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ACCESS AND BENEFIT-SHARING  
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COLLATION OF OPERATIVE TEXT SUBMITTED 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, 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 of the same decision, 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 collation of operative text submitted by Parties, Governments, international organizations, indigenous and local communities and relevant stakeholders. As requested, the text reproduces the structure and text of annex I to decision IX/12 and includes submitted operative text under each heading.

**OPERATIVE TEXT RELATED TO THE INTERNATIONAL REGIME FOLLOWING THE  
STRUCTURE OF ANNEX I TO DECISION IX/12 <sup>1/</sup>**

**I. OBJECTIVE**

**Text of decision IX/12, annex I <sup>2/</sup>**

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.]

**India**

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.

**Namibia on behalf of the African Group**

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

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<sup>1/</sup> For ease of reference, the text of annex I to decision IX/12 reproduced in this document has been shaded.

<sup>2/</sup> These proposals were neither negotiated nor agreed.

- 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'.

### **Norway**

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.

### **European Seed Association (ESA)**

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



## II. SCOPE

### Text of decision IX/12, annex I <sup>3/</sup>

#### *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,] [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].

[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 [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:

(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];]

(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];]

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

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

4. [The international regime on access and benefit-sharing 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].]

[5. [In the further elaboration and negotiation of the international regime on access and benefit-sharing [special] [due] [consideration] will given to]:

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<sup>3/</sup> These proposals were neither negotiated nor agreed.

(a) [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;]

(b) [Animal genetic resources for food and agriculture;]

(c) [Genetic resources within the remit of the FAO Commission on Genetic Resources for Food and Agriculture;]

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

(e) [The work within the WIPO [including the] Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore;]

(f) [Marine genetic resources found in areas beyond national jurisdiction;]

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

### *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.

### *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.

### **India**

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.

### **Namibia on behalf of the African Group**

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

### **Norway**

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.

### **European Seed Association (ESA)**

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 and subject to specific sectoral provisions set out in the International Regime.

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;

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

(a) Human genetic resources;

(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;

(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 genetic resources found in areas beyond national jurisdiction;

/...

- (f) Genetic resources located in the Antarctic Treaty Area.
  - (g) Human, animal and plant pathogens
- [...]

### III. MAIN COMPONENTS

#### A. *Fair and equitable benefit-sharing*

##### India

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.

### **Namibia on behalf of the African Group**

#### *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 be 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

**Norway**

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.

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;

- 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.

## ***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**

#### **European Union and its Member States**

*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]<sup>4</sup> 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) Benefits to be shared on mutually agreed terms**

### **European Union and its Member States**

*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;

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<sup>4/</sup> 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.

- 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.

### **3) Monetary and/or non-monetary benefits**

#### **European Union and its Member States**

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

### **4) Access to and transfer of technology**

#### **European Union and its Member States**

See above III.A.1.2)

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

#### **European Union and its Member States**

See above III.A.1.2)

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

#### **European Union and its Member States**

See above III.A.1.2)

### **7) Mechanisms to promote equality in negotiations**

#### **European Union and its Member States**

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.

## **8) Awareness-raising**

### **European Union and its Member States**

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<sup>5</sup>, 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.

## **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**

### **European Union and its Member States**

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.

## ***2. Components for further consideration***

### **1) Development of international minimum conditions and standards**

### **2) Benefit-sharing for every use**

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

### **4) Establishment of trust funds to address transboundary situations**

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

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<sup>5/</sup> 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.

### **European Union and its Member States**

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.

## **6) Enhanced utilization of Bonn Guidelines**

### **European Union and its Member States**

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]

#### ***B. Access to genetic resources 6/***

### **India**

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.

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6/ The title is without prejudice to the eventual scope of the international regime.

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.

### **Namibia on behalf of the African Group**

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.

### **Norway**

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*

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
- 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.

### ***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**

##### **European Union and its Member States**

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]

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

### **European Union and its Member States**

*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.

## **3) Legal certainty, clarity and transparency of access rules**

### **European Union and its Member States**

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).*

## **2. Components for further consideration**

### **1) Non-discrimination of access rules**

#### **European Union and its Member States**

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

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

### **European Union and its Member States**

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.

### **3) Internationally developed model domestic legislation**

#### **European Union and its Member States**

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)].

### **4) Minimization of administration and transaction costs**

### **5) Simplified access rules for non-commercial research**

#### **European Union and its Member States**

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.

### **C. Compliance**

#### **India**

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.

## **Namibia on behalf of the African Group**

### *In Country Measures to Ensure Compliance:*

- (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: 7/*

- 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<sup>8/</sup>:*

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

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<sup>7/</sup> *UNU Certificates of Clarity or Confusion -IAS report.*

<sup>8/</sup> *Barber, C.V, et al, 2003, User Measures: Options for Developing Measures in User Countries to Implement ABS Provisions of the CBD.*

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: 9/*

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 and ex-situ collections. 10/
  
- c. Contracting Parties shall facilitate an efficient, easy to use certification process through the use of new technology which may include: 11/
  - (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

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9/ 2007 report of Group of Technical Experts on the Certificate.  
10/ Cunningham, D et al, 2004, Background paper for Smithsonian/UNU-IAS Roundtable on Certificates of Origin.  
11/ Brendan Tobin et al, Certificates of Clarity or Confusion, UNU-IAS 2008 report.

- 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.

***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**

**European Union and its Member States**

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.

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

**(a) Mechanisms for information exchange**

**European Union and its Member States**

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.

#### **(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**

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

##### **European Union and its Member States**

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.

**(c) Codes of conduct for important groups of users**

**European Union and its Member States**

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.

**(d) Identification of best-practice codes of conduct**

**European Union and its Member States**

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.

**(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**

**European Union and its Member States**

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]

**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**

**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 benefit-sharing to help providers obtain relevant information in specific cases of alleged infringements of prior-informed-consent requirements**

**(e) Remedies and sanctions**

**Norway**

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.

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

***D. Traditional knowledge associated with genetic resources <sup>12/</sup>***

**India**

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.

**Namibia on behalf of the African Group**

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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<sup>12/</sup> The title is without prejudice to the eventual scope of the international regime.



- 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.

### **Norway**

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.

### ***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 traditional knowledge 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***

#### **Namibia on behalf of the African Group**

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) Participations 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**

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.

#### ***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**

**Text of decision IX/12, annex I**

***Compilation of proposals on nature 13/***

***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

***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.

**Namibia on behalf of the African Group**

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

**ADDITIONAL OPERATIVE TEXT RELATED TO THE INTERNATIONAL REGIME ON  
ISSUES NOT COVERED BY ANNEX I TO DECISION IX/12**

**Namibia on behalf of the African Group**

**Definitions**

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<sup>13/</sup> These proposals were neither discussed, negotiated nor agreed.

*Fair and Equitable Benefit Sharing*

The definition of 'fair and equitable benefit sharing' is non-exhaustive and inclusive. <sup>14/</sup> 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.

*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'. <sup>15/</sup>

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

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<sup>14/</sup> "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.

<sup>15/</sup> 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.

- 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<sup>16</sup> 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, nutraceutical (agropharmaceuticals), 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 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].

*Benefits arising from the utilization of GR:*

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<sup>16/</sup> *Ibid*

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.

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