



# CONVENTION ON BIOLOGICAL DIVERSITY

Distr.  
GENERAL

UNEP/CBD/WG-ABS/5/3  
13 September 2007

ORIGINAL: ENGLISH

---

AD HOC OPEN-ENDED WORKING GROUP ON  
ACCESS AND BENEFIT-SHARING  
Montreal, 8-12 October 2007  
Item 3 of the provisional agenda\*

## **ANALYSIS OF GAPS IN EXISTING NATIONAL, REGIONAL AND INTERNATIONAL LEGAL AND OTHER INSTRUMENTS RELATING TO ACCESS AND BENEFIT-SHARING**

*Note by the Executive Secretary*

### **I. INTRODUCTION**

1. In its decision VII/19 D, the Conference of the Parties mandated the Ad Hoc Open-ended Working group on Access and Benefit-sharing to elaborate and negotiate an international regime on access to genetic resources and benefit-sharing with the aim of adopting an instrument/instruments to effectively implement the provisions in Article 15 and 8(j) of the Convention and the three objectives of the Convention. The terms of reference set out for the Working Group on Access and Benefit-sharing provide that the negotiation of the international regime will draw on “*inter alia*, an analysis of existing legal and other instruments at national, regional and international levels relating to access and benefit-sharing, including: access contracts; experiences with their implementation; compliance and enforcement mechanisms; and any other options”.
2. Following the seventh meeting of the Conference of the Parties to the Convention on Biological Diversity, a document was prepared for the third meeting of the Working Group on Access and Benefit-sharing entitled “Analysis of existing national, regional and international legal instruments relating to access and benefit-sharing and experience gained in their implementation, including identification of gaps”. At this meeting, in order to facilitate further analysis of gaps in existing national, regional and international legal and other instruments relating to access and benefit-sharing, the Working Group developed a matrix for the analysis of gaps. Based on this matrix, the Working Group invited Parties, Governments, indigenous and local communities, international organizations and all relevant stakeholders to provide information to the Secretariat to fill in the matrix. The matrix containing a consolidation of the information provided was submitted to the Working Group at its fourth meeting in document UNEP/CBD/WG-ABS/4/3. In addition, the submissions relating to the matrix were compiled and made available in document UNEP/CBD/WG-ABS/4/INF/4.
3. In decision VIII/4 A, paragraph 9, the Conference of the Parties requested the Executive Secretary to prepare, for the fifth meeting of the Working Group, the final version of the gap analysis referred to in decision VII/19 D, annex, paragraph (a) (i), bearing in mind that this work will proceed in

---

\* UNEP/CBD/WG-ABS/5/1.

/...

parallel and not hold up the work relating to the elaboration and negotiation of the international regime. In paragraph 8 of the same decision, Parties, Governments, indigenous and local communities, international organizations and all relevant stakeholders were invited to submit to the Secretariat further information relevant to the gap analysis.

4. In light of the above, the analysis of gaps as contained in this document takes into account and should be read in conjunction with:

(a) The overview of recent developments at national and regional levels relating to access and benefit-sharing available in document UNEP/CBD/WG-ABS/5/4;

(b) The overview of recent developments at the international level relating to access and benefit-sharing available in document UNEP/CBD/WG-ABS/5/4/Add.1;

(c) The matrix on the analysis of gaps prepared for the fourth meeting of the Working Group available in document UNEP/CBD/WG-ABS/4/3; and

(d) Contributions provided by Parties and relevant stakeholders for the fifth meeting of the Working Group available in information documents UNEP/CBD/WG-ABS/5/INF/1 and UNEP/CBD/WG-ABS/5/INF/2.

5. In addition, in order to assist with the analysis of gaps, the following studies were commissioned to provide relevant information to the gap analysis:

(a) A study on administrative and judicial remedies available in countries with users under their jurisdiction and in international agreements, available in document UNEP/CBD/WG-ABS/5/INF/3;

(b) An analytical study of access and benefit-sharing arrangements in different sectors. This study is to provide an overview of how different sectors address prior informed consent, mutually agreed terms including benefit-sharing, intellectual property rights and issues of compliance, in order to identify commonalities and divergences among sectors and potential gaps.

6. The latter study on access and benefit-sharing arrangements will only be available for the sixth meeting of the Working Group on Access and Benefit-sharing. It will provide information on access and benefit-sharing contracts/partnerships in a number of sectors and shed some light on access and benefit-sharing practices.

7. For ease of reference and to facilitate its use in the negotiating process, the structure of this document follows the agenda items for the fifth and sixth meetings of the Working Group on Access and Benefit-sharing. As highlighted in the annotated agenda, the agenda items build on the possible elements of an international regime listed in the terms of reference, as set out in Annex to decision VII/19 D. These elements were grouped in clusters corresponding to key thematic headings. In order to analyse the gaps in the existing system, this document follows the same structure. For each of these thematic headings, the document examines how the Convention has addressed these elements, how they were addressed at regional and national levels, <sup>1/</sup> and whether they are addressed by other international instruments and in access and benefit-sharing arrangements. Finally, the document identifies potential gaps with respect to each of these thematic headings. Section III addresses additional gaps in the existing access and benefit-sharing system and section IV provides a summary for consideration by the Working Group. This analysis does not purport to be comprehensive as it is based on information available to the Secretariat at the time of drafting.

8. A number of gaps can be identified in the existing instruments relating to access and benefit-sharing as demonstrated below. However, it should be noted that what constitutes a gap may be a matter of interpretation. Parties will need to determine whether the issues raised in this document consist in

---

<sup>1/</sup> Although Parties may be both users and providers of genetic resources, in order to facilitate the examination of national measures related to access and benefit-sharing adopted by Parties, the document examines in parallel national measures adopted by Parties as providers of genetic resources and measures adopted by Parties as users of genetic resources.

gaps that warrant addressing and if so, whether these should be addressed by the international regime or, rather, at the regional or national levels.

## II. ANALYSIS OF GAPS

### A. *Fair and equitable sharing of benefits*

9. Among the elements to be considered by the Working Group for inclusion in the international regime (Terms of Reference for the Working Group, in decision VII/19 D, Annex, (d)), the following elements (i), (ii), (iii), (v), (vi) relate to the fair and equitable sharing of benefits:

“(i) Measures to promote and encourage collaborative scientific research, as well as research for commercial purposes and commercialization, consistent with Articles 8(j), 10, 15, paragraph 6, paragraph 7 and Articles 16, 18 and 19 of the Convention;

(ii) Measures to ensure the fair and equitable sharing of benefits from the results of research and development and the benefits arising from the commercial and other utilization of genetic resources in accordance with Articles 15.7, 16, 19.1, 19.2. of the Convention;

(iii) Measures for benefit-sharing including, *inter alia*, monetary and non-monetary benefits, and effective technology transfer and cooperation so as to support the generation of social, economic and environmental benefits;

(v) Measures to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources;

(vi) Measures to ensure the sharing of benefits arising from the commercial and other utilization of genetic resources and their derivatives and products, in the context of mutually agreed terms;”

10. The following examines how the issue of benefit-sharing has been addressed by provisions of the Convention on Biological Diversity, in regional and national instruments and in access and benefit-sharing arrangements, in order to identify gaps. It should be noted that measures to support compliance with prior informed consent (PIC) and mutually agreed terms (MAT), including those referred to under elements (i) and (ii) are addressed below under section C. This section examines how benefit-sharing has been addressed by national regimes (types of benefits, timing, distribution and mechanisms) and in access and benefit-sharing arrangements.

#### 1. *Provisions of the Convention*

11. Articles 1, 8(j), 15.7, 16.3, 16.4, 17.2, 18.4, 18.5, 19.1 and 19.2 of the Convention address directly or indirectly the fair and equitable sharing of benefits.

#### 2. *Bonn Guidelines*

12. The Bonn Guidelines under section IV D refer to Article 15.7 and under section IV D 3 address specifically benefit-sharing by addressing types of benefits, the timing of benefits, the distribution of benefits and mechanisms for benefit-sharing. In addition, appendix II of the Bonn Guidelines provides a list of potential monetary and non-monetary benefits.

### 3. *Regional and national instruments*

#### *Regional measures*

13. The following examines how regional measures have addressed benefit-sharing through mutually agreed terms, on the basis of the analysis carried out in document UNEP/CBD/WG-ABS/3/2.

14. The regional measures provide for the development of access and benefit-sharing agreements and include a minimum list of terms which are to be covered by the agreement (Article 11 of the draft ASEAN agreement; Decision 391, chapter III, article 17; Central American agreement, article 19; African Model Law, article 8). Decision 391 is unique in that it provides for the signature of both an access contract between the competent national authority and the applicant requesting access (chapter III) and the signing of an ancillary contract between the applicant and the provider of the genetic resources (title IV, article 41) and an annex to the genetic resource contract, between the provider of the associated knowledge (scientific or traditional), when it is also being accessed (Chapter III). It is also worth noting that both the African Model Law and the draft ASEAN agreement propose that indigenous and local communities should be involved in the negotiation of access and benefit-sharing agreements.<sup>2/</sup> As set out in these regional instruments, access and benefit-sharing contracts would include non-monetary benefits and monetary benefits, as appropriate (e.g. Decision 391, articles 17 and 35).

15. Finally, it is interesting to note that the African Model Law suggests the establishment of a Community Gene Fund, deriving its funds from the sharing of benefits with local farming communities which would be used to finance projects developed by the farming communities (Part VII, article 66).

#### *National measures adopted by Parties as providers of genetic resources*

16. With respect to access and benefit-sharing measures adopted by countries, as noted in document UNEP/CBD/WG-ABS/5/4, it is difficult to draw general conclusions from the analysis of these measures because countries have adopted different approaches. According to official sources, at least 58 countries are in the process of developing or have adopted access and benefit-sharing measures. Out of these 58 countries, measures from 39 countries are included in the database of the Convention on Biological Diversity. Some have adopted measures referring to access and benefit-sharing without providing detailed procedures for access and benefit-sharing.

17. On the basis of available information on access and benefit-sharing measures, one of the main conclusions to be drawn is the absence of a harmonized approach due to the multiplicity of approaches Parties and countries have taken based on their existing legislation, needs and constitutional structures. While some countries have adopted a single measure on access and benefit-sharing, others have adopted a package of measures (e.g. a strategy, a law and guidelines). In addition, a number of countries are still in the process of developing their national regimes and therefore the package is often incomplete.

18. With respect to benefit-sharing in particular, regional instruments provide for access and benefit-sharing contracts that include both non-monetary and monetary benefits. In national measures, indications regarding the types of benefits to be shared vary depending on the measures. In general, measures provide for both non-monetary benefits, such as capacity-building, access and transfer of technology and for monetary benefits derived from the commercial utilization of the resources accessed through the sharing of royalties and/or milestone payments.

19. It is interesting to note that some access and benefit-sharing measures (i.e. legislation and/or regulations) identify that access and benefit-sharing agreements need to be negotiated before access can be granted, and others also provide a list of possible benefits to be shared.

20. Based on the analysis of national measures in document UNEP/CBD/WG-ABS/5/4, it appears that a majority of existing national systems provide that mutually agreed terms for access and benefit-

---

<sup>2/</sup> See article 7 of African Model Law and article 11 of the draft ASEAN agreement for further details.

sharing are to be set out in a document or set of documents which may include permits, contracts, and material transfer agreements. Measures generally provide for benefit-sharing with the State (or the competent national authority), or with indigenous and local communities or other resource providers, <sup>3/</sup> and in most cases for both. <sup>4/</sup> Benefit-sharing terms can be set out in different kinds of agreements. Depending on the national regime, they can be established in a contract of access or a material transfer agreement with other mutually agreed terms (regarding access conditions, use of collected resources, commitment to report, etc.) or in a separate benefit-sharing agreement. In some countries, the agreement containing benefit-sharing arrangements is negotiated by the competent national authority (CNA) <sup>5/</sup> while in others, the CNA is restricted to approving the agreement negotiated by indigenous and local communities or any relevant stakeholder and the applicant. <sup>6/</sup> Some measures also provide for the consultation of relevant stakeholders by the CNA before entering into an agreement <sup>7/</sup> or the possibility of parallel agreements between the applicant and both of the CNA and relevant stakeholders (local communities, providers). <sup>8/</sup> It should be noted that many national measures also provide that owners/holders of traditional knowledge associated with genetic resources shall get a share of benefits arising from the use of their traditional knowledge. <sup>9/</sup>

21. Indications regarding the types of benefits to be shared vary depending on the measures. In general, measures provide for both non-monetary benefits, such as capacity-building, access and transfer of technology, and for monetary benefits derived from the commercial utilization of the resources accessed through the sharing of royalties. <sup>10/</sup> As a non-monetary benefit, some countries provide, for the involvement of local citizens or institutions in the research, collection and the technological development of the products derived from the biological and genetic resources. <sup>11/</sup> Some measures also require the disclosure of origin of genetic resources or traditional knowledge referred to in publications or other uses and disseminations. <sup>12/</sup> However, it is interesting to note that some countries only focus on monetary <sup>13/</sup>

---

<sup>3/</sup> Such as Afghanistan Environment Act under section 64; Australian Regulations under section 8A.07; South African Biodiversity Act under section 80 (1) (c); and Vanuatu Environmental Act under section 36 (6)(b)(iii).

