



Convention on Biological Diversity

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INTERNATIONAL REGIME ON ACCESS AND BENEFIT-SHARING ^{1/} _{2/}

Consolidated draft submitted by the Co-Chairs

I. OBJECTIVE

The objective of the International Regime on Access and Benefit-sharing is to effectively implement the provisions in Articles [1,] [3,] 8(j), 15, [16 and 19.2] of the Convention on Biological Diversity and pursue its three objectives by:

- [[Facilitating] [regulating] [transparent] [appropriate] access to [biological resources] genetic resources, [their derivatives][and products] [containing genetic material] [through a transparent regulatory framework]; [for environmentally sound uses recognizing 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.];]
- Ensuring [the establishment of enabling conditions for] the effective, fair and equitable sharing of benefits arising out of the utilization of [biological resources] genetic resources, [their derivatives][and products] and associated traditional knowledge;
- [Preventing the misappropriation and misuse of [biological resources] genetic resources, [their derivatives] and/or associated traditional knowledge;]
- [[Securing] [supporting] compliance [in user countries with] [the International Regime, and] [national laws and requirements] [with domestic regulatory ABS frameworks [in provider countries]], including prior informed consent and mutually agreed terms, [of the country [of origin] providing such 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] [all sovereign rights of States over their natural resources], including the rights of indigenous and local communities, [subject to national legislation] [and the United Nations Declaration on the Rights of Indigenous Peoples][, where appropriate]].

II. SCOPE

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

^{2/} Reference to the International Regime on Access and Benefit-sharing in this text is without prejudice to the nature of the International Regime.

/...

1. The International Regime on Access and Benefit-sharing applies to [all] [biological resources,] genetic resources, [including viruses and other pathogenic [, as well as potentially pathogenic] organisms and genetic sequences regardless of their origin] [derivatives,] [products] [benefits arising from commercial and other utilization] as well as [to their] [associated] traditional knowledge, innovations and practices [covered by the Convention on Biological Diversity] [in accordance with Article 8(j)] [within national jurisdiction and of a transboundary nature] [in accordance with the relevant provisions of the Convention on Biological Diversity] [subject [and mutually supportive] to other [relevant] international obligations] [and without prejudice to other international obligations]. [The International Regime will also apply to genetic resources of migratory species that for natural reasons are found on the territories of the Parties.]

[2. Subject to paragraph 1, the international regime on access and benefit-sharing applies to:

[a) Benefits [including access to [funding] and transfer of technology,] arising from commercial and other utilization] [from] [biological resources] [derivatives] [products] [genetic resources acquired after] [and associated traditional knowledge] [the effective date of] [the entry into force of] the [International Regime] [Convention on Biological Diversity];

[b) Continuing benefits [and benefits from new uses arising from commercial and other utilization of genetic resources, [biological resources], [products] [and derivatives] and associated traditional knowledge acquired prior to the entry into force of the Convention on Biological Diversity.] arising from commercial and other utilization taken prior to the coming into force of the Convention on Biological Diversity.]

[c) All intellectual property rights (IPRs) associated with research and technology arising from the use of all genetic resources, [biological resources], [their derivatives], [products] and associated traditional knowledge of indigenous and local communities]]

3. The International Regime on Access And Benefit-sharing does not apply to:

(a) [Human genetic resources;]

(b) [[Biological resources], genetic resources [derivatives][and products] that were acquired [before the entry into force of the Convention on Biological Diversity [for a Party]] [or before the effective date of the international regime];] [on the understanding that any additional obligations under the international regime on access and benefit-sharing will not apply retroactively.]]

(c) [[Biological resources], genetic resources [and/or derivatives][and products] which a Party decides to offer or maintain without access requirements and/or benefit-sharing, provided that the rights of that Party over those biological resources, genetic resources,[and/or derivatives][and products] are fully respected]

(d) [[Species] [Crops] [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];]

[Plant genetic resources for food and agriculture (PGRFA) accessed under the Multilateral System established under the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and other plant genetic resources for food and agriculture, which a Contracting Party to the ITPGRFA has determined shall be subject to the Standard Material Transfer Agreement (SMTA) under the ITPGRFA. Plant genetic resources for food and agriculture which have been transferred by an IARC or other international institutions under the SMTA in accordance with the agreements between the Governing Body of the ITPGRFA and the IARCs and other international institutions.]

(e) [[[Biological resources] genetic resources [derivatives],[products] including] marine genetic resources in areas beyond the limits of national jurisdiction;]

(f) [[Biological resources], genetic resources [derivatives] [products] located in the Antarctic Treaty Area[, which is the area south of latitude 60°S,][or the Area of the Convention on the Conservation of Antarctic Marine Living Resources];]

(g) [Commodities in trade;]

(h) [The exchange of genetic resources, [their derivatives,] [the biological resources containing them], [products] or their associated traditional knowledge among indigenous and local communities for their own consumption based on their customary practices;]

(i) [Specific uses of pathogens.]

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].] [The international regime on access and benefit-sharing will not apply if and in so far as [determined by the Governing Body of the international regime,] other more specialized international access and benefit-sharing systems apply.] [Nothing in the international regime will prevent the development, recognition and accommodation of intergovernmental agreements relating to access and benefit-sharing [, which as determined by the Governing Body of the international regime,] [achieves] that achieve the objectives of the Convention on Biological Diversity and are consistent with the provisions of the international regime.]

[OR]

[The International Regime on Access and Benefit-sharing and [other] relevant international treaties [shall][should] [be interpreted and applied] in harmony [and in a mutually supportive manner]. In the implementation and further development of the international regime, special consideration should be given to [other] intergovernmental multilateral agreements in regard to access to [biological resources] genetic resources [derivatives] [products] and associated traditional knowledge [in a manner that will not run counter to the objectives of the Convention on Biological Diversity and the international regime].]

[OR]

[The International Regime on Access and Benefit-sharing [shall] [should] [be interpreted and applied] in harmony [and in a mutually supportive manner] with [other] relevant international treaties on access and benefit-sharing.]

5. [This International Regime on Access and Benefit-sharing [shall] [should] [be interpreted and applied] in harmony [and in a mutually supportive manner] with the International Treaty on Plant Genetic Resources for Food and Agriculture [to ensure] their effective, adequate and coherent implementation.

5.1 [[Parties] recognize that the Multilateral System created under the International Treaty on Plant Genetic Resources for Food and Agriculture [governs][regulates] access and benefit-sharing arrangements for crops specified in the coverage of the Multilateral System, in accordance with the decisions taken by the Governing Body of that Treaty.]

5.2 This international regime [shall][should] reinforce the relationship between the Convention on Biological Diversity and the International Treaty on Plant Genetic Resources for Food and Agriculture in order to develop the cooperation that has been provided for in the International Treaty.

5.3 [[Parties] reaffirm that genetic resources of Annex I of the International Treaty on Plant Genetic Resources for Food and Agriculture used for purposes other than those regulated by the Multilateral System of that Treaty are subject to national legislative, administrative or policy measures.]]

6. [The International Regime on Access and Benefit-sharing will be implemented in harmony with [and not duplicate] relevant [work of other organizations and] treaties [including, inter alia, the FAO Commission on Genetic Resources for Food and Agriculture (CGRFA), [the International Union for the Protection of New Varieties of Plants (UPOV),] the World Intellectual Property Organization (WIPO), the World Health Organization (WHO), the International Plant Protection Convention (IPPC), and the World Organization for Animal Health (OIE) [and the International Labour Organization (ILO)].]

III. MAIN COMPONENTS

A. FAIR AND EQUITABLE BENEFIT-SHARING

1) Linkage of access to the fair and equitable sharing of benefits ^{3/}

[Recognizing that the fair and equitable sharing of benefits can only be realized 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. (a) [Parties requiring]Prior informed consent for access to [their] [genetic resources][biological resources][, their derivatives][and products] [and/or associated traditional knowledge], where applicable, [shall][should] be obtained [according to the access and benefit-sharing requirements of][from] [the Party] [country of origin or Party that has acquired the genetic resources [, their derivatives][and products] [in accordance with the Convention] providing such resources[, their derivatives][and products] [and/or associated traditional knowledge] [through its competent national authority(ies)][, [as defined in {...},]] unless otherwise determined by that Party.

[(b) Subject to the national legislation[, regulations and/or requirements] of the country where these [indigenous and local] communities are located, [international law, [indigenous and local] community protocols and relevant customary laws of indigenous peoples and local communities] where access is sought to traditional knowledge, innovations and practices associated to [genetic resources][biological resources][, their derivatives][and products], users [shall][should] obtain the prior informed consent of [indigenous] and/or local communities holding such traditional knowledge, innovations and practices, in accordance with Article 8(j) of the Convention. [Such consent should also be obtained with regard to indigenous peoples and local communities rights to [genetic resources][biological resources][, their derivatives][and products].]]

(c) [[Parties may provide in their national legislation and regulations that][Prior informed consent] [shall][should] be based on the specific uses of specific [genetic resources][biological resources][, their derivatives][and products][and/or associated traditional knowledge] for which consent

^{3/} There is also a section on linkages of access to the fair and equitable sharing of benefits under section III.B.1.2 of annex I to decision IX/12.

has been granted [under mutually agreed terms].] [Parties requiring prior informed consent for access to their [genetic resources][biological resources][, their derivatives][and products] [shall][should] clearly stipulate the permitted uses.][Permitted uses [shall][should] be clearly stipulated and further prior consent for changes or unforeseen uses [not covered by mutually agreed terms] [shall][should] be required].

(d) Specific needs of taxonomic and systematic research as specified by the Global Taxonomy Initiative [shall][should] be taken into consideration.]

2. Parties [requiring prior informed consent for access to their [genetic resources][biological resources][, their derivatives][and products]] [shall][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 utilization of [genetic resources][biological resources][,their derivatives][and products][.][, whilst recognizing that the fair and equitable sharing of benefits can only be realized after access to [genetic resources][biological resources][, their derivatives][and products] has been granted.] **[Mutually agreed terms [shall][should] be established by the time of access to the [genetic resources][biological resources][, their derivatives][and products].]**

3. Each Contracting Party [shall][should] take [appropriate] legislative, administrative, or policy measures[, as appropriate,] 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 utilization of [genetic resources][biological resources][, their derivatives][and products] with the [Contracting Party] [and/or indigenous peoples and local communities] [providing such resources][, their derivatives][and products][country of origin or Party that has acquired the genetic resources in accordance with the Convention]. [Such sharing [shall][should] be subject to prior informed consent] of the [Contracting Party] [and/or indigenous peoples and local communities] [providing such resources][, their derivatives][and products][country of origin or Party that has acquired the genetic resources in accordance with the Convention], unless otherwise determined by that Party and on mutually agreed terms.

4. Each Contracting Party [shall][should][may] take the following measures:

[(a) Establish mechanisms to provide information to potential users concerning [their] [any] obligations regarding access to [genetic resources][biological resources][, their derivatives][and products] [and/or associated traditional knowledge] [within that Party's jurisdiction];]

[(b) Introduce rules requiring that users of [genetic resources][biological resources][, their derivatives][and products] comply with national legislation [in] [of] the providing country [or, where relevant, the]/country of origin [customary protocols and relevant customary laws of indigenous peoples and local communities] and the mutually agreed terms on which access was granted, including requirements to equitably share the benefits arising from the utilization of such resources[, their derivatives][and products].]

2) Benefits to be shared on mutually agreed terms

[*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 Convention the fair and equitable sharing of benefits arising from the commercial and other utilization of genetic resources shall be upon mutually agreed terms as decided between the provider and user {*preambular paragraph*}]

[*Recognizing* that benefit-sharing on mutually agreed terms may include monetary and/or non-monetary benefits {*preambular paragraph*}]

[Recognizing that the benefit sharing measures under this Protocol are effective tools for the eradication of poverty and the promotion of economic and social development {preamble paragraph}]

[Emphasizing that the resources of biological diversity and the environmental services that depend on them have an immense strategic, economic and social value, and offer development opportunities to our populations and to the international community {preamble paragraph}]

1. [Each Party [shall][should][may] stipulate [in its national legislation] measures to ensure the fair and equitable sharing of the benefits arising out of the use of [genetic resources][biological resources][, their derivatives][and products] and/or associated traditional knowledge. [Those measures [shall][should] be incorporated in mutually agreed terms and in prior informed consent.][Parties requiring prior informed consent for access to their [genetic resources][biological resources][, their derivatives][and products] [shall][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 utilization of [genetic resources][biological resources][, their derivatives][and products], whilst recognizing that the fair and equitable sharing of benefits can only be realized after access to [genetic resources][biological resources][, their derivatives][and products] has been granted.][Each Contracting Party][Contracting Parties] [shall][should] in accordance with Article 15(7) of the Convention take [legislative, administrative or policy] measures [, as appropriate, with the aim of sharing in a fair and equitable way the][to ensure the fair and equitable sharing of] benefits arising from the commercial and other utilization of [genetic resources][biological resources][, their derivatives][and products] with the [country of origin][Contracting Party providing the resources][. Such sharing shall be] on mutually agreed terms.]

[2. The conditions for the equitable sharing of the benefits arising out of the use of traditional knowledge, innovations and practices associated with [genetic resources][biological resources][, their derivatives][and products] [shall][should] be stipulated in mutually agreed terms[, in accordance with national legislation][, community protocols and relevant customary laws of indigenous peoples and local communities]:

[a) between the indigenous or local communities and the users; or b) between users and the national authority of the provider country, with active involvement of concerned indigenous and local communities].]

3. Parties [requiring prior informed consent for access to their [genetic resources][biological resources][, their derivatives][and products]] [shall][should] take measures to [ensure] [encourage providers and users of [genetic resources][biological resources][, their derivatives][and products], when establishing mutually agreed terms, to consider]:

[(a) Including in these terms [model] clauses and using relevant inventories/catalogues of typical utilizations of [genetic resources][biological resources][, their derivatives][and products] and related monetary or non-monetary benefits developed in accordance with {...};]

(b) Sharing of results of research and development;

(c) Access to and transfer of technology which makes use of those resources;

(d) The effective participation of [providers][country of origin] of the [genetic resources][biological resources][, their derivatives][and products] in research activities and/or to facilitate the joint development of research activities between the [provider][country of origin] and the user;

[(e) The Bonn Guidelines].

[4. The elements of paragraph 44 of the Bonn Guidelines [shall][should] be considered in the development of mutually agreed terms.]

[5. Sharing of benefits shall proceed upon mutually agreed terms. Mutually agreed terms may consider, *inter alia*, time, amount, conditions and other characteristics of such sharing of benefits in accordance with applicable national law. However, the existence of mutually agreed terms must not constitute grounds for the denial or non-recognition of the sharing of benefits. In such cases Contracting Parties shall promote the reaching of an agreement between the conflicting parties. If the user denies to enter into an agreement, or if the parties fail to reach such agreement, the competent authorities of the Contracting Parties in which the claim is filed will take a decision and make it effective. The decision shall take into account the legitimate rights and interests of both parties and shall be given in a timely manner, observe due process of law, be transparent, non-discriminatory, and shall be made public.]

3) Monetary and/or non-monetary benefits

[Recognizing that benefit-sharing on mutually agreed terms may include monetary and/or non-monetary benefits {*preambular paragraph*}]

1. [Parties [shall][should] take measures to [ensure][encourage] that benefit-sharing includes, as far as possible, [all forms of utilization of] [genetic resources][biological resources][, their derivatives][and products] and/or associated traditional knowledge.]

2. [The International Regime on Access and Benefit-sharing will include an indicative list of mutually agreed terms.] Mutually agreed terms [may][shall][should] identify the types of monetary and/or non-monetary benefits to be shared for the utilization of [genetic resources][biological resources][, their derivatives][and products] and/or associated traditional knowledge, innovations and practices.

3. [Parties [shall][should], subject to Article 16 of the Convention, take measures to share the benefits of research and technology linked to conservation and sustainable use, irrespective of access to [genetic resources][biological resources][, their derivatives][and products] and/or associated traditional knowledge.]

[4. Parties [shall][should] establish a financial mechanism for the International Regime on Access and Benefit-sharing, including a trust-fund for benefit-sharing arrangements.]

