. The Executive Secretary is circulating herewith a submission by the European Union regarding operational text as an addendum to the collation of contributions on compliance, fair and equitable benefit-sharing and access prepared for the eighth meeting of the Working Group on Access and Benefit-sharing (UNEP/CBD/WG-ABS/8/6 and Add.1-3).
2. The submission is being circulated in the form in which it was received by the Secretariat.

---

\* UNEP/CBD/WG-ABS/8/6/1.

## **EU SUBMISSION to ABS WG7 in response to notification 2009-50**

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.

Further recalling paragraph 121 of document UNEP/CBD/WG-ABS/7/8 which invites Parties, other Governments, international organizations and indigenous and local communities, and relevant stakeholders to submit views and proposals including operational text, where relevant, in respect of nature, traditional knowledge associated with genetic resources, and capacity-building; and further submissions on fair and equitable benefit-sharing, access and compliance building on the annex to that document.

The EU submits the views below and examples of operational text with supporting rationale in respect to the main components compliance and access building on the annex to document UNEP/CBD/WG-ABS/7/8.

The EU reserves its right to amend, modify or withdraw its examples of operational text included in this submission in response to other proposals made and to the course of negotiations.

### **B. ACCESS TO GENETIC RESOURCES <sup>1/</sup>** **1) Recognition of the sovereign rights and the authority of Parties to determine access**

#### **Example of Operational Text**

[...]

7. Each Party requiring prior informed consent for access to its genetic resources may at any time confirm in writing to the Secretariat details of whether and how its domestic access and benefit-sharing framework is in conformity with the international standards set out in [include cross-reference to operational text under component III.B.5]. The Secretariat shall register any such communication in the CBD clearing house mechanism.

#### **Explanations and rationale**

Paragraph 7 is added to the existing paragraphs in the negotiating text developed in Paris. It underlines that the full and effective implementation of the proposed operational text on misappropriation of genetic resources will benefit from the availability of information on the conformity of domestic access frameworks with the international access standards. Such conformity assessments are best conducted by each Party itself. The results of such assessment should be notified to the Secretariat for registration in the clearing house mechanism, effectively by means of a unilateral declaration of conformity by a Party. This would enable user countries to easily determine whether additional measures should be applied in appropriate cases, without the need for recourse to an external assessment process. Such unilateral declaration of conformity by a Party would help to enhance legal certainty and transparency and ensure the full functioning of the international ABS regime.

### **C. COMPLIANCE**

---

<sup>1/</sup> The title is without prejudice to the eventual scope of the International Regime on Access and Benefit-sharing.

**1) Development of tools to encourage compliance**

**(b) International understanding of misappropriation/misuse**

**Example of Operational Text**

1. Misappropriating genetic resources means to acquire, either intentionally or negligently, genetic resources in violation of applicable domestic legislation of a Party that requires prior informed consent and mutually agreed terms for access to its genetic resources.
  2. Each Party shall
    - a) require natural or legal persons who use genetic resources on its territory to take, to the best of their ability, appropriate actions to prevent the acquisition or utilisation of misappropriated genetic resources, and
    - b) provide for measures where users fail to apply such actions.
  3. Each Party shall apply measures to
    - a) natural or legal persons having the nationality of that Party, who misappropriated a genetic resource in the jurisdiction of another Party,
    - b) natural or legal persons who, on its territory, acquire or use a genetic resource knowing that it has been misappropriated in the jurisdiction of another Party,
    - c) natural or legal persons who, on its territory, acquire or use a genetic resource and who should have known, based on available information, that the genetic resource has been misappropriated in the jurisdiction of another Party.
- Parties may refrain from taking such measures if the domestic access and benefit sharing framework of another Party providing a misappropriated genetic resource, at the time of misappropriation, was not in conformity with the international standards set out in section III.B.5.
4. Measures taken by Parties in accordance with paragraphs 2 and 3 shall provide for remedies and effective, proportionate and dissuasive sanctions.
  5. Each Party shall cooperate with other Parties' inquiries into possible instances of misappropriation of genetic resources.

**Explanations and rationale**

Paragraph 1 establishes an internationally agreed understanding of the term "misappropriating" genetic resources. The focus of the international understanding is on the acquisition of a genetic resource in the provider country. Subsequent acquisitions or use of a misappropriated genetic resource in the chain of users would not constitute a new act of misappropriation. Instead, subsequent uses, are addressed in paragraph 2 and paragraphs 3b) and c) of the operational provision.

Situations of "misuse", that is breaches of contract, are kept outside the scope of the proposed international understanding of "misappropriation", since breaches of contracts can already be pursued through a well established set of national and international rules.

Paragraph 2 establishes an obligation on each Party to adopt measures that would require all users of genetic resources on its territory to take, to the best of their ability, appropriate actions to prevent the acquisition or utilisation of misappropriated genetic resources. Effectively

implemented, such measures would clean the marketplace in "user countries" of genetic resources of questionable or unclear legal status in relation to access and benefit-sharing.

This general obligation on Parties to take preventive measures is complemented by obligations on Parties to apply measures in specific instances where genetic resource have been misappropriated or misappropriated genetic resources are being used:

Paragraph 3(a) establishes an obligation on Parties to apply measures to *natural or legal persons having the nationality of that Party, who misappropriated a genetic resource* in another Party. It is important that measures are applied only to the nationals of a Party. Otherwise, country A would be obliged to apply its measures also to nationals of country B who misappropriated a genetic resource in country C.

