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Convention on Biological Diversity

Distr.

GENERAL

UNEP/CBD/WG-ABS/7/5 28 January 2009

ORIGINAL: ENGLISH

AD HOC OPEN-ENDED WORKING GROUP ON ACCESS AND BENEFIT-SHARING Seventh meeting Paris, 2-8 April 2009

COLLATION OF OPERATIVE TEXT INCLUDING RELATED EXPLANATIONS AND RATIONALE 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 including related explanations and rationale 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 and rationale under each heading.

OPERATIVE TEXT INCLUDING RELATED EXPLANATIONS AND RATIONALE RELATED TO THE INTERNATIONAL REGIME FOLLOWING THE STRUCTURE OF ANNEX I TO DECISION IX/12 1/

I. OBJECTIVE

Text of decision IX/12, annex I 2/

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

Operative text

- 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.

Mexico

Operative text

Effectively implement the provisions [in Articles 15, 8(j), 1, 16 and 19.2] of the Convention [and its three objectives], specifically by:

Related explanation and rationale

^{1/} For ease of reference, the text of annex I to decision IX/12 reproduced in this document has been shaded.

^{2/} These proposals were neither negotiated nor agreed.

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Page 8

Remove the first set of brackets from the preamble, and keep the reference to Articles 15, 8j), 1, 16 and 19.2. It is particularly important to keep Article 19.2, so that the wording is not restrictive with regard to what the international regime will cover. In the last set of brackets, change the wording so as to refer only to the CBD's third objective.

Operative text

[Facilitating][Regulate] access to genetic resources, [their derivatives] [and products] [and associated traditional knowledge];]

Related explanation and rationale

The term 'regulate' is appropriate for a regime. In our view, the regime should be binding, with non-binding elements. We suggest that the term 'facilitating' be removed, seeing as it is already in the CBD with regard to implementation of the Bonn Guidelines. If this term is not removed, the wording should indicate that the purpose of the Regime is to regulate access to genetic resources, and facilitate the implementation of CBD provisions.

An international Regime is transparent per se, given the process undertaken to build such a regime.

The term 'derivatives' is proposed for inclusion in the first paragraph. That term is still under debate. No decision has been made regarding which of many possible definitions will be used for the Regime. It is therefore relevant to await the report of the Expert Group meeting in Namibia. It is very important to keep in mind that the argument that including derivatives goes beyond the scope of the Convention is unfounded, seeing as the IR was approved at COP 10, which is the equivalent of a legislative body, and can therefore extend the Convention in this manner.

Operative text

Ensuring the effective, fair and equitable sharing of benefits arising out of their utilization, [their derivatives] [and associated traditional knowledge] [and to prevent their misappropriation and misuse];

Related explanation and rationale

We propose to include derivatives and associated traditional knowledge. We suggest that the text in the final bracket be deleted because it is redundant and has a negative connotation that should not be part of the objective.

The word 'productos' (products) in the Spanish text should also be removed, because the definition of derivatives will determine whether or not it should be included. In our view, a moderately broad definition of derivatives would not require the addition of the word 'productos' in the Spanish text.

Operative text

[Securing compliance in user countries with national laws and requirements, including PIC and MAT, of the country providing those resources or of the Party that has acquired those resources in accordance with the Convention on Biological Diversity].

Related explanation and rationale

The brackets should be removed. The Word 'origen' (origin) should also be deleted from the Spanish text.

In our view, in biological terms, it is relevant to refer to the country providing the resource, rather than the country of origin.

Operative text

[taking into account all rights over those resources, including the rights of indigenous and local communities, and ensuring compliance with PIC.]

Related explanation and rationale

Delete the wording about indigenous communities. This section could go in the preamble or scope, but not in the objectives.

Namibia on behalf of the African Group

Operative Text

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
- 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'.

Related explanation and rationale

Rethinking Access- Gaining Clarity on the principle of 'Access' within the CBD:

Much of the discussion in the ABS WG around the objective of the IR in Annex 1 of COP decision IX/12 relates to facilitating or regulating access to genetic resources (GR) and associated traditional knowledge (TK) by provider countries in exchange for the fair and equitable sharing of benefits resulting from the commercial use of such GR and associated TK. We submit that notions of access and benefit sharing in the CBD are far wider than how it has been conceptualized so far.

Kinds of Access:

There are three kinds of access listed within Article 1 (Objectives) of the CBD. This is an inclusive definition that speaks of 1) appropriate access to GR 2) appropriate access to transfer of relevant technologies and 3) appropriate funding. Art 1 seems to indicate that fair and equitable benefit sharing can occur only in the context of access of this nature. The question before us now is what does "appropriate access" mean and the answer has to lie in understanding the 'appropriateness' of access in the context of the other provisions of the CBD.

Appropriate Access to Technology:

There are two kinds of access to technology in the CBD.

- 1) Access to technology that is relevant to conservation and sustainable use of biodiversity and
- 2) Access to technology that is related to the GR that is accessed.
 - 1) Access to technology that is relevant to conservation and sustainable use:

Art 16 (1)(2) refers to access to and transfer of technology that is useful for conservation and ustainable use of biological diversity and such access shall be provided to developing countries on favorable, concessional and preferential terms. Art 16(4) makes it incumbent on contracting parties to ensure that the private sector also facilitates such an access to joint development and transfer of technology. Art 16 (5) states that intellectual property rights related to such technology must be supportive of the CBD and not run counter to its objectives. Art 17 (2) speaks of free exchange of different kinds of technologies and knowledge that is relevant for conservation and sustainable use of biological diversity from publicly available sources. Finally Art 18 addresses technical and scientific cooperation in the field of conservation and sustainable use of biological diversity between contracting parties.

2) Access to technology that is related to the GR that is accessed:

Art 15 (6) (7), Art 16 (3) and Art 19 (1) emphasize that there must be access in the form of transfer of technology and joint development with the provider country regarding any new scientific activities which relate to the GR from the provider country. The full participation of the provider country in the development of the GR would also involve where possible the scientific research taking place in the provider country itself (Art 15(6)).