Option 1

3. The benefits shared [shall][should][could] be monetary[, including, *inter alia*, Appendix II of the Bonn Guidelines,] and/or non-monetary. Monetary benefits [may][shall][should] include[, but are not limited to]:

- (a) Access fees/fee per sample;
- (b) Up-front payments;
- (c) Milestone payments;
- (d) Payment of royalties;
- (e) Licence fees in case of commercialization;
- (f) Research funding; and
- (g) Investment in joint ventures.

4. Non-monetary benefits [may][shall][should] include[, but are not limited to]:

- (a) Sharing of research and development results;

- (b) Participation in product development;
- (c) Collaboration, cooperation and contribution in education and training;
- (d) [Transfer to the provider of the [genetic resources][biological resources][, their derivatives] [and products] and/or associated traditional knowledge, the technology developed using such resources [, their derivatives][and products] and/or associate traditional 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;]
- (e) [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][biological resources][, their derivatives] [and products]. Also to facilitate abilities of indigenous and local communities to conserve and sustainably use their [genetic resources][biological resources] [, their derivatives][and products];]
- (f) Institutional capacity-building;
- (g) Human and material resources to strengthen the capacities for the administration and enforcement of access regulations;
- (h) Training related to [genetic resources][biological resources][, their derivatives][and products] with the full participation of providing Parties, and where possible, in such Parties;
- (i) Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;
- (j) Contributions to the local economy;
- (k) Food and livelihood security benefits; and
- (l) Joint ownership of relevant intellectual property rights.

Option 2

- 3. The benefits to be shared may include, but are not limited to:
 - (a) Monetary and non-monetary benefits listed in Appendix II of the Bonn Guidelines; and
 - (b) Non-monetary benefits in accordance with Articles 15(6), 16(3), 16(4) and 19 of the Convention.

4) Access to and transfer of technology

[Option 1

1. Each Party that develops technologies making use of [genetic resources][biological resources][, their derivatives][and products] [and/or associated traditional knowledge] [shall][should] take legislative, administrative or policy measures [with the aim that the private sector facilitates][, as appropriate, with the aim that] [to facilitate] access to, [joint development] and transfer of those technologies [is provided] to developing countries [which provide genetic resources][biological resources][that are the origin of such resources,] [, their derivatives][and products] [and/or associated traditional knowledge] under mutually agreed terms, in accordance with Article 16 of the Convention.]

2. [Parties [shall][should] subject to Article 16 of the Convention also facilitate access to and transfer of technologies that are relevant to conservation and sustainable use, or make use of [genetic resources][biological resources] [, their derivatives][and products] to all other Contracting Parties to the Convention irrespective of access to [genetic resources][biological resources][, their derivatives] [and products.]

[Option 2

Parties [requiring prior informed consent for access to their [genetic resources][biological resources][, their derivatives][and products]] [shall][should] take measures to [encourage][ensure] [providers][countries of origin or countries providing the resource in accordance with the Convention] and users of [genetic resources][biological resources][, their derivatives][and products], when establishing mutually agreed terms, to [consider][ensure] access to and transfer of technology which makes use of those resources.]

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

[1. Parties [shall][should] establish, taking into account Article 15, paragraph 7, Article 16, paragraph 3 and 4, Article 19, paragraph 1 and 2, and Article 20, paragraph 4, of the Convention, measures to ensure the fair and equitable sharing of benefits from the results of research and development, including through facilitating access to the results of such research and development and through access to and technology transfer, and other utilization of [genetic resources][biological resources][, their derivatives][and products] and/or associated traditional knowledge[, including technology protected by patents and other intellectual property rights on concessional and preferential terms to developing countries], taking into account prior informed consent and mutually agreed terms and respecting national legislations of the country of origin of such resources or the parties that have acquired the resources in accordance with the Convention.]

2. Parties requiring prior informed consent for access to their [genetic resources][biological resources][, their derivatives] [and products] [shall][should] take measures to encourage providers and users of [genetic resources][biological resources][, their derivatives][and products], when establishing mutually agreed terms, to consider sharing of results of research and development.

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

[1. Parties [shall][should] agree to strengthen research capability and **[promote the establishment of collaborative research networks between partner countries, institutions and indigenous [peoples] and local communities directed towards the [three] objectives of the Convention [and the generation of mutually agreed public goods]. Strengthening of research capability and establishment of collaborative research networks will be directed towards the [[identified] research needs [of][identified by] developing countries, in particular the least developed among them, small island developing States, countries with economies in transition, and] indigenous [peoples] and local communities participating in the International Regime on Access and Benefit-sharing]**[ensure effective involvement of national counterparts, taking into account the special needs of developing country Parties in particular the least developed among them, small island developing States and countries with economies in transition].]

[2. Parties [requiring prior informed consent for access to their genetic resources][biological resources][, their derivatives][and products] [shall][should] take measures to [ensure][encourage the [providers][countries of origin] and users when establishing mutually agreed terms, to [consider][ensure] the effective participation of [providers][countries of origin] of the [genetic resources][biological resources][, their derivatives][and products] [in research activities and/or to facilitate the joint development of research activities **[including collaborative research networks]** between the

[provider][country of origin] and [the user][**users within the context of the International Regime on Access and Benefit-sharing**]. **[To this end, Parties [will][may] elaborate access and benefit-sharing [commons] [licenses] to support effective participation in research activities, joint research and development and establishment of collaborative research networks between providers and users.]**

[3. Parties [shall][should] take measures to ensure that the private sector facilitates joint development of technologies relevant to the conservation and sustainable use of biodiversity or make use of [genetic resources][biological resources][, their derivatives][and products] for the benefit of both government institutions and the private sector of developing countries in accordance with Article 16 of the Convention.] **[Such measures may include promotion of the use of [non-exclusive commercial access and benefit-sharing licenses] to be elaborated within the context of the International Regime on Access and Benefit-sharing.]**

[4. Parties [shall][should] in accordance with Article 18 of the Convention promote the establishment of joint research programmes and joint ventures **[and collaborative research networks]** for the development of technologies relevant to the objectives of the Convention.]

[5. When [accessing] [genetic resources][biological resources][, their derivatives][and products] **[and/or associated traditional knowledge]** for purposes of scientific and technological research, foreign researchers and foreign research institutions or legal entities [shall][should] undertake such research in partnership and/or collaboration with a nationally approved research institution in the [country of origin][provider country] of such [genetic resources][biological resources][, their derivatives][and products] **[and/or [associated] traditional knowledge]**, in accordance with the national legislation of the [country of origin][provider country].]

7) Mechanisms to promote equality in negotiations

[Recognizing the importance of promoting equality in negotiations of mutually agreed terms between providers and users of genetic resources{*preambular paragraph*}]

1. Parties [shall][should][may] take measures such as:

(a) Making information available to users and [providers][countries of origin or Parties that have acquired [genetic resources][biological resources][, their derivatives][and products] in accordance with the Convention] through the designated access and benefit-sharing focal point in a timely manner[.], including the [model] clauses and relevant inventories developed [in accordance with {...}][under the International Regime on Access and Benefit-sharing];

(b) [Enabling engagement between][Developing consultative arrangements with] relevant stakeholders and indigenous and local communities holding traditional knowledge associated with [genetic resources][biological resources][, their derivatives][and products];

(c) Supporting the capacity of [providers][countries of origin or indigenous and local communities] and[, where appropriate,] users of [genetic resources][biological resources][, their derivatives][and products] to negotiate mutually agreed terms[, prior informed consent] and contractual arrangements[, as appropriate].

[2. Contracting Parties [providing [genetic resources][biological resources]][, their derivatives][and products] which are countries of origin of [genetic resources][biological resources][, their derivatives][and products], or other Parties which have acquired the [genetic resources][biological resources][, their derivatives][and products] in accordance with the Convention, [shall][should][may]:]

[(a) Take measures to ensure appropriate participation by relevant indigenous peoples and local communities in access procedures where their rights are associated with the [genetic resources][biological resources][, their derivatives][and products] being accessed or where traditional knowledge associated with these [genetic resources][biological resources][, their derivatives][and products] is being accessed;]

[(b) Establish mechanisms to ensure that decisions are made available to relevant indigenous peoples and local communities and relevant stakeholders;]

[(c) The effective involvement of indigenous and local communities should be promoted by:

- (i) Providing information especially regarding scientific and legal advice in order for them to be able to participate effectively;
- (ii) 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.]

[(iii) Providing capacity-building in the use of tools for [tracking and monitoring compliance] with the terms of access and benefit-sharing agreements including [compliance with licensing terms].]

8) Awareness-raising ^{4/}

Parties [shall][should] take [the following] measures to raise awareness of access and benefit-sharing issues [in support of [mandatory][voluntary] compliance measures to [ensure][promote] benefit-sharing]. Such measures could include[, but not be limited to]:

(a) Making available up to date information about their domestic access and benefit-sharing framework, in particular national laws, policies and procedures;

(b) Steps to promote the International Regime on Access and Benefit-sharing [, including the promotion of a wider understanding among the public on the concepts of misappropriation, misuse, and biopiracy as well as for the recognition of the contribution made by indigenous and local communities to biological diversity and the benefits generated by that contribution];

(c) Organization of stakeholder meetings;

(d) Establishment and maintenance of a help desk for stakeholders;

(e) Information dissemination through [a specialized website][an access and benefit-sharing clearing house][, as well as hard copies];

(f) Promotion of codes of conduct [and best practice tools] in consultation with stakeholders;

(g) Promotion of regional exchange of experiences related to access and benefit-sharing;

[(h) Communication, education and awareness-raising of access and benefit-sharing-related issues to the relevant sectors and stakeholders.]

^{4/} There is also a section on awareness-raising under section III.C.1.1.(a) of annex I to decision IX/12.

[2. Awareness-raising, or the lack of any effort on it, by the Parties and users [shall][should] not be made a precondition for the implementation of benefit-sharing arrangements.]

9) Measures to ensure participation and involvement of indigenous and local communities in mutually agreed terms and sharing of benefits with traditional knowledge holders

[1. The elements of the International Regime on Access and Benefit-sharing [shall][should] be developed and implemented in accordance with Article 8(j) of the Convention:

(a) [In consultation with the relevant indigenous and local communities,] Parties [may][shall][should] consider developing, adopting and/or recognizing, as appropriate, **[customary laws,]** [community protocols **[and access and benefit-sharing [licences]]** and/or other] sui generis systems for the [protection][and/or promotion] of traditional knowledge, innovations and practices associated to [genetic resources][biological resources][, their derivatives][and products];

(b) Parties [shall][should] [respect,] recognize and protect the rights of indigenous and local communities to their knowledge, innovations and practices and ensure the equitable sharing of benefits arising from the utilization of the knowledge, innovations and practices associated with [genetic resources][biological resources][, their derivatives][and products] **[through respect for their [customary laws,] community protocols and the terms of access and benefit-sharing [licenses] under which [knowledge] and resources are made available]**, subject to the national legislation[, regulations and requirements] of the countries where these communities are located;

(c) [When access to traditional knowledge associated with [genetic resources][biological resources][, their derivatives][and products] is sought,] Users [shall][should] obtain the prior informed consent of indigenous and local communities holding [that] traditional knowledge associated with [genetic resources] in accordance with Article 8(j) of the Convention, [subject to][in accordance with] national legislation[, regulations and requirements] of the country where these communities are located[, **[customary laws,]** community protocols[, **the terms of access and benefit-sharing [licenses]]** and **[consistent with]** relevant international law].]

[2. Contracting Parties [shall][should] in accordance with Article 8(j) of the Convention [encourage][ensure] fair and equitable sharing of benefits arising from the utilization of knowledge, innovations and practices [associated with [genetic resources] of indigenous and local communities. The benefits referred to here are [benefits to humanity in general and] benefits to indigenous and local communities in particular:

(a) *Benefits to humanity:*

[All Contracting Parties [shall][should]:

(a) Promote the wider application of **traditional** knowledge **[associated to [genetic resources][biological resources][, their derivatives][and products]]**, innovations and practices of indigenous and local communities with their [voluntary] approval and involvement in accordance with Article 8(j) of the Convention [, **in a manner consistent with [customary laws,] community protocols, the terms of access and benefit-sharing [commons licences], and respectful of their rights]**;

(b) 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 Article 10(c) of the Convention;

(c) Take into account **[community protocols, customary laws,]** the customs, decision-making processes and systems integral to indigenous and local communities in the process of seeking access to their [genetic resources][biological resources][, their derivatives][and products] and/or associated traditional knowledge, and also in negotiating mutually agreed terms;]

(d) Encourage and develop methods of cooperation for the development and use of indigenous and traditional technologies in furtherance of the objectives of the Convention by the training of personnel and provision of expertise by representatives of indigenous and local communities in accordance with Article 18(4) of the Convention [**and take measures to promote compliance with the terms of access and benefit-sharing [licences] developed to [ensure] respect for the rights of indigenous [peoples] and local communities in the context of the International Regime on Access and Benefit-sharing.**]

[(b) Benefits to indigenous and local communities:

Contracting Parties [shall][should] [ensure][encourage] the fair and equitable sharing of benefits with indigenous and local communities arising from the utilization of their knowledge, innovations and practices[, and their [genetic resources][biological resources][, their derivatives][and products]. These benefits [shall][should] be based on mutually agreed terms with the indigenous and local communities and may include but not be limited to monetary and non-monetary benefits listed in Appendix II of the Bonn Guidelines.]]

[3. Indigenous peoples and local communities [shall][should] be consulted by the appropriate national authorities, and their views taken into consideration, when their rights are associated with the [genetic resources][biological resources][, their derivatives][and products] being accessed or where traditional knowledge associated with these [genetic resources][biological resources][, their derivatives][and products] 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, [shall][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[**[, customary laws,] community protocols, and access and benefit-sharing [licensing terms];**

(f) Documentation of traditional knowledge, innovations and practices, [shall][should] be subject to the prior informed consent of indigenous peoples and local communities[, **and be consistent with the [customary laws,] community protocols, and access and benefit-sharing [licensing terms] under which indigenous [peoples] and local communities participate in documentation of their [traditional knowledge, innovations and practices associated to [genetic resources][biological resources][, their derivatives][and products]]];**

(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 **[and selection of appropriate access and benefit-sharing [licensing] terms with respect to their [[traditional] knowledge [and resources], innovations and practices associated to [genetic resources][biological resources][, their derivatives][and products]].]**

[4. Contracting Parties which are countries of origin of [genetic resources][biological resources][, their derivatives][and products] or other Parties which have acquired the [genetic resources][biological resources][, their derivatives][and products] in accordance with the Convention, [shall][should]:

(a) Take measures to ensure appropriate participation by relevant indigenous peoples and local communities in access procedures where their rights are associated with the [genetic resources][biological resources][, their derivatives][and products] being accessed or where traditional knowledge associated with these [genetic resources][biological resources][, their derivatives][and products] is being accessed;

(b) Establish mechanisms to ensure that decisions are made available to relevant indigenous peoples and local communities and relevant stakeholders.]

[5. Parties shall provide timely guidance, legal representation, monitoring, information and assistance in prior informed consent and mutually agreed terms of traditional knowledge of indigenous and local communities at the request of indigenous and local communities seeking the recognition and/or enforcement of their rights.]

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

Parties [shall][should] encourage users and providers, in their mutually agreed terms [**and licensing provisions**], to consider directing benefits arising from the utilization of [genetic resources][biological resources][, their derivatives] [and products] towards the conservation and sustainable use of biological diversity in accordance with the objectives set out in Article 1 of the Convention, [and] to contribute to [domestic] sustainable [socio-economic] development [strategies]. [**Parties [shall][should][will] elaborate [and promote] the use of access and benefit-sharing [licenses] directed towards the pursuit of the realisation of the Millennium Development Goals following adoption of the International Regime on Access and Benefit-sharing.**]

11) Development of international minimum conditions and standards

[1. Parties [shall][should] 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 form of utilization of [genetic resources][biological resources][, their derivatives][and products] and/or associated traditional knowledge, upon mutually agreed terms.]

[2.5/ The definition of “fair and equitable benefit-sharing” is non-exhaustive and inclusive. It [shall][should] however encompass the following minimum conditions. Fair and equitable benefit-sharing [shall][should]:

(a) Contribute to strengthening the situation of the less powerful party/parties at all levels in the sharing relation, including by enabling:

- (i) Equal access to information;
- (ii) Effective participation by all relevant stakeholders;
- (iii) Capacity building;

^{5/} The placement of the paragraphs in this text must be further considered.