<sup>4/</sup> It is the case, for example, of Bolivia, Brazil, Ethiopia, Panama and Philippines. It is interesting to note that Ethiopia provide to local communities the “right to obtain 50 % of the benefit shared by the State in the form of money from the benefits derived out of the utilization of their genetic resources”: Ethiopian Proclamation, section 9 (2).

<sup>5/</sup> Such as the Bolivian Decree, section 36; the Bhutan Biodiversity Act, sections 9 (f) and 10; the Indian Biological Diversity Act, section 21; and the Ethiopian Proclamation, sections 14 (2) (3) and 16 (9) (10).

<sup>6/</sup> For example, see Afghanistan Environment Act, section 64 (4); Australian Regulations, section 8A.07; Brazilian Provisional Act, sections 27 and 29; Philippines Guidelines for bioprospecting activities, section 14; South-African Biodiversity Act, articles 82 (2), 82 (3), 83 (2) and 84 (2); and Vanuatu Environment Act, article 34 (6) (a).

<sup>7/</sup> Such as in Ethiopian Proclamation, sections 14 (2) (3) and 16 (9) (10) and in Indian Biological Diversity Act, section 21 and Biological Diversity Rules, sections 14 (5) (6) and 20 (5), for example.

<sup>8/</sup> Such as in Bhutan Biodiversity Act, section 10 and in Panamanian Decree, sections 38 and 41.

<sup>9/</sup> See Australian Regulations, section 8A.08; Bhutan Biodiversity Law, section 38 (b); Bolivian Decree, sections 15 (2), 44 and 47; Brazilian Provisional Act, section 9; Ethiopian Proclamation, sections 16 (10), 17(15) and 18; Indian Biological Diversity Act, section 21 and Indian Biological Diversity Rules, section 20 (8); Panamanian General Law, section 105; South African Biodiversity Act, sections 82 (1) (b) and 82 (3); and Vanuatu Environmental Act, section 34 (6) (a).

<sup>10/</sup> For examples, see Bhutan Biodiversity Act, section 10; Brazilian Provisional Act, section 25, Ethiopian Proclamation, sections 19; Indian Biological Diversity Act, section 21 (2) and Biological Diversity Rules, section 20; Kenyan Regulations, section 20; Philippines Guidelines for Bioprospecting activities, sections 15-17; and Ugandan Regulations, section 20.

<sup>11/</sup> For example, see Bolivian Regulations, section 42 (b); Kenyan Regulations, section 20 (1); Malawi Procedures and Guidelines for Access and Collection of Genetic Resources, sections E(2) (3) and H (1); Ugandan Regulations, sections 15 (2) h) and 20 (2) (a); and Venezuelan Biological Diversity Act, article 74(4). In Philippines, commercial bioprospecting activities require the participation of a local collaborator (section 19). It is also interesting to note that the Provisional Act of Brazil mentions that research on genetic resources should preferably be carried out on Brazilian territory (section 16 (7)).

<sup>12/</sup> See, for example, Brazilian Provisional Act, section 9 and Panamanian Decree, section 23. Requirements for the disclosure of origin/source/legal provenance is intellectual property rights applications are addressed below.

<sup>13/</sup> Such as South Africa, under section 85 of the Biodiversity Act.

or non-monetary <sup>14/</sup> benefits. While some countries only address equitable benefit-sharing on a case-by-case basis, <sup>15/</sup> others establish the minimum or maximum percentage of their participation in benefits. <sup>16/</sup> Few countries also provide further details regarding the purpose for which obtained benefits should be allocated such as, for example, the conservation of biodiversity and the promotion of community knowledge. <sup>17/</sup> Some countries also provide for the establishment of funds, in which the benefits received by the State or not allocated to stakeholders will be kept. <sup>18/</sup> Finally, some measures also establish conditions with respect to the transfer of genetic resources to third parties or provide that these conditions shall be set out in the agreement. <sup>19/</sup>

22. *Intellectual property rights* as they relate to access and benefit-sharing are addressed by a majority of the access and benefit-sharing regimes examined, in different ways and to various degrees. <sup>20/</sup> A number of measures consider intellectual property rights in the context of benefit-sharing through the sharing of royalties <sup>21/</sup> or provide that the agreement is to recognize the joint ownership of intellectual property rights <sup>22/</sup> or establish mutually agreed conditions for determination of the owner/holder of these rights. <sup>23/</sup>

#### *Measures adopted by Parties as users of genetic resources*

23. These measures are addressed below under “Measures to support compliance with prior informed consent and mutually agreed terms”.

#### 4. *Access and benefit-sharing arrangements*

24. The analytical study on access and benefit-sharing arrangements in different sectors will assist in determining how these sectors have addressed the sharing of benefits. It will provide information with respect to the types of monetary and non-monetary benefits provided for, the timing of benefits (near-term, medium-term, and long term), the distribution of benefits among those that have been

---

<sup>14/</sup> Such as Venezuela, under section 74 (4) of the Biodiversity Law.

<sup>15/</sup> Such as the Ethiopian Proclamation, section 18; the Indian Biological Diversity Rules, section 20; and the Ugandan Regulations, section 20 (2).

<sup>16/</sup> For example, in Costa Rica, the interested party should deposit, for basic research or bioprospection, up to 10 % of the research or bioprospection’s budget and, for occasional or regular economic exploitation, to pay up to 50% of the royalties obtained. (Biodiversity Act, section 76 and Decree on General Rules for the Access to Genetic Resources, section 9 (4) (5)). In Philippines, a minimum amount of 2% of total global gross sales of the product(s) made or derived from collected samples should be paid annually to national government and resources providers for as long as the product is sold (25% to the government and 75% to the providers) (Guidelines for bioprospecting activities in the Philippines, section 16).

<sup>17/</sup> That is, for example, the case of Ethiopia with its Proclamation to Provide for Access to Genetic Resources and Community Knowledge and Community Rights, section 18 (2). This regime also requires that benefits obtained by local communities arising from the use of their genetic resources or community knowledge are put to the common advantage of the concerned community (section 9(3)). The procedure to ensure the application of these two requirements shall be specified by further regulations (sections 9 (4) and 18 (2)). See also the Bolivian Regulations, section 40; the Brazilian Provisional Act, section 33; the Indian Biological Diversity Rules, section 20 (7); and the Panamanian Decree, section 40 (a).

<sup>18/</sup> For example, Brazilian Provisional Act, section 33; Indian Biological Diversity Act, sections 21 (3) and 27 (2) and the Biological Diversity Rules, section 20 (8); and South African Biodiversity Act, section 85.

<sup>19/</sup> For example, see Afghanistan Environment Act, section 65 par.1 (7); Australian Regulations, section 8A.08; Bhutan Biodiversity Act, section 9 (d); Ethiopian Proclamation, section 17 (9); Indian Biological Diversity Act, article 20 and Biological Diversity Rules, section 19; South African Biodiversity Act, article 84 (1) (vii); Ugandan Regulations, section 15 (2) d); and Venezuelan Biodiversity Law, article 74 (3).

<sup>20/</sup> See measures adopted by Afghanistan, Bolivia, Brazil, Bhutan, Costa Rica, Ethiopia, India, Peru, Philippines, Uganda, Vanuatu and Venezuela. It should be noted that for Andean Pact countries, intellectual property rights related to access and benefit-sharing are addressed by decisions 391 and 486 of the Andean Community.

<sup>21/</sup> For example, article 5 of the Costa Rican Decree provides for the obligation to pay up to 50% of royalties.

<sup>22/</sup> Such as Bhutan Biodiversity Act, section 10 (e) and Ugandan Regulations, section 20 (2) (i).

<sup>23/</sup> For example, see the Bolivian Regulations, section 36; the Brazilian Provisional Act, section 28 (v); and the Indian Biological Diversity Rules, section 14 (6) (iv).

identified as having contributed to the resource management, scientific and/or commercial process. Mechanisms for benefit-sharing will also be examined such as trust funds, joint ventures and licences with preferential terms. They will also indicate whether issues set out in articles 15, 16 and 19 of the Convention have been addressed, such as participation in biotechnological research activities, technology transfer and results and benefits arising from biotechnologies.

25. The case-studies carried out for each sector will reveal the commonalities and divergences among sectors in terms of how they address the various aspects of benefit-sharing mentioned above.

#### 5. *Possible gaps on fair and equitable sharing of benefits*

26. As demonstrated above, due to the limited number of access and benefit-sharing measures adopted and the different approaches adopted, it is difficult to draw conclusions regarding gaps with respect to benefit-sharing.

27. Nevertheless, it has been suggested that gaps related to the sharing of benefits may include:

(a) The limited number of countries that have established access and benefit-sharing regimes may be considered an obstacle to creating an enabling environment for the generation of scientific, commercial and social benefits from genetic resources, limiting the ability for equitable benefit-sharing;

(b) The lack of uniform standards for benefit-sharing;

(c) The fact that harmonized benefit-sharing measures have not been developed for transboundary genetic resources;

(d) The fact that existing national access and benefit-sharing measures do not always link benefit-sharing to biodiversity conservation and sustainable use;

(e) The absence of measures adopted by Parties with users under their jurisdiction to support the sharing of benefits between users and providers of genetic resources (see below under measures to support compliance with PIC and MAT);

(f) The fact that processes related to prior informed consent and mutually agreed terms rarely differentiate between access for scientific or commercial purposes may have created a disincentive to scientific research and reduced the potential sharing of non-monetary benefits through non-commercial scientific research cooperation, such as the exchange of researchers and joint research projects. However, resources initially accessed for scientific purposes may subsequently be used for commercial purposes.

28. The study on access and benefit-sharing arrangements will assist in determining the types of benefits that are provided for in these arrangements for different sectors. Based on these findings it will be possible to determine whether there are gaps in existing access and benefit-sharing arrangements and at what level these need to be addressed.

29. As set out in the Bonn Guidelines, the development of standardised Material Transfer Agreements (MTAs) and benefit-sharing arrangements for similar resources and similar uses has been suggested as a means to provide legal certainty and clarity and minimise transaction costs.

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

#### 1. *Provisions of the Convention on Biological Diversity*

30. Articles 1 and 15 of the Convention are relevant to access to genetic resources.

#### 2. *Bonn Guidelines*

31. Access to genetic resource in the Bonn Guidelines is addressed through provisions dealing with prior informed consent. Section IV.C. of the Bonn Guidelines addresses Prior Informed Consent,

including basic principles of a prior informed consent system, elements of a prior informed consent system, competent authority(ies) granting prior informed consent, timing and deadlines, specifications of use and procedures for prior informed consent and the process for obtaining prior informed consent.

### 3. *Regional and national instruments*

32. The overview of access and benefit-sharing measures contained in document UNEP/CBD/WG-ABS/5/4 illustrates how regional and national measures have addressed the issue of access to genetic resources through prior informed consent (PIC).

#### *Regional measures*

33. Prior informed consent is covered by all regional access and benefit-sharing measures in a similar way. They provide that the prior informed consent of competent national authorities (CNA) is required prior to accessing a resource. They also provide for an application to be filled out which includes similar requirements such as: the identification of the applicant, the disclosure of information regarding local collaborators and the specific geographical area where the genetic resource is located. The involvement of indigenous and local communities and/or other relevant stakeholders in prior informed consent procedures are addressed by the Andean Pact decision 391, the draft ASEAN agreement (article 10), the draft Central American agreement (article 13) and the African Model Law (article 5). The draft Central American agreement provides that the competent national authority will deliver a certificate of origin establishing the legality of access to the resource and traditional knowledge (article 21).

#### *National measures*

34. In each of the access and benefit-sharing regimes covered by document UNEP/CBD/WG-ABS/5/4, some type of application for access has to be made in order to obtain access to genetic resources. These provisions also provide indications regarding the specific information an application for access should contain <sup>24/</sup> and the procedure leading to approval or refusal. <sup>25/</sup> In certain countries, application or collection fees are also requested. <sup>26/</sup> The approval or the refusal to grant access is determined by the competent national authority. However, while some regimes settle for the approval of the competent authority, <sup>27/</sup> a majority of the measures examined also require the prior informed consent of the relevant authority/the resource provider in the geographical area where genetic resources are to be accessed. These resource providers are generally indigenous and local communities or other relevant stakeholders, such as private owners or conservation area authorities. <sup>28/</sup> Many countries also provide for the protection of traditional knowledge associated to genetic resources within their national regime.