Appropriate access to technology in the context of Art 1 of the CBD must then be interpreted as not merely access to technology in exchange for the use of genetic resources but facilitated, concessional and preferential access to all technology that is related to conservation and sustainable use of biological diversity to all contracting parties irrespective of whether or not any GR is being accessed. So access to technology in this case should not be understood as a benefit that will be shared with developing countries only in exchange for complementary access to their GR. It is only access to technology that is related to the GR being used that can be understood in the form of benefit sharing where the technological advances that relate to the GR being accessed will be shared by the user country with the country providing the GR.

The importance of such an understanding for developing countries is that merely because a country does not have any GR that may be of commercial interest does not mean that it must not be entitled to any access to technology. The IR on ABS must ensure in its objectives that it is addresses such a universal access to technology which is exclusive of any benefit sharing agreement that may be reached between user and provider countries.

Access to Appropriate Funding:

Art 20 of the CBD addresses the importance of appropriate funding for developing countries in order to meet their commitments under the CBD. Art 20 (4) is unequivocal when it says that abilities of developing countries to implement the CBD is intrinsically linked to access to appropriate funding.

Here too it is important for developing countries to understand that access to funding for conservation and sustainable use of biological diversity is not a benefit that will be shared in exchange for providing access to their genetic resources but an independent right in itself under the CBD. The IR on ABS within its objectives must also highlight this aspect of access that isn't often highlighted in the ABSWG negotiations except under voluntary efforts towards capacity building.

Appropriate Access to GR:

Appropriate access to GR in the context of the CBD can be understood through a reading of Art 15 (2) which says that access to GR will be facilitated by provider countries only for environmentally sound uses and provider countries will not impose any restrictions that run counter to the objectives of the CBD- these objectives being conservation, sustainable use and benefit sharing.

There has been a lot of debate in ABSWG 6 and in the Informal Consultative Group (ICG) at COP 9 about the nature of such an access to GR. While developed countries have tended to focus on Art 15 (2) which speaks of facilitating access to GR, developing countries have instead focused on Art 15 (1) which refers to States having sovereign rights over their GR. The crux of this debate has been whether developed countries have a right to access GR under the CBD or whether this right is subject to the discretion of provider countries.

We submit that such a debate may be counter productive since the objective of the CBD is the conservation and sustainable use of biological diversity coupled with the sharing of benefits that arise from the use of such biological diversity. Art 15 (1) and (2) of the CBD is explicit that countries have sovereign rights over their resources but the exercise of the sovereign right to

exclude access to GR can only be done if such an access would not be environmentally sound. Restrictions on any other ground would run counter to the objectives of the CBD whose foundation seems to be that GR can be accessed for environmentally sound reasons. However Art 15 (4) (5) speak of such access being subject to MAT (mutually agreed terms) and PIC (prior informed consent) of the provider country and such an access must involve the fair and equitable sharing of benefits resulting from the use of such GR with the provider country.

Conclusion:

Appropriate access then in the context of the CBD and for the purposes of the IR on ABS should involve:

- a) Universal access to research and technology that is linked to conservation and sustainable use of biological diversity irrespective of any reciprocal access to GR.
- b) Access to research and technology relevant to the GR in question in exchange for the use of such GR
- c) Access to appropriate funding for developing countries to implement the CBD irrespective of any reciprocal access to GR
- d) Appropriate access to GR only for environmentally sound uses based on MAT with and PIC of the provider country and the fair and equitable sharing of benefits resulting from the use of the GR.

Norway

Operative text

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)

Related explanation and rationale

Access to genetic resources (GR) should be actively supported as it is a precondition for the generating of benefits and for the sharing of these benefits. An effective International Regime (IR) on Access and Benefit Sharing (ABS) should maintain and foster the diversity of uses of these resources as well as the commercial arrangements through which they are acquired. The IR should be a transparent, non-discriminatory, predictable, and facilitative structure narrowly targeted. The establishment of a workable system with regards to traditional knowledge (TK) should also be an essential part of the IR. Accordingly, ESA suggests the following amended version of the Objective text as proposed in Annex I of Decision IX/12 adopted at COP 9:

Operative text

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 3/

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;]

These proposals were neither negotiated nor agreed.

- (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]:
 - (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

Operative text

- 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.

Mexico

Operative text

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,] as well as [to their] [associated] traditional knowledge, 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]

Related explanation and rationale

The Scope should determine the legal instrument's reach. The CBD seems to give a fairly clear indication of said reach. However, as it has already been mentioned, this issue is very complex, and touches on aspects of cutting-edge technology for which governing legal provisions are at an embryonic stage. This begs the question of how far the reach of an IR like the one we are creating should be. Here is the answer to the question "what should the IR cover?":

We suggest deleting the last part that applies to Article 4 of the CBD referring to the jurisdictional scope of the Convention. The scope of the IR should at least cover the following aspects:

Material: Genetic resources and derivatives, associated traditional knowledge, benefits arising from access.

Time: It will only cover material after the date of the CBD's entry into force on December 29, 1993.

This means biological and genetic resources accessed within the territory of the Parties, following the Convention's entry into force.

Space: The Regime will apply to the Parties.

Jurisdiction: According to Article 4 of the CBD, the areas located within the limits of national jurisdiction.

Operative text

- [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];

Related explanation and rationale

We believe that it should be in effect from the time of the Convention's entry into force. We therefore suggest that the reference to the international regime be deleted, and that the brackets be removed from the rest of the sentence.

Operative text

[(b) Continuing benefits arising from commercial and other utilization taken prior to the coming into force of the Convention on Biological Diversity.]]

Related explanation and rationale

We agree, remove brackets

Operative text

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

(a) [Human genetic resources;]

Related explanation and rationale

We agree, remove brackets

Operative text

(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];]

Related explanation and rationale

We agree, remove the first and second brackets.

Mexico requires further clarification regarding ex situ collections, in order to specify its opinion.

Operative text

- (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];]

Related explanation and rationale

Mexico has not ratified this Treaty, but such resources should not be excluded. Rather, the Treaty should be considered as a specific regime within this IR. The same species are considered, regardless of whether they are used for food, which means that they must be covered by this IR, though the Treaty grants them exceptional treatment for certain uses.