[(iv) Participation in international collaborative research networks;]

- (v) Preferential access to markets, new technology and products;
- (b) 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;
- (c) Not interfere with existing forms of fair and equitable benefit-sharing, including customary benefit-sharing mechanisms;
- (d) Respect value and legal systems across cultural borders, including customary laws[, **community protocols, and access and benefit-sharing [licences] of indigenous [peoples] and local communities**] and practices and indigenous intellectual property systems;
- (e) Allow democratic and meaningful participation in policy decisions and contract negotiation by all stakeholders, including stakeholders at the local level;
- (f) Be transparent enough that all parties understand the process equally well, especially indigenous and local communities, and have time and opportunity to make informed decisions (effective prior informed consent);
- (g) Include provisions for independent third party review to ensure that all transactions are on mutually agreed terms and preceded by effective prior informed consent;
- (h) Provide for identification of the origin of [genetic resources][biological resources][, their derivatives][and products] and/or associated traditional knowledge;
- (i) Make information about agreed terms publicly available.]

12) Benefit-sharing for every use

[There [shall][should] be measures and principles established in the International Regime on Access and Benefit-sharing to ensure benefit-sharing for every use of [genetic resources][biological resources][, their derivatives][and products].

13) Multilateral benefit-sharing options when origin is not clear or in transboundary situations

[1. [Genetic resources][biological resources] [, their derivatives][and products] accessed pre-Convention, [shall][should] be subject to access and benefit-sharing agreements with provider countries and all continuing benefits arising from these [genetic resources][biological resources][, their derivatives][and products] will be fairly and equitably shared with their countries of origin. In cases where the origin of the [genetic resources][biological resources][, their derivatives][and products] is unclear, a multilateral system of exchange [shall][should] be developed.]

[2. Contracting Parties who share [genetic resources][biological resources][, their derivatives][and products] [shall][should] enter into bilateral or multilateral agreements based on mutually agreed terms to ensure the fair and equitable sharing of benefits arising from the utilization of transboundary [genetic resources][biological resources][, their derivatives][and products].]

[3. Contracting Parties [shall][should] facilitate the inclusion of the different indigenous and local communities, within and across their boundaries that share a particular knowledge, innovation or practice in the negotiation of relevant access and benefit-sharing agreements and support the fair and

equitable sharing amongst these indigenous and local communities of the benefits arising from such agreements.]

14) Establishment of trust funds to address transboundary situations

[Knowledge, innovations and practices of indigenous and local communities accessed pre-Convention [shall][should] be subject to access and benefit-sharing agreements with the indigenous and local communities concerned and all continuing benefits arising from such knowledge, innovations and practices [shall][should] be fairly and equitably shared with the relevant indigenous and local communities. In cases where the origin of the knowledge, innovations and practices **associated to [genetic resources][biological resources][, their derivatives][and products]** are unclear, a fund [shall][should] be established which [shall][should] be administered by representatives of indigenous and local communities who [shall][should] ensure that it is used to further the rights of indigenous and local communities.]

15) Development of menus of model clauses for potential inclusion in material transfer agreements ^{6/}

[Option 1

Parties [shall][should][may][, in addition to [promoting][ensuring binding] compliance measures]:

- a) In consultation with users and providers from key sectors, develop sectoral menus of [model] clauses for contracts;
- b) Encourage users and providers to use these sectoral menus of [model] clauses when negotiating mutually agreed terms.]

[Option 2

[*Emphasizing* 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 utilizations 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[, in addition to [promoting][ensuring binding] compliance measures, [shall][should] [take measures to] encourage providers and users of [genetic resources][biological resources][, their derivatives][and products], when establishing mutually agreed terms, to consider:

(a) Including in these terms [model] clauses developed in accordance with paragraphs 2 and 3 below[, as appropriate];

(b) Relevant inventories/catalogues of typical utilizations of [genetic resources][biological resources][, their derivatives][and products] 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 [collectively][shall][should][consider to][may wish to][establish[, as appropriate,] a procedure] [at the national level] [for the] develop[ment] [menus] of [sectoral] [model] clauses [and inventories/catalogues] of typical utilizations of [genetic

^{6/} There are also sections on sectoral menus of model clauses in section III.C.2.1.b and in section III.E.1.5 of annex I to decision IX/12.

resources][biological resources][, their derivatives][and products] and related monetary or non-monetary benefits. [The procedure [shall][should][may]][In this context, they should]:

(a) Identify sectors[, *inter alia* those] for which [model] clauses and inventories/catalogues of typical utilizations of [genetic resources][biological resources][, their derivatives][and products] and related benefits should be developed [in cooperation with key international sectoral organizations and relevant users and providers] [and reflect best practices];

(b) Identify issues that [should][may] be addressed in [model] clauses [taking account of common elements of various sectors and the particularity of each sector];

(c) Include clear and transparent [rules][suggestions] to facilitate the involvement of stakeholders.

3. The Parties [shall][should][may] [collectively] consider and, where appropriate, [adopt [at the national level] recommendations for][submit a compilation to the clearing house mechanism of menus of] [model] clauses [and inventories/catalogues] of typical uses of [genetic resources][biological resources][, their derivatives][and products]. They [shall][should][may] regularly review and, where appropriate, update such [model] clauses [and inventories/catalogues] of typical uses of [genetic resources][biological resources] [, their derivatives][and products].]

4. Parties [shall][should] take measures to encourage the use of the [model] clauses of Annex {...} of the International Regime on Access and Benefit-sharing to be included into mutually agreed terms between providers and users of [genetic resources][biological resources][, their derivatives][and products] and/or associated traditional knowledge for the following three categories of utilization of [genetic resources][biological resources][, their derivatives][and products]:

- (a) Research not aiming at commercialization;
- (b) Research and development aiming at commercialization; and
- (c) Commercialization.]

5. Indicators for the identification of these three categories of utilization of [genetic resources][biological resources][, their derivatives][and products] are provided in Annex {...} of the International Regime on Access and Benefit-sharing.]

16) Enhanced utilization of the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of Their Utilization

[Recalling decision VI/24 of the Conference of the Parties adopting the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of Their Utilization {*preambular paragraph*}]

B. ACCESS TO GENETIC RESOURCES ^{7/}

1) Recognition of the sovereign rights and the authority of Parties to determine access

[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*}]

^{7/} The title is without prejudice to the eventual scope of the International Regime on Access and Benefit-sharing.

[*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 *recognizing* 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 of the Convention on Biological Diversity {*preambular paragraph*}]

[*Stressing the importance of facilitating access to genetic resources in emergency situations when public health, food security or the biological diversity are seriously threatened* {*preambular paragraph*}]

[*Reaffirming the sovereign rights of the States over their own natural resources and according to the provisions of the Convention on Biological Diversity and our commitment to meet its three objectives, and in particular Articles 8(j), 15, 16, 19, 20 and 21* {*preambular paragraph*}]

[*Reaffirming that the authority to determine access to genetic resources rests with national governments and is subject to national legislation* {*preambular paragraph*}]

[1. Contracting Parties have sovereign rights over their natural resources and the authority to determine access to [genetic resources][biological resources][, their derivatives][and products] **[and associated traditional knowledge]** rests with the national governments **and is subject to national legislation.** [Where access to [genetic resources][biological resources][, their derivatives][and products] has an impact on the knowledge, innovations and practices of indigenous and local communities [embodying traditional lifestyles], the indigenous and local communities concerned [shall][should] have a say in determining access[, subject to national legislation].]

Option 1

[2. Access to [genetic resources][biological resources][, their derivatives][and products] and/or associated traditional knowledge [shall][should] be subject to the free prior informed consent of indigenous and local communities.][Access to the genetic resources and associated traditional knowledge of indigenous and local communities [shall][should] be subject to their prior informed consent.]

Option 2

[2. a) Access to traditional knowledge, innovations and practices of indigenous and local communities associated to [genetic resources][biological resources][, their derivatives][and products] [shall][should] be subject to the [prior informed consent][approval and involvement] of these communities, through their representatives where applicable, and subject to national legislation.

b) Where applicable, access to [genetic resources][biological resources][, their derivatives][and products] owned by indigenous and local communities [shall][should] be subject to the [prior informed consent][approval and involvement] of these communities, subject to national legislation.]

[3. Each Party [shall][should] introduce rules to ensure facilitated access to genetic resources.]

[4. Each Party [shall][should] designate one national focal point for access and benefit-sharing which [shall][should] be responsible on its behalf for liaison with the Secretariat. The national

focal point [shall][should] inform applicants for access to [genetic resources][biological resources][, their derivatives][and products] on applicable procedures, including procedures for prior informed consent, mutually agreed terms and benefit-sharing. [It [shall][should] also [inform applicants of [any][the] rights][make available, as appropriate, information] pertaining to indigenous peoples and local communities and relevant stakeholders.]]

[5. Each Party [requiring prior informed consent for access to its [genetic resources][biological resources][, their derivatives][and products]] [shall][should] also, as appropriate, designate one or more competent national authorities, which [shall][should] be responsible for handling and processing of access applications, including mutually agreed terms and benefit-sharing arrangements. [A Party [may][shall][should] designate a single entity to perform the functions of both Focal Point and competent national authority.]]

[6. Each Party [shall][should] no later than the [effective] date [of entry into force] of this International Regime on Access and Benefit-sharing [for it], notify the Secretariat of the names and addresses of the focal point and competent [national] authority or authorities.] ^{8/} _{9/}

[7. Access to [genetic resources][biological resources][, their derivatives][and products] [shall][should] be undertaken only when prior informed consent, as determined by national legislation, has been granted.]

[8. Each Party [shall][should] take the necessary legislative, administrative or policy measure[, as appropriate,] [to ensure that any application for obtaining prior informed consent [shall][should] contain, at a minimum,] the following information:

[(a) Legal entity and affiliation of the applicant and/or collector and contact person when the applicant is an institution;]

[(b) Type and quantity of [genetic resources][biological resources][, their derivatives][and products] to which access is sought;]

[(c) Starting date and duration of the activity;]

[(d) Geographical prospecting area;]

[(e) Evaluation of how the access activity may impact on conservation and sustainable use of biodiversity, to determine the relative costs and benefits of granting access;]

[(f) Accurate information regarding intended use (e.g.: taxonomy, collection, research, commercialization);]

[(g) Identification of where the research and development will take place;]

[(h) Information on how the research and development is to be carried out;]

[(i) Identification of local bodies for collaboration in research and development;]

[(j) Possible third party involvement;]

^{8/} The placement of paragraphs 4 to 6 above must be further considered.

_{9/} There is also a section on competent domestic authority, as addressed in paragraphs 4 to 6 above, in section III.C.1.2.b of annex I to decision IX/12.

[(k) Purpose of the collection, research and expected results;]

[(l) Kinds/types of benefits that could come from obtaining access to the [genetic resources][biological resources][, their derivatives][and products], arising from the commercial and other utilization of the [genetic resources][biological resources][, their derivatives][and products];]

[(m) Indication of benefit-sharing arrangements;]

[(n) Budget;]

[(o) Treatment of confidential information.]

[(p) Identification of bodies from the Party that is the [country of origin][provider country] of the [genetic resources][biological resources][, their derivatives][and products] [and/or associated traditional knowledge] that will [fully] participate in the scientific research and development based on such [genetic resources][biological resources][, their derivatives][and products] [and/or associated traditional knowledge];]

[(q) Information on the modalities for access to the results of such research and development];

[(r) Information on the modalities for access to and transfer of any technology making use of such [genetic resources][biological resources][, their derivatives][and products] [and/or associated traditional knowledge], on mutually agreed terms.]]

[9. [Each Party requiring prior][Prior] informed consent for access to [its] [genetic resources][biological resources][, their derivatives][and products] may [at any time] [be] confirm[ed] in writing to the Secretariat [details of [whether and how] its domestic access and benefit-sharing framework [is in conformity with the international standards set out in {...}]]. The Secretariat [shall][should] register any such communication in the CBD clearing house mechanism.]

[10. [Without prejudice to the obligations imposed by the International Regime on Access and Benefit-Sharing, particularly with respect to prior informed consent, mutually agreed terms and benefit-sharing,] [Parties requiring prior informed consent] for access to their [genetic resources][biological resources][, their derivatives][and products] [shall][should] provide for accelerated access procedures in emergency situations when public health, food security or the biological diversity are seriously threatened.]

2) Linkage of access to fair and equitable sharing of benefits ^{10/}

[Recognizing that the fair and equitable sharing of benefits can only be realized 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}]

^{10/} There is also a section on the linkage of access to fair and equitable sharing of benefits under section III.A.1.1 of annex I to decision IX/12.

[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 [shall][should][may] take [the] necessary measures [, as appropriate,] to establish an appropriate national regulatory framework to protect their rights over [genetic resources][biological resources][, their derivatives][and products] [and/or associated traditional knowledge][, as well as rights of indigenous peoples and local communities] and ensure [that] benefit-sharing [is on mutually agreed terms].]

2. [Parties [requiring prior informed consent for access to their [genetic resources][biological resources][, their derivatives][and products]] [shall][should] take measures to [encourage][ensure] [providers][countries of origin or Parties that have acquired the resources in accordance with the Convention] and users to provide in their mutually agreed terms [, as appropriate,] for the fair and equitable sharing of benefits arising from the utilization of [genetic resources][biological resources][, their derivatives][and products][.], whilst recognizing that the fair and equitable sharing of benefits can only be realized after access to [genetic resources][biological resources][, their derivatives][and products] has been granted.][Contracting Parties [shall][should] ensure that access to [genetic resources][biological resources][, their derivatives][and products] [shall][should] be subject to the prior informed consent of the country of origin/provider country[.] and be based on mutually agreed terms with fair and equitable sharing of benefits arising from the utilization of the [genetic resources][biological resources][, their derivatives][and products].] Where the access to the [genetic resources][biological resources][, their derivatives][and products] is linked to the use of any knowledge, innovations and practices of indigenous and local communities, it [shall][should] [where necessary] be subject to the prior informed consent and mutually agreed terms of the concerned indigenous and local communities with fair and equitable sharing of benefits [in accordance with national legislation].]

3. [Contracting Parties may provide that] New uses of [genetic resources][biological resources][, their derivatives][and products] [they have provided] [and/or associated traditional knowledge] beyond the scope what has been consented to under [prior informed consent and] mutually agreed terms [shall][should] [require new prior informed consent and mutually agreed terms[.]] from the country of origin and/or the indigenous and local communities][may be addressed under such mutually agreed terms].]

[4. Access to [genetic resources][biological resources][, their derivatives][and products] [and associated traditional knowledge] [may][shall][should] be revoked by the country of origin/provider country [or the indigenous and local communities providing access to [genetic resources][biological resources][, their derivatives][and products] and associated traditional knowledge] if any of the mutually agreed terms are violated by the user and/or the continuing use of the [genetic resources][biological resources][, their derivatives][and products] has negative environmental implications.]

5. [Parties [shall][should] 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 [genetic resources][biological resources][, their derivatives][and products], so as] to ensure fair and equitable sharing of benefits arising from such use to the country providing the resource [takes place on mutually agreed terms] [including by using certificates of compliance with national legislation].][Contracting Parties which are countries of origin of [genetic resources][biological resources][, their derivatives][and products], or other Parties which have acquired the [genetic resources][biological resources][, their derivatives][and products] in accordance with the Convention, [shall][should] endeavour to [facilitate] access to [genetic resources][biological resources][, their derivatives][and products] for environmentally sound uses by other Contracting Parties. In accordance with Article 15, paragraph 5, of the Convention, access to genetic resources shall be subject to prior

informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.]

3) Legal certainty, clarity and transparency of access rules

[1. To create conditions to [facilitate][ensure the sovereign rights of States of their natural resources and their authority to determine] access to [genetic resources][biological resources][, their derivatives][and products] and to support compliance with access and benefit-sharing related obligations across jurisdictions, Parties requiring prior informed consent [shall][should] take [the] necessary legislative, policy or administrative measures [referred to in {...}] to provide for legal certainty, clarity and transparency of their domestic access and benefit-sharing frameworks.]