---

<sup>24/</sup> See, for example, Bhutan (section 7 of the Biodiversity Act) and Afghanistan (section 63 of the Environment Act).

<sup>25</sup> See, for example, Bhutan (sections 9-10 of the Biodiversity Act), Bolivia (sections 23-29 of its Decree and Ethiopia (sections 13-14 of its Proclamation).

<sup>26/</sup> For example: Afghanistan, under section 62 (2) of the Environment Act; Costa Rica, articles 76 of the “Ley de Biodiversidad” (Costa Rican Law), and 9(4)(c) of the “Normas Generales para el Acceso a los Elementos y Recursos Genéticos y Bioquímicos de la Biodiversidad, Decreto 31 514” (Costa Rican Decree); India, under section 41(3) of the Biological Diversity Act, 2002 and section 14 (2) of the Biological Diversity Rules 2004; Kenya, under section 9 (1) of its Regulations; Malawi, under section D(3) of Procedures and Guidelines for Access and Collection of Genetic Resources in Malawi; Philippines under section 15 of Guidelines for bioprospecting activities in the Philippines (Philippine Guidelines) and sections 15.9 and 21.1 of the Implementing Rules and Regulations; and Uganda under sections 12, 14 and 19 of its Regulations.

<sup>27/</sup> Such as Bhutan and Ethiopia (except in cases of access to traditional knowledge).

<sup>28/</sup> For example, see section 64 the Afghanistan Environment Act; sections 8.04 and 8.09 of the Australian Regulations; article 16 par. 9 of the Brazilian Provisional Act; articles 63, 65 and 66 of the Costa Rican Law; section E(8) of the Procedures and Guidelines for Access and Collection of Genetic Resources in Malawi, section 87BIS of the Mexico General Law of Ecological Balance and Environmental Protection; sections 21-22 of the Panamanian Decree; section 14 of the Philippines Wildlife Resources Conservation Act; section 82 of the South African Biodiversity Act, section 12 of the Ugandan; and section 34 (6)(b) of Vanuatu Environmental Management and Conservation Act (Vanuatu Environmental Act).



29/ In this respect, some of these countries require to obtain the prior informed consent from the owners/holders of the traditional knowledge. 30/

35. Some regimes require the prior informed consent of relevant stakeholders and/or that evidence of prior informed consent is provided to the competent national authority before the deliverance of the permit of access or signature of the contract of access (such as Afghanistan, Panama, South Africa, Uganda and Vanuatu). 31/ In addition, some countries have adopted different requirements for access depending on the type of applicant. For example, the Indian, 32/ Bolivian, 33/ Brazilian 34/ and Philippines 35/ regimes provide for different procedures for nationals and foreigners who wish to obtain access to genetic resources. Other countries, such as Australia, 36/ Bhutan, 37/ Costa Rica, 38/ the Philippines 39/ and South Africa, 40/ have established different requirements depending on whether access is to be granted for commercial or non-commercial purposes. Some countries, such as

---

29/ Such as, Afghanistan, Bhutan, Bolivia, Brazil, Costa Rica, Ethiopia, India, Panama, South Africa and Vanuatu.

30/ For example, sections 37-38 of the Bhutan Biodiversity Act; section 66 of the Costa Rican Law; sections 7 and 12 (2) of the Ethiopian Proclamation; section 82 of South African Biodiversity Act; and section 34 (6) (b) of the Vanuatu Environmental Act.

31/ In Afghanistan, an access permit can only be issued if the Competent national authority is satisfied of the achievement of the prior informed consent of the relevant stakeholders (section 64(4) of Environment Act) In Panama, the contract between providers and the applicant must be known by the competent national authority before the signature of the contract of access (Panamanian Decree, article 22). In South Africa, the issuance of permit of access requires that the applicant and the stakeholder have entered into a material transfer agreement and a benefit-sharing agreement (section 82 of Biodiversity Act). In Uganda, before the competent authority can issue an access permit, the applicant has to obtain the prior informed consent of, and entered into an accessory agreement with, a lead agency, a local community or the owner of the land. The applicant also has to enter into a material transfer agreement with the lead agency (Sections 12, 14 and 19 of the Ugandan Regulations). In Vanuatu, the competent authority “must satisfy itself that a legally binding and enforceable contract is concluded with custom landowners, or any owners of traditional knowledge” (section 34 (6)(b) of the Environmental Act).

32/ For example, within the Indian Biological Diversity Act, the prior informed consent of the National Biodiversity Authority is requested for foreigners as defined under sections 3 (2) and 19. Different procedures are established for Indian nationals under sections 7, 23 and 24 of the same act.

33/ The article 17 of the Bolivian Decree requires that the applications for access be submitted to a different body depending on whether the applicant is a foreigner or not.

34/ The article 16 (6) of the Brazilian Provisional Act states that participation of foreign legal entity in access of genetic resources and associated knowledge shall be “authorized only when it is joined by a Brazilian public institution, the latter having mandatory coordination of activities”.

35/ The article 14 and 15 of the Philippines Wildlife Resources Conservation and Protection Act (Philippine Republic Act No 9147) requires that “[i]f an applicant is a foreign entity or individual, a local institution should be actively involved in the research, collection and, whenever applicable and appropriate in the technological development of the products derived from the biological and genetic resources”. See also section 19.2 of the Philippine Guidelines for bioprospecting activities.

36/ Divisions 8A.2 and 8A.3 of the Australian Regulations provide different requirements for access to biological resources for commercial, or a potential commercial, purposes than for non-commercial purposes. If they both need a permit of access, commercial, or potential commercial, purposes require informed consent of owners of the land and a benefit-sharing agreement with each access provider for the resources while non-commercial purpose require only a written permission of access providers and a copy of a statutory declaration given to each access provider declaring that the applicant does not intend to use the biological resources for commercial purposes and undertakes to give written report on results of research, to give a taxonomic duplicate of each sample, not to transfer any sample without permission of each access provider and not to carry out, or allow others to carry out, research or development for commercial purposes on any genetic resources or biochemical compounds.

37/ See section 6 of the Bhutan Biodiversity Act.

38/ See article 71 of the Costa Rican Law.

39/ In the Philippines, collection and utilization of biological resources for non-commercial purposes shall be allowed upon execution of an agreement with the CAN and the issuance of an gratuitous permit require, while bioprospecting for commercial purposes require the prior informed consent from concerned local communities and private individuals and payment of bioprospection fees. See sections 14-15 of the Philippines Republic Act 9147.

40/ The access and benefit-sharing regime of the South African Biodiversity Act regulates bioprospecting (section 80) which cover only “research on, or development or application of, indigenous biological resources for commercial or industrial exploitation” (section 1 (1)).

Ethiopia, <sup>41/</sup> Kenya <sup>42/</sup> and Uganda <sup>43/</sup> take into account these two considerations to exempt from their access and benefit-sharing regime research activities intended for educational purposes and undertaken by national institutions. Finally, some countries issue a certificate once prior informed consent has been obtained or for permission to export. <sup>44/</sup>

#### *Competent national authorities and national focal points*

36. Out of the 190 Parties to the Convention, as of 18 July 2007, seventy-two had established national focal points for access and benefit-sharing and fifteen had established competent national authorities for access and benefit-sharing.

#### *4. Access and benefit-sharing arrangements*

37. The analysis of a selection of access and benefit-sharing arrangements in different sectors will assist in identifying who grants the permission to access genetic resources under prior informed consent and under what conditions in different types of partnerships. It will examine who has the responsibility to grant permission for access to genetic resources, including whether the prior informed consent of landowners is required, whether access is granted for research or commercial utilization and under which conditions, whether a new consent is required if the intended use changes, or if the resource is transferred to a third party.

#### *5. Possible gaps related to access to genetic resources*

38. As demonstrated in the overview of national measures, a majority of Parties have still not adopted national access and benefit-sharing regimes. Also, in a number of countries that have adopted access and benefit-sharing legislations, regulations are still to be developed to implement them. A large variety of approaches have been adopted to deal with access and benefit-sharing, adapted to the national administrative structures, priorities, cultural and social specificities. Consequently, there is a lack of uniformity among access and benefit-sharing measures, including with respect to the specific procedures to follow to obtain access to genetic resources. Many countries are still relying on wildlife and environmental regulations which pre-date the Convention and may not have taken benefit-sharing considerations into account.

39. In addition it may be difficult for those seeking access to identify the competent authorities to grant access. According to information made available to the Secretariat, only 72 Parties have established national focal points for access and benefit-sharing and 15 Parties have established competent national authorities. In addition, there is often more than one authority at the national level dealing with access and benefit-sharing issues depending on the location of the genetic resources to be accessed. Many countries are still relying on wildlife and environmental authorities which pre-date the Convention and reflect the multiple constituencies around biological diversity.

---

<sup>41/</sup> According to the section 15 (1) of the Ethiopian Proclamation, Ethiopian national public research and higher learning institutions and intergovernmental institutions based in the country may obtain an access permit without the need to strictly follow the access procedure.

<sup>42/</sup> Kenyan Regulations approved research activities intended for educational purposes within recognized Kenyan academic and research institutions, which are governed by relevant intellectual property laws (section 3 (d)).

<sup>43/</sup> Ugandan Regulations does not apply to approved research activities intended for educational purposes by Ugandan institutions recognised by the competent authority, and which do not result in access to genetic resources for commercial purposes or export to other countries (section 4 (2) (e)).

<sup>44/</sup> For example, the Philippines Guidelines on bioprospecting, under section 13.2 (c) and Annex IV, provide for the issuance of a PIC certificate once prior informed consent has been obtained. The Costa Rican Decree, in article 19, provides that a certificate of origin is to be issued by the Technical Office of CONAGEBIO certifying the legality of access and the observance of the terms set out in the access permit. Some countries (such as South Africa and Vanuatu) require a permit to export specimen obtained from bioprospecting while others (such as Kenya) require a material transfer agreement (South African Biodiversity Act, section 81 (1) (b); Vanuatu Environmental Act, section 32 (2); and Kenyan Regulations, section 18).

40. It has been argued that this situation has created legal uncertainty and lack of predictability for users of genetic resources. It has also been argued that some access and benefit-sharing measures are cumbersome and that procedures are non-transparent leading to confusion and lack of effectiveness.

41. A number of countries have only recently adopted access and benefit-sharing measures, however some access and benefit-sharing regimes have been in place for a number of years. Therefore, some experience with implementation has been acquired but it has been limited to a small number of countries. In addition, implementation has been hampered by limited human and institutional capacity and enforcement, and the low level of awareness of those involved in access and benefit-sharing. It has been argued that, intentionally or not, national legislation has often impeded access due to delays, cumbersome bureaucracy, the lack of explicit prior informed consent mechanisms and uninformed national authorities.

42. Some also argue that additional lacunas include the failure to:

- (a) Differentiate between access of genetic resources for research or commercial purposes;
- (b) Link access regulations to measures to guarantee that access to genetic resources will not be detrimental to biodiversity conservation;
- (c) Positive incentives for sustainable economic uses of genetic resources.

43. With respect to the differentiation between access for research or commercial purposes, some would argue that the potential movement of materials from non-commercial to commercial use is a loophole which needs to be monitored and addressed, perhaps through access regulations which have different clauses which trigger new requirements if the use of the material changes.

44. Based on the third national reports, obstacles to implementation may have included the following:

- (a) Limited capacity;
- (b) The fact that access and benefit-sharing is not considered a national priority;
- (c) The multiplicity of actors and sectors involved in access and benefit-sharing;
- (d) The complexity of the issue or various facets of the issue touching upon a range of different types of genetic resources and different sectors that creates an obstacle in developing national strategies for access and benefit-sharing.

45. In response to the diversity of approaches to implementation of access and benefit-sharing measures, which some have considered as a source of legal uncertainty for users of genetic resources, it has been suggested that minimum standards or best practices could be developed at the international level to harmonize access and benefit-sharing legislation.

46. In addition, some stakeholders have advocated the need for more speedy, transparent and simple procedures for obtaining access to genetic resources under the provisions of the Convention on Biological Diversity. They have also argued the need for streamlined processes for obtaining prior informed consent from relevant authorities and communities on mutually agreed terms, and for national treatment that does not differentiate between local and foreign applicants.