Paragraph 3(b) establishes an obligation on Parties to apply measures to *natural or legal persons who acquire or use a genetic resource on its territory knowing* that the genetic resource has been misappropriated in another Party. It is important that the obligation of Parties focus on activities under their respective territorial jurisdiction to avoid Parties being forced to exercise universal jurisdiction.

Paragraph 3(c) establishes an obligation on Parties to apply measures to *natural or legal persons who acquire or use a genetic resource on its territory although the said person should have known* that the genetic resource has been misappropriated in another Party.

Paragraph 3 subparagraph 2 establishes the link to the international access standards: Parties may refrain from taking the measures in paragraph 3 subparagraph 1 if, at the time of the alleged misappropriation, the domestic access framework of another Party was not in conformity with the international access standards at the time the misappropriating occurred.

Paragraph 4 establishes that, in cases of misappropriation, measures taken by Parties shall include remedies and effective, proportionate and dissuasive sanctions.

Paragraph 5 underpins the obligations of Parties in paragraphs 3 and 4 with an obligation of Parties to cooperate in relevant inquiries into possible instances of misappropriation of genetic resources.

The proposal of misappropriation of genetic resources does not address misappropriation of traditional knowledge associated with genetic resources. The General Assembly of the World Intellectual Property Organization in September 2009 agreed to embark on an ambitious text based negotiation "with the objective of reaching agreement on a text of an international legal instrument (or instruments) which will ensure the effective protection of GRs, TK and TCEs."<sup>2</sup> This negotiation will, *inter alia*, address a draft Article prepared by the WIPO Secretariat on "misappropriation of traditional knowledge".<sup>3</sup> It is important to avoid duplication and inconsistencies between these two parallel negotiations.

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

**Example of Operational Text**

---

<sup>2</sup> See decision for Agenda item 28 of WIPO General Assembly Thirty-Eighth (19th Ordinary) Session September 22 to October 1, 2009 Matters Concerning the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore.

<sup>3</sup> See WIPO revised draft Position for the Protection of Traditional Knowledge, substantive provisions, article 1, Protection against misappropriation.

Parties should encourage research funding agencies to seek to ensure that recipients of funding for research related to genetic resources and/or associated traditional knowledge act in accordance with the domestic ABS legislation of Parties providing access.

### **Explanations and rationale**

Researchers are a key stakeholder group in the negotiations of the international ABS regime. Research funding agencies might play a complementary role in supporting ABS compliance. Therefore, the regime should give general recognition to the potential role of research funding agencies in supporting compliance.

## **2) Development of tools to monitor compliance**

### **(b) Internationally recognized certificate issued by a domestic competent authority**

#### **Example of Operational Text**

1. The decision to grant prior informed consent, as registered by a Party in the clearing house mechanism, shall be the internationally recognised certificate of compliance.
2. Where a genetic resource is covered by an internationally recognised certificate of compliance, Parties shall deem that this genetic resource has been obtained in compliance with the domestic ABS framework of the provider country and has not been misappropriated.

### **Explanations and rationale**

Paragraph 1 reflects the EU's view that the decision to grant prior informed consent, as registered by a Party in the clearing house mechanism, shall be the internationally recognised certificate of compliance.

The focus is on the national decision to grant PIC. This reflects that Article 15 CBD leaves it to the discretion of each Party to determine at domestic level whether MAT should be in place before PIC could be granted or registered, and if so at which point MAT should be established.

However, if a genetic resource is covered by a certificate, Parties would be obliged to give some recognition to such certificate. Genetic resources covered by a certificate shall be deemed to have been obtained in compliance with the domestic ABS framework of the relevant provider country. Hence, such resources have not been misappropriated.

Recognizing the sovereign rights of States over their natural resources, the EU also holds the view that it must remain voluntary for provider countries to decide whether to issue certificates or not.

### **(c) Tracking and reporting systems**

#### **Example of Operational Text**

*Recognising* the important role of modern communication tools and internet based systems for tracking of genetic resources and reporting on ABS obligations as a key component of any efficient and cost-effective tool to monitor compliance. [*preambular paragraph*]

1. Each Party shall encourage users and providers of genetic resources to employ, to the best of their ability, the best available, cost-effective communication tools and internet based systems for tracking

of genetic resources and for reporting on compliance with access and benefit-sharing requirements set out in prior informed consent decisions and mutually agreed terms.

2. Parties will collectively support an exchange on best available technologies for tracking of and reporting on transactions of genetic resources reflecting specificities of different sectors.

### **Explanations and rationale**

Given the very rapid technological developments in the field of tracking and reporting, it is neither possible nor desirable to identify in the text of the international ABS regime the best available technology. However, the text of the international ABS regime must articulate the clear commitment of Parties to support employment of the latest technology as a cost-effective way of supporting compliance with ABS requirements, including across jurisdictions.

### **3) Development of tools to enforce compliance**

**(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**

#### **Example of Operational Text**

addressed in paragraph 5 of the EU proposal on "misappropriation"

#### **Explanations and rationale**

addressed in paragraph 5 of the EU proposal on "misappropriation"

### **(e) Remedies and sanctions**

#### **Example of Operational Text**

addressed in paragraph 4 of the EU proposal on "misappropriation"

#### **Explanations and rationale**

addressed in paragraph 4 of the EU proposal on "misappropriation"

-----