[2. Contracting Parties [shall][should] create conditions of legal certainty, clarity and transparency to [facilitate][ensure the sovereign rights of States over their natural resources and their authority to determine] access to [genetic resources][biological resources][, their derivatives][and products] and not impose any restrictions that run counter to objectives of the Convention in accordance with Article 1 of the Convention. [Access [may][shall][should] however be denied if it is required for uses that are not environmentally sound. Countries of origin [shall][should] have the authority to determine the environmental soundness of a particular use. [The notion of 'use' [shall][should] be understood as including restrictions to use by third parties and countries of origin [shall][should] have the authority to determine whether the restriction of the use of [genetic resources][biological resources][, their derivatives][and products] 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 which are countries of origin of [genetic resources][biological resources][, their derivatives][and products], or other Parties which have acquired the [genetic resources][biological resources][, their derivatives][and products] in accordance with the Convention, [shall][should]:

(a) [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;]

(b) [Report on access applications through the clearing-house mechanism][Provide information on the process for obtaining access in accordance with national legislation and regulations];

(c) [Require providers only to supply [genetic resources][biological resources][, their derivatives][and products] and/or associated traditional knowledge when they are entitled to do so;]

(d) The Contracting Parties [shall][should][may] 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.]

4) Non-discrimination of access rules

[Each Party, when applying its domestic access and benefit-sharing framework, [shall][should] not [arbitrarily and unjustifiably] discriminate between users from other Contracting Parties [and between national and foreign users][, save when it is in its national interest to do so in accordance with its sovereign right over its resources which gives it authority to determine access compatible with the recognition of this right in Article 15(1) of the Convention].]

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

[*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*}]

[*Recognizing* 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 of the Convention on Biological Diversity {*preambular paragraph*}]

[*Further recognizing* that the fair and equitable sharing of benefits can only be realized after access to genetic resources has been granted {*preambular paragraph*}]

1. To create conditions to [facilitate][ensure the sovereign rights of States over their natural resources and their authority to determine] access to [genetic resources][biological resources][, their derivatives][and products] and to support compliance with access and benefit-sharing related obligations across jurisdictions, Parties requiring prior informed consent [shall][should] take [such][the] [necessary] legislative, policy or administrative measures[, as they may determine,] to provide for legal certainty, clarity and transparency of their domestic access and benefit-sharing frameworks. These [shall][should][may] include[, where possible]:]

(*General issues*)

[(a) [Clear] rules on accessing [genetic resources][biological resources][, their derivatives][and products] existing in in situ and ex situ conditions [that do not [arbitrarily and unjustifiably] discriminate between users from other Contracting Parties] [and between national and foreign users][, save when it is in its national interest to do so in accordance with its sovereign right over its resources which gives it authority to determine access compatible with the recognition of this right in Article 15(1) of the Convention];]

[(b) A [clear] procedure for applying for prior informed consent [from a competent national authority and, where applicable, from indigenous and local communities];]

[(c) A simplified procedure for access to [genetic resources][biological resources][, their derivatives][and products] for non-commercial research in accordance with [/{...}][national law];]

[(d) Making available and easily accessible information on their domestic access and benefit-sharing frameworks, in particular on how to apply for prior informed consent;]

[(e) Providing and regularly updating the information generated under subparagraph (d) to the clearing house mechanism of the Convention, including information on access and benefit-sharing focal points;]

[(f) Requiring the competent national authority to [provide periodically to][register its decision to grant prior informed consent in] the clearing house mechanism of the Convention [up to date information on the number of requests processed];]

[(g) [Appropriate] administrative or judicial appeals procedures in respect of prior informed consent[, including for failure to act and [arbitrary and unjustifiably] discriminatory access practices];]

(Specific aspects for obtaining decisions on prior informed consent from the competent [national] authority)

[(h) Requiring that decisions by competent national authorities granting or refusing prior informed consent are reasoned, set out in writing, and notified to the applicant;]

[(i) Identifying in the domestic access and benefit-sharing framework the grounds upon which prior informed consent may be denied;]

[(j) Requiring competent national authorities to take decisions on prior informed consent within a reasonable period of time as specified in the domestic access and benefit-sharing 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 national authority to include in its decision to grant prior informed consent available passport data as well as a reference code of the [genetic resources][biological resources][, their derivatives][and products] covered by this decision;]

(Specific aspects related to mutually agreed terms (normally set out in contracts))

[(m) [Clear] rules, in domestic access and benefit-sharing frameworks, for establishing mutually agreed terms;]

[(n) Requiring the establishment of mutually agreed terms;]

[(o) Requiring that mutually agreed terms be set out in writing;]

[(p) Requiring that mutually agreed terms include a clause on the settlement of disputes;]

[(q) Requiring that mutually agreed terms reflect that consideration has been given to benefit-sharing;]

[(r) Reference to the [model] clauses and inventories/catalogues of utilizations of [genetic resources][biological resources][, their derivatives][and products] and related benefits developed in accordance with {...}.]

[2. The additional measures set out in {...} to support compliance in cases of misappropriation will [have no relationship whatsoever with][be applicable if] the domestic access and benefit-sharing framework of a Contracting Party providing a genetic resource [is in conformity with paragraph 1].]

6) Internationally developed model domestic legislation

[Recalling that Article 15(1) of the Convention provides that states have sovereign rights over their resources, and that the authority to determine access to genetic resources rests with the national governments and is subject to national legislation {*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*}]

[Noting that Parties have differing legal systems, and accordingly have chosen to implement the access and benefit-sharing provisions of the Convention according to their national conditions {*preambular paragraph*}]

1. Parties [are encouraged to][shall][should] provide examples of [model] provisions for domestic legislation to the Secretariat, and the Secretariat to provide these to [P][p]arties on request, in order to assist and support those [P][p]arties in their domestic implementation of the access and benefit-sharing provisions of the Convention.

[2. The Parties [collectively] [shall][should][, as soon as practicable,] [adopt][compile] 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 {...}][and distribute them through the clearing house mechanism].]

[3. If a Party has implemented in its national framework the user measures to monitor compliance referred to in {...} of the International Regime on Access and Benefit-sharing, a [provider country][country of origin] may decide, in the exercise of its sovereign rights and at the national level, to make available to applicants from that Party, the subsidiary access procedure set out in {...}.]

7) Minimization of administration and transaction costs

8) Simplified access rules for non-commercial research

Option 1

[1. Parties requiring prior informed consent [shall][should] provide for a simplified administrative procedure for access to [genetic resources][biological resources][, their derivatives][and products] for non-commercial research.]

[2. The classification of research as “non-commercial” [may][shall][should] 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 [shall][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 resources][biological resources][, their derivatives][and products] in cases of changes in intent by non-commercial users where appropriate;

(d) Avoiding that users of [genetic resources][biological resources][, their derivatives][and products] without obligations vis-à-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][biological resources][, their derivatives][and products] to access and benefit-sharing best practice codes of conduct applicable to the research community.]

[4. Parties [shall][should] take measures to encourage providers and users of [genetic resources][biological resources][, their derivatives][and products], when establishing mutually agreed terms, to consider including in these terms [model] clauses [and relevant inventories/catalogues of typical utilizations of [genetic resources][biological resources][, their derivatives][and products] developed in accordance with {...}.]

5. Parties [shall][should] collaborate in the exchange of experience in the use of and the development of electronic tools for the tracking of [genetic resources][biological resources][, their derivatives][and products].

6. Parties [shall][should] exchange information on best practices[, as appropriate,] in the application of simplified administrative procedures for access [and benefit-sharing] to [genetic resources][biological resources][, their derivatives][and products] for non-commercial research.

Option 2

Contracting Parties which are countries of origin of [genetic resources][biological resources][, their derivatives][and products], or other Parties which have acquired the [genetic resources][biological resources][, their derivatives][and products] in accordance with the Convention, [shall][should]:

(a) Consider simplified access rules [to][for] [genetic resources][biological resources][, their derivatives][and products] to be used for taxonomy [and other non-commercial] purposes;

(b) [Require that [substantially] new or changed uses of a [genetic resource][biological resource] beyond [the scope of] what has been consented to under mutually agreed terms, [shall][should] be subject to new prior informed consent and mutually agreed terms from the providing country and/or the indigenous peoples and local communities concerned.][Parties shall encourage users and providers to consider, when establishing mutually agreed terms, including in these terms obligations to renegotiate mutually agreed terms should the use of the genetic resources change.]

C. COMPLIANCE

1) Development of tools to encourage compliance

(a) Awareness-raising activities

[Noting that awareness of domestic access and benefit-sharing regulatory frameworks is important for users and providers to ensure compliance {*preambular paragraph*}]

1. Parties [shall][should] take [the following] measures to raise awareness of access and benefit-sharing issues [in support of [mandatory][voluntary] compliance measures to [ensure][promote] benefit-sharing]. Such measures could include[, but not be limited to]:

(a) Making available up to date information about their domestic access and benefit-sharing framework, in particular national laws, policies and procedures;

(b) Steps to promote the International Regime on Access and Benefit-sharing[, including the promotion of a wider understanding among the public on the concepts of misappropriation, misuse and biopiracy, as well as for the recognition of the contribution made by indigenous and local communities to biological diversity and the benefits generated by that contribution];

- (c) Organization of stakeholder meetings;
- (d) Establishment and maintenance of a help desk for stakeholders;
- (e) Information dissemination through [a specialized website][an Access and Benefit-sharing Clearing House][, as well as hard copies];
- (f) Promotion of codes of conduct [and best practice tools] in consultation with stakeholders;
- (g) Promotion of regional exchange of experiences related to access and benefit-sharing;
- [(h) Establishment of an online system through which [providers] [countries of origin or Parties that have acquired the resources in accordance with the Convention] and users can register to generate, use, and display access and benefit-sharing licenses for [genetic resources][biological resources][, their derivatives][and products] and [associated] traditional knowledge falling within the scope of the International Regime on Access and Benefit-sharing;]**
- [(i) Development of publicly visible symbols for [genetic resources][biological resources][, their derivatives][and products] and traditional knowledge covered under access and benefit-sharing licenses for display in electronic and other formats;]**
- [(j) Awareness-raising among indigenous and local communities, the non-commercial research sector, research groups aiming at commercialisation and research and development funding agencies on the development, the availability, the use and the terms and conditions of access and benefit-sharing licenses;]**
- [(k) Awareness raising about the possibility of product labelling for certifying access and benefit-sharing compliance;]**
- [(l) Establishment of an online register of collaborative research networks and scientific publications using access and benefit-sharing licenses].**

[2. Parties [shall][should] raise awareness in accordance with Articles 8(j) and 10(c) of the Convention to promote the wider application of indigenous knowledge, innovations and practices by actively involving indigenous and local communities with their consent in the planning and implementation of research and training (Article 12), public education and awareness (Article 13), exchange of information (Article 17.2) and technical and scientific cooperation (Article 18.4).]

(b) International understanding of misappropriation/misuse¹¹

Option 1

[1. Misappropriating genetic resources means to acquire, either intentionally or negligently, genetic resources in violation of applicable domestic legislation of a Party that requires prior informed consent and mutually agreed terms for access to its genetic resources.]

[2. Each Party [shall][should]:

¹¹ Further submissions may be made relating to a definition of misappropriation including on the need for such a definition.

(a) Require natural or legal persons who use [genetic resources][biological resources][, their derivatives][and products] [and/or associated traditional knowledge] on its [territory] [jurisdiction] to take, [to the best of their ability], appropriate actions to prevent the acquisition or utilisation of misappropriated [genetic resources][biological resources][, their derivatives][and products] [and/or associated traditional knowledge]; and

(b) Provide for measures where users fail to apply such actions.]

[3. Each Party [shall][should] [, *inter alia*,] apply [legal, administrative and policy] measures [as well as customary laws, community level procedures and/or community protocols of indigenous and local communities] [, including [disclosure requirements] as specified in {...},] to [prevent [and address] the misappropriation of [genetic resources][biological resources][, their derivatives][and products] [and/or associated traditional knowledge] to]:

a) Natural or legal persons [having the nationality [of]] [or a permanent place of business in] [within the jurisdiction of] that Party, who misappropriated a [genetic resource][biological resource][, its derivatives][and products] [in the jurisdiction of another Party] [in violation of the International Regime on Access and Benefit-sharing, laws and/or administrative measures of [the country of origin or the country that has acquired the genetic resource in accordance with the Convention] [the country providing genetic resources [within the meaning of the Convention]] [a third party which is of the country of origin];

(b) Natural or legal persons who, [on its territory] [within its jurisdiction], [acquire] [access] or use a [genetic resource][biological resource][, its derivatives][and products] [knowing] that [it] has been misappropriated [in the jurisdiction of another Party] [in violation of the International Regime on Access and Benefit-sharing, laws and/or administrative measures of [the country of origin or the country that has acquired the genetic resources in accordance with the Convention] [the country providing genetic resources [within the meaning of the Convention]]];

[(c) Natural or legal persons who, on its territory, [acquire][access] or use a [genetic resource][biological resource][, its derivatives][and products] and who should have known, based on available information, that the [genetic resource][biological resource][, its derivatives][and products] has been misappropriated [in the jurisdiction of another Party] [in violation of the International Regime on Access Benefit-sharing, laws and/or administrative measures of [the country of origin or the country that has acquired the genetic resource in accordance with the Convention] [the country providing genetic resources [within the meaning of the Convention]]].]

[Parties may refrain from taking such measures if the domestic access and benefit sharing framework of another Party providing a misappropriated [genetic resource][biological resource][, its derivatives][and products], at the time of misappropriation, [was] [deemed by the Parties to be] not in conformity with [the international standards set out in { ... }] [the access provisions set out in the International Regime on Access Benefit-sharing]]

[4. Measures taken by Parties in accordance with paragraphs 2 and 3 [shall][should] provide for remedies and effective[, proportionate and dissuasive] sanctions.]

[5. Each Party [shall][should] cooperate with other Parties' inquiries into possible instances of misappropriation of [genetic resources][biological resources][, their derivatives][and products].]¹²

Option 2

Alternative A

[Misappropriation of genetic resources refers to access to genetic resources without prior informed consent and/or mutually agreed terms pursuant to the national access legislation of the country providing the genetic resources and the access provisions set out in the International Regime on Access and Benefit-sharing in force at the time of access.]¹³

Alternative B

[For the purposes of the International Regime on Access and Benefit-sharing, it constitutes an act of misappropriation/unauthorized access to:

i) access and/or use genetic resources and/or associated traditional knowledge without obtaining the relevant indigenous peoples or local community's free prior and informed consent, or

ii) access and/or use genetic resources and/or associated traditional knowledge when found ex situ, and/or the traditional knowledge already in the public domain, and when no free prior and informed consent requirements apply, without providing fair and equitable benefit sharing with the relevant indigenous people or local community.]¹⁴

Option 3

[Each Contracting Party [shall][should] take measures aimed at preventing the use of misappropriated [genetic resources][biological resources][, their derivatives][and products] and traditional knowledge.]

(c) Sectoral menus of model clauses for material transfer agreements ^{15/}

[Option 1

Parties [shall][should][may][,in addition to [promoting][ensuring binding] compliance measures]:

¹² Paragraph 1 of Option 1 was proposed as an integral part of a proposal for an operational provision and the proposer did not intend it as a definition. Other delegations were of the view that paragraph 1 constitutes a definition. Discussion of paragraph 1 was left in abeyance both as regards content and placement and will occur at the next meeting of the Working Group.

¹³ Discussion of this paragraph was left in abeyance both as regards content and placement and will occur at the next meeting of the Working Group. It is the intention of the proposer that this paragraph is an alternative to Option 1, paragraph 1.

¹⁴ Discussion of this paragraph was left in abeyance both as regards content and placement and will occur at the next meeting of the Working Group. It is the intention of the proposer that this paragraph is an addition to Option 1, paragraph 1.

^{15/} There are also sections on sectoral menus of model clauses in section III.A.2.5 and in section III.E.1.5 of annex I to decision IX/12.

a) In consultation with users and providers from key sectors, develop sectoral menus of [model] clauses for contracts [**and licensing terms**];

b) Encourage users and providers to use these sectoral menus of [model] clauses when negotiating mutually agreed terms [**and licensing terms**].]