Operative text

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

Related explanation and rationale

We agree, remove brackets

Operative text

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

Related explanation and rationale

We agree, remove brackets

Operative text

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.

Related explanation and rationale

We consider that this is the best option for the scope. In our opinion, the regime should cover:

- (b) Genetic resources and derivatives.
- (c) Traditional knowledge associated with genetic resources and derivatives.
- (a) Benefits arising from the use of genetic resources, derivatives and products.

Namibia on behalf of the African Group

Operative text

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 *in situ* and *ex situ* 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.

Related explanation and rationale

Pre-CBD Collections

The African position is that genetic resources that were acquired before the CBD's entry into force on 29 December 1993 should be included within the scope of the international regime.

The Nairobi Final Act that adopted the text of the CBD viewed the access to plant genetic resources within the Global System for the Conservation and Sustainable Use of Plant Genetic Resources for Food and Sustainable Agriculture held in ex-situ collections and not acquired in accordance with the CBD as an unresolved matter and in Resolution 3 asked the FAO to look into the matter. This led to the development of the ITPGRFA. The ownership over GRs not covered by the ITPGRFA is therefore still controversial. It is for this reason that the Andean Pact countries disregard the common interpretation of Art. 15.3 of the CBD as stating that Arts.15, 16 and 19 apply only to GR acquired after the CBD came into force. The Andean common regime on access applies to all GR originating from Andean Pact countries whether they were acquired pre or post CBD. The Andean Pact's access regime has not been challenged yet.

African countries feel that the exclusion of pre-CBD ex-situ collections from the IR would significantly weaken the benefits of the CBD for developing countries. This is because most of the GR that have been documented are pre-CBD and in ex-situ collections and therefore most likely to have commercial use in the near future. To argue that the scope of the IR is restricted only to post-CBD GR would limit the IR only to new GR that have been discovered since 1994 and are still being researched and unlikely to be commercialized in the next few decades.

African countries acknowledge that the origins of a large amount of GR in ex-situ collections would be hard if not impossible to trace. Many of them would be of transboundary nature. In cases such as this African countries feel that a fund should be set up to receive the benefits from the commercial and other utilization of pre-CBD GR and the monies of such a fund will be used to aid in conservation and sustainable use of biodiversity in developing countries and to support their socio-economic development.

Norway

Operative text

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.

Related explanation and rationale

We may need to come back to the scope in relation to other multilateral agreements.

European Seed Association (ESA)

Related explanation and rationale

The IR should not apply to biological resources, derivatives and products. This should be subject to agreement between the Provider and the Recipient. The IR should only apply to acquisitions of GR which take place after entry into force of the IR in the provider country, and be without prejudice to prior acquisitions carried out in good faith The IR should not provide the possibility of changing obligations relating to such acquisitions after they have been made.

Pathogens should be explicitly excluded from the IR. The IR approach on ABS is not suitable for pathogens as these do not appear to fit within the objectives of the CBD on conservation and sustainable use. With regards to plant genetic resources (PGR), the IR should not create overlaps with the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and species covered by the ITPGRFA should not fall under the scope of the IR.

Therefore, among the three options of the Scope text still to be negotiated, ESA favours the Option 1 in Annex I of Decision IX/12 amended as follows (additional provisions or wording proposed by ESA are underlined):

Operative text

- 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

Operative text

- 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

Operative text

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 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

Related explanation and rationale

Rethinking Benefit Sharing:

There are two kinds of sharing of benefits under the CBD:

- 1) Sharing of benefits arising from the use of GR (Art 1)
- 2) Sharing of benefits arising from the use of knowledge, innovations and practices of indigenous and local communities (Art 8j)

We will discuss both these types of benefit sharing in turn:

1) Sharing of benefits arising from the use of GR (Art 1):

In the case of provider countries, the reason the sharing of benefits from the use of GR is emphasized is because of the increasing enclosure of such benefits through the use intellectual property systems (e.g. patents on food and medicines). Knowledge enclosure systems like patents are sets of relations that exclude some groups from accessing the benefits of the use of GR while providing others with a monopoly over such benefits.

We submit that the goal of developing countries that are providers of GR should not be focused on legitimating such enclosures in exchange of monetary and non-monetary benefits (agreeing to GR related patents by users in ABS agreements) but must instead insist for the inclusion in their benefits, free access to knowledge resulting from the use of GR. This is the only way that developing countries can ensure that they collectively benefit from the use of GR. Otherwise it will only be countries that provide GR that benefit from their use while other countries are still excluded from accessing such benefits.

Developing countries must focus on Articles 15, 16 and 19 of the CBD through which they begin to participate effectively in the development of research and technology related to the use of GR. Where possible they must ensure that such research and technology takes place within provider countries itself. These benefits could focus on skills upgrading, job creation, improving quality of education etc. all of which make certain that developing countries no longer remain as mere

providers of raw GR but meaningfully participate in ensuring that their people benefit from the new uses of GR.

It is such an approach that would be in line with the first two objectives of the CBD which is conservation and sustainable use of biodiversity. Communities generally do not have an incentive to conserve and sustainably use biological diversity unless their lives are integrally linked to the ecosystem. To legitimize enclosures of new uses of GR in exchange for monetary and non monetary benefits would narrowly benefit only the country that provides the GR but in the long run prevent its people from benefiting from the new uses of the GR. Also enclosures while incentivizing its beneficiaries disincentivizes those who are excluded from the benefits. For e.g. while a provider country may monetarily gain from allowing access which includes patenting some of the new uses of the GR, other countries in the region that may have the same GR will be excluded from the new uses of the GR and will not be compensated monetarily thereby disincentivizing them from conserving and sustainably using the GR.

