

**Date: February 8, 2013**

**Consolidated Document Relating to Intellectual Property  
and Genetic Resources  
Rev. 2**

## LIST OF TERMS

### **[Associated Traditional Knowledge**

“Associated Traditional knowledge” means knowledge which is dynamic and evolving, generated in a traditional context, collectively preserved and transmitted from generation to generation including but is not limited to know-how, skills, innovations, practices and learning, that [subsist in] [that are associated with] genetic resources.]

### **[Traditional Knowledge Associated with Genetic Resources**

“Traditional Knowledge Associated with Genetic Resources” means substantive knowledge of the properties and uses of genetic resources and their [derivatives] held by indigenous [peoples] and local communities [and which directly leads to a claimed [invention] [intellectual property]].]

### **[Biotechnology**

“Biotechnology” [as defined in Article 2 of the Convention on Biological Diversity] means any technological application that uses biological systems, living organisms or [derivatives] thereof, to make or modify products or processes for specific use.]

### **[Country of Origin**

“Country of origin” is the country which possesses genetic resources in in-situ conditions.]

### **[[Country Providing] [Providing Country]**

“Country Providing/Providing Country” means, [in accordance with Article 5 of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity], a [providing country] [country providing] that is the country of origin or that has acquired the genetic resources and/or that has accessed the traditional knowledge in accordance with the [Convention on Biological Diversity].]

### **[Country providing genetic resources**

“Country providing genetic resources” is the country supplying genetic resources collected from in-situ sources, including populations of both wild and domesticated species, or taken from ex-situ sources, which may or may not have originated in that country.]

### **[Derivative**

“Derivative” means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.]

## **Ex-Situ conservation**

“Ex-Situ conservation” means the conservation of components of biological diversity outside their natural habitats.

## **Genetic Material**

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

## **Genetic Resources**

"Genetic Resources" are genetic material of actual or potential value.

## **In situ conditions**

“In situ conditions” means conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties [Article 2, CBD].

## **[Internationally Recognized Certificate of Compliance**

“Internationally recognized certificate of compliance” shall mean the instrument foreseen in Article 17.2 of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity.]

## **[Misappropriation**

“Misappropriation” is the [acquisition] [utilization] of genetic resources [and] [or] associated traditional knowledge without the [free] [prior informed] consent of [those who are authorized to give [such] consent] [competent authority] to such [acquisition] [utilization], [[in accordance with national legislation] [of the country of origin or providing country]].]

## **[[Physical] Access**

“[Physical] access to the genetic resource” is its possession or at least contact which is sufficient enough to identify the properties of the genetic resource relevant for the [invention] [intellectual property].]

## **[Source**

Option 1. “Source” refers to any source from which the applicant has acquired the genetic resource other than the country of origin, such as a resource holder, research centre, gene bank or botanical garden.

[Option 2 . “Source” should be understood in its broadest sense possible:

- (i) Primary sources, including in particular [Contracting Parties] [Countries] providing genetic resources, the Multilateral System of ITPGRFA, indigenous and local communities; and
- (ii) Secondary sources, including in particular ex situ collections and scientific literature.]]

**[Utilization**

“Utilization of Genetic Resources” means to conduct research and development [including commercialization] on the genetic and/or biochemical composition of genetic resources, [their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources] [including through the application of biotechnology] [as defined in Article 2 of the Convention on Biological Diversity].]

[PREAMBLE

[Ensure respect for [sovereign rights] [the rights] of indigenous [peoples] and local communities [as well as [peoples] partially or entirely under occupation] over their genetic resources and [associated traditional knowledge] [traditional knowledge associated with genetic resources], including the principle of [prior informed consent and mutually agreed terms] and total and effective participation in accordance with international [agreements and] declarations [, in particular the UN Declaration on the Rights of Indigenous Peoples].]

[The [intellectual property] [patent] system should provide certainty of rights for legitimate users and providers of genetic resources, [their derivatives] and/or [associated traditional knowledge] [traditional knowledge associated with genetic resources].]