[Option 2

[Emphasizing 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 utilizations 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[, in addition to [promoting][ensuring binding] compliance measures,][shall][should] [take measures to] encourage providers and users of [genetic resources][biological resources][, their derivatives][and products], when establishing mutually agreed terms, to consider:

(a) Including in these terms [model] clauses [**and licensing terms**] developed in accordance with paragraphs 2 and 3 below[, as appropriate];

(b) Relevant inventories/catalogues of typical utilizations of [genetic resources][biological resources][, their derivatives][and products] 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 [collectively][shall][should][consider to][may wish to][establish[, as appropriate,] a procedure] [at the national level] [for the] develop[ment] [menus] of [sectoral] [model] clauses [**and licensing terms**] [and inventories/catalogues] of typical utilizations of [genetic resources][biological resources][, their derivatives][and products] and related monetary or non-monetary benefits. [The procedure [shall][should][may]][In this context, they should]:

[(a) Identify sectors[, *inter alia* those] for which [model] clauses[, **licensing terms**] and inventories/catalogues of typical utilizations of [genetic resources][biological resources][, their derivatives][and products] and related benefits should be developed [in cooperation with key international sectoral organizations and relevant users and providers] [and reflect best practices]];

(b) Identify issues that [should][may] be addressed in [model] clauses [**and licensing terms**] [taking account of common elements of various sectors and the particularity of each sector];

(c) Include clear and transparent [rules][suggestions] to facilitate the involvement of stakeholders.

3. The Parties [shall][should][may] [collectively] consider and, where appropriate, [adopt [at the national level] recommendations for][submit a compilation to the clearing house mechanism of menus of] [model] clauses [**and licensing terms**] [and inventories/catalogues] of typical uses of [genetic resources][biological resources][, their derivatives][and products]. They [shall][should][may] regularly review and, where appropriate, update such [model] clauses [**and licensing terms**] [and inventories/catalogues] of typical uses of [genetic resources][biological resources] [, their derivatives][and products].]

[4. Parties [shall][should] take measures to encourage the use of the [model] clauses [**and licensing terms**] of Annex {...} of the International Regime on Access and Benefit-sharing to be included into mutually agreed terms between providers and users of [genetic resources][biological resources][,

their derivatives][and products] and/or associated traditional knowledge for the following three categories of utilization of [genetic resources][biological resources][, their derivatives][and products]:

- (a) Research not aiming at commercialization;
- (b) Research and development aiming at commercialization; and
- (c) Commercialization.]

[5. Indicators for the identification of these three categories of utilization of [genetic resources][biological resources][, their derivatives][and products] **will be developed using standardized classification schemes including, inter alia: the International Patent Classification, the United Nations International Standard Industrial Classification of All Economic Activities, the Nomenclature of Territorial Units for Statistics and their regional and national equivalents. Details of indicators**] are provided in Annex {...} of the International Regime on Access and Benefit-sharing.]]

(d) Codes of conduct for important groups of users

[*Recognizing* 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 fair and equitable sharing of benefits arising out of the utilization of genetic resources, the third objective of the Convention {*preambular paragraph*}]

Parties [shall][should][may][, in addition to [promoting][ensuring binding] compliance measures]:

(a) Support, as appropriate, the development, review and update of access and benefit-sharing-related [voluntary] codes of conduct[, and best practice standards,] for users of [genetic resources][biological resources][, their derivatives][and products];

(b) Take measures to [encourage][ensure] users [to] adhere to the codes of conduct [and encourage users to adhere to best practice standards;]

[(c) Ensure the communication, education and awareness of these codes of conduct and best practice standards to the relevant user groups].

(e) Identification of best-practice codes of conduct

[*Recognizing* 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*}]

Parties [shall][should] collectively establish a procedure for identifying and regularly reviewing access and benefit-sharing related codes of conduct and guidelines that constitute best-practice.

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

Parties [shall][should] [encourage] [**research funding agencies to seek to**] [ensure that] [research, funding and publishing entities] [**recipients of funding for research related to [genetic resources][biological resources][, their derivatives][and products] and/or associated traditional knowledge**] [to] [ask for [the unique identifier code referred to in the certificate of compliance] [evidence of compliance with relevant national law] as part of their application procedures or research results, as appropriate, when [genetic resources][biological resources][, their derivatives][and products] and

associated traditional knowledge [is][are] involved] **[act in accordance with the [domestic access and benefit-sharing legislation of Parties providing access] [International Regime on Access Benefit-sharing, laws and/or administrative measures] [and customary laws, community level procedures and/or community protocols of indigenous and local communities]]**

(g) Unilateral declaration by users

[Parties may provide users seeking access to [genetic resources][biological resources][, their derivatives][and products] and associated traditional knowledge with the opportunity to signal advanced acceptance of the terms of a non-exclusive non-commercial access and benefit-sharing licence.]

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

[The additional measures set out in {...} to support compliance in cases of misappropriation [shall][should] be applicable if the domestic access and benefit-sharing framework of a Contracting Party providing a genetic resource is in conformity with {...}.]

2) Development of tools to monitor compliance

[Each Contracting Party [shall][should] take [appropriate legislative, [regulatory,] administrative or policy] measures [aimed at building capacity to develop tools to monitor compliance;]]

(a) Mechanisms for information exchange

1. [Parties [shall][should] collaborate to facilitate information exchange on access and benefit-sharing between Parties, providers and users of [genetic resources][biological resources][, their derivatives][and products] and, where appropriate, between national access and benefit-sharing focal points, including through:][[Parties [shall][should] use] [An Access and Benefit-sharing Clearing-House is hereby established as part of] the clearing-house mechanism [pursuant to] [under] Article 18, paragraph 3, of the Convention, [as well as other means agreed by Parties, including non-internet means,] in order to:]

[(a) [Monitor][Support] compliance with national access and benefit-sharing legislation[, regulation][or community protocols] and with this International Regime on Access and Benefit-sharing [through the exchange of information];]

(b) Facilitate the [equitable] exchange of scientific, technical, environmental and legal information on, and experience with, access and benefit-sharing[, and on best practices in the application of simplified administrative procedures for access to [genetic resources][biological resources][, their derivatives][and products] for non-commercial research] **[including experience in the use of access and benefit-sharing licenses];**

[(c) Facilitate adequate funding and capacity building for effective participation in the Access and Benefit-sharing Clearing House Mechanism, taking into account the special needs of developing country Parties, in particular the least developed among them and small island developing States, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity;]

(d) Assist Parties to implement this International Regime on Access and Benefit-sharing, taking into account the special needs of developing country Parties, in particular the least developed and small island developing States among them, and countries with economies in transition as well as

countries that are centres of origin and centres of genetic diversity[, through the provision of information as set out in paragraph 3 below];

[(e) Support potential users of genetic resources in accessing relevant information].

[2. The [Access and Benefit-sharing] Clearing-House [shall][should] serve as a means through which information is made available for the purposes of paragraph 1 above. It [shall][should] provide access to information made available by the Parties relevant to the implementation of [domestic access and benefit-sharing frameworks and] this International Regime on Access and Benefit-sharing.]

3. Without prejudice to the protection of confidential information, each Party [shall][should] make available to the [Access and Benefit-sharing] Clearing-House[, as appropriate,] [any information required to be made available to the Access and Benefit-sharing Clearing-House under this International Regime on Access and Benefit-sharing,] and:

(a) [Any existing laws, regulations and guidelines for][Mode of] implementation of this International Regime on Access and Benefit-sharing;

[(b) [Relevant] **Customary law**[,] [and] community protocols [**and access and benefit-sharing licenses**] [**of indigenous and local communities**];]

(c) Any bilateral, regional and multilateral agreements and arrangements [related to access and benefit-sharing];

(d) Information about national focal point and competent national authority(ies);

[(e) List of defaulters of access and benefit-sharing agreements (“name and shame”);]

[(f) Information on [model] domestic access and benefit-sharing legislation and [menus of] model clauses [**and licensing terms**] for contracts;]

[(g) Experience in the development of electronic tools for the tracking of genetic resources;]

[(h) Codes of conduct and best practices in access and benefit-sharing].

[4. The [Access and Benefit-sharing] Clearing House [shall][should] include[, if appropriate,] an international [registration][and inquiry point][database of examples] of certificates of compliance with national legislation[, [community protocols and relevant customary laws] [**customary laws, community protocols [and licenses]**] of indigenous peoples and local communities] and requirements on access and benefit-sharing, issued by the competent national authority(ies), in accordance with provisions in {...}.]

[5. The modalities of the operation of the [Access and Benefit-sharing] Clearing-House, including reports on its activities, [shall][should] be considered and decided upon by the Governing Body of the International Regime on Access and Benefit-sharing at its [first][next] meeting, and kept under review thereafter.]

[6. In facilitating information exchange, Parties [shall][should] ensure that confidential information is fully protected according to national laws consistent with international agreements.]

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

[Recognizing the importance of providing legal certainty to the various stakeholders involved in the conservation, sustainable use and the fair and equitable sharing of benefits derived from the use of genetic resources, their derivatives and associated traditional knowledge {preambular paragraph}]

1. Each Party [shall][should] designate one national focal point for access and benefit-sharing [and make [any] information relevant to access and benefit-sharing available through the clearing-house mechanism][, as appropriate]. The national focal point [shall][should] [provide][make available] information [to the [access and benefit-sharing] clearing-house mechanism] [as well as other means agreed by Parties, including non-internet means] on procedures for acquiring prior informed consent and mutually agreed terms, including benefit-sharing, and on competent national authorities[, relevant indigenous and/or local communities and relevant stakeholders].

2. Each Party [shall][should] also designate one or more competent national authorities, which [shall][should] be responsible for and duly authorized to act on its behalf with respect to the following functions:

[(a) Performing the administrative functions [required by][to support the implementation of] this International Regime on Access and Benefit-sharing[, including the [issuance][emission][and transferring inquiry] of certificates of compliance with national legislation and[/or national] requirements on access and benefit-sharing];]

[(b) The receipt, administration and transfer to the financial mechanism of the funds collected through the enforcement of {...};]

[(c) Help 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].

A Party may designate a single entity to fulfil the functions of both focal point and competent national authority.

3. Each Party [shall][should], no later than the [effective date] [date of entry into force] of this International Regime on Access and Benefit-sharing for it, notify the Secretariat of the names and addresses of its focal point and its competent national authority or authorities. Where a Party designates more than one competent national authority, it [shall][should] convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of those authorities. Each Party [shall][should] forthwith notify the Secretariat of any changes in the designation of its national focal point or in the name and address or responsibilities of its competent national authority or authorities.

4. The Secretariat shall forthwith inform the Parties of the notifications it receives under paragraph 3 above, and shall also make such information available through the [Access and Benefit-sharing] Clearing-House. ^{16/}

Option 1

[[The International Regime on Access and Benefit-sharing [shall][should] establish a system [of an internationally recognized certificate of [origin][source][legal provenance][compliance]][of certification][Each Party shall issue a certificate of compliance with international legal effectiveness and applicability] which [shall][should] [establish the origin of the [genetic resources][biological resources][, their derivatives][and products] and associated traditional knowledge and] [certify the compliance of a user] of [such] [genetic resources][biological resources][, their derivatives][and products] [and/or associated traditional knowledge] with the relevant [requirements and/or] laws [or regulations] of the

^{16/} The placement of paragraphs 1 to 4 above must be further considered.

[provider country][country of origin][countries of origin of such resources or of the Parties that have acquired the [genetic resources][biological resources][, their derivatives][and products] in accordance with the Convention][, [community protocols and relevant customary laws] **[customary laws[,] [and] community protocols [and licences]]** of indigenous and local communities][. [Genetic resources][Biological resources][, their derivatives][and products] being provided by a Contracting Party are only those that are provided by Contracting Parties that are countries of origin of such resources or of the Parties that have acquired the genetic resources in accordance with the Convention.] The certificate [shall][should] be a public document to be issued by a competent national authority appointed in accordance with national law and [shall][should] 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.]

[Parties may, on a voluntary basis, make available to users a certificate of compliance with domestic access and benefit-sharing legislation issued by a relevant national authority, allowing users to demonstrate compliance with national access and benefit-sharing legislation.]

(a) The [voluntary] certificate [shall][should][may] include the following [minimum] information:

- (i) Issuing national authority;
- (ii) Details of the provider;
- (iii) A codified unique alpha numeric identifier **assigned by the competent national authority;**

[(iii bis) Whether there is traditional knowledge associated with a [genetic resource][biological resource][, their derivatives][and products], and whether that [genetic resource][biological resource][, its derivatives][and products] and associated traditional knowledge has been accessed in accordance with the [free prior informed consent] [or approval and involvement] of relevant indigenous [peoples] and local communities;]

- (iv) Details of the rights holders of [genetic resources][biological resources][, their derivatives][and products] and/or [associated traditional knowledge], as appropriate;

- (v) Details of the user;

- (vi) **Specification of subject matter[, as appropriate]** ([genetic resources][biological resources][, their derivatives][and products] [and/or associated traditional knowledge]) covered by the certificate[, subject to confidential information as identified in national requirements or by indigenous and local communities providing associated traditional knowledge];

- [(vii) Geographic location of the [access][collection] activity][Source of [genetic resources][biological resources][, their derivatives][and products] **[and geographic location of associated traditional knowledge];]**

[(vii bis) Name and location of relevant indigenous [peoples] and local communities;]

- [(viii) Prior informed consent granted by [countries of origin][provider countries][or the Parties which have acquired the [genetic resources][biological resources][,

their derivatives][and products] in accordance with the Convention] or indigenous and local communities and mutually agreed terms;]

[(viii bis) Evidence that prior informed consent and mutually agreed terms have been fulfilled, when traditional knowledge associated to a [genetic resource][biological resource][, its derivatives][and products] has been accessed, in accordance with the national legislation of [the country of origin or the country that has acquired the genetic resource in accordance with the Convention] [the country providing genetic resources [within the meaning of the Convention]] of that [genetic resource][biological resource][, its derivatives][and products];]

[(ix) Uses permitted [and][,] restrictions of use [**and licensing terms for**]:

a) Research not aiming at commercialization;

b) Research and development aiming at commercialization; and

c) Commercialization;]

[(x) Conditions of transfer to third parties [**including licensing terms**];]

(xi) Date of issuance;

[(xii) Confirmation of compliance with domestic access requirements **including prior informed consent and mutually agreed terms**].

[(a bis) The certificate shall not include confidential information related to prior informed consent and mutually agreed terms.]

[(b) Contracting Parties [shall][should] establish checkpoints for the certificate for commercial and non- commercial uses. Checkpoints for commercial uses [may][shall][should] include customs controls, intellectual property offices and registration points for other commercial applications not covered by intellectual property rights. [Checkpoints for non- commercial uses [may][shall][should] include publishing houses of scientific journals[, **online data depositories**], grants making bodies and ex-situ collections.]]

[(c) Contracting Parties [shall][should] facilitate an efficient, easy to use [voluntary] certification process through the use of new technology [and other means agreed to by Parties including capacity building and funding] which [may][shall][should] include:

(i) Cost efficient publicly searchable certificate [**and license**] databases providing evidence of prior informed consent [[and] mutually agreed terms, [**and licensing provisions**]];

[(ii) Recording of progressive compliance on such databases as conditions of prior informed consent and mutually agreed terms 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.
 - [(vii) Use of standardized classification schemes including, *inter alia*: the International Patent Classification (IPC) under the 1971 Strasbourg Agreement and the United Nations International Standard Industrial Classification of All Economic Activities (ISIC) and their regional or national equivalents;]**
- [(d) Contracting Parties where viable [shall][should]:
- [(i) Use existing tracking procedures by innovatively reconceptualizing them to track [genetic resources][biological resources][, derivatives and products] and/or associated traditional knowledge;]
 - (ii) Minimize the creation of new levels of bureaucracy;
 - (iii) [Where a Party requires prior informed consent,] Promote automatic issuing of certificates upon compliance with specific criteria[, such as completion of material transfer agreements [or] access and benefit-sharing agreements] [**or acceptance of the terms of an access and benefit-sharing license**];
 - [(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[, in particular the least developed among them and small island developing States, and countries with economies in transition,] to develop online systems to support an international documentation system.]]

[(e) Contracting Parties [shall][should] ensure that no intellectual property rights based on the utilization of [genetic resources][biological resources][, derivatives and products] and/or associated traditional knowledge will be granted unless the applications for such intellectual property rights include the disclosure of an Internationally Recognized Certificate of Compliance with the access and benefit-sharing legislation of the provider country.]