The impact of intellectual property rights (IPRs) on GR was addressed in COP Decision VI/24 C(3a) which requested the Executive Secretary to undertake further information gathering and analysis with regard to the impact of IP regimes on access to and use of GR and scientific research. The paper that was prepared was presented to ABSWG 2 which identified access related problems in reference to IPRs. These were:

- Tensions between IPRs and achievement of their wider social objectives, particularly those related to the needs of poor producers
- Impediments to the effective development of science due to restricted flow and exchange of information (also referred to as the 'tragedy of the anti-commons' where resources are under-utilized due to the high transaction costs)
- Increased product development costs (that translates to high prices for consumers)

It is to prevent situations like this that Art 12 (3) (d) of the ITPGRFA states that "Recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral system"

It is important for developing countries that are providers of GR to ensure that IPRs will not restrict access to the uses of the GR by other developing countries. Developing countries must interpret 'appropriate access' in Art 1 and 'facilitated access' in Art 15 (2) of the CBD to mean that no IPRs can be granted for the original organism, it's isolated components as well as for modified organisms and modified genetic material. This will ensure that the first two objectives of the CBD can be upheld and we submit that this is the way to understand 'appropriate access for environmentally sound uses' under Art. 15(2).

2) Sharing of benefits arising from the use of knowledge, innovations and practices of indigenous and local communities (Art 8j)

The sharing of benefits arising from the use of knowledge, innovations and practices (TK) of ILCs is established in Art 8j. It is however important to understand the scope and therefore the

real essence of Art 8j to overcome common misunderstandings of it. Art 8j has the following components:

- a) The obligation of Art 8j is not only limited to the Contracting Parties where the specific ILCs live but extends to all Contracting Parties. This despite the fact that Art 8j speaks of in-situ conservation since the TK of ILCs can be promoted and widely applied in any country irrespective of their presence there, thus aiding in-situ conservation in different regions.
- b) Art 8j makes it incumbent on Contracting Parties to not just respect, preserve and maintain TK of ILCs but to also promote their wider application with the approval and involvement of the holders of such TK (our emphasis).
- c) There will be an equitable sharing of benefits arising from the use of such TK.

To sum up, Art 8j makes it mandatory on all Contracting Parties to respect, preserve and maintain TK of ILCs embodying traditional lifestyles and also promote their wider application with the approval and involvement of the holders of such TK. The underlying reason this provision falls under the head 'in-situ conservation' is because of an acknowledgement by the CBD that the traditional lifestyles of ILCs has conserved biological diversity. This is also the reason why Art 8j doesn't speak of all TK of ILCs but only of those embodying traditional lifestyles where such TK have relevance for the conservation and sustainable use of biological diversity. The critical link here is that the use or application of TK must ensure conservation and sustainable use of biodiversity.

Conclusion:

While fair and equitable benefit sharing for the use of GR and associated TK must be ensured by developing countries, what constitutes fair and equitable benefit sharing is as much about process as it is about outcomes. Outcomes can be measured in terms of the monetary and non-monetary benefits that providers are able to negotiate from users. Fair and equitable process on the other hand is about ensuring that certain ethical principles are not compromised upon and the long term implications of an agreement on conservation and sustainable use of biological diversity and protection of traditional lifestyles is seriously considered.

In an African context the ethical principles are derived from African Charter on Human and Peoples' Rights (OAU Charter) as interpreted by the 2005 report of the African Commission's Working Group of Experts on Indigenous Populations/Communities which makes a case for collective rights of indigenous and local communities. This is also evidenced by the OAU's African Model Law for 'The Protection of the Rights of Local Communities, Farmers and Breeders and for the Regulation of Access to Biological

Resources'. It is crucial for African countries to use these ethical principles to define what they mean by 'fair and equitable benefit sharing' in the context of ABS. This will ensure values that are most important for Africa are not traded away in exchange for short term monetary rewards.

<u>Note</u>: It is important for Parties to clearly distinguish between benefit sharing as provided for in article 15 and incentive measures under article 11. Under article 11, parties are encouraged to adopt economically and socially sound measures that act as incentives for the conservation and sustainable use of components of biological diversity. These measures are meant to satisfy the first two objectives of the CBD, but not the third.

Norway

Operative text

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.

Related explanations and rationale:

Alternatively, relevant elements of the Bonn Guidelines could be included in an Annex to a protocol under the CBD.

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;

Related explanations and rationale

A reference to "the agreed multilateral system" should be considered in order to cover plant genetic resources accessed through the multilateral system under the ITPGRFA.

- 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.

Related explanation and rationale

This section including measures to be taken by Contracting Parties may be developed in more detail at a later stage. There could be a need for an Annex specifying various types of utilisation of genetic resources and trigger points for benefit-sharing.

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

Operative text

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]4 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.

Related explanations and rationale

The first preambular paragraph clarifies that benefits from the utilisation of genetic resources can only be realised after access has been granted. The second and third preambular paragraphs recall relevant provisions in Article 15 CBD.

The operational paragraph picks up on the fundamental notion in Article 15.7 that specific benefit-sharing arrangements will be established on mutually agreed terms between the provider and the user of genetic resources. Parties should take measures to encourage providers and users of genetic resources to provide in their mutually agreed terms, as appropriate, for the fair and equitable sharing of benefits arising from the utilisation of genetic resources.

The same operational paragraph also appears in III.A.1.2) operational paragraph 1.

The same component appears in the section on Access under III.B.1.2).

2) Benefits to be shared on mutually agreed terms

European Union and its Member States

Operative text

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.

^{4/} 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.

- 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;
- 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.

Related explanations and rationale

The first and second preambular paragraphs recall the relevance given to mutually agreed terms in the context of Article 15 CBD for both access to genetic resources and the fair and equitable sharing of benefits arising from their commercial and other utilisation. The third preambular paragraph recalls the relevance of monetary and/or non-monetary benefits as already acknowledged in the Bonn Guidelines and shows the close relationship of this operational text to operational text III.A.1.3).

The operational provision in paragraph 1 is the same as provided in paragraph 1 of Operational Text III.A.1.1) and once again shows the close relationship between these two bricks.

The operational paragraph 2 lists specific aspects/issues that providers and users of genetic resources should be encouraged to consider when establishing mutually agreed terms. i) on model clauses is a component under consideration in this section as well as in Section III.C. on compliance.

ii) to v) bring together further components that Parties have agreed to further elaborate or consider in this section of the International Regime-Annex.

3) Monetary and/or non-monetary benefits

European Union and its Member States

Operative text

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

Related explanations and rationale

Provider and user of genetic resources will identify in mutually agreed terms the type of benefits to be shared. Examples of monetary and non-monetary benefits are provided in Appendix II of the Bonn Guidelines. The mix between non-monetary and monetary benefits identified in mutually agreed terms will likely vary between different sectoral uses of genetic resources. Particularly in the case of non-commercial research on genetic resources, non-monetary benefits will be more readily available.