[Recognize the role the [intellectual property] [patent] system plays in promoting innovation, [transfer and dissemination of technology] to the mutual advantage of stakeholders, providers, holders and users of genetic resources, their [derivatives] and/or [associated traditional knowledge] [traditional knowledge associated with genetic resources].]

[Promote transparency and dissemination of information.]

[A global and compulsory system creates a level playing field for industry and the commercial exploitation of [intellectual property] [patents], and also facilitates the possibilities [under Article 15(7) of the CBD] for the sharing of the benefits arising from the use of genetic resources.]

[Foster [patent] [industrial property] development of genetic resources and [associated traditional knowledge] [traditional knowledge associated with genetic resources] and encourage international research leading to innovation.]

[The disclosure of the source would increase mutual trust among the various stakeholders involved in access and benefit sharing. All of these stakeholders may be providers and/or users of genetic resources and traditional knowledge. Accordingly, disclosing the source would build mutual trust in the North – South – relationship. Moreover, it would strengthen the mutual supportiveness between the access and benefit sharing system and the [intellectual property] [patent] system.]

[Ensure that no [patents] [intellectual property] on life forms, including human beings, are granted.]]

## POLICY OBJECTIVES

### **OBJECTIVE 1: [Compliance with International/National laws relating to ABS [and disclosure]]**

[Ensure [applications for [intellectual property rights] [patents] [utilizing] genetic resources [their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources]] [those accessing [and/or using]] genetic resources [,their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources] comply with [international rights and national legislations] [national law and relevant conditions] for [requirements of the country providing for prior informed consent, mutually agreed terms, fair and equitable] [access and benefit-sharing] [and disclosure of origin].]

### **OBJECTIVE 2: Ensuring [intellectual property] [patent] offices have the required information to / and make proper decisions in granting [intellectual property] [patent] rights.**

#### Option 1

Recognise the need for [intellectual property] [patent] offices to have access to appropriate information on genetic resources and [associated traditional knowledge] [traditional knowledge associated with genetic resources] needed to make informed decisions to prevent grant of [intellectual property] [patents] that do not comply with novelty, inventiveness or industrial applicability.

#### Option 2

Ensure that [intellectual property] [Patent] offices [should] have [access to] [all] the appropriate information [on genetic resources, [their derivatives] and/or [associated traditional knowledge] [traditional knowledge associated with genetic resources]] needed to make proper and informed decisions in granting [intellectual property rights] [patents], to prevent granting of erroneous [patents] [intellectual property], [prevent misappropriation] and enhance transparency in the [patent] [intellectual property] system.

**[ARTICLE 1]**  
**SUBJECT MATTER OF [PROTECTION] [INSTRUMENT]**

1.1 [[Protection under this instrument ] [This international legal instrument][shall] [extend] apply to any [intellectual property] [patent] right or application [derived from [utilization of]] [directly based on] genetic resources, [their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources].]

**[ARTICLE 2]**  
**[BENEFICIARIES]**

2.1 [Effective ABS systems implemented in national [patent] [intellectual property] laws should be beneficial to the public, [genetic resource holders, supplier countries,] indigenous and local communities, providers, the country of origin or providing country, and users of the genetic resources.]

2.2 [[This instrument should apply to] [Protection] [Measures] related to the compliance with existing rules of access and benefit-sharing derived from the [utilization] [for the protection] of genetic resources, [their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources] shall be for the benefit of country [providing such resources and knowledge] [of origin of genetic resources] and indigenous [peoples] and local communities who develop, use and maintain the genetic resources and [associated traditional knowledge] [traditional knowledge associated with genetic resources]].

[2.3 The beneficiaries of genetic resources, [derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources] under this instrument must have the right to authorize or deny [access to the] [use] [utilization] of genetic resources and [associated traditional knowledge] [traditional knowledge associated with genetic resources].]