47. However, while some seem to be in favour of some degree of harmonisation among access and benefit-sharing measures, others rather advocate that the fact that the Convention does not provide a detailed system for access and benefit-sharing is a strength, as it allow sufficient flexibility for access and benefit-sharing regimes to be established within existing national legislative contexts.

48. These opposite perceptions show that what may be conceived as a gap by some may be considered as a strength by others.

### *C. Compliance*

49. This section examines: (a) measures to support compliance with prior informed consent of the Contracting Party providing genetic resources and mutually agreed terms on which access was granted in Contracting Parties with users under their jurisdiction; (b) an internationally recognized certificate of origin/source/legal provenance as a potential tool to assist compliance with prior informed consent and mutually agreed terms on which access was granted; and finally (c) monitoring, enforcement and dispute settlement.

*(a) Measures to support compliance with prior informed consent and mutually agreed terms*

50. In accordance with the list of elements to be considered by the Working Group for inclusion in the international regime (terms of reference for the Working Group, in decision VII/19 D, annex, (d)), the following elements address measures to support compliance with PIC and MAT:

“(ix) Measures to ensure compliance with national legislations on access and benefit-sharing, prior informed consent and mutually agreed terms, consistent with the Convention on Biological Diversity;

(x) Measures to ensure compliance with prior informed consent of indigenous and local communities holding traditional knowledge associated with genetic resources, in accordance with Article 8(j);

(xi) Measures to ensure compliance with the mutually agreed terms on which genetic resources were granted and to prevent the unauthorized access and use of genetic resources consistent with the Convention on Biological Diversity;

(xiv) Disclosure of origin/source/legal provenance of genetic resources and associated traditional knowledge in applications for intellectual property rights;”

51. In addition, listed above under the section addressing the fair and equitable sharing of benefits are two additional elements which relate to measures to support compliance with PIC and MAT:

“(i) Measures to promote and encourage collaborative scientific research, as well as research for commercial purposes and commercialization, consistent with Articles 8(j), 10, 15, paragraph 6, paragraph 7 and Articles 16, 18 and 19 of the Convention;

(iv) Measures to ensure the fair and equitable sharing of benefits from the results of research and development and the benefits arising from the commercial and other utilization of genetic resources in accordance with Articles 15.7, 16, 19.1, 19.2. of the Convention;”

#### *1. Provisions of the Convention on Biological Diversity*

52. The provisions of the Convention that address the obligations of Parties when acting as users of genetic resources are the following: 15.7, 16.3, 16.4, 19.1 and 19.2.

#### *2. Bonn Guidelines*

53. Section II of the Bonn Guidelines on the “Roles and responsibilities in access and benefit-sharing pursuant to Article 15 of the Convention on Biological Diversity” address under sub-section C on Responsibilities, paragraph 16(d), the responsibilities of Contracting Parties with users under their jurisdiction:

“Contracting Parties with users of genetic resources under their jurisdiction should take appropriate legal, administrative, or policy measures, as appropriate, to support compliance with prior informed consent of the Contracting Party providing such resources and mutually agreed

terms on which access was granted. These countries could consider, inter alia, the following measures:

- (i) Mechanisms to provide information to potential users on their obligations regarding access to genetic resources;
- (ii) Measures to encourage the disclosure of the country of origin of the genetic resources and of the origin of traditional knowledge, innovations and practices of indigenous and local communities in applications for intellectual property rights;
- (iii) Measures aimed at preventing the use of genetic resources obtained without the prior informed consent of the Contracting Party providing such resources;
- (iv) Cooperation between Contracting Parties to address alleged infringements of access and benefit-sharing agreements;
- (v) Voluntary certification schemes for institutions abiding by rules on access and benefit-sharing;
- (vi) Measures discouraging unfair trade practices;
- (vii) Other measures that encourage users to comply with provisions under subparagraph 16 (b) above.”

54. In addition, section IV D of the Bonn Guidelines, on “Mutually Agreed Terms” refers to Article 15.7 and provides a list of “Basic requirements for mutually agreed terms”, an “Indicative list of typical mutually agreed terms” and under “Benefit-sharing” addresses types of benefits, the timing of benefits, distribution of benefits and mechanisms for benefit-sharing.

### 3. *Regional and national measures*

55. This section examines how Governments have addressed their obligations under articles 15, 16, and 19 of the Convention. Initiatives by Contracting Parties with users under their jurisdiction to support compliance with PIC and MAT are further described in document UNEP/CBD/WG-ABS/5/4.

56. The majority of these initiatives have so far focussed on activities related to assessing the awareness of stakeholders with respect to access and benefit-sharing and their experience in implementing access and benefit-sharing. In order to enhance awareness to access and benefit-sharing, initiatives have included: the development of national web-portals, the translation and dissemination of the Bonn Guidelines, and workshops dialogues and consultations to enhance awareness to access and benefit-sharing, identify the specific needs of different stakeholders and consult stakeholders with respect to the development of appropriate policies and tools to assist with the implementation of access and benefit-sharing provisions.

57. Some Parties have supported stakeholder initiative for the development of codes of conducts or guidelines to assist specific user groups with access and benefit-sharing implementation, such as microbial culture collections and academic researchers.

58. In addition, in a few countries access and benefit-sharing requirements are to be met as prerequisites for public funding.

59. The disclosure of the origin or source of genetic resources in intellectual property rights applications have also been adopted as a requirement in a number of countries as an incentive for users of genetic resources to comply with the access and benefit-sharing requirements of the provider country.

60. According to Articles 16.3 and 16.4, Contracting Parties shall take legislative, administrative or regulatory measures taken by Parties “with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights, where necessary...” and “as appropriate, with the aim that the private sector facilitates access to, joint development and transfer of technology referred to in paragraph

1 above for the benefit of both governmental institutions and the private sector of developing countries and in this regard shall abide by the obligations included in paragraphs 1, 2 and 3 above”.

61. Information on national implementation of these Articles, in particular on the provision of incentives to the private sector, were provided by a number of Parties in the third national reports, the thematic reports on technology transfer and cooperation, as well as in a number of submissions for the preparation of the compilation and synthesis of information on institutional, administrative, legislative and policy frameworks that facilitate access to and adaptation of technologies, prepared pursuant to activity 3.1.2 of the programme of work on technology transfer and scientific and technological cooperation adopted by the Conference of the Parties at its seventh meeting. The compilation and synthesis is available in an information document (UNEP/CBD/COP/8/INF/9).

62. In the national reports, a total of 26 countries claimed that some policies and measures are in place. Only 2 countries indicated that comprehensive policies and measures are in place, and 11 countries said that the question is not applicable.

63. The thematic reports on technology transfer and technological cooperation, as well as the recent submissions provided by Parties <sup>45/</sup> seem to indicate that incentives to private sector actors to engage in technological cooperation and technology transfer are frequently provided in the framework of bilateral development cooperation, through various programmes that seek to facilitate private-sector collaboration with developing countries, including collaboration with public institutions of developing countries, by providing training and by supporting joint research and technology transfer. <sup>46/</sup> In addition, in a number of countries, incentives for the private sector for enhancing the transfer of technology are also implemented in form of tax concessions, refunds or deferrals for research and development investments and relating them to the commercialization of technology; however, it is not clear whether and to what extent these measures are specifically geared towards technologies of relevance to the Convention.

64. Articles 19.1 and 19.2, provides that Contracting Parties shall take measures to provide for the effective participation in biotechnological research activities by those Contracting Parties which provide the genetic resources for such research and whether they have taken all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties.

65. The literature, the thematic reports and the recent submissions provide information on a number of project-based activities that promote access for Parties to the results and benefits arising from technologies based upon genetic resources provided by those Parties. As further described in the overview of recent developments at national, regional and international levels relating to access and benefit-sharing (UNEP/CBD/WG-ABS/5/4), projects have included joint ventures, research projects and the training of developing country scientists.

66. In the third national reports, <sup>47/</sup> a number of Parties reported on some positive outcomes of the activities undertaken, including: increased knowledge and expertise; additional funding provided; access to new technology facilitated; and reduced adverse impact on biodiversity. Several Parties also pointed to specific examples of good practice cases and to successful activities in technology transfer and scientific and technological cooperation, pertaining to the work of national institutions and initiatives as well as of international networks and other arrangements for scientific, technological and research cooperation.

---

<sup>45/</sup> See the thematic reports on Technology Transfer and Cooperation from Austria, Canada, China, Finland, Germany, Japan, Norway, Spain, Switzerland, as well as the submissions on technology transfer from Canada, the Czech Republic, and the European Communities.

<sup>46/</sup> See UNEP/CBD/COP/8/INF/9, paragraph 82.

<sup>47/</sup> See boxes LV and LVI of the questionnaire for the third national reports.

67. However, despite these positive outcomes, many comments seem to indicate that more needs to be undertaken on national and international levels in order to effectively implement Article 16 and 19, and the programme of work on technology transfer and scientific and technological cooperation, with Parties labelling the contribution of their activities towards the Strategic Plan with terms such as “unclear” or “limited” or “partial”, and one Party stating that technology transfer and cooperation is “the weak part of implementing the Convention.” In addition, several Parties noted the uneven speed of progress on technology transfer in different sectors and areas of work – it is noteworthy that the need for more activities on the transfer of technology that make use of genetic resources was also highlighted.

#### 4. *Voluntary codes of conduct/guidelines/institutional policies*

68. A number of voluntary codes of conduct and guidelines have been developed by organizations, such as botanic gardens, culture collections, the academic research community and professional associations. As illustrated in the overview of recent developments at national, regional and international levels relating to access and benefit-sharing (UNEP/CBD/WG-ABS/5/4) these were developed to create awareness to access and benefit-sharing and assist with the implementation of access and benefit-sharing provisions by responding to the particular needs of their constituents.

#### 5. *Developments at the international level on the issue of disclosure requirements in intellectual property rights applications*

69. As noted above, one of the measures adopted in some Contracting Parties with users under their jurisdiction to support compliance with PIC and MAT is the requirement to disclose the origin/source/legal provenance of genetic resources in applications for intellectual property rights.

70. Although disclosure requirements have been adopted by a number of countries as described in document UNEP/CBD/WG-ABS/5/4, there is no international obligation to disclose the origin/source/legal provenance of genetic resources and associated traditional knowledge in applications for intellectual property rights at the present time.

71. Discussions on the disclosure requirement in a number of international forums such as the Convention on Biological Diversity, the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO) have been inconclusive thus far.

72. The following provides a brief overview of developments in each of these forums. Further detail regarding developments under the WTO and WIPO with respect to this issue are further described in document UNEP/CBD/WG-ABS/5/4/Add.1 which includes recent developments in both these forums on issues related to access and benefit-sharing.

#### *Convention on Biological Diversity*

73. Under the framework of the Convention on Biological Diversity, as described above, section II of the Bonn Guidelines, under paragraph 16(d) (ii) provides that:

“Contracting Parties with users of genetic resources under their jurisdiction should take appropriate legal, administrative, or policy measures, as appropriate, to support compliance with prior informed consent of the Contracting Party providing such resources and mutually agreed terms on which access was granted. These countries could consider, inter alia, the following measures:

(...)

"(ii) Measures to encourage the disclosure of the country of origin of the genetic resources and of the origin of traditional knowledge, innovations and practices of indigenous and local communities in applications for intellectual property rights;"

74. In decision VI/24 C, paragraphs 1 and 2 respectively, the Conference of the Parties also invited Parties and Governments to encourage the disclosure of the country of origin of genetic resources or of

traditional knowledge associated to traditional knowledge, where the subject matter of the application concerns or makes us of genetic resources or traditional knowledge associated with genetic resources in its development, as a possible contribution to tracking compliance with the prior informed consent and mutually agreed terms on which access to those resources was granted.

75. In the same decision, the Conference of the Parties invited WIPO to prepare a technical study on methods consistent with obligations in treaties administered by the WIPO for requiring the disclosure within patent applications. As requested, the technical study was prepared and provided to the Conference of the Parties at its seventh meeting. At its seventh meeting, the Conference of the Parties noted with appreciation the Technical Study on Disclosure Requirements Concerning Genetic Resources and Traditional Knowledge prepared by the World Intellectual Property Organization and considered the study to be helpful in the consideration of intellectual property-related aspects of user measures.

76. At its seventh meeting, the Conference of the Parties further invited WIPO to examine issues regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications, taking into account the need to ensure that this work is supportive and does not run counter to the objectives of the Convention (decision VII/19 E, paragraph 8). The Conference of the Parties also invited the United Nations Conference on Trade and Development (UNCTAD) and other relevant international organizations to examine the issues related to the disclosure of origin of genetic resources and associated traditional knowledge in applications for intellectual property rights in a manner supportive of the objectives of the Convention on Biological Diversity (paragraph 9 of the same decision). The studies respectively carried out by WIPO and UNCTAD in response to these invitations were presented to the Conference of the Parties at its eighth meeting.