[(f) For tracking [access to] [utilisation of] traditional knowledge associated with [genetic resources][biological resources][, their derivatives][and products], the certificate shall include the following [minimum] information:

- (i) **[Licensing terms, including] permitted uses and restrictions of use[,]** for:
 - a. **Research not aiming at commercialization;**
 - b. **Research and development aiming at commercialization; and**

c. Commercialization;

(ii) Conditions of transfer to third parties [including licensing terms].]

Option 2

Contracting Parties [agree to establish hereby][which are countries of origin of [genetic resources][biological resources][, their derivatives][and products], or other Parties which have acquired the [genetic resources][biological resources][, their derivatives][and products] in accordance with the Convention,] [shall][should][may] [require that][as appropriate according to national circumstances, provide that][, through its competent national authority, issue], upon granting access, [an internationally recognized certificate provided to certify the compliance of a user of [genetic resources][biological resources][, their derivatives][and products] with the relevant law of the country of origin], [a certificate of compliance][[(or documentary evidence())]] [is issued,][by a national competent authority][allowing users of the [genetic resources][biological resources][, their derivatives][and products] to demonstrate compliance with the providing Party's access and benefit-sharing legislation [or regulation] or framework][with information on the country providing the resources and information on whether national legislation on access and benefit-sharing has been complied with].

Option 3

1. [The decision to grant] prior informed consent [granted], as registered by a Party in the clearing house mechanism, [shall][should] be [evidenced through the issuance of] the internationally recognised certificate of compliance.]

2. Where a [genetic resource][biological resource][, its derivatives][and products] [and/or associated traditional knowledge] is covered by an internationally recognised certificate of compliance, Parties [shall][should] deem that this [genetic resource][biological resource][, its derivatives][and products] [and/or associated traditional knowledge] has been obtained in compliance with the domestic access and benefit-sharing framework of [the country of origin or the country that has acquired the genetic resource in accordance with the Convention] [the country providing genetic resources [within the meaning of the Convention]] [, as well as [customary laws, community level procedures and] community protocols of indigenous and local communities] and has not been misappropriated.]

(c) Tracking and reporting systems

[Recognizing the important role of modern communication tools and internet based systems for tracking of genetic resources and reporting on access and benefiting-sharing obligations as a key component of any efficient and cost-effective tool to monitor compliance {preamble paragraph}]

1. Contracting Parties [shall][should] [develop tracking and monitoring systems that identify breaches of contractual obligations or misappropriation of [genetic resources][biological resources][, their derivatives][and products] and/or associated traditional knowledge and bring such breaches to the attention of the rights holders and stakeholders.][facilitate exchange of information, including through the clearing house mechanism, related to the development of tracking and monitoring systems of [genetic resources][biological resources][, their derivatives][and products], and encourage the further development of information technologies appropriate to that purpose].

2. Parties [shall][should] encourage users and providers to include provisions in access and benefit-sharing contracts to cover monitoring and tracking the use of the [genetic resources][biological

resources][, their derivatives][and products] **and/or associated traditional knowledge** accessed, including measures to monitor compliance with mutually agreed terms [and licensing provisions] .]

[3. Each Party shall [encourage] [require] users and [providers][countries of origin or countries that have acquired the genetic resource in accordance with the Convention] of [genetic resources][biological resources][, their derivatives][and products] to employ, to the best of their ability, the best available, cost-effective communication tools and internet based systems for tracking of [genetic resources][biological resources][, their derivatives][and products] and for reporting on compliance with access and benefit-sharing requirements set out in prior informed consent decisions and mutually agreed terms.]

[4. Parties will collectively [support][establish] an exchange on best available technologies for tracking of and reporting on transactions of [genetic resources][biological resources][, their derivatives][and products] reflecting specificities of different sectors.]

[5. Parties shall establish an information exchange framework between access and benefit-sharing competent national authorities [and intellectual property offices] to monitor the intellectual property rights based on the utilization of [genetic resources][biological resources][, their derivatives][and products] and associated traditional knowledge.]

[6. To facilitate tracking Parties may make use of established international classification schemes for [genetic resources][biological resources][, their derivatives][and products] [and/or associated traditional knowledge] including, *inter alia*: the International Patent Classification established under the 1971 Strasbourg Agreement, the United Nations International Standard Industrial Classification of All Economic Activities, The Nomenclature of Territorial Units for Statistics and their regional or national equivalents.]

(d) Information technology for tracking

(e) Disclosure requirements

[*Recognizing* that intellectual property rights play an important role in the fair and equitable sharing of benefits arising from the use of genetic resources, their derivatives and associated traditional knowledge, and that these rights need to be supportive of and do not run counter to the objectives of the Convention {*preambular paragraph*}]

Option 1

[1. [Patent] [Intellectual property rights] applications [and product approval applications] whose subject matter concerns, is [directly based on][derived from or makes use of] [genetic resources][biological resources][, their derivatives][and products] and[/or] associated traditional knowledge [shall][should][may] disclose the country [providing [genetic resources][biological resources][, their derivatives][and products]] [of origin] [and/or the country providing the resource] [in accordance with the Convention] [or source of such] [genetic resources][biological resources], [their derivatives] [and products,] and [/or] associated traditional knowledge[.], as well as [information on prior informed consent and] evidence that provisions regarding prior informed consent, mutually agreed terms and benefit-sharing have been complied with, in accordance with the national legislation[, regulations and/or requirements] of the country providing the resources [in accordance with the Convention].]

[1 *bis*. Parties [shall][should] ensure that the [declaration of [source] [legal compliance]] [certificate of compliance with national legislation] of the [genetic resources][biological resources][, their derivatives][and products] and associated traditional knowledge are notified to the [Clearing-House Mechanism of the Convention] [Access and Benefit-sharing Clearing-House] [referred to in {... }]].

[2. Each Party [shall][should][may] put in place effective enforcement procedures so as to ensure compliance with the obligations set out in **paragraph 1 above**. In particular, each Party [shall][should] establish administrative[, civil] and/or criminal measures for non-disclosure of the relevant information and the dissemination of false information to the national authorities, and [shall][should] ensure that administrative and/or judicial authorities have the authority to prevent the further processing of an application and to revoke or render unenforceable an intellectual property right or a product approval when the applicant has, knowingly or with reasonable grounds to know, failed to comply with the obligations in the above paragraph or provided false or fraudulent information.]

[3. [Compliance with national legislation and requirements in user countries [shall][should] be promoted][The obligations above-mentioned in paragraph 1 [may][shall][should] be met] by the presentation of a certificate of compliance with national legislation and requirements on access and benefit-sharing, issued by the country of origin in accordance with {...}.]

Option 2

[Recognizing that patents and other intellectual property rights may have an influence on the implementation of the Convention in accordance with Article 16(5), Parties may encourage providers and users to include contract clauses relating to intellectual property, as appropriate, in mutually agreed terms.]

(f) Identification of check points

[1. Parties [shall][should] establish other effective supporting mechanisms for compliance at [border] check points[, intellectual property rights offices, entities funding research, etc., including by using certificates of compliance with national legislations [**and/or access and benefit-sharing licenses**], so as to prevent misappropriation of resources].]

[2. Contracting Parties [shall][should] establish check points at, *inter alia*, intellectual property rights offices, market approval authorities and entities funding research, to ensure that the use of [genetic resources][biological resources][, their derivatives][and products] is accompanied by, and is in line with, the relevant international recognized certificate [**and/or access and benefit-sharing licences**].]

[3. The check points established by the Contracting Parties [shall][should] cover all uses of [genetic resources][biological resources][, their derivatives][and products] according to the definition included in the International Regime on Access and Benefit-sharing, in their jurisdiction.]

3) Development of tools to enforce compliance

[Recalling that Parties to the CBD are required to take legislative, administrative and/or policy measures to address benefit-sharing, so as to comply with the objective of this Protocol {*preambular paragraph*}]

[Taking into account the need to ensure compliance with access and benefit-sharing national legislations, regulations and requirements, with the aim of ensuring the fair and equitable sharing of benefits arising from the commercial and other utilization of genetic resources, their derivatives and associated traditional knowledge {*preambular paragraph*}]

[1. Each Party [shall][should] ensure that users of [genetic resources][biological resources][, their derivatives][and products] and/or associated traditional knowledge under its jurisdiction comply with the national legislation [or regulation] of the countries of origin of such resources[, their derivatives][and products] and/or traditional knowledge or of the Parties that have acquired the [genetic resources][biological resources][, their derivatives][and products] in accordance with the Convention, when accessing and/or using such resources[, their derivatives][and products] and/or associated traditional knowledge[.]by taking the following measures:]

[(a) Rules requiring that users of [genetic resources][biological resources][, derivatives][and products] and/or associated traditional knowledge comply with national legislation in the country of origin and the mutually agreed terms on which access was granted, including requirements to equitably share the benefits arising out of the utilization of such resources [, derivatives][, and products] and/or associated traditional knowledge;]

[(b) [Introduce][rules requiring that][measures encouraging] the importation of [genetic resources] [biological resources][, their derivatives][and products] and/or associated traditional knowledge] [from a country which requires prior informed consent] [**comply with the domestic requirements regarding prior informed consent of [the country of origin or the country that has acquired the genetic resource in accordance with the Convention] [the country providing genetic resources [within the meaning of the Convention]] of such [resources][, derivatives][and products] and/or associated traditional knowledge [as well as customary law and community level procedures of indigenous and local communities]** for utilization or for the export of this resource[, only takes][to take] place in compliance with such prior informed consent ;]

[(c) [Measures aimed at preventing the [use of misappropriated][**misuse and misappropriation of] [use of misused and misappropriated]** [genetic resources][biological resources][, their derivatives][and products] and/or traditional knowledge;]

[(e) [Require that [genetic resources][biological resources][, their derivatives][and products][and/or associated traditional knowledge] are only used for purposes consistent with [prior informed consent and mutually agreed terms] [the terms and conditions under which they were acquired];]

[(f) Require that when [genetic resources][biological resources][, their derivatives][and products][and/or associated traditional knowledge] 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][biological resources][, their derivatives][and products] requires prior informed consent for access to the material, the documentation [shall][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][should] also be disclosed.] If some of the information referred to in this subparagraph does not exist, this [shall][should] be stated in the documentation accompanying the material;]

[(g) [Introduce] rules requiring that when genetic resources covered by the [Multilateral System created under the] International Treaty on Plant Genetic Resources for Food and Agriculture are used for research and commercial purposes, they [shall][should] be accompanied by information confirming that these resources are accessed in accordance with the Standard Material Transfer Agreement under [the Multilateral System of] the Treaty;]

[(h) Other measures requiring users to comply with the provisions in the Convention and this International Regime on Access and Benefit-sharing.]]

[2. Each Party [shall][should] take appropriate, effective and proportionate measures to [establish sanctions and remedies][prevent situations] when users under their jurisdictions [have] violate[d] national access and benefit-sharing legislation of the countries of origin of [genetic resources][biological resources][, their derivatives][and products] and/or traditional knowledge or of the Parties that have acquired the [genetic resources][biological resources][, their derivatives][and products] in accordance with the Convention. [Among others, the Parties [may][shall][should] establish the following sanctions and remedies:

- (a) The cessation of the acts related to the infraction;
- (b) Compensation for damages;
- (c) The withdrawal from the market of products resulting from the infringement;
- (d) The prohibition on the import or export of goods, materials or any means referred to in the previous paragraph;
- (e) The necessary action to avoid continuation or repetition of the offence;
- (f) Publication of the judgement and notification to interested persons at the expense of the person(s) who made the infraction;
- (g) Criminal penalties for use of [genetic resources][biological resources][, their derivatives][and products] and associated traditional knowledge without compliance with conditions of access and benefit-sharing in the country of origin;
- (h) Others as appropriate.]]

[3. Each Party [shall][should], at the request of any interested Party, [in accordance with national law and existing agreements or arrangements,][if any,] cooperate in the investigation and follow up of cases of alleged violations of the national access and benefit-sharing legislation of the country of origin of [genetic resources][biological resources][, their derivatives][and products] and/or associated traditional knowledge or of the Party that has acquired the [genetic resources][biological resources][, their derivatives][and products] in accordance with the Convention, including prior informed consent and mutually agreed terms.]

4. Each Party [shall][should] [provide timely guidance and][make available] information on the types of assistance that are available to nationals of other jurisdictions [to assist in the][to ensure that lack of funds and lack of experience with the law of the users are not elements preventing] exercise and enforcement of their rights.

[5. User Parties [shall][should] provide financial assistance for the settlement of legal disputes.] ^{17/}

[6. Parties may encourage providers and users of [genetic resources][biological resources][, their derivatives][and products] under their jurisdiction to include provisions relating to dispute resolution and other enforcement matters, in mutually agreed terms relating to access and benefit-sharing of those resources in order to facilitate enforcement of the mutually agreed terms.]

(a) Measures to ensure access to justice with the aim of enforcing ABS arrangements

[1. Parties [shall][should] take [the necessary] measures to ensure access to justice by establishing appropriate national regulatory framework which [shall][should] protect [their rights] [the rights of [the country of origin or the country that has acquired the genetic resource in accordance with the Convention] [the country providing genetic resources [within the meaning of the Convention]] and indigenous and local communities] over [genetic resources,] [biological

^{17/} The placement of paragraphs 1 to 5 above must be further considered.

resources][, their derivatives][and products] [and/or associated traditional knowledge] and ensure benefit-sharing.]

[2. Access to justice [shall][should] be in accordance with Principle 10 of the Rio Declaration.]

[3. The Governing Body of the International Regime on Access and Benefit-sharing [shall][should][may] [consider][ensure] such [voluntary] measures or mechanisms as appropriate to support effective implementation of the International Regime on Access and Benefit-sharing, including by providing assistance to Parties[, as well assistance that covers issues related to the financial cost of legal expertise] [and/or indigenous and local communities], upon request, in litigation related to cases of alleged non-compliance [with national access and benefit-sharing laws, regulations and/or requirements and/or breach of access and benefit-sharing agreements]. Such measures/mechanisms [shall][should][may] be considered by the Governing Body of the International Regime on Access and Benefit-sharing not later than at its [first][next] meeting.]

[4. The International Regime on Access and Benefit-sharing [shall][should] [establish an international access and benefit-sharing ombudsman's office][**include a legal aid body, such as an ombudsperson including representatives of indigenous [peoples] and local communities, with a task to address imbalances in legal capacity between providers and users of [genetic resources][biological resources][, their derivatives][and products] and associated traditional knowledge**]. The ombudsman's office [shall][should] be responsible for provider countries[, or, where relevant,] [/] countries of origin and indigenous and local communities to identify breaches of their rights and to provide aid in seeking fair and equitable resolution of disputes. The ombudsman's office [shall][should] be empowered to take action on behalf of [provider] countries [of origin/provider countries] and indigenous and local communities through the binding Dispute Resolution Mechanism. The ombudsman's office [shall][should] also where necessary and when requested represent [provider] countries [of origin/provider countries] [and/or] indigenous and local communities in proceedings in foreign jurisdiction, take depositions from indigenous and local communities and provide evidence of customary law and practice as and where appropriate.]

[5. **In case of any alleged breach of access and benefit-sharing legislation, regulations or requirements, any Party and/or its nationals affected by that breach may take legal action in the jurisdiction of the user that allegedly committed the breach.**]

[6. **In the above case, the Party that has jurisdiction over the user [shall][should] grant effective access to its relevant authorities, including courts and alternative dispute resolution mechanisms.**]

(b) Dispute settlement mechanisms:

(i) Inter-State

(ii) Private international law

(iii) Alternative dispute resolution

[1.(a) The International Regime on Access and Benefit-sharing [shall][should] establish a Dispute Resolution Mechanism accessible to both countries and also other aggrieved parties who include indigenous and local communities, non-governmental organizations, research and commercial interests, and other providers and users of [genetic resources][biological resources][, their derivatives][and products] and/or associated traditional knowledge.]

[(b) The Dispute Resolution Mechanism [shall][should] also have regional offices that use local languages and have personnel conversant with the cultural, social, economic and environmental realities of the region.]

[(c) The Dispute Resolution Mechanism [shall][should] be guided in its work by principles of equity[, impartiality and independence] drawn from a wide range of legal sources including customary law and practices of indigenous and local communities.]

[(d) The International Regime on Access and Benefit-sharing [shall][should] establish mechanisms to provide legal assistance to developing countries and indigenous and local communities.]