**[ARTICLE 3]**  
**[SCOPE OF [INSTRUMENT] [PROTECTION]] [LEGAL OBLIGATIONS]**

Option 1

3.1 [The scope of this instrument is [to provide measures for the [intellectual property] [patent] system to support compliance with ABS regimes through the disclosure of [country of source and origin of] [information on] genetic resources, [derivatives], and [associated traditional knowledge] [traditional knowledge associated with genetic resources] and [the provision of information to [intellectual property] [patent] offices to [prevent] [grant of erroneous [patents] [intellectual property]] and [misappropriation]] and to enhance transparency in the [intellectual property] [patent] system].]

Option 2

3.2 [Member States may consider implementing national laws outside the [patent] [intellectual property] system to regulate conduct and manage access to genetic materials.]

## [DISCLOSURE PROTECTION]

### OPTION 1

#### FORMALITIES REQUIREMENTS FOR DISCLOSURE

##### Trigger

3.3 [Each] [Party] [Country] [Intellectual property] [Patent] [offices] shall have a [mandatory] [disclosure] requirement for [disclosure that applies to] [patent] [intellectual property rights] applications that [claim [inventions] [intellectual property]] [involve] [arising from] [are directly based on] [utilization of] genetic resources, [derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources] [wherein:

- (a) the [invention] [intellectual property] makes immediate use of the genetic resource, that is, the [invention] [intellectual property] depends on the specific properties of the resource; and
- (b) the inventor possessed, or at least had contact which is sufficient enough to identify the properties of, the genetic resource relevant for the [invention] [intellectual property].]

3.4 Patent offices shall have a mandatory requirement for disclosure, as elaborated in this international legal instrument, when patenting of genetic resources would cause harm to the interests of indigenous [peoples] and local communities

3.5 The disclosure requirement for traditional knowledge in this instrument will only apply to patent applications that claim [inventions] [intellectual property] for which the inventor consciously derived the [invention] [intellectual property] from [associated traditional knowledge] [traditional knowledge associated with genetic resources].

##### [Exclusions]

3.6 A [patent] [intellectual property] disclosure requirement related to genetic resources [their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources] shall not apply to the following:

- (a) all human genetic resources including human pathogens;
- (b) [derivatives];
- (c) commodities;
- (d) traditional knowledge in the public domain;
- (e) genetic resources found outside of national jurisdictions; and
- (f) all genetic resources acquired before the national implementations of [the Convention on Biological Diversity and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity].]

##### Contents of Disclosure

3.7 [Contracting Parties] [Countries] [Intellectual property] [Patent] offices shall require applicants [in good faith] to disclose

- (a) [Provider country]
- (b) [Source in provider country]



- (c) [Internationally Recognised Certificate of Compliance, or evidence of compliance, with ABS requirements, including PIC where relevant]
- (d) [Certificate of origin]
- (e) [Country of origin]
- (f) [If Country of origin not known, information on the source that the [inventor] [developer of intellectual property] had physical access to]
- (g) [Statement that origin is not known]
- (h) [Statement that source is not known]
- (i) [Primary source, or if not known, the secondary source]
- (j) [Written and oral information regarding [traditional knowledge associated with genetic resources] [associated traditional knowledge], [their derivatives] for enabling search and examination of the [patent] [intellectual property] application including the details of the holder of the traditional knowledge]
- (k) [a copy of the standard material transfer agreement stipulated in the ITPGRFA if access to genetic resources has been provided in pursuance of the ITPGRFA]

### **Actions of the Office**

3.8 The disclosure requirement shall not place an obligation on the [intellectual property] [patent] offices to verify the contents of the disclosure.

3.9 [Contracting Parties] [Countries] [Intellectual property] [patent] offices or other relevant authorities shall put in place an adequate information dissemination system to enable an opportunity by relevant authorities for other [Contracting Parties] [Countries], indigenous and local communities or any other interested parties to take appropriate actions regarding ABS rules or submit information relevant to search and examination of an [intellectual property] [patent] application.