77. At its eighth meeting (decision VIII/4 D), the Conference of the Parties invited “relevant forums to address and/or continue their work on disclosure requirements in intellectual property rights applications taking into account the need to ensure that this work is supportive and does not run counter to the objectives of the Convention, in accordance with Article 16, paragraph 5”.

78. *In WIPO.* The overview of recent developments at national, regional and international levels relating to access and benefit-sharing (UNEP/CBD/WG-ABS/5/4/Add.1) describes the work carried out by WIPO in response to the invitations by the Conference of the Parties to examine the issue of the interrelation of access to genetic resources and the disclosure requirement. Separate proposals put forward by the European Community and its member States and Switzerland respectively to address the issue of disclosure at the international level are also further described in the same document.

79. *In WTO.* As further described in the above-mentioned overview, since 1999 a number of proposals have been put forward and discussed by Member States in the WTO/TRIPS Council regarding the relationship between the TRIPS Agreement and the Convention on Biological Diversity and more specifically the potential conflict between the two agreements.

80. One of the latest proposals introduced by Brazil, China, Colombia, Cuba, Ecuador, India, Pakistan, Peru, Thailand, Tanzania and South Africa in June 2006 proposes an amendment to the TRIPS Agreement to incorporate requirements for disclosure of the origin of genetic resources and associated traditional knowledge in patent applications along with evidence of prior informed consent and ensure benefit-sharing. <sup>48/</sup> At a later meeting of the TRIPS Council in June 2007, additional countries have added their support to this proposal, including Venezuela, members of the African Group and the members of the Group of Least Developed Countries. Although a permanent agenda item in the TRIPS Council and also one of the outstanding implementation issues in the context of the Doha Work Programme, no significant outcomes have yet been reached.

---

<sup>48/</sup> For further details see documents WT/GC/W/564/Rev.2, TN/C/W/41/Rev.2, IP/C/W/474 and WT/GC/W/564/Rev.2/Add.2, TN/C/W/41/Rev.2/Add.2, IP/C/W/474/Add.2.



6. *Possible gaps related to measures to support compliance with prior informed consent and mutually agreed terms in Parties with users under their jurisdiction*

81. Based on the information made available to the Secretariat with respect to measures taken by Parties with users under their jurisdiction to support compliance with PIC and MAT, it would appear that few legally binding measures have been adopted by Parties to implement their obligations under articles 15.7, 16.3 and 16.4 and 19.1.

82. Discussions have focussed on the issue of the disclosure of origin/source/legal provenance in intellectual property rights applications. As illustrated above, only a few countries have introduced disclosure requirements in their national patent laws. These provisions vary greatly among countries. As there is no consensus of the utility of disclosure, there is of yet no international requirement for disclosure.

83. A majority of the initiatives carried out by Parties with users under their jurisdiction have focussed on assessing the level of awareness of relevant stakeholders, raising awareness of users with respect to the access and benefit-sharing provisions of the Convention and the Bonn Guidelines and carrying out consultations with a view to policy development.

84. A number of initiatives have also been undertaken by groups of users to develop guidelines and codes of conduct to assist users to carry out access and benefit-sharing activities in compliance with the access and benefit-sharing provisions of the Convention. They provide the basis for best practices and standards for behaviour. However, these initiatives are voluntary. They can therefore not be enforced and do not provide any remedies for providers in situations where the user chooses not to adhere to the guidelines. They provide guidance and therefore are not monitored, though some research funding agencies, research organisation and commercial firms use them in their processes of awarding grants and developing projects. Given that no monitoring or verification of their compliance is provided for through third parties, some have questioned their effectiveness. While it is argued by some that these can provide a useful incentive and flexibility which would not be afforded by legal obligations, they are viewed with some scepticism by others who believe that stronger obligations are needed.

85. On the transfer of technology, many comments provided by Parties in their third national reports seem to indicate that more needs to be undertaken on national and international levels in order to effectively implement Article 16 and the programme of work. Such comments were made both by developing and by developed county Parties. Some Parties also noted that, while activities were undertaken and were reported accordingly, they were incidental in that there was no explicit, deliberative focus on implementing Article 16 and the programme of work.

86. Major constraints identified include mostly the lack of human capacity and financial resources. Institutional weaknesses including the absence of legislation were mentioned by a number of Parties, some of them making explicit reference inter alia to the absence of legislation on access to genetic resources. The lack of capacity for the adaptation of technology was also mentioned, as well as a lack of information and knowledge.

87. A number of developing country Parties mentioned the low level of technology transfer from developed countries and of international technological cooperation, with one Party underlining the need for developed country Parties to adjust their technology transfer policies so that technologies for conservation and sustainable use of biodiversity are transferred in a preferential manner instead of a commercial manner, and another Party noting the “embryonic nature” of the mechanism on access to and transfer of technology under the Convention. Patents and the prohibitive level of fees were identified by one Party as a barrier for effective transfer of modern technologies to developing countries.

**(b) *Internationally recognized certificate of origin/source/legal provenance***

88. The list of elements to be considered by the Working Group for inclusion in the international regime (terms of reference for the Working Group, in decision VII/19 D, annex, (d)), includes under (xiii) an:

“Internationally recognized certificate of origin/source/legal provenance of genetic resources and associated traditional knowledge”

89. At its eighth meeting, in paragraph 1 of decision VIII/4 C, the Conference of the Parties decided “to establish a group of technical experts to explore and elaborate possible options, without prejudging their desirability, for the form, intent and functioning of an internationally recognized certificate of origin/source/legal provenance and analyze its practicality, feasibility, costs and benefits, with a view to achieving the objectives of Article 15 and 8(j) of the Convention. The Expert Group shall provide technical input to the Ad Hoc Open-ended Working Group on Access and Benefit-sharing and will operate in accordance with the following terms of reference:

"(a) Consider the possible rationale, objectives and the need for an internationally recognised certificate of origin/source/legal provenance;

"(b) Define the potential characteristics and features of different options of such an internationally recognised certificate;

"(c) Analyse the distinctions between the options of certificate of origin/source/legal provenance and the implications of each of the options for achieving the objectives of Articles 15 and 8(j) of the Convention;

"(d) Identify associated implementation challenges, including the practicality, feasibility, costs and benefits of the different options, including mutual supportiveness and compatibility with the Convention and other international agreements.”

90. The meeting of the Group of Technical Experts on an internationally recognised certificate of origin/source/legal provenance was held in Lima, from 22 to 25 January 2007, in accordance with decision VIII/4 C of the Conference of the Parties to the Convention on Biological Diversity (COP).

91. The Group of Technical Experts attempted to provide information and guidance in response to each of the elements contained in decision VIII/4 C, paragraph 1, of the Conference of the Parties. The report of the meeting, available as UNEP/CBD/WG-ABS/5/2 reflects the outcome of discussions without prejudice to the desirability of the options or agreement on any specific option.

*An internationally recognized certificate as a possible instrument to bridge a gap*

92. As suggested by the Group of Technical Experts, “national legal systems alone are not sufficient to guarantee benefit-sharing once genetic resources have left the provider country. In this respect, the certificate as part of a broader access and benefit-sharing regime, could be an important tool to reduce this limitation.”

93. One gap in the existing system of access and benefit-sharing is the difficulty for provider countries to monitor genetic resources once they have left their country. An internationally recognized certificate is one tool that has been suggested to address this gap. Among the several objectives identified by the Group of Technical Experts, the certificate could support compliance with national law and mutually agreed terms and enable and facilitate cooperation in monitoring and enforcement of access and benefit-sharing arrangements.

94. As stated by the GTE, “advantages of adopting a certificate could include, in addition, ensuring greater compliance with requirements of the Convention, assisting the fair and equitable sharing of the monetary and non-monetary benefits from the utilization of genetic resources and associated traditional knowledge, and facilitating cooperation among different jurisdictions.”

**(c) Monitoring, enforcement and dispute settlement**

95. The Working Group is invited to consider how the international regime can address monitoring, enforcement and dispute settlement by referring, inter alia, to elements (viii), (xix), (xx), (xxi), (xxii), of the list of elements for consideration by the Working Group, in accordance with the Terms of Reference for the Working Group, in decision VII/19 D, annex, (d):

“(viii) Measures to facilitate the functioning of the regime at the local, national, subregional, regional and international levels, bearing in mind the transboundary nature of the distribution of some *in situ* genetic resources and associated traditional knowledge;

(xix) Means to support the implementation of the international regime within the framework of the Convention;

(xx) Monitoring, compliance and enforcement;

(xxi) Dispute settlement, and/or arbitration, if and when necessary;

(xxii) Institutional issues to support the implementation of the international regime within the framework of the Convention;”

96. Monitoring, enforcement and dispute settlement under this section are being considered in two situations: (i) in the context of compliance with access and benefit-sharing requirements of provider countries and of compliance with access and benefit-sharing arrangements; and (ii) monitoring, enforcement and dispute settlement is considered in the context of the application of the international regime.

**(i) Monitoring, enforcement and dispute settlement related to compliance with the access and benefit-sharing requirements of provider countries and with respect to compliance with access and benefit-sharing arrangements**

97. Based on a study on administrative and judicial remedies in countries with users under their jurisdiction and in international agreements prepared by IUCN-Canada, <sup>49/</sup> this sub-section examines more specifically administrative and judicial remedies available in situations of breach of compliance with either access and benefit-sharing legislation of the provider country or of an access and benefit-sharing contract by either the provider or the user of the genetic resource.

**1. Compliance with access and benefit-sharing requirements of provider countries**

*Overview of existing compliance measures in national access and benefit-sharing regimes*

98. The access and benefit-sharing measures examined in document UNEP/CBD/WG-ABS/5/4 generally include provisions dealing with compliance. These provisions may cover, depending on the country, monitoring, reporting, enforcement, infractions/offences, penalties/sanctions and dispute resolution.

99. Only few measures address monitoring, reporting and enforcement to ensure compliance with access and benefit-sharing measures. Mechanisms established in certain countries include the appointment of inspectors, the involvement of civil society for monitoring purposes and reporting requirements imposed upon users. <sup>50/</sup>

---

<sup>49/</sup> The study is available in document UNEP/CBD/WG-ABS/5/INF/3.

<sup>50/</sup> For examples, in Australia, under Environment Protection and Biodiversity Conservation Regulations, section 8A.18, the permit holders must keep records of samples taken. The Biodiversity Act of the State of Queensland, in part 8, includes elaborate provisions on monitoring and enforcement. It provides for the appointment of inspectors and details the powers and duties of these inspectors. Costa Rica, in article 20 of the Decree, provide that the Technical Office will carry out

100. The measures generally indicate that any infraction to the provisions of the legislation, regulation or guidelines and any unauthorized access to genetic or biological resources will be subject to sanctions. Moreover, many measures indicate that the non-compliance with the provisions of an agreement related to access and benefit-sharing will also be subject to sanctions. In addition, certain measures provide for sanctions in the case where a person gives false or misleading documents or information for the purpose of obtaining an application for a collection permit (such as State of Queensland (Australia), Ethiopia, Panama, South Africa and Uganda 51/) and/or creates obstruction to an inspector in the exercise of his powers or duties (such as Afghanistan 52/)

101. The sanctions range from a written warning, 53/ to a fine (in some cases, a scale of fines is included), 54/ a seizure of samples, 55/ the suspension of the sale of product, 56/ the revocation/cancellation of the permission or license of access or of the agreement, 57/ a ban on undertaking prospecting of biological and genetic resources 58/ and, finally, imprisonment. 59/

102. Certain provisions also address dispute settlement mechanisms, such as the Philippines Guidelines. 60/ In this respect, some countries give power to the competent national authority to apply sanctions 61/ and have designated judicial instance(s) with jurisdiction to hear disputes related to the

---

verification and control duties through inspections on the site where access is granted. In Ethiopia, section 20 of the Proclamation also provides that the competent national authority shall follow-up the execution of access agreements through, inter alia, inspection and periodic progress and status report by access permit holders and the relevant institutions designated to accompany the collection, participate in the research and monitor the implementation of access agreement. In the case of the Philippines, the Bioprospecting Guidelines, under section 27, indicate that the Government encourages the role of civil society in monitoring the implementation of bioprospecting undertaking. It also states, under section 23, that the resource user shall submit an Annual Progress report to the implementing agencies concerned. Finally, section 27 mentions that some department of Philippines may help implementing agencies in monitoring inventions and commercialization undertaken in foreign countries through, inter alia, Embassies and Missions. The Ugandan Regulations, under section 7(3)(b), states that lead agencies, in collaboration with the competent national authority, shall monitor “the application and use of genetic resources transferred from Uganda and deposited outside Uganda” but does not provide any other detail in respect to the manner or the mechanism. It should be mentioned that section 34(6)(c) of the Vanuatu Environmental Act requires, as condition for competent national authority approbation for bioprospecting, that “a monitoring and auditing system is established to verify all activities undertaken by the applicant” but does not provide any further details with respect of the mechanism.