4) Access to and transfer of technology

European Union and its Member States

Operative text

See above III.A.1.2)

Related explanations and rationale

Access to and transfer of technology is addressed in Operational Text III.A.1.2) paragraph 2 iii).

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

European Union and its Member States

Operative text

See above III.A.1.2)

Related explanations and rationale

The sharing of results of research and development on mutually agreed terms is addressed in Operational Text III.A.1.2) paragraph 2 ii).

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

European Union and its Member States

Operative text

See above III.A.1.2)

Related explanations and rationale

The effective participation in research activities, and/or joint development in research activities is addressed in Operational Text III.A.1.2) paragraph 2 iv).

7) Mechanisms to promote equality in negotiations

European Union and its Member States

Operative text

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.

Related explanations and rationale

Negotiations of mutually agreed terms will be more successful if both sides to an agreement are well informed about its practical and legal implications. The availability of model clauses and relevant inventories/catalogues of typical utilisations of genetic resources as well as related benefits will strengthen particularly the "weaker" party in such negotiations. Further support could be given through national ABS focal points in both provider and user countries.

The provisions will furthermore strengthen the ability of indigenous and local communities to successfully engage in negotiations of mutually agreed terms. These provisions are linked to Section III.D on Traditional Knowledge and Section III.E on Capacity, respectively.

8) Awareness-raising

European Union and its Member States

Operative text

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, 5/ 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.

Related explanations and rationale

Awareness about access and benefit-sharing issues is critical for the successful establishment of mutually agreed terms and the further development and effective implementation of ABS frameworks at domestic level. It will be important to raise

 $[\]underline{5}$ / 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.

awareness amongst users, providers, indigenous and local communities and other groups. Awareness-raising activities also appear in section on Compliance - III.C.1.1) a).

- 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

Operative text

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.

Related explanations and rationale

An important element of the international ABS regime will be that it also supports the other two objectives of the Convention in order to enhance socio-economic development, in particular, in the run up to 2015, the Millennium Development Goals.

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

European Union and its Member States

Operative text

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.

Related explanations and rationale

The availability of model clauses for potential inclusion in material transfer agreements and inventories/catalogues of typical utilisations of genetic resources and related benefits 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.

The Preambular paragraph underlines the multiple benefits of model clauses.

According to operational paragraph 1 providers and users of genetic resources should be encouraged to <u>consider</u> using such model clauses and relevant inventories/catalogues of typical utilisations of genetic resources when establishing mutually agreed terms, reflecting that this component refers to menus of model clauses for <u>potential</u> inclusion in material transfer agreements.

Operational paragraphs 2 and 3 establish a procedure through which Parties collectively initiate the development of as well as the eventual consideration, adoption and review of model clauses and inventories/catalogues of typical utilisations of genetic resources and related benefits.

The same component appears in Section III.C.2.1)b) under Development of tools to encourage compliance.

6) Enhanced utilization of Bonn Guidelines

European Union and its Member States

Operative text

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]

Related explanations and rationale

The Bonn Guidelines set out a best practice "baseline" for the international regime on access and benefit-sharing and as such provide an important source of inspiration in the development and implementation of the international ABS regime. Operational provisions of the international ABS regime should make reference to the Bonn Guidelines or parts thereof whenever relevant and appropriate.

B. Access to genetic resources 6/

India

Operative text

- 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.
- 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

Operative text

- 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.

Related explanations and rationale

Art 15.1 of the CBD which recognizes the sovereign rights of States over their natural resources has to be read with Art 8j. The knowledge, innovations and practices of ILCs embodying traditional lifestyles is integrally linked to the GR within their ecosystems. Any impact on these GR would affect the traditional lifestyles/relationships within these communities thereby having consequences on their knowledge, innovations and practices. Therefore it is important to harmonise both the rights of States over GR under Art 15.1 and the rights of communities to have their knowledge, innovations and practices respected, preserved and maintained under Art 8j. The only way to do this under the International Regime on ABS is by ensuring that where access to a particular GR in terms of how it will be collected and used has an effect on the knowledge, innovations and practices of particular ILCs, these ILCs will be involved in the decision making process. It is important to remember that while Art 8j begins with 'subject to national legislation', this must be understood not as 'the rights of ILCs being at the discretion of the State' but rather that States are bound to respect these rights but have the discretion to enact locally suited laws to uphold these rights. It is also pertinent to remind ourselves of Para 37 of the Bonn Guidelines which states that "Permission to access GR does not necessarily imply permission to use associated TK and vice versa".

While access to GR cannot be arbitrarily denied under Art 15.2 of the CBD, they can be regulated based on the environmental soundness of the use to which the GR will be put to. Environmentally sound use need not be understood only in a negative sense where the use of a particular GR will directly harm the environment- it can also be understood positively whereby preventing the use of a particular GR through use restriction strategies such as patents could also harm biological diversity. This has been referred to by some environmentalists as the 'tragedy of the anti-commons' where legal enclosures such as IPRs tend to make the use of certain innovations so expensive that they are under-utilized by people who need it the most. Studies have shown that biological diversity can be nurtured and increased not by restricting the free flow of GR but rather by facilitating its access to primary users such as farmers, plant breeders etc- thus any restriction on such free flows can be understood as environmentally unsound. It is for this reason that Art 12.3.d of the ITPGRFA under the heading 'Facilitated Access' states that "Recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral system". It is also important to bear in mind that the scope of facilitated access under Art 12.3.a which states that "Access is to be provided only for the purposes of utilization and conservation for research and breeding and training for food and agriculture" thereby emphasizing the importance of free flow of GR for primary users and researchers.