3.10 A simple notification procedure should be introduced to be followed by the [patent] [intellectual property] offices every time they receive a declaration; it would be adequate to identify in particular the Clearing House Mechanism of the CBD/ITPGRFA as the central body to which the [intellectual property] [patent] offices should send the available information.

3.11 [Genetic resources and their [derivatives] as found in nature or isolated therefrom shall not be considered as [inventions] [intellectual property] and therefore no [patent] [intellectual property] rights shall be granted.]

3.12 [Intellectual property] [Patent] offices receiving patent applications containing disclosures should inform a competent government agency that the respective State is declared as the source.

### **[Relationship with [PCT] and [PLT]**

3.13 The [PCT] and [PLT] will be amended to [include] [enable Parties to the [PCT] and [PLT] to provide for in their national legislation] a mandatory disclosure requirement of the origin and source of the genetic resources, [their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources]. The amendments shall also include requiring confirmation of prior informed consent, evidence of benefit sharing under mutually agreed terms with the country of origin.]

## Sanctions and Remedies

### Sub-Option 1

3.14 [Each [Party] [country] shall take appropriate, effective and proportionate measures to address situations of non-compliance under this international legal instrument [and relevant national laws and requirements] and to ensure that [accessible] [transparent, predictable] and appropriate compliance and dispute resolution mechanisms, sanctions and remedies are available.]

### Sub-Option 2

3.15 [Each [Party] [country] shall take appropriate, effective and proportionate measures to address situations of non-compliance under this international legal instrument [and relevant national laws and requirements] and to ensure that [accessible] [transparent, predictable] and appropriate compliance and dispute resolution mechanisms, sanctions and remedies are available. Such measures shall include at least:

- (a) Publication of judicial ruling regarding failure to disclose, and
- (b) Prevent further processing of [patent] [intellectual property] applications, and
- (c) Prevent or refuse granting of [patent] [intellectual property] applications, and
- (d) A [relevant authority] [[patent] [intellectual property] office] can consider the application [withdrawn] [lapsed] [nullified] [revoked] [invalidated] and
- (e) A [relevant authority] [[patent] [intellectual property] office] can consider the disclosure requirement shall affect the [revocation], [validity] or [enforceability] of granted patents.

Members may, but shall not be obliged to, apply other sanctions.]

### Sub-Option 3

3.16 [Each [Party] [country] shall take appropriate, effective and proportionate measures to address situations of non-compliance under this international legal instrument [and national laws and requirements] and to ensure that [accessible] [transparent, predictable] and appropriate compliance and dispute resolution mechanisms, sanctions and remedies are available. Such measures shall include:

- (a) Publication of judicial ruling regarding failure to disclose
- (b) Prevent further processing of [patent] [intellectual property] applications
- (c) Prevent or refuse granting of [patent] [intellectual property] applications
- (d) A [relevant authority] [[patent] [intellectual property] office] can consider the application withdrawn.
- (e) A [relevant authority] [[patent] [intellectual property] office] can invite the applicant to comply within a time limit.

Failure to fulfill the disclosure requirement [, in the absence of fraud,] shall not affect the validity or enforceability of granted patents.]]

**[OPTION 2  
NO DISCLOSURE REQUIREMENT**

3.17 [Intellectual property] [Patent] disclosure requirements shall not include a mandatory disclosure relating to genetic resources [, their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources] unless such disclosure is material to the patentability criteria of novelty, inventive step or enablement.

3.18 [Intellectual property] [Patent] applicants shall be under no requirement to disclose the source, origin or other information relating to genetic resources in [intellectual property] [patent] applications [unless such information is material to the patentability requirements of novelty, inventive step or enablement.]]

**[DEFENSIVE PROTECTION**

[3.19 Establishment of databases of [traditional knowledge] [associated traditional knowledge] [traditional knowledge associated with genetic resources] and genetic resources that are accessible to [intellectual property] [patent] offices [to

- (a) avoid granting of erroneous [intellectual property] [patents]
- (b) [prevent missappropriation]
- (c) [ensure [free] prior informed consent]
- (d) [ensure transparency, traceability and mutual trust taking into account access and benefit sharing arrangements [as provided for under the CBD and the Nagoya Protocol].]]