51/ See article 52 of the Queensland Biodiversity Act; section 35 (1) (b) of the Ethiopian Proclamation; section 51 (h) of the Panamanian Decree; article 93 a) of the South African Biodiversity Act; and section 26 (2) of the Ugandan Regulations.

52/ See section 73 par. 1 (3) of the Afghanistan Environment Act.

53/ Such as in Afghanistan, under section 72 par. 1 of the Environment Act (where it takes form of a compliance order); in Brazil, under section 30 par. 1(I) of the Provisional Act; in Ethiopia, under section 16 (2) of its Proclamation; and in Panama, under section 52 (a) of its Decree.

54/ Some measures provide the specific amount or a scale for the fine (such as Afghanistan Environment Act under section 73 par.1; Brazilian Provisional Act, section 30 par. 1 (II) et par. 2; Indian Biological Diversity Act under sections 55 and 56; Ethiopian Proclamation under section 35; Kenyan Regulations, under section 24; Ugandan Regulations, under section 26; Vanuatu Environmental Act, under section 32; and Venezuelan Biological Diversity Act, title XI), while others (such as Costa Rican Decree under section 28 and Bhutan Biodiversity Act under section 44 (a)), indicate how it should be calculated.

55/ Such as under Bhutan Biodiversity Act, section 44 (b); Brazilian Regulations, section 30 par.1 (III); Ethiopian Proclamation, section 35 (1); Ugandan Regulations, section 25; and Venezuelan Biodiversity Act, section 117.

56/ Such as in Brazil under section 30 par. 1 (V) of the Provisional Act.

57/ It is the case of most of countries, including for example, Afghanistan, Bhutan, Brazil, Costa Rica, Ethiopia, India, Kenya, Panama, South Africa and Uganda.

58/ Such as in Panama, under section 52 (d) of its Decree.

59/ Countries which provide for imprisonment establish a time period, ranging from a few mouths up to few years. See, for example, Afghanistan Environment Act, section 73 par. 1; Bhutan Biodiversity Act, section 44 (a) (d); Kenyan Regulations, section 24; South African Biodiversity Act, section 102; Ugandan Regulations, section 26; and Vanuatu Environmental Act, section 32.

60/ Section 30 of the Philippines Guidelines covers conflict resolution.

61/ Such as the Bolivian Regulations, section 60 and the Panamanian Decree, section 52 (b).

access and benefit-sharing regime. <sup>62/</sup> In case of an offence committed by a company, some measures also provide that every person in charge of the company at the moment of the offence shall be liable and punished accordingly. <sup>63/</sup>

103. Some measures also authorize the restriction of the initial granted access or the alteration of an access agreement, in specific circumstances, such as significant adverse effect on the environment, threat of genetic erosion or violation of cultural values of communities. <sup>64/</sup>

104. Although some measures are provided in national access and benefit-sharing measures, as described above, these may be difficult to enforce once the user has left the provider country with the genetic resources.

*Remedies available in countries with users under their jurisdiction*

105. As illustrated in the section above on compliance with PIC and MAT, a number of countries with users under their jurisdiction are still at the preliminary stages of raising the awareness of potential users of genetic resources. Based on the information made available to the Secretariat, administrative and judicial remedies available in countries with users under their jurisdiction regarding non-compliance with prior informed consent and mutually agreed terms, have been limited to those which apply in cases of non-compliance with disclosure requirements in patent applications.

106. At present, although all countries are recognised to be both users and providers, based on available information, it appears that no country has adopted any user measures. According to the study carried out by IUCN-Canada, Norway would seem to be the only country thus far to have elaborated a specific requirement calling for compliance with access and benefit-sharing requirements of provider countries. “The Norwegian draft legislation represents the only publicised legislative proposal to squarely attempt to meet the primary obligation of Article 15.7. It specifically states that the utilization in Norway of genetic resources from other countries of origin or providers may only happen if the user has complied with the requirements of those other countries – specifically with the requirement of PIC and the contents of any MAT. Although this law does not provide remedies, its penalty provisions offer another kind of possible remedial impact.” <sup>65/</sup>

1. In situations of non-compliance with access and benefit-sharing requirements, in the absence of an access and benefit-sharing contract and of measures adopted in user countries to ensure compliance by users with access and benefit-sharing requirements, the availability of remedies is unclear. In the presence of an access and benefit-sharing agreement, the availability of remedies is examined in section 2 below.

2. Although some national legislation provide remedies in situations of non-compliance with their access and benefit-sharing requirements, the possibility for a provider to obtain remedies once the genetic resources have left the provider country is difficult as with all claims dealing with transboundary transactions.

107. In the event that a judgement was rendered against a user in a provider country, enforcement problems are likely to arise, particularly if the user and the genetic resources accessed are no longer in the provider country. Issues related to the enforcement of foreign judgements may need to be further examined.

---

<sup>62/</sup> Such as Bhutan Biodiversity Act, section 48; Indian Biological Diversity Act, sections 52-53; South African Biodiversity Act, sections 94-96; and Ugandan Regulations, section 27.

<sup>63/</sup> For example, see section 57 of the Indian Biological Diversity Act and section 75 of the Afghanistan Environment Act.

<sup>64/</sup> See, for example, Afghanistan Environment Act, section 71; Ethiopian Proclamation, section 21 (1); and Indian Biological Diversity Rules, section 16.

<sup>65/</sup> See “Administrative and Judicial Remedies Available in Countries with Users under their Jurisdiction and in International Agreements” available in document UNEP/CBD/WG-ABS/5/INF/5/3.

## 2. *Compliance with access and benefit-sharing arrangements*

108. The situation will be different in situations of breach of compliance with an access and benefit-sharing contract.

109. Access and benefit-sharing arrangements generally address issues related to compliance and determine possible remedies applicable in situations of breach of compliance. The study underway on access and benefit-sharing arrangements will provide information on how access and benefit-sharing arrangements in different sectors address issues of compliance and remedies in situations of breach of contract.

110. As highlighted in the study carried out on “Administrative and judicial remedies Available in Countries with Users under their Jurisdiction and in International Agreements”, it has generally been assumed that access and benefit-sharing implementation, enforcement and remedies would be based on the law of contract. As stated, in the study “This assumption is partially correct –

- Contract law will provide a remedy where the terms of the contract are “unambiguous and enforceable”
- Even where some parts of the contract are ambiguous, contract law may still provide a remedy, if the remedy is specified in the contract, and the conditions that trigger the remedy are unambiguous and have occurred
- Even where some parts of the contract are ambiguous, the contract may provide a remedy directly where it binds the parties to arbitration or other ADR, and the arbitrator or mediator feels that the situation is clear enough to enable the resolution.”<sup>66/</sup>

111. However, as suggested by the author of the study, ambiguities in the access and benefit-sharing system, such as different interpretations of key terms in Article 15 could pose problems to courts and other bodies attempting to interpret access and benefit-sharing obligations and/or to provide access and benefit-sharing remedies.

112. In essence, as summarized in the conclusions of the same study:

“national law in user countries contains a variety of remedial options that might function well in addressing ABS claims by source countries and other providers, however, there is a basic functional gap which prevents their application. At present, no country has adopted any law which requires users of foreign-origin genetic resources to comply with source country ABS requirements, including PIC and MAT. This means that a user will not be subject to legal action in the user country, unless he has obtained an ABS contract, and the source country or other provider takes action in the user country to enforce that contract.

“Where a contract exists, the source country will face two primary challenges

- the challenge of costs, access to information and evidence gathering which are common to all commercial parties who are not located in the country in which the action is being taken; and
- the challenge of making certain that the contract is sufficiently clear and specific to enable a court, arbitration or other remedial action to come to an unambiguous decision.

“There are many factors relating to ABS which suggest that the Parties may need to have access to special measures and protections in order to utilise national remedial laws and processes, including the fact that many source countries and traditional communities will lack the funds, expertise and ability to engage in a protracted action in another country seeking redress from an

---

<sup>66/</sup> “Administrative and judicial remedies Available in Countries with Users under their Jurisdiction and in International Agreements”, available as document UNEP/CBD/WG-ABS/5/INF/3, section 5.1.

entity which is probably better funded, more familiar with the relevant legal system, and better positioned to participate in a legal action.

“Where no contract exists, there is at present no legal basis on which a claim for a remedy could be asserted in the courts, agencies or other adjudicating institutions in any country. The only exception occurs where the source country still has jurisdiction over the user (because the user of some of his assets or activities remain in the source country).”<sup>67/</sup>

113. Finally, in situations where there is no access and benefit-sharing regime in the provider country, hence no access and benefit-sharing requirements, and if no legal obligations have been agreed between the provider and the user, the access and benefit-sharing provisions of the Convention can not be implemented.

3. *Possible gaps relating to compliance with access and benefit-sharing requirements or access and benefit-sharing arrangements*

114. Monitoring and compliance measures are weak in a majority of access and benefit-sharing measures in provider countries. As indicated above, a number of Parties are still at the stage of raising awareness of their user communities at the national level. No user country measures have yet been adopted by countries to request compliance with PIC and MAT by users under their jurisdiction. In the absence of national measures to address the illegal access of genetic resources from a foreign country, enforcement may be a difficult if not impossible task.

115. It could be argued that there is therefore currently a lack of incentives for users to comply with access and benefit-sharing measures and a lack of efficient compliance and enforcement mechanisms in the countries where genetic resources are being used.

(ii) *Monitoring, enforcement and dispute settlement in the application of the international regime*

116. Once the nature, scope and components of an international regime have been further defined, Parties may wish to consider monitoring, enforcement and dispute settlement in the application of the international regime. Elements (xix) and (xxii) address these particular circumstances.

**D. Traditional knowledge**

117. The scope of the mandate to negotiate an international regime on access and benefit-sharing includes “traditional knowledge, innovations and practices in accordance with Article 8(j)” (e.g. decision VII/19, Annex). In addition, among the elements to be considered for inclusion in the international regime listed in section (d) of the terms of reference, the following relate to traditional knowledge:

- (x) Measures to ensure compliance with prior informed consent of indigenous and local communities holding traditional knowledge associated with genetic resources, in accordance with Article 8(j);
- (xiii) Internationally recognized certificate of origin/source/legal provenance of genetic resources and associated traditional knowledge;
- (xiv) Disclosure of origin/source/legal provenance of genetic resources and associated traditional knowledge in applications for intellectual property rights;

---

<sup>67/</sup> Ibid, see section 7 entitled “Conclusion- A Balance of Certainties”.

- (xv) Recognition and protection of the rights of indigenous and local communities over their traditional knowledge associated to genetic resources subject to the national legislation of the countries where these communities are located;
- (xvi) Customary law and traditional cultural practices of indigenous and local communities;
- (xviii) Code of ethics/Code of conduct/Models of prior informed consent or other instruments in order to ensure fair and equitable sharing of benefits with indigenous and local communities;"

### 1. *Developments under the Convention on Biological Diversity*

118. The tasks of the first phase of the programme of work on Article 8(j) and related provisions (e.g. decision V/16, Annex) include tasks 2 (participatory mechanisms), as well as tasks 7 and 12, which are of direct relevance to the international regime on access and benefit-sharing. Task 10 (second phase) is also relevant. Task 7 provides that the Working Group is "... to develop guidelines for the development of mechanisms, legislation or other appropriate initiatives to ensure: (i) that indigenous and local communities obtain a fair and equitable share of benefits arising from the use and application of their knowledge, innovations and practices; (ii) that private and public institutions interested in using such knowledge, practices and innovations obtain the prior informed approval of the indigenous and local communities; (iii) advancement of the identification of the obligations of countries of origin, as well as Parties and Governments where such knowledge, innovations and practices and the associated genetic resource are used." The Working Group on Article 8(j) and Related Provisions has not yet initiated this task. Task 12 provides that the Working Group is to develop guidelines that will assist Parties and Governments in the development of legislation or other mechanism, to implement article 8(j), and related provisions at international, regional and national levels that recognize, safeguard and fully guarantee the rights of indigenous and local communities over their traditional knowledge within the context of the Convention. Finally, task 10 of the second phase of the work programme provides that the Working Group on Article 8(j) is to develop standards and guidelines for the reporting and prevention of unlawful appropriation of traditional knowledge and related genetic resources. The development of guidelines, as foreseen in tasks 7, 12 and 10 of the work programme, could make a significant contribution to addressing the issue of traditional knowledge in the negotiation of an international regime on access and benefit-sharing.