[2. Parties to the Convention [shall][should] encourage users and providers to utilize, to the fullest extent possible, existing mechanisms on alternative dispute resolution.]

(c) Enforcement of judgments and arbitral awards across jurisdictions

[*Noting the importance of compliance with ABS agreements/contracts to the international regime {preambular paragraph}*]

[*Noting also that the existing body of private international law provides a range of options for dispute resolution across national borders {preambular paragraph}*]

[*Noting the 1958 United Nations Convention on the Recognition and Enforcement of Foreign Arbitral Awards (the New York Convention) and the assistance it provides parties in the enforcement of foreign arbitral awards {preambular paragraph}*]

[1. Contracting Parties [shall][should] ensure that their courts will enforce the decisions of the courts of the country of origin/provider countries against unlawful users under the former's jurisdiction subject to basic principles underlying enforcement of foreign judgments under comity in international law.] **[Parties [shall][should] take legislative, administrative or policy measures to facilitate recognition and enforcement of judgements of courts and arbitral awards with regard to the interpretation or infringement of access and benefit-sharing contracts and to violations of national access and benefit-sharing legislation, regulation or requirements of the country of origin of [genetic resources][biological resources][, their derivatives][and products] and/or associated traditional knowledge or of the Party that has acquired such resources [, their derivatives][and products] according to the Convention.]**

2. Parties [shall][should] encourage access and benefit-sharing users and providers to include provisions in access and benefit-sharing contracts to cover international dispute resolution including:

(a) The jurisdiction to which they will subject any dispute resolution processes;

[(b) The applicable law;]

(c) Options for alternative dispute resolution, such as mediation or arbitration, in the event of contractual disputes.

(d) Information exchange procedures between national focal points for access and benefit-sharing to help providers obtain relevant information in specific cases of alleged infringements of prior-informed-consent requirements

[[The international ombudsman [shall][should] facilitate, through national focal points and/or competent authorities][**National focal points and/or competent authorities [shall][should] facilitate, through the international mechanism of compliance**], the provision of relevant information on infringement of prior informed consent requirements of providers of [genetic resources][biological resources][, their derivatives][and products] and/or associated traditional knowledge.]

(e) Remedies and sanctions

[1. National legislation [shall][should] provide for remedies to sanction lack of compliance with the requirements set out in paragraph {...} which must include inter alia revocation of the intellectual property rights in question, as well as co-ownership of the intellectual property rights and its transfer.]

[2. Contracting Parties [shall][should] 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.]

[3. Each Contracting Party [shall][should] introduce measures to facilitate cooperation between Contracting Parties to address alleged infringements of access and benefit-sharing agreements and misappropriation of [genetic resources][biological resources], [their derivatives][and products,] and/or associated traditional knowledge, such as access to justice and support for claimants in actions of breach of contract or misappropriation.]

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

[Noting that customary law provides a sub-set of existing rules related to access and benefit-sharing of [genetic resources][biological resources], and measures to comply with such rules {preambular paragraph}]

[Recognizing that customary law functions within a specific belief system, is dynamic and includes mechanisms to preserve its underlying values and principles {preambular paragraph}]

[1. Contracting Parties [shall][should]:

(a) Take necessary policy, administrative[, regulatory] and legislative measures to recognize the rights of indigenous peoples and local communities to [genetic resources][biological resources][, their derivatives][and products] and/or associated traditional knowledge. Until, and to the extent such policies, administrative and legislative measures have not been put in place, the State shall nonetheless uphold obligations with respect to indigenous peoples' and local communities' rights to [genetic resources][biological resources][, their derivatives][and products] and/or traditional knowledge under international law;

(b) With the full and effective participation of the indigenous and local communities concerned support and facilitate local, national and/or regional community protocols regulating access to traditional knowledge taking into consideration the relevant customary laws and ecological values of indigenous and local communities in order to prevent the misappropriation of their associated traditional knowledge and to ensure the fair and equitable sharing of benefits arising from the utilization of such associated traditional knowledge;

(c) Ensure that any acquisition, appropriation or utilization of traditional knowledge in contravention of the relevant **[customary laws[,] [and]]** community protocols **[and/or associated access and benefit-sharing licensing terms]** constitutes an act of misappropriation;

(d) Ensure that the application, interpretation and enforcement of protection against misappropriation of traditional knowledge, including determination of equitable sharing and distribution of benefits, [shall][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;

(e) Encourage and support the development of community protocols **[and/or access and benefit-sharing licences]** that [shall][should] provide potential users of traditional knowledge with clear and transparent rules for access to traditional knowledge where associated traditional knowledge is shared between: (i) indigenous and local communities spread across national boundaries; and (ii) between indigenous and local communities with different values, customary norms, laws and understandings;

(f) Where such community protocols are developed with the full and effective participation of indigenous and local communities, give effect to such community protocols through an appropriate legal framework;

(g) Community protocols in their efforts to prevent misappropriation of associated traditional knowledge and ensure fair and equitable benefit-sharing must also make efforts to respect, preserve and maintain relations within and between indigenous and local communities that generate and sustain the traditional knowledge by ensuring the continued availability of traditional knowledge for the customary practice, use and transmission;

(h) Consider relevant customary law and its potential application to access and benefit-sharing transactions in taking measures to raise awareness of access and benefit-sharing issues **[including through the use of access and benefit-sharing licences];**

[(i) Parties [shall][should] ensure that users disclose the [the country of origin or the country that has acquired the genetic resource in accordance with the Convention] [the country providing genetic resources [within the meaning of the Convention]], the identity of the indigenous and local communities and evidence of [prior informed consent] [or approval and involvement], where available in applications for intellectual property rights, product registration and plant variety protection;]

[(j) Parties [shall][should] ensure that any benefits arising out of the misappropriation of [genetic resources][biological resources][, their derivatives][and products] and/or traditional knowledge are directed as compensation towards the relevant indigenous and local communities of such traditional knowledge and/or [genetic resources][biological resources]][, their derivatives][and products].]

[2. Parties are encouraged to provide information on the indigenous community which has the responsibility to identify the appropriate customary law expert relevant to an access and benefit-sharing transaction.]

[3. States [shall][should] respect indigenous [peoples'] and local communities' customary laws, norms and protocols pertaining to [genetic resources][biological resources][, their derivatives][and products] and associated traditional knowledge.]

[4. Lack of prior informed consent[, where required by national legislation or customary laws or community protocols,] [shall][should] be grounds for [disqualification][invalidation] in product registration or grant of intellectual property rights. In

such cases of [disqualification][invalidation] the right to apply for the product registration or intellectual property rights vests with the [country providing the resources][country of origin] or the holders of the traditional knowledge.]

D. TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES¹⁸

[Preambular paragraphs or principles

A.

The International Regime [should][shall] uphold the rights of indigenous peoples and local communities to benefit-sharing whenever there is use or access of their genetic resources and/or associated traditional knowledge.

B.

Equitable sharing and distribution of benefits [should][shall] be guided by respect for the holders of the traditional knowledge as well as other relevant cultural, spiritual, ecological and economic values also including customary norms, customary laws and community protocols.

C.

In view of the inseparability of traditional knowledge and genetic resources and co-evolved biological and cultural systems recognizes the interests of indigenous and local communities over genetic resources that have developed as a direct result of their knowledge, innovations and practices and seeks to protect these interests.

D.

Genetic resources [should][shall] be interpreted in a holistic manner with regards to the provisions of the Convention on Biological Diversity and will include a reproducible source, its functional units, excluding commodities marketed as such rather than as a means of developing such units.

E.

Biological resources and traditional knowledge are inseparable, and this relationship must always be taken into account whenever they are used. There may however be certain uses of biological resources or traditional knowledge, where they are used alone, and this must also be taken into account in the determination of benefit sharing schemes that may be availed of.

F.

The rights of States and indigenous and local communities over these resources must be respected at all times whenever they are used, taking into account the corresponding duty of nation States under the United Nations Declaration on the Rights of Indigenous Peoples to protect the exercise of these rights by the indigenous and local communities.

G.

The Parties, in accordance with the principles of international law and their national legislation, [should][shall] recognize the traditional forms of organization of each indigenous and local community.

¹⁸

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

H.

Emphasizing that both holders of traditional knowledge associated with genetic resources and those seeking access to such knowledge benefit from the availability of model clauses for potential inclusion in material transfer agreements, since the use of such clauses will raise legal certainty, may lower transaction costs and will contribute to creating a level playing field between the holder of traditional knowledge associated with genetic resources and those seeking access, when negotiating mutually agreed terms.]

Operative Text**1.***[Option 1*

Parties [should][shall] take measures to encourage holders ^{19/} of traditional knowledge associated with genetic resources [and derivatives] and those seeking access to such knowledge to provide in their mutually agreed terms, as appropriate, for the fair and equitable sharing of benefits arising from the utilization of traditional knowledge associated with genetic resources [and derivatives].]

Option 2

[Each Contracting Party [should][shall] take legislative, administrative or policy measures [to ensure] the fair and equitable sharing of benefits in accordance with mutually agreed terms with indigenous and local communities arising from the commercial and other utilization of:

(a) Genetic resources/biological resources, [derivatives or products] when such a genetic resource/biological resources, [derivatives or products] has resulted from or been guided by or whose [potential] use has been made apparent by a sharing of the traditional knowledge associated with genetic resources [and derivatives] of indigenous or local communities or where indigenous or local communities have collective rights to such genetic resources [and derivatives] under national law;

(b) Genetic resources [and derivatives] when they are integrally linked to the traditional knowledge of the specific indigenous and local community regardless of whether or not such ILC own the said genetic resource [and derivatives]; and]

(c) Traditional knowledge associated with genetic resources [and derivatives], when the indigenous or local community has developed or nurtured such traditional knowledge including when the State, under national and international law, is the owner/holder of a genetic resource [and derivatives].]

[2. The conditions for equitable sharing in the benefits derived from the use of traditional knowledge, innovations and practices associated with genetic resources [and derivatives] [should][shall] be stipulated in terms mutually agreed upon, in accordance with national legislation, including: a) between indigenous and local communities and users; or b) between users and the national or local authority of the [provider country][country of origin], with the active participation of the indigenous and local communities involved, and prior informed consent.]

¹⁹ The language of “holder of traditional knowledge” will be reviewed in light of the agreement regarding indigenous and local communities reached during the sixth meeting of the Working Group on 8(j) contained in paragraph 4 of section 1 of the annex to recommendation 6/3 of UNEP/CBD/COP/10/2, annex: “Where consent or authority of indigenous and local communities is required with respect to traditional knowledge associated with the conservation and sustainable use of biological diversity, it is the right of indigenous and local communities, according to their customary law and procedures, to identify the relevant holders of their knowledge.”

[3.] Traditional knowledge associated with genetic resources [and derivatives] of indigenous and local communities accessed prior to the entering into force of the CBD, [should][shall] be subject to the [International Regime on ABS][Protocol]:

(a) With all continuing benefits arising from the use of such traditional knowledge to be fairly and equitably shared with the relevant indigenous and local community;

(b) With all new uses of such traditional knowledge arising after the entry into force of the CBD [should][shall] be subject to PIC and MAT negotiated with the relevant indigenous [peoples] and local communities concerned in accordance with their community procedures, customary laws or community protocols;

(c) In cases where the origin of the traditional knowledge associated with genetic resources [and derivatives] is unclear, regional traditional knowledge funds [should][shall] be established under the [International Regime on ABS][Protocol] and administered by the representatives of indigenous and local communities and a fair and equitable share of the benefits arising from the use of such traditional knowledge [should][shall] flow into such funds.]

[4.] Parties [should][shall] take measures to address transboundary and shared traditional knowledge associated with genetic resources [and derivatives]. In instances when more than one indigenous or local community share traditional knowledge associated with genetic resources [and derivatives], and an ABS agreement is reached with one indigenous or local community, Parties may take measures to ensure that benefits are shared also with other indigenous or local communities holding the same traditional knowledge. This however does not preclude indigenous and local communities that are the holders of the shared traditional knowledge to enter into separate ABS agreements with the users of such traditional knowledge under the supervision of the Competent National Authority on the condition that such agreements are non-exclusive and do not adversely affect the rights, customary laws or community protocols of other indigenous and local communities that share such traditional knowledge.]

[5.] Parties, in consultation with indigenous [peoples] and local communities [should][shall] develop minimum conditions and standards for MAT relating to transboundary and shared traditional knowledge associated with genetic resources [and derivatives] that would have to be complied with by users of such traditional knowledge when negotiating MAT with any of the indigenous and local communities sharing such knowledge.]

6. Parties [should][shall] take measures to address traditional knowledge associated with genetic resources [and derivatives] that is accessed *in situ* [as well as *ex situ*, including in databases, scientific publications or libraries][, as well as genetic resources [and derivatives] accessed *ex situ*,] and the [potential] sharing of benefits[, recognizing that indigenous [peoples] and local communities have rights to such genetic resources [and derivatives] and traditional knowledge].

[7.] Parties [should][shall] take measures to ensure that benefit-sharing arrangements pertaining to [as well as the protection of] traditional knowledge associated with genetic resources [and derivatives] [should][shall] recognize the rights of indigenous and local communities to [free,] [prior informed consent] [or approval and involvement] and be subject to the customary laws of indigenous and local communities at all times. The protection of traditional knowledge associated with genetic resources [and derivatives] shall ensure that the traditional knowledge associated with genetic resources [and derivatives] protected will remain to be vital and useful in the day-to-day lives and cultural context of the indigenous and local communities.]

8. [Subject to national legislation,] when addressing access to traditional knowledge associated with genetic resources [and derivatives], Parties [should][shall] take administrative, legislative, or policy

measures to:

[(a) Recognize the traditional forms of organization of ILCs and to respect [and enforce] their customary laws, norms and protocols pertaining to such knowledge; and]

[(b) [Ensure] that [free,] [prior informed consent] [or approval and involvement] and mutually agreed terms of ILCs are respected when such knowledge is accessed or used.]

[9.] Parties [should][shall], with the full and effective participation of the indigenous and local communities concerned, support [and facilitate] the development, implementation [and compliance] of local, national and/or regional community protocols [regulating] access to traditional knowledge associated with genetic resources [and derivatives], taking into consideration the relevant customary laws and ecological values relevant for conservation and sustainable use of biological diversity of indigenous and local communities [in order to prevent the misappropriation of their traditional knowledge associated with genetic resources [and derivatives]].]

10. Each [Contracting] Party [should][shall] include a requirement in national legislative, policy, or administrative measures that mutually agreed terms should be developed [at the community level] when traditional knowledge associated with genetic resources [and derivatives] is [accessed or used].

11. Parties [should][shall] [establish mechanisms or procedures] in consultation with all relevant stakeholders, in particular indigenous and local communities, to provide information to potential users of traditional knowledge associated with genetic resources [and derivatives] concerning obligations of users regarding access to traditional knowledge associated with genetic resources [and derivatives] and benefit sharing arising from the use of such traditional knowledge.

[12.] Parties [should][shall] ensure the application of measures and best practices to respect the rights of the holders of traditional knowledge²⁰ associated with genetic resources [and derivatives] in research.]

[13.] Parties [should][shall] collectively establish a procedure for identifying and regularly reviewing access and benefit-sharing related codes of conduct and guidelines that constitute best-practice, including for research related to traditional knowledge associated with genetic resources [and derivatives].]

[14.] Parties [should][shall] take measures to encourage holders ^{21/} of traditional knowledge associated with genetic resources [and derivatives] and those seeking access to such knowledge, when establishing mutually agreed terms, to consider, including in these terms model clauses developed in accordance with paragraph 2 below.]

[15.] In order to enhance legal certainty, lower transaction costs and promote equality in negotiations

^{20/} The language of “holder of traditional knowledge” will be reviewed in light of the agreement regarding indigenous and local communities reached during the sixth meeting of the Working Group on 8(j) contained in paragraph 4 of section 1 (p. 23 of document UNEP/CBD/COP/10/2): “Where consent or authority of indigenous and local communities is required with respect to traditional knowledge associated with the conservation and sustainable use of biological diversity, it is the right of indigenous and local communities, according to their customary law and procedures, to identify the relevant holders of their knowledge.”