It is hard to separate the knowledge, innovations and practices of ILCs from the GR (which include whole ecosystems) on which this knowledge, innovations and practices are based. For example Company A, a user of a GR, the use of which is linked to TK, would need to get PIC from the Country of Origin to access the GR and PIC from the ILC concerned for the use of the associated TK. But within the supply chain, there would be users of the GR involved in activities not directly linked to the associated TK. For example Company B which acquires the GR so as to process it into the form that the Company A requires. While the ultimate product of Company A is based both on the GR and associated TK, Company B which merely processes the GR is also indirectly reliant on the associated TK without which there would be no commercial use for the GR. This means that Company B must also acquire PIC from the ILC on whose TK, the use of the GR by Company A is based, even though technically speaking Company B is using only the GR and not the associated TK. This ensures that anyone who commercially profits from the knowledge, innovations and practices of ILCs must require their PIC.

Norway

Operative text

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.

Related explanations and rationale

<u>Comment to subpara j)</u>: It is important to notice that the term *genetic resource* is defined from its utilisation. What is a genetic resource may therefore depend on the intended or the actual use of the genetic material. It can only be characterized as a genetic resource when the intended or actual use is based on the genetic information in the biological material. We do not consider use of a biological resource solely for taxonomy purposes to be a genetic resource and therefore simplified or no access procedures should be considered for this category.

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

Operative text

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]

Related explanations and rationale

Article 15.1 CBD recognises the sovereign rights of States over their natural resources and in this context, that the authority to determine access to genetic resources rests with the national governments and is subject to national legislation. For Contracting Parties, the authority of national governments to determine access to genetic resources is qualified by Article 15.2: Contracting Parties are obliged to endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of the CBD.

Preambular paragraph 3 recalls that Contracting Parties may, in exercising their sovereign rights over genetic resources, determine that access to their genetic resources will not be subject to prior informed consent (Article 15.5 CBD, "unless otherwise determined").

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

European Union and its Member States

Operative text

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.

Related explanations and rationale

The first preambular paragraph clarifies that benefits from the utilisation of genetic resources can only be realised after access has been granted. The second and third preambular paragraphs recall relevant provisions in Article 15 CBD.

The operational paragraph picks up on the fundamental notion in Article 15.7 that specific benefit-sharing arrangements will be established on mutually agreed terms between the provider and the user of genetic resources. Parties should take measures to encourage providers and users of genetic resources to provide in their mutually agreed

terms as appropriate for the fair and equitable sharing of benefits arising from the utilisation of genetic resources.

The same operational paragraph also appears in III.A.1.2) operational paragraph 1.

The same component appears in section III.A.1.1).

3) Legal certainty, clarity and transparency of access rules

European Union and its Member States

Operative text

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*).

Explanations and rationale

According to Article 15.2 CBD Parties shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Parties and not to impose restrictions that run counter to the objective of the CBD. Legal certainty, clarity and transparency of national access frameworks are general principles concretising this obligation of Parties under Article 15.2 CBD. The international regime should include guidance on specific measures to give effect to these general principles. An example of relevant operational text is provided below under III.B.2.2).

2. Components for further consideration

1) Non-discrimination of access rules

European Union and its Member States

Operative text

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

Related explanations and rationale

Non-discrimination between users of genetic resources from other Contracting Parties is an important concept adding to the predictability and legal certainty of national access decisions.

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

European Union and its Member States

Operative text

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 benefitsharing;
- 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.

Related explanations and rationale

The first and second Preambular paragraphs recall Article 15.1 and 15.2 CBD and are the same as in Operational Text III.B.1.1).

The third Preambular paragraph acknowledges that Contracting Parties may, in exercising their sovereign rights over genetic resources, determine that access to their genetic resources will not be subject to prior informed consent (Article 15.5 CBD, "unless otherwise determined"). The text is the same as in Operational Text III.B.1.1).

The fourth Preambular paragraph clarifies that benefits from the utilisation of genetic resources can only be realised after access has been granted. The text is the same as in Operational Text III.A.1.1).

Operational paragraph 1 concretises the obligation of Contracting Parties to endeavour to create conditions to facilitate access to genetic resources. The first sentence of this paragraph is the same as the operative paragraph submitted for component III.B.1.3) on legal certainty, clarity and transparency of access rules. The second sentence of this

paragraph and sub-paragraphs a) to r) translate the general principles of legal certainty, clarity and transparency into specific issues and measures that should be reflected in national access frameworks.

Operational paragraph 2 establishes the link between implementation of the essential elements listed in paragraph 1 a) to r) and additional measures to support compliance: 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 operational paragraph 1. – The EU has consistently underscored the relevance of the link between access and compliance. The operational text suggests how this link between access-related decisions in the jurisdiction of Parties providing genetic resources and measures to support compliance in jurisdictions where these genetic resources are utilised could be addressed through operational text.

3) Internationally developed model domestic legislation

European Union and its Member States

Operative text

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)].

Related Explanations and rationale

The ABS-related provisions of the Convention and the future International ABS Regime need to be implemented at national level to be effective. Recent studies indicate that so far only few CBD Parties have developed national legislation on access and benefit-sharing. Internationally developed model domestic legislation would have an important role in strengthening national capacity for developing national legislation and for implementing the international ABS regime.

The operational text suggests that model domestic legislation is developed internationally <u>after</u> negotiations on the international ABS regime have been concluded and the specific content of the international ABS regime is known.

4) Minimization of administration and transaction costs

5) Simplified access rules for non-commercial research

European Union and its Member States

Operative text

- 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.

Related Explanations and rationale

Biodiversity-research makes an important contribution to the implementation of the CBD. Simplified access is particularly important for non-commercial research, such as taxonomic work.

Operative paragraph 1 establishes that each Party requiring prior informed consent should provide for a simplified procedure for access to genetic resources for non-commercial research. Operative paragraphs 2 and 3 provide guidance on how Parties may identify the non-commercial intent of those seeking simplified access and the steps that may be taken to ensure that the simplified access rules for non-commercial are not abused.

Operative paragraph 4 repeats operational text provided under component III.A.2.5).

Operative paragraphs 5 and 6 establish an exchange of experience and information that will support Parties in building the necessary confidence in the effective functioning of and integrity of their simplified access procedures for non-commercial research.

C. Compliance

India

Operative text

- 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

Operative text

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/

^{7/} UNU Certificates of Clarity or Confusion -IAS report.

- 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: 8/

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 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.

^{8/} Barber, C.V, et al, 2003, User Measures: Options for Developing Measures in User Countries to Implement ABS Provisions of the CBD.