119. The Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization provide that the involvement of "stakeholders" is essential in the development and implementation of benefit-sharing arrangements, and that they should be consulted and their views taken into consideration in each step of the process, including when determining access, negotiating and implementing mutually agreed terms and in the sharing of benefits, as well as in the development of a national strategy, policies or regimes on access and benefit-sharing (article 18). Furthermore, appropriate consultative arrangements, such as national consultative committees, should be made (Article 19) to facilitate the involvement of stakeholders, including indigenous and local communities.

### 2. *Regional and national instruments*

120. Currently, five regions including the African Union, the Andean Community, ASEAN, Latin America and the Pacific Forum have developed or are developing regional agreements, frameworks or model laws, concerning *sui generis* systems based on customary laws for the protection of traditional knowledge. At least eleven countries have introduced legislation, draft legislation, special intellectual property regimes, community intellectual rights protection acts, indigenous peoples rights acts, regulations, trade arrangements, and draft agreements to address traditional knowledge protection and such issues as prior informed consent of the knowledge holders and benefit sharing arrangements.



### 3. *Other international instruments*

121. For a number of years, WIPO has addressed the issue of the relationship between intellectual property rights and traditional knowledge through its Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). The work of this Committee is of relevance to the negotiation of an international regime on access and benefit-sharing and could conceivably contribute to the development of a future international regime by addressing such issues as *sui generis* systems of protection for traditional knowledge, as well as prior art and disclosure of origin in patent applications.

122. Other forums of relevance include the United Nations Permanent Forum on Indigenous Issues. In 2005, the Forum facilitated an International Technical Workshop on Indigenous Traditional Knowledge (E/C.19/2006/2), to promote a collaborative, complementary and holistic approach to traditional knowledge and in order to enhance better understanding of indigenous concerns and their possible solution. The workshop noted at least eleven intergovernmental organizations and United Nations agencies carry out programmes, activities and processes addressing, in one way or another, issues related to indigenous traditional knowledge.

123. At its sixth session, the Forum recommended that Parties to the Convention specifically address the issues of access and benefit-sharing of genetic resources, as well as the protection of traditional knowledge and the development of *sui generis* systems.

124. In particular, the Forum on Indigenous Issues discussed at length, issues of relevance to the protection of traditional knowledge, *sui generis* systems and genetic resources. The Permanent Forum stated that there are clear linkages between lands, territories and natural resources and the protection of traditional knowledge. The Forum emphasized that the Working Group on Access and Benefit-sharing recognize the rights of indigenous peoples over the biological and genetic resources of their own territories. It also stressed that Governments should consider the development of *sui generis* systems based on customary laws for the protection of traditional knowledge. The Forum also suggested that relevant members of the Inter- Agency Support Group, and in collaboration with indigenous experts, could conduct timely technical reviews at critical stages in the negotiations of international standards on the protection of traditional knowledge, including the development of an international regime for access and benefit-sharing.

125. A related development is the report of the international expert group meeting on the international regime on access and benefit-sharing and indigenous peoples' human rights of the Convention on Biological Diversity (E/C.19/2007/8), organized by the Forum. The report provides an overview of issues of relevance, such as elements of customary law vested in traditional knowledge, indigenous peoples' participation in decision-making, relevant human rights treaties, existing and other emerging instruments that are applicable to traditional knowledge, and comments on the proposed certificate of origin, source or legal provenance for genetic resources. Also the report provides both general and specific recommendations to assist in the development of an international regime. The report of the 6th session of the Permanent Forum is available in E/2007/43 at <http://www.un.org/esa/socdev/unpfii/>

### 4. *Possible gaps*

126. Apart from the provisions of the Convention on Biological Diversity, there are currently no instruments at the international level establishing standards to ensure that indigenous and local communities obtain a fair and equitable share of benefits arising from the use and application of their knowledge, innovations and practices associated to genetic resources. Nor has a consensus emerged regarding the need for international measures in this regard.

127. There may be a number of practical difficulties to overcome in the implementation of benefit-sharing arrangements with indigenous and local communities, such as how to identify authorized representatives of indigenous and local communities for the purpose of prior informed consent

procedures and relevant customary laws, how to identify beneficiaries and how to share eventual benefits, and what form such benefits should take, etc. Furthermore, customary law and cultural practices of indigenous and local communities vary greatly and their prior informed consent is not universal.

128. In a majority of countries, it is not mandatory to disclose the origin of genetic resources or associated traditional knowledge in patent applications.

129. By their very nature, existing intellectual property rights are ill adapted to the protection of traditional knowledge. Therefore there may be a need for *sui generis* measures of protection of traditional knowledge. However, some argue that intellectual property rights, such as copyrights, trademarks, trade secrets and other certification systems may be adapted to offer some protection for traditional knowledge associated with genetic resources.

130. It has been suggested that an international traditional knowledge database or digital library would provide an important tool to patent examiners and others in the recognition of traditional knowledge as prior art. However, it has been argued that documenting traditional knowledge through databases should not be seen as a prerequisite for protection.

### *E. Capacity-building*

131. “Capacity-building measures based on country needs” are included in the list of elements to be considered by the Working Group for inclusion in the international regime under element (xvii).

132. An Action Plan on Capacity-building for Access to Genetic Resources and Benefit-sharing was adopted by the Conference of the Parties at its seventh meeting, by decision VII/19 F. The objective of the Action Plan is to facilitate and support the development and strengthening of capacities of individuals, institutions and communities for the effective implementation of the provisions of the Convention relating to access to genetic resources and benefit-sharing...”. The Action Plan provides a framework for identifying country, indigenous and local community and all relevant stakeholder needs, priorities, mechanisms of implementation and sources of funding. It identifies key areas requiring capacity-building and mechanisms for the implementation of capacity-building at the national, regional, subregional and international levels. The Action Plan also promotes mutual-information sharing and coordination at all levels among actors involved in capacity-building related to access and benefit-sharing in order to encourage synergies and identify gaps in coverage.

133. In order to provide an overview of ongoing capacity-building activities and to ensure their complementarity, the Secretariat has established a database on capacity-building projects on access and benefit-sharing based on information provided by Parties and relevant organizations carrying out capacity-building activities. The database is available at the following address: <http://www.cbd.int/programmes/socio-eco/benefit/projects.aspx>

134. It should also be noted that, in the preamble to this decision VII/19 F, the Conference of the Parties underlined that “the implementation of an international regime on access and benefit-sharing and of national legislation on access and benefit-sharing could require additional activities to build capacity”.

#### *Capacity-building: a response to a gap*

135. Lack of awareness to access and benefit-sharing among users and providers and absence of capacity have been identified as major gaps of the existing system. Parties may wish to consider how capacity-building could be addressed by the international regime as one way to address existing gaps.

### **III. ADDITIONAL GAPS**

136. A number of additional issues not addressed by existing instruments could also be considered as gaps. These are examined below:

*Lack of awareness*

137. As highlighted above, lack of awareness to access and benefit-sharing issues among both users and providers of genetic resources (GR), in both developed and developing countries are major gaps of the existing system. Although a number of initiatives are being carried out to increase awareness to access and benefit-sharing in countries among both providers and users of genetic resources, considerable efforts are still needed. This includes lack of awareness among providers of genetic resources, such as indigenous and local communities, private owners, conservation area authorities, and users including researchers/scientists, academics, taxonomists and private companies operating in various sectors (e.g. pharmaceuticals, cosmetics, agriculture, industry).

*Lack of capacity*

138. As illustrated by the Action Plan on capacity-building for access and benefit-sharing, 17 key areas for capacity-building have been identified by Parties.

139. Although a number of capacity-building projects are currently being carried out, due in part to the complexity of the issue of access and benefit-sharing and the large number of actors that it involves (i.e. local communities, government representatives, land owners, conservation area authorities, researchers, academics, the business community), continued efforts will be needed to further develop the capacity of all relevant actors at all levels to ensure that the system can function well.

*Asymmetries*

140. Asymmetries between providers and users of genetic resources in terms of information, knowledge, negotiating skills and capacity may affect bargaining power in the negotiation of access and benefit-sharing arrangements. In order to ensure the fair and equitable sharing of benefits there may therefore be a need to level the playing field between providers and users of genetic resources. The chain of access and benefit-sharing may often involve multiple actors, from the initial provider, who may be a local or indigenous community, until the end user who may be a private company.

141. In order to address these asymmetries, capacity-development has an important role to play as noted above. In addition, intermediaries have been playing an important role in the chain of access and benefit-sharing and may assist in levelling the playing field between the initial provider and the final user provided that these intermediaries are acting in good faith.

142. It has been suggested that standard material transfer agreements may also provide a solution to addressing these asymmetries.

*Absence of regulation of intermediary entities*

143. In part due to the asymmetries mentioned above, intermediaries are playing an important role in access and benefit-sharing arrangements. Different types of intermediaries may be involved in access and benefit-sharing. Annex II of the report of the Panel of Experts on Access and Benefit-sharing usefully illustrates the growing role of “intermediary entities in the commercial exploration and use of genetic resources” and the potential concerns raised by this largely unregulated sector of activity: [68/](#)

“As markets for genetic resources have grown and diversified over the past decade, a wide range of entities have come into being which provide specialized services to the commercial end-users of genetic resources. Such services include the collection and provision of genetic-resource samples, extracts, and associated information, as well as assistance in assuring that access and benefit-sharing laws and procedural requirements in provider countries have been met with respect to the samples provided. These entities, sometimes termed “intermediaries”, are

---

[68/](#) Report of the Panel of Experts on Access and Benefit-sharing (UNEP/CBD/COP/5/8, 2 November 1999), annex II.

appearing in a wide range of institutional forms. They may be for-profit private-sector firms operating in multiple countries, small domestic firms working in their own country, or local universities. In several biodiversity-rich countries, specialized parastatal institutions have been established to fulfil these functions, Costa Rica's National Biodiversity Institute (INBio) being the most well-known.

“These service-providing entities are in some cases fulfilling valuable functions in facilitating access to genetic resources and fair and equitable benefit-sharing on mutually agreed terms, in compliance with the Convention on Biological Diversity and relevant national legislation. This is the case when such entities:

“(a) Add value to the resource; and

“(b) Diligently ensure that all national access and benefit-sharing laws and procedural requirements have been met, thus providing end-users with reliable guarantees of legal certainty and compliance.

“When these entities provide these functions, they are of considerable value to commercial end-users, and also assist Governments in ensuring compliance with national access and benefit-sharing measures. Where such entities are established within a country providing genetic resources and add value to genetic resources in-country (through, for example, maintaining genetic-resource "libraries", preparation of extracts, and preliminary screening of samples), they can also contribute to local capacity-building and the maximization of the provider country's share of benefits.

“It must be emphasized, however, that despite the utility to commercial end-users of the services provided by these intermediate entities, most commercial end-users stress their preference for direct contractual arrangements with the ultimate providers of genetic resources, as designated by the laws of the country from which genetic resources are obtained.

“Since these "intermediaries", represent a new and largely unregulated sector of activity, however, there exists potential for unscrupulous or technically incompetent entities to move into this field as well. Where such entities do not truly add value to the resource, or give intentionally false or mistaken assurances that genetic material has been legally obtained, they pose a threat to the access and benefit-sharing objectives of both the Convention on Biological Diversity and national access and benefit-sharing measures. In addition, where such entities merely insert themselves as "middle-men" without adding value or ensuring legal certainty, they merely add another layer of bureaucracy and increase transaction costs.

“Governments therefore need to consider the growing importance of such intermediate entities when they are developing access and benefit-sharing legislation, and use their legislation to support legitimate intermediaries while discouraging those that are not performing useful or legitimate functions. Contractual arrangements also need to take into account the increasingly multipartite nature of the institutional landscape of commercial utilization of genetic resources that the proliferation of these intermediate entities represents. Finally, ultimate commercial end-users of genetic resources – such as the major pharmaceutical firms – can play a crucial role by establishing standards for the entities that they deal with, and promoting best practices, which truly implement the access and benefit-sharing objectives of the Convention on Biological Diversity and their national manifestations.”

144. It would seem that “Almost without exception, every biodiversity-prospecting collection effort undertaken on behalf of companies is done through intermediaries”. <sup>69/</sup> As suggested by the Panel of

---

<sup>69</sup> S.Laird, “ Biodiversity and Traditional Knowledge – Equitable Partnerships in Practice”, Peoples and Plants Conservation Series, Earthscan, 2002, chapter 13, p. 422-423.