3.20 Each country has responsibility for [codifying oral information], compiling and maintaining such databases, in accordance with national law.

3.21 There shall be minimum standards to harmonize the structure and content of such databases.

3.22 These databases will be accessible [only to [intellectual property] [patent] offices and other registered IP addresses] [to any interested parties].

3.23 The content of the databases will be

- (a) [in languages that can be understood by patent examiners]
- (b) [written and oral information regarding traditional knowledge associated with genetic resources, [their derivatives] for enabling search and examination of the [intellectual property] [patent] application including the details of the holder of the TK]
- (c) relevant written and oral [information] prior art relating to genetic resources, [their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources].
- (d) information related to genetic resources, [their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources].

3.24 [Such databases would [ensure the [free] prior informed consent] [prevent misappropriation] avoid the erroneous granting of [intellectual property] [patents] for genetic resources and [associated traditional knowledge] [traditional knowledge associated with genetic

resources] and ensure transparency, traceability [and mutual trust taking into account access and benefit sharing arrangements [as provided for under the CBD and the Nagoya Protocol]].]

3.25 National [intellectual property] [patent] offices [shall] should develop appropriate and adequate guidelines for the purpose of conducting search and examination of [intellectual property] [patent] applications relating to genetic resources, [their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources] considering [existing] [prior art] [this relevant information] accessible to the examiners, as appropriate [and additional information provided by the applicants, as well as accessible to the examiners].

3.26 [Establishment of an international gateway on traditional knowledge.]

#### **[ARTICLE 4] RELATIONSHIP WITH INTERNATIONAL AGREEMENTS**

4.1 [[Contracting Parties] [Countries] shall establish a mutually supportive relationship between [intellectual property] [patent] rights [directly based on] [involving] [the utilization of] genetic resources, [their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources] and existing international agreements and treaties, [but will not create a hierarchy between such international agreements and treaties, nor impose any of the obligations established under other international agreements or treaties upon any [party][country] that is not a [member] [party] to such international agreements or treaties].]

4.2 [[Contracting Parties] [Countries] shall support, in particular, the implementation of the [Convention on Biological Diversity] [(including communication with its Clearing House)] and [the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization to the Convention of Biological Diversity], the ITPGRFA, [Article 31 of the UN Declaration on the Rights of Indigenous Peoples] and the TRIPS Agreement and, as the case may be, of regional agreements.]

#### **[ARTICLE 5] INTERNATIONAL COOPERATION**

5.1 [[Relevant WIPO bodies to encourage Patent Cooperation Treaty members to develop a set of guidelines for the [search and examination] administrative disclosure of origin or source by the international search and examination authorities under the Patent Cooperation Treaty including additional information arising from the disclosure requirement as provided in this instrument.][WIPO could, in close collaboration with the [CBD]/ITPGRFA, consider the possible establishment of such a list of competent government agencies.]]

#### **[ARTICLE 6] TRANSBOUNDARY COOPERATION**

6.1 [In instances where the same genetic resources [, their derivatives] and [associated traditional knowledge] [traditional knowledge associated with genetic resources] are found in in-situ conditions within the territory of more than one Party, those Parties shall endeavor to cooperate, as appropriate, with the involvement of indigenous [peoples] and local communities concerned, where applicable, by taking measures that make use of customary laws and protocols, that are supportive of and do not run counter to the objectives of this instrument and national legislation.]

**[ARTICLE 7]**  
**TECHNICAL ASSISTANCE, COOPERATION AND CAPACITY BUILDING**

7.1 [Relevant WIPO bodies shall develop modalities for the creation, funding and implementation of the provisions under this instrument. WIPO shall provide technical assistance, cooperation, capacity building and financial support for developing countries in particular the least developed countries to implement the obligations under this instrument.]

[End of Document]