^{9/ 2007} report of Group of Technical Experts on the Certificate.

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
- 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.

Related explanations and rationale

Determining what to call any certificate system prior to defining its component elements and procedures for its implementation is considered a distraction and potentially counter-productive. Terms may easily prove interchangeable. Compliance with the national ABS laws of provider countries would, for instance, raise the presumption of legal provenance of resources. Provider countries as defined under the CBD will have to be countries of origin or countries which have obtained resources in accordance with the CBD, i.e. from countries of origin. A certificate of origin would therefore imply both compliance and legal provenance. A legitimate source for resources would, in order to be compliant with the CBD, so have to be a country of origin or country which had obtained resources in accordance with the CBD. Although the actual provider of genetic resources

 $[\]underline{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

may be an ex-situ collection or indigenous people, landowner, etc., to be a legitimate source they must still be providing resources for which that country is considered a provider country. Although each proposal has provided differing interpretations of the scope of any certification system, it is clear that to be CBD compliant they must fall within the same defined parameters regarding who can provide resources and under what terms, including PIC and MAT. Furthermore, all of the proposals could be applied in either a voluntary or mandatory system, making distinctions in nomenclature even less significant. Deciding what any certificate system is to be called is very much secondary to defining what a certificate system is meant to do and how it is to do it. Pressure to adopt a specific term to designate a future certification system may inhibit full and informed debate of all options. That way the name will describe the system rather than having a system defined to fit the name. In the long run it's not what a certificate is called that will matter but rather how - and if - it does what it is supposed to do. 12/

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

Operative text

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.

Related explanations and rationale

Awareness about access and benefit-sharing issues is critical for the successful establishment of mutually agreed terms and the further development and effective implementation of ABS frameworks at national level. It will be important to raise awareness amongst users, providers, indigenous and local communities, and other groups. Awareness-raising activities also appear in section on Fair and equitable benefit-sharing - III.A.1.8).

2) Development of tools to monitor compliance:

(a) Mechanisms for information exchange

European Union and its Member States

Operative text

- 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.

Related explanations and rationale

Information-exchange under the international ABS regime should support Parties, providers and users in obtaining information relevant to them. Furthermore, information-sharing between ABS focal points could provide (case-) specific information.

(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

Operative text

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.

Related explanations and rationale

The availability of model clauses for potential inclusion in material transfer agreements and inventories/catalogues of typical utilisations of genetic resources and related benefits 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.

The Preambular paragraph underlines the multiple benefits of model clauses.

According to operational paragraph 1 providers and users of genetic resources should be encouraged to <u>consider</u> using such model clauses and relevant inventories/catalogues of typical utilisations of genetic resources when establishing mutually agreed terms, reflecting that this component refers to menus of model clauses for <u>potential</u> inclusion in material transfer agreements.

Operational paragraphs 2 and 3 establish a procedure through which Parties collectively initiate the development of as well as the eventual consideration, adoption and review of model clauses and inventories/catalogues of typical utilisations of genetic resources and related benefits

The same component appears in Section III.A.2.5).

(c) Codes of conduct for important groups of users

European Union and its Member States

Operative text

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.

Related explanations and rationale

The adoption of the CBD and the Bonn Guidelines has resulted in the development of a range of codes of conduct and best practice guidelines on access and benefit-sharing. Codes of conduct and best practice guidelines contribute to and enhance the effective implementation of domestic regulatory frameworks. It is therefore important that Parties appreciate codes of conduct and best practice guidelines as potential building blocks of the international regime on access and benefit-sharing.

(d) Identification of best-practice codes of conduct

European Union and its Member States

Operative text

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.

Related explanations and rationale

Codes of conduct and best practice guidelines contribute to and enhance the effective implementation of domestic regulatory frameworks. It is therefore important that Parties appreciate codes of conduct and best practice guidelines as potential building blocks of the international regime on access and benefit-sharing. This should be supported by collective efforts of Parties to identify those codes 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

Operative text

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]

Related explanations and Rationale

The EU considers that international access standards should be a key component of the international ABS regime, including a simplified access procedure for cases of non-

commercial research. The establishment of international access standards is, in our view, also a pre-requisite for potential additional measures to support compliance in cases of misappropriation of genetic resources. As identified in Operational Text III.B.2.2) paragraph 2, the additional measures to support compliance in cases of misappropriation will only be applicable if the domestic ABS framework of a Contracting Party providing a genetic resource is in conformity with paragraph 1 of Operational Text 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 benefitsharing to help providers obtain relevant information in specific cases of alleged infringements of prior-informed-consent requirements
 - (e) Remedies and sanctions

Norway

Operative text

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 13

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

India

Operative text

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

Operative text

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.
- 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.

Related explanations and rationale

Community Protocols

The knowledge, innovations and practices of ILCs emerge at the intersection of their lands and culture. Art 8 j states that that ILCs embodying traditional lifestyles have conserved and sustainably used biological diversity and aspects of those lifestyles relevant to the conservation and sustainable use of biological diversity must be protected and promoted by Contracting Parties. Art 8 j also recognizes the rights of ILCs over their traditional knowledge, innovations and practices and obliges Contracting Parties to ensure that benefits arising from the use of such knowledge, innovations and practices are fairly and equitable shared with the ILCs in question.

The dominant interpretation of Art 8 j in the current negotiations towards the IR on ABS seems to focus on the protection of the TK of ILCs and ensuring the fair and equitable sharing of benefits arising from the use of such TK with the ILCs from whom it was taken.

Art 8 j however is far wider in its reach and should be read in the broader context of the CBD, particularly its aims of conserving and sustainably using biodiversity. Article 8 j is clear that the conservation and sustainable use of biological diversity in the context of ILCs is dependent on aspects of their TK which is rooted in their 'ecological values'. This is the reason why Art 8 j does not refer to the protection and promotion of all the TK of all ILCs but specifically the TK of ILCs embodying traditional lifestyles relevant to the conservation and sustainable use of biodiversity. Such ecologically integral TK is based on a value framework that regulates the relationship between the cultures of ILCs and their lands. Thus TK relevant for the conservation and sustainable use of biodiversity rests on 'ecological values' which in turn rests on secure rights to land and culture. The truth of the matter is that ILCs have conserved and sustainably used biological diversity for thousands of years not because they have been able to trade in their TK but because they have been able to live on their traditional lands in accordance with their 'ecological values'.