Experts, consideration may therefore need to be given to the need to regulate these activities at the appropriate level.

#### *Geographical gap*

145. Transboundary genetic resources: Existing instruments do not take into account the fact that the same genetic resources may be found across borders. Some have suggested that regional approaches may provide the solution to this. In order to address the issue of transboundary genetic resources, it has been suggested that the harmonization of requirements for access and benefit-sharing at the regional level would have the benefit of creating similar conditions for access and benefit-sharing across the region. Such harmonization would also provide users with greater predictability and certainty through streamlined processes for obtaining access to genetic resources. Regional approaches could also facilitate the exchange of information and technical cooperation in dealing with common genetic resources. Others believe that while the taxon from which genetic resources were obtained may exist in many countries, the unique characteristics may have come from the locality and therefore the benefits should be shared with the specific country from which it was accessed.

146. Genetic resources found beyond national jurisdiction: It has been suggested that some of the gaps may be geographical in nature. Article 15 only covers genetic resources found under the national jurisdiction of countries. Therefore genetic resources found beyond national jurisdiction, such as in the deep seabed are not covered by the access and benefit-sharing provisions of the Convention. The issue of bioprospecting in areas beyond national jurisdiction is currently attracting increasing attention as further described in document UNEP/CBD/WG-ABS/5/4.

#### *Gaps relating to the membership of international instruments*

147. The terms of reference established for the Working Group on Access and Benefit-sharing includes a list of relevant elements of existing instruments and processes, to be considered by the Working Group for inclusion in the international regime. Document UNEP/CBD/WG-ABS/5/4 provides an update of recent developments in this various agreements or processes which are of relevance to access and benefit-sharing. When considering gaps in existing international instruments, it should be noted that these instruments do not have the same membership and none benefit from universal membership. In other words, for example, some countries may be Parties to the Convention and not have ratified the International Treaty on Plant Genetic Resources for Food and Agriculture (PGRFA). Others, not a Party to the Convention may be Contracting Parties of the World Trade Organization and the World Intellectual Property Organization. These gaps in coverage in terms of membership of international instruments could have implications at the level of implementation of these various instruments and potentially be the source of conflicts between countries.

#### *Use of terms*

148. It may be argued that the absence of a common understanding of a number of terms related to access and benefit-sharing is a gap. While some are of the opinion that internationally recognized definitions may be useful, others are of the opinion that the use of terms should rather be addressed at the national level.

149. The issue of the use of terms related to access and benefit-sharing was initially raised during the negotiations of the Bonn Guidelines. When the Bonn Guidelines were developed, in October 2001, some Parties suggested that in addition to the terms already defined by the Convention, additional terms of direct relevance could be included and defined in the Bonn Guidelines. Due to lack of time, this issue was not discussed in detail at the sixth meeting of the Conference of the Parties and it was decided that the Bonn Guidelines should only include reference to terms already defined in the Convention on Biological Diversity.

150. Nevertheless, a number of Parties stressed that further work was needed in order to determine whether additional terms needed to be defined in the guidelines (access to genetic resources, benefit-sharing, commercialization, derivatives, provider, user, stakeholder, *ex situ* collection and voluntary nature), or whether a glossary of these terms could be annexed to the guidelines.

151. At its seventh meeting, the Conference of the Parties noted that the terms as defined in Article 2 of the Convention shall apply to the Bonn Guidelines in accordance with paragraph 8 of the Bonn Guidelines and noted further that a number of other relevant terms not defined in the Convention may need to be examined. Based on information provided by Parties, Governments, relevant organisations, indigenous and local communities and all relevant stakeholders compiled by the Secretariat, the Working Group was requested to further examine the issue of the use of terms.

152. At its fourth meeting, in January 2006, the Working Group on Access and Benefit-sharing decided to postpone consideration of the item until the negotiation of the international regime on access and benefit-sharing had reached a more advanced stage.

153. It has since been suggested that an internationally agreed definition of “misappropriation” of genetic resources could support efforts to strengthen compliance with access and benefit-sharing requirements and mutually agreed terms.

*Different types of genetic resources used for different purposes by different types of users*

154. Some may consider as a gap the fact that the particular circumstances of different types of genetic resources (plant, animal, micro-organism) used for different purposes by different users are not taken into account by the access and benefit-sharing provisions of the Convention. The only other legally binding international instrument yet developed, in harmony with the Convention, is the Multilateral System of Access and Benefit-sharing established under the International Treaty on Plant Genetic Resources for Food and Agriculture when specific crops and forages are accessed for the purpose of utilization and conservation for research, breeding and training for food and agriculture.

155. A forum of particular relevance in this regard is the inter-governmental Commission on Genetic Resources for Food and Agriculture of the Food and Agriculture Organization of the United Nations. In accordance with its statutes, it has, over the years, addressed aspects of access and benefit-sharing, most recently by negotiating the International Treaty on Plant Genetic Resources for Food and Agriculture, which entered into force in 2001, and now in the context of the development of *The State of the World's Animal Genetic Resources for Food and Agriculture*, and *Global Plan of Action*. The Conference of the Parties has recognized the importance of both for Access and Benefit-sharing.

156. The Commission adopted a ten-year rolling Multi-year Programme of Work at its Tenth Regular Session in 2007, with priority given to considering policies and arrangements for all components of biological diversity of interest to food and agriculture — including animal genetic resources, aquatic genetic resources, forestry genetic resources, the genetic resources of micro-organisms and invertebrates, and plant genetic resources — at its Twelfth Regular Session in 2009. This could facilitate a sectoral approach that takes into account the special nature of agricultural biodiversity, its distinctive features and problems needing distinctive solutions, as well as the specific factors of importance to the various communities of users.

157. While bearing in mind that codes of conduct and guidelines have already been developed by some organizations such as MOSAICC and Kew Gardens to respond to the particular needs of their constituents in meeting access and benefit-sharing obligations, Parties may wish to consider whether different approaches still need to be developed under the International Regime to respond to the particular needs of different sectors, whether it is necessary to further develop a common framework applicable to all types of genetic resources or whether there may be a need for a mixture of both approaches. For example, model or standard agreements could be considered for specific uses of genetic resources.

158. Parties may wish to consider whether sectoral approaches may be needed, including through standard Material Transfer Agreements, or other tailored policies and arrangements that take into account the special needs of the sector.

159. Scientific vs. commercial use: The access and benefit-sharing provisions of the Convention on Biological Diversity provide the same obligations for Parties notwithstanding whether genetic resources are being used for scientific or commercial purposes.

160. Some have argued that access and benefit-sharing regimes developed in some countries have created an impediment to research because they are too cumbersome. In order to address this concern, some have suggested to establish a simplified procedure for access to genetic resources which are to be used for the purpose of basic research. However, this could potentially create a loophole through which resources initially accessed for research purposes could be used subsequently for commercial purposes without having obtained the consent of the provider for the subsequent use. In addition, the line between basic scientific research and commercial use may be difficult to draw. Others have suggested that ABS agreements could include benchmarks or milestones requiring additional negotiations when scientific research is subsequently used for commercial purposes, and that these ABS agreements be conveyed along with the genetic resources to subsequent users.

#### *Knowledge gap*

161. Little is known with respect to the chain of innovation of genetic resources accessed. The analytical studies on access and benefit-sharing arrangements in different sectors will attempt to shed some light on different practices in various sectors, highlighting commonalities and divergences. A similar study on the use of genetic resources for scientific purposes may also usefully inform the process, including by examining when and how genetic resources used for research purposes are subsequently used for commercial purposes.

162. Insufficient knowledge of biodiversity and limited information regarding the value of genetic resources may also be considered as a gap of the existing system and an obstacle in the negotiation of fair and equitable benefit-sharing arrangements.

#### *Rights and ownership*

163. The Convention establishes that States have sovereignty over their genetic resources. However, the issue of ownership and property rights is to be addressed by national law. In the absence of clearly defined ownership in national law, difficulties may arise in the negotiation of benefit-sharing agreements.<sup>70/</sup>

---

<sup>70/</sup> See Jorge Cabrera Medaglia, "Bioprospecting Partnerships in Practice: A Decade of Experiences at INBio in Costa Rica", IP Strategy Today, No. 11-2004. See also "Report on the Legal Status of Genetic Resources in National Law in a Selection of Countries" available as document UNEP/CBD/WG-ABS/5/5.

#### IV. SUMMARY

164. The following is a summary of potential gaps in access and benefit-sharing examined in this document. Parties may wish to consider whether there is a need to address these issues at the national, regional or international level:

**(a) *Convention provisions not fully implemented by Parties at the national level***

- (i) A majority of Parties have still not adopted national access and benefit-sharing regimes. Seventy two Parties have established national focal points and fifteen have established competent national authorities. A large variety of approaches have been adopted by Parties to deal with access and benefit-sharing which are the source of a lack of uniformity among access and benefit-sharing measures and consequently procedures to obtaining access to genetic resources.
- (ii) In addition, it would appear that few legally binding measures have been adopted by Parties, with users of genetic resources under their jurisdiction, to support compliance with access and benefit-sharing requirements.
- (iii) The consequence of this lack of implementation of the access and benefit-sharing provisions of the Convention has been the lack of predictability and legal certainty for both providers and users of genetic resources. On the one hand, providers are concerned about the potential misappropriation of genetic resources and the absence of legal certainty, in particular once genetic resources have left their country. On the other hand, users of genetic resources are concerned about the lack of predictability and legal certainty due to absence of clear procedures for access and benefit-sharing in many countries, the absence of easily identifiable competent national authorities, or existing access and benefit-sharing procedures which are sometimes considered too cumbersome, time consuming and involve high transaction costs.

**(b) *No traceability***

The difficulty in tracing or monitoring genetic resources once they have left the provider country has also been a source of concern for developing countries in relation to the misappropriation of their genetic resources. An internationally recognized certificate of origin/source/legal provenance is one possible instrument being considered to address this gap. Standard material transfer agreements for particular sectors could also be considered to address this concern.

**(c) *Absence of specific access and benefit-sharing remedies***

The absence of specific access and benefit-sharing remedies at national and international levels may be an obstacle to obtaining access to remedies and access to justice in situations of breach of compliance with access and benefit-sharing requirements of provider countries or in cases of breach of compliance with access and benefit-sharing contracts.

**(d) *Geographical gap***

- (i) Transboundary genetic resources: The existing system does not take into account the fact that access requirements may differ between neighbouring countries for access to the same genetic resources. Some have suggested that regional approaches may provide the solution to this.



- (ii) Genetic resources found in areas beyond national jurisdiction: Article 15 only covers genetic resources found under the national jurisdiction of countries. Therefore genetic resources found beyond national jurisdiction, such as in the deep seabed are not covered by the access and benefit-sharing provisions of the Convention.

**(e) *Gaps related to the membership on international instruments***

Gaps in the membership of international instruments related to access and benefit-sharing may be challenging for countries at the level of implementation and be a potential source of conflict between countries.

**(f) *Different types of genetic resources used for different purposes by different types of users***

The provisions of the Convention provide one system applicable to all genetic resources (with the exception of human genetic resources) used by all types of users for different purposes. The only other access and benefit-sharing system yet developed is provided by the International Treaty on Plant Genetic Resources for Food and Agriculture through its Multilateral System, though it should be noted that the Commission on Genetic Resources for Food and Agriculture is now working, as a priority, on policies and arrangements for access and benefit-sharing for genetic resources for food and agriculture generally. Parties may wish to consider whether sectoral approaches to access and benefit-sharing are needed.

**(g) *Issue of intermediaries***

Intermediaries are playing an important role in access and benefit-sharing. Consideration may therefore need to be given to regulate these activities at the appropriate level.

**(h) *Asymmetries between users and providers***

Asymmetries between users and providers in terms of access to information, knowledge, negotiating skills and capacity may need to be addressed to promote the fair and equitable sharing of benefits arising out of the utilization of genetic resources.

**(i) *Knowledge gap***

Little is known with respect to the chain of innovation of genetic resources accessed. The analytical studies on access and benefit-sharing arrangements in different sectors will attempt to shed some light on different practices in various sectors, highlighting commonalities and divergences. More information is also needed on the value of genetic resources.

**(j) *Use of terms***

Parties may wish to consider whether the use of terms related to access and benefit-sharing should be addressed at the international level or whether it should rather be addressed at the regional or national levels.

**(k) *Rights and ownership***

In the absence of clearly defined ownership over genetic resources in national law, difficulties may arise in the negotiation of benefit-sharing agreements.

-----