^{21/} The language of “holder of traditional knowledge” will be reviewed in light of the agreement regarding indigenous and local communities reached during the sixth meeting of the Working Group on 8(j) contained in paragraph 4 of section 1 (p. 23 of document UNEP/CBD/COP/10/2): “Where consent or authority of indigenous and local communities is required with respect to traditional knowledge associated with the conservation and sustainable use of biological diversity, it is the right of indigenous and local communities, according to their customary law and procedures, to identify the relevant holders of their knowledge.”

of mutually agreed terms, the Parties [should][shall] establish a procedure for development of model clauses for traditional knowledge associated with genetic resources [and derivatives], with the involvement of representatives of indigenous and local communities.]

[16. Parties [should][shall] designate one or more Competent National Authorities who [should][shall] guide and link potential users of traditional knowledge associated with genetic resources [and derivatives] to the relevant [indigenous or local community [authorities]] identified by the ILCs and, where necessary, offer support for the establishment of [ILC authority] for the purposes of [PIC][or approval and involvement] and MAT by providing adequate information on the rights of ILCs and legal, administrative policies governing [PIC][or approval and involvement] of ILCs when access to traditional knowledge associated with genetic resources [and derivatives] is sought, taking into account the customary laws, community procedures and/or community protocols where they exist. Competent National Authorities should also inform users regarding their obligations [regarding benefit-sharing] arising out of the use of traditional knowledge associated with genetic resources [and derivatives].]

[17. In accordance with the traditional forms of organization of each indigenous and local community, such communities shall define the appropriate [authorities] and entities to serve as interlocutors in order to grant, or not, access to and use of traditional knowledge, innovations and practices associated with genetic resources [and derivatives].]

[18. [Each Party [should][shall] respect, recognize and protect the collective rights of indigenous and local communities within its jurisdiction to their traditional knowledge associated with genetic resources [and derivatives] and shall establish an appropriate regulatory framework to effectively protect and implement their rights.] Until, and to the extent such policies and measures have not been put in place, the Party [should][shall] nonetheless uphold its obligations under the Regime.]

[19. Parties [should][shall] include a requirement in national legislation or policy measures [to ensure] [prior informed consent] [or approval and involvement] and/or mutually agreed terms of indigenous and local communities by the relevant ILC authorities in accordance with their customary laws, community protocols and community-level procedures before access is granted to:

(a) genetic resources [and derivatives] when the indigenous or local community has rights to such genetic resources [and derivatives] under national and international law, and

(b) traditional knowledge associated with genetic resources [and derivatives], when the indigenous or local community has developed or nurtured such knowledge.]

[20. If [PIC] [or approval and involvement] is granted, this shall be documented in MATs [as agreed with the National Competent Authority with the participation of indigenous and local communities concerned] [with the indigenous [people] or local community concerned].]

[21. Parties [should][shall]:

(a) Ensure that any access to and use of traditional knowledge associated with genetic resources [and derivatives] shall be based on the [prior informed consent] [or approval and involvement] of indigenous and local communities who are the holders of such knowledge

(b) Make available all relevant information in order to facilitate the effective participation and PIC of indigenous and local communities in any ABS agreement relating to their traditional knowledge associated with genetic resources [and derivatives]. This provision shall not undermine the interest of the applicant regarding confidential business information approved by the Competent National Authority

(c) Ensure that any documentation of traditional knowledge associated with genetic resources [and derivatives] of indigenous and local communities should be subject to the [prior informed consent] [or approval and involvement] of the indigenous and local communities;

(c)bis Ensure that the documented traditional knowledge associated with genetic resources [and derivatives] is safeguarded and does not enter the public domain

(d) Ensure that decisions regarding access to traditional knowledge associated with genetic resources [and derivatives] made by indigenous or local communities authorities established in accordance with their customary norms, laws or community protocols or otherwise appointed by them in accordance with national law are made available to other relevant stakeholders;

(e) Require that MAT address scope of use of traditional knowledge associated with genetic resources [and derivatives], and that substantially new or changed uses of traditional knowledge associated with genetic resources [and derivatives] beyond the intended use of what has been consented by PIC and agreed to under MAT, are subjected to new PIC and MAT from the indigenous and local communities who are the holders of such traditional knowledge.]

22. The implementation of this [Protocol][Regime] [should][shall] not restrict the exchange of genetic resources [and derivatives] and traditional knowledge associated with genetic resources [and derivatives] among indigenous and local communities for traditional purposes.

23. Parties [should][shall] also [establish mechanisms to ensure][encourage] that users of traditional knowledge associated with genetic resources [and derivatives] fulfil their obligations regarding access to and benefit sharing arising from the use of traditional knowledge associated with genetic resources [and derivatives].

[24. Each Contracting Party [should][shall] include a requirement in national legislative, policy, or administrative measures that:

(a) Access to traditional knowledge associated with genetic resources [and derivatives] is based on mutually agreed terms;

(b) Mutually agreed terms should be developed at the community level; and

(c) Mutually agreed terms address access to, uses of, and benefit sharing arising from the use of the traditional knowledge associated with genetic resources [and derivatives].]

[25. Parties [through their appropriate CNAs] [should][shall] consult ILCs regarding their rights associated with genetic resources [and derivatives] and traditional knowledge associated with genetic resources [and derivatives] including:

(a) In the development of a national strategy, legislation, policies, administrative measures or regimes on access and benefit-sharing;

(b) Appropriate consultative arrangements such as national consultative committees comprising relevant stakeholders shall be established.]

[26. An internationally recognized certificate of compliance [should][shall] establish that genetic resources/biological resources, [derivatives and products] and traditional knowledge associated with genetic resources [and derivatives] have been duly acquired. Each party, upon request, [should][shall] issue a certificate of compliance with international legal effectiveness and applicability that certifies that

genetic resources/biological resources, [derivatives and products] and traditional knowledge associated with genetic resources [and derivatives] have been acquired in accordance with the laws of the [provider country][country of origin] and the PIC of relevant indigenous or local communities. The certificate shall denote who the [holders 22]/[providers] of relevant genetic resources/biological resources, [derivatives and products] and traditional knowledge associated with genetic resources [and derivatives] are as documented in MATs. The certificate shall denote whether there is traditional knowledge associated with a genetic resource [and derivatives] and the name and location of relevant indigenous [peoples] and local communities.]

[27. For tracking access to traditional knowledge associated with genetic resources [and derivatives] the certificate shall include but not be limited to the following minimum information:

(a) [Licensing] terms, including permitted uses and restrictions of use, for:

- Research not aiming at commercialization
- Research and development aiming at commercialization; and
- Commercialization;

(b) Conditions of transfer to third parties including [licensing] terms;

(c) Evidence that [prior informed consent] [or approval and involvement] and mutually agreed terms have been fulfilled when traditional knowledge associated with genetic resources [and their derivatives] has been accessed, in accordance with the national legislation, regulation [and/or requirements of the country of origin of such resources [and derivatives]].]

Definitions 23

[1. The term ‘indigenous and local communities’ refers to either or both of the entities which the term describes, within the definition given by national legislation and international commitments

2. Associated traditional knowledge means knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity that are:

- (a) Associated with an *in situ* genetic resource; and
- (b) not in the public domain.

3. For the purposes of the International Regime, non-commercial research shall be understood as research with the goal of adding knowledge to the public domain, without restrictions or proprietary ownership.]

²² The language of “holder of traditional knowledge” will be reviewed in light of the agreement regarding indigenous and local communities reached during the sixth meeting of the Working Group on 8(j) contained in paragraph 4 of section 1 (p. 23 of document UNEP/CBD/COP/10/2).: “Where consent or authority of indigenous and local communities is required with respect to traditional knowledge associated with the conservation and sustainable use of biological diversity, it is the right of indigenous and local communities, according to their customary law and procedures, to identify the relevant holders of their knowledge.”

²³ Discussion on definitions was left in abeyance both as regards content and placement and will occur at the next meeting of the Working Group.

E. Capacity²⁴

1. The [Protocol][international regime] recognizes the importance of capacity-building for the effective implementation of its provisions.²⁵ Parties [shall][should] cooperate in the development and/or strengthening of human resources and institutional capacities in access and benefit-sharing, for the purpose of the effective implementation of [the Convention and] [this [Protocol][International Regime]], in developing country Parties, in particular the least developed countries and small islands developing States among them, and Parties with economies in transition, [through new and additional funding,] including through existing global, regional, subregional and national institutions and organizations and, as appropriate, through facilitating the involvement of other relevant stakeholders [including the private sector,] and in that respect promote coordination of relevant capacity-development initiatives at all levels.

2. For the purposes of implementing paragraph 1 above, in relation to cooperation, the needs identified at the national level by developing country Parties themselves, in particular the least developed countries and small islands developing States among them, and Parties with economies in transition, for financial resources and access to and transfer of technology and know-how in accordance with the relevant provisions of the Convention, shall be taken fully into account for access and benefit-sharing.

3. Developing country Parties, [in particular the least developed countries and small island developing States among them, and Parties with economies in transition,] [shall] [should] [could] identify their national needs and priorities, including those of indigenous and local communities with their full and effective participation, where applicable, through national capacity self-assessments [including through established mechanisms], as the basis for capacity development/capacity building measures, and [shall] [should] provide this information [to the financial mechanism of [the international regime] [this Protocol] and] to the Secretariat for distribution through the clearing-house mechanism of the Convention.

4. Parties [shall][should] undertake [special] capacity-building measures for technology transfer and cooperation[, in accordance with the relevant provisions of the Convention[, in particular with Articles 8(j), 12, 13, 16, 17(2) and 18(4) of the Convention]][, taking into account the needs of developing country Parties, in particular the least developed countries and small islands developing States among them, and Parties with economies in transition.]

[5. [Parties shall cooperate through capacity-building programmes for][Measures in accordance with paragraph 1 may focus on]:

(a) Development and implementation of [domestic/national] [ABS laws] [and other relevant] [legislation][, upon request of the interested Party];

(b) Development and training of national competent authorities;

(c) [Training of patent examiners for the study of patent applications related to genetic resources, their derivatives and associated traditional knowledge, innovations and practices, particularly the determination of the state of the art, so as to guarantee the rights of countries of origin and indigenous and local communities;]

(d) [Programmes to support the required institutional developments in each country, especially developing countries, for the implementation of the commitments established in this international regime, including certificate of compliance and disclosure of origin;]

²⁴ The contact group agreed that maintaining the sub-headings was not necessary for the further consideration of main component E. and therefore recommends to the Working Group to delete the sub-headings under main component E.

²⁵ Sentence possibly to be considered as preambular text.

- (e) Training in negotiations including on contractual arrangements;
- (f) Employment of best available communications tools and internet-based systems for ABS activities;
- (g) Development and use of valuation methods;
- (h) Bioprospecting, associated research and taxonomic studies;
- (i) ABS compliance management;
- (j) [Monitoring and enforcing compliance];
- (k) Enhancing the contribution of access and benefit-sharing activities to the conservation and sustainable use of biodiversity;
- (l) Developing and enhancing synergies and coordination of capacity building initiatives at national, regional and international levels;
- (m) [Training in tracking the use of biological resources and genetic resources across sectors, including understanding cases of biopiracy and digitalization of biodiversity.]

[6. Capacity-building measures [shall] [may] include, but not be limited to:

- (a) *For Governments:*
 - (i) [Capacity to conserve and sustainably use genetic resources [, their derivatives] and promote their associated traditional knowledge;]
 - (ii) [Capacity to identify, assert and protect [their] different forms of intellectual property rights relating to their genetic resources;]
 - (iii) [Capacity to promote the sustainable use of genetic resources and traditional knowledge [associated with genetic resources] for [conservation and sustainable use of biodiversity and] socio-economic development, with the participation and involvement of indigenous and local communities as appropriate;]
 - (iv) Capacity to ensure communication, education and public awareness regarding access and benefit-sharing;
- (b) Capacity requirements of academia and research institutions may include but not be limited to:
 - (i) Capacity for curriculum development, training, research and technical support and institutional capacity for access and benefit sharing [and biodiversity];
 - (ii) Capacity to use intellectual property systems[, other alternatives including open-source licences,] and [community-public-private] partnerships in the commercialization of research results[, and study their possible impacts on realizing benefit sharing];
 - (iii) Capacity to increase collaboration and understanding between researchers and indigenous and local communities, including the rights of indigenous and local communities, their customary laws and practices;

- (c) Capacity requirements of the private sector may include but not be limited to:
 - (i) Capacity for bioprospecting and to ensure best practice access and benefit-sharing processes and agreements i.e. prior informed consent, mutually agreed terms, and benefit-sharing;
 - (ii) Capacity to identify and utilize business opportunities that arise from being ABS compliant;
 - (iii) Differentiated capacity development for different kinds of businesses relating to access and benefit-sharing which include contract negotiation, product development, creating good-value chains, access to markets and sustainable management and utilization of natural resources;

[7. Parties [shall][should] take measures to strengthen, where necessary, the capacity of ABS stakeholders:

(a) To participate in the development of [sectoral] model clauses[, contracts, arrangements and/or agreements,] and inventories/catalogues of typical utilizations of genetic resources [and derivatives] in accordance with <cross reference to operational provision on development of model clauses>; and

(b) To make use of model clauses[, contracts, arrangements and/or agreements,] and relevant inventories/catalogues developed in accordance with <cross reference to operational provision on model clauses>.]

8. Parties [shall][should] undertake special capacity-building measures for indigenous and local communities, on the basis of the needs identified with the full and effective participation of indigenous and local communities, particularly indigenous women. [These capacity building measures for indigenous and local communities [shall][should] include, but not be limited to:

(a) Capacity to conserve, sustainably use and promote their traditional knowledge associated with genetic resources [and derivatives];

(b) Capacity to identify, assert and safeguard their rights over their traditional knowledge associated with genetic resources [and derivatives] in the context of negotiation and implementation of ABS agreements;

(c) Capacity to develop and implement and/or enforce community protocols relating to access to [genetic resources [and derivatives] and] [associated] traditional knowledge [associated with genetic resources [and derivatives]];

(d) Capacity to document their traditional knowledge associated with genetic resources [and derivatives] including the capacity to enforce their rights over the process and outcome of such documentation[, whenever appropriate];

(e) Capacity to ensure the protection of database[s] of traditional knowledge associated with genetic resources [and derivatives] from unauthorized use;

(f) Capacity to ensure communication, education and public awareness regarding ABS;

(g) Capacity in accordance with Article 8(j) [and 10 (c)] of the Convention on Biological Diversity to promote the wider application of indigenous knowledge, innovations and practices [associated with genetic resources] [and derivatives] by actively involving indigenous and local

communities with their consent in the planning and implementation of 'Research and Training' (Article 12), 'Public Education and Awareness' (Art 13), 'Exchange of Information' (Art 17.2) and 'Technical and Scientific Cooperation' (Art 18.4);

(h) Increasing the understanding of the [importance of the] economics of biodiversity and ecosystem services and to integrate them in workable benefit-sharing schemes that are beneficial to indigenous and local communities;

(i) Support the utilization of methodologies for the valuation of [biological and] genetic resources [and derivatives] and traditional knowledge [associated with genetic resources] [and derivatives];

(j) Develop human resources and institutional capacity of indigenous and local communities to undertake research and development activities related to genetic resources [and their derivatives] and traditional knowledge [associated with genetic resources] [and derivatives], at the local level, including [through] technology transfer [and] [of] biotechnology[, in accordance with the relevant provisions of the Convention];

(k) [Support capacity [of the indigenous and local communities] to undertake measures to monitor and [enforce] compliance with [this Protocol][the international regime,] community procedures, customary laws or community protocols of indigenous and local communities with regard to access and benefit sharing, and contracts based on mutually agreed terms.] [ABS compliance management.]

[9. There shall be a fund/financial mechanism to support capacity-building programmes with the objectives described above, taking into account that capacity should be strengthened at systemic, institutional and individual levels for all key areas. This fund will be established within six months following the entry into force of this Protocol/international regime, and will be constituted by contributions from developed country Parties and from other interested stakeholders.]

[10. The Parties [shall] [should] take the appropriate measures with regard to donors and other relevant organizations as well as within the Governing bodies of the relevant international funding mechanisms[, funds and bodies] including the Global Environmental Facility to ensure [due consideration be given to] the provision of financial resources for capacity building programmes including resources to indigenous and local communities to implement their own capacity building strategies and mechanisms.]