ABS in the context of ILCs focuses inordinately on an agenda of TK protection that perceives TK outside of the relationships which generate it, divorcing it from the ecological values that lead to its formation. The relations that the ILCs have with nature is one of a perpetual dialogue between land and culture each constituting and reconstituting the other. Ecological values are therefore rooted in an experience of relatedness between community and nature. Current IPR systems perceive TK in a manner that is quite similar to conventional property systems where land for example is viewed as a commodity separate from the network of relations within which it operates. TK is also viewed as an object separate from the cultural and spiritual relationships with the land within which it is embedded.

TK in reality is the manifestation of a particular kind of relationship with nature. TK is not just information but a set of relations that is embodied in traditional lifestyles of ILCs which ensure conservation and sustainable use of biodiversity. Currently there are no internationally agreed definitions of traditional knowledge and all efforts towards defining it tend to treat it as a product rather than as a process.

Efforts to protect traditional knowledge should be oriented less towards protection of knowledge as information and more towards sustaining the relationships based on ecological values that produce the knowledge. It is the ecological values that have sustained indigenous peoples within natural habitats, and the erosion of these values through the dispossession of indigenous lands and consequent annihilation of their cultures has seriously threatened biological diversity. To treat TK as a commodity and to assume that protecting this commodity will ensure conservation and sustainable use of biological diversity is akin to thinking that the sale of ivory will necessarily lead to the conservation of elephants and their habitats.

Community Approaches to Art 8 j:

The real extent of Art 8 j mandates Contracting Parties to go beyond creating databases of TK and ensuring benefit sharing when TK is utilized. The process and the outcome of ABS negotiations must uphold the spirit of Art 8 j and to do so the emphasis should not just be on the sale of TK but focus equally on the conservation and sustainable use of biological diversity and protection and promotion of traditional lifestyles including rights to land and culture. This implies ensuring that the

ecological values of the ILCs in question are central to all stages of the ABS negotiation i.e. at the stage of 'PIC', 'MAT' and 'benefit sharing'.

While the overarching framework of ecological values within which ABS agreements must be negotiated does not preclude monetary and non-monetary benefits to ILCs in exchange for the use of their TK, these benefits should not be the sole aim of ABS agreements. The process and the outcome of an ABS agreement between ILCs and the relevant stakeholders must affirm aspects of their traditional lifestyles that conserve and sustainably use biological diversity.

Contracting Parties are also bound by Art 8 j to ensure the wider application of the TK and by inference the ecological ethics of ILCs. This implies that ILCs must be integrally involved in Research and Training (Art 12) and Public Education and Awareness (Art 13). Art 12 and 13 must be read with Art 8 j where the research and training and public education is not only done by scientists, technical experts and ecologists but also by ILC representatives, elders and healers who have ensured the conservation and sustainable use of biodiversity by virtue of their lifestyles. ILCs have much to teach the world about their 'ecological values' and how they can be applied in non-traditional contexts – an application that would lead to genuine in situ conservation by challenging contemporary consumption patterns and lifestyle choices. Art 10c and 18 (4) already point us in this direction and we would do well to pay heed to them.

Conclusion- Working towards Community Protocols:

In order for ILCs to realise the full extent of their rights under Art 8 j it is crucial for them to develop community protocols based on their 'ecological values' that will inform all future ABS negotiations between them and other stakeholders who want access to their TK. While the ILCs themselves may be aware of their 'ecological values' on which their traditional lifestyles are based, setting them out in the form of community protocols would give parties interested in accessing the TK of ILCs clear guidelines as to the ethical preconditions and terms of potential ABS agreements. Community protocols amongst ILCs that are spread across national boundaries and/or between ILCs that share the same TK but belong to different cultural and ethnic groups would also be the only way in which to provide potential non community users of TK transparent instructions as to how and from whom to secure PIC, negotiate MAT and share benefits with.

States can at best insist that any access to TK must be based on ABS agreements with communities to whom the TK belongs, but neither national nor international law can go any further than this. It is communities to whom the TK belongs that must through community protocols guide parties interested in using TK on how to secure legitimate use rights. If this is not done than every potential user of TK despite having negotiated an ABS agreement risks being accused of misappropriation by: (i) either the community members who feel that the community representative who negotiated the agreement had no authority to do so or (ii) by other communities that share the same TK who feel that they were wrongfully excluded from the ABS agreement.

The process of developing community protocols would involve communities developing ethical guidelines for ABS negotiations and agreements involving their TK that include but go beyond highlighting best practice standards for obtaining PIC and MAT. A community protocol is an outlining of ecological values on which PIC, MAT and benefit sharing would be based. A useful analogy for a community protocol would be the 'bill of rights' in the Constitution of a country that lists the core values of a people. It enunciates a community's core values and while it remains a flexible instrument, it provides community members and outside interests a level of certainty about the principles upon which any ABS agreement will be negotiated.

Community protocols are perhaps the best chance for ILCs to ensure that their ways of life and values are respected and promoted. Merely relying on the benefits of ABS agreements without affirming their 'ecological values' would reduce ILCs to sellers of TK who warm themselves on the embers of a lifestyle that is fast dying out.

Norway

Operative text

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 traditionalknowledge 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

Operative text

- 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) 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
- 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

Operative text

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
 - IV. NATURE

Text of decision IX/12, annex I

Compilation of proposals on nature 14/

1. Recommendation of Co-Chairs of the Working Group

Options

^{14/} These proposals were neither discussed, negotiated nor agreed.

UNEP/CBD/WG-ABS/7/5

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- 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

Operative text

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

Operative text

Definitions

Fair and Equitable Benefit Sharing

The definition of 'fair and equitable benefit sharing' is non-exhaustive and inclusive. <u>15</u>/ 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'. 16/

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

- 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

^{15/ &}quot;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

^{16/} 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.

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 <u>17</u>/ 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, neutraceutical (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 resourceutilization 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:

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.
