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GROUP ON ACCESS AND
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Items 3, 4, 5, 6 and 7 of the provisional agenda*

FURTHER CONSIDERATION OF OUTSTANDING ISSUES RELATED TO ACCESS AND BENEFIT-SHARING: USE OF TERMS, OTHER APPROACHES AND COMPLIANCE MEASURES

Note by the Executive Secretary

I. INTRODUCTION

1. At its sixth meeting, the Conference of the Parties, in decision VI/24 A, adopted the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits arising out of their Utilization. It recognized "that the Guidelines are a useful first step of an evolutionary process in the implementation of relevant provisions of the Convention related to access to genetic resources and benefit-sharing" and decided "to keep under review the implementation of the guidelines and consider the need for their further refinement on the basis of, i*nter alia*, relevant work under the Convention, including work on Article 8(j) and related provisions".

2. In paragraph 8 of decision VI/24 A, the Conference of the Parties decided to reconvene the Ad Hoc Open-ended Working Group on Access and Benefit-sharing to advise the Conference of the Parties on:

(a) Use of terms, definitions and/or glossary, as appropriate;

(b) Other approaches as set out in decision VI/24 B;

(c) Measures, including consideration of their feasibility, practicality and costs, to support compliance with prior informed consent of the Contracting Party providing such resources and mutually agreed terms on which access was granted in Contracting Parties with users of genetic resources under their jurisdiction;

(d) Its consideration of any available reports or progress reports arising from the present decision;

(e) Needs for capacity-building identified by countries to implement the Guidelines.

* UNEP/CBD/WG-ABS/2/1.

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3. The Executive Secretary has prepared the present note to assist the Working Group in its consideration of the substantive items of its provisional agenda (UNEP/CBD/WG-ABS/2/1). Section II of the document addresses the use of terms. Section III reviews other approaches and provides an overview of instruments that can usefully complement the Bonn Guidelines and assist Parties and relevant stakeholders with the implementation of the access and benefit-sharing provisions of the Convention. Section IV addresses the issue of measures to support compliance with prior informed consent and mutually agreed terms in Contracting Parties with users under their jurisdiction. Finally, section V provides an overview of recent developments on capacity-building for access and benefit-sharing within the framework of the Convention.

4. In addition, further to paragraph 44 (o) of the Plan of Implementation of the World Summit on Sustainable Development and the recommendations of the Inter-Sessional Meeting on the Multi-Year Programme of Work of the Conference of the Parties up to 2010, held in Montreal in March 2003, the Working Group is also to consider, under the item on other approaches, "the process, nature, scope, elements and modalities of an international regime and provide advice to the Conference of the Parties at its seventh meeting on how it may wish to address this issue". As requested by the Inter-Sessional Meeting, the Executive Secretary has prepared a compilation of information regarding the views of Parties, other Governments, indigenous and local communities and relevant organizations on this issue (UNEP/CBD/WG-ABS/2/4).

II. USE OF TERMS, DEFINITIONS AND/OR GLOSSARY, AS APPROPRIATE

5. At its meeting in Bonn, held from 22 to 26 October 2001, the Ad Hoc Open-ended Working Group on Access and Benefit-sharing recommended, *inter alia*, that the Executive Secretary, in consultation with the Bureau of the Conference of the Parties, convene a group of ten experts nominated by Parties, having due regard to the principle of equitable geographical representation, to develop draft elements of a decision on the use of terms as contained in the original paragraph 6 of the draft Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits arising out of their Utilization endorsed by the Working Group on Access and Benefit-sharing at its first meeting, in Bonn.

6. On the basis of nominations received, the Secretariat selected 10 experts, in consultation with the Bureau, on the basis of their expertise, the need to ensure equitable geographical distribution and with due regard to gender balance, from the following countries: China, Cuba, Ethiopia, Germany, India, Nigeria, Peru, Poland, Switzerland and Ukraine.

7. Subsequent to the Bonn meeting, experts from these countries were invited to provide to the Secretariat their suggestions regarding elements which should be included in the use of the following terms included in paragraph 6 of the draft Bonn Guidelines: access to genetic resources; benefit-sharing; commercialization, derivatives, provider, user, stakeholder, *ex situ* collection, and voluntary nature. The submissions received by experts were compiled by the Secretariat and made available to the sixth meeting of the Conference of the Parties in an information document (UNEP/CBD/COP/6/INF/40, annex I). In addition, in order to assist experts in their work, a preliminary list of existing definitions of the terms listed in the original paragraph 6 of the draft Bonn Guidelines was compiled by the Secretariat. This list, available in annex II of the same document, contains definitions taken from existing guidelines, codes of conduct, agreements and legislation, which address the issue of access to genetic resources and benefit-sharing. The list is not exhaustive and was only meant to assist in launching the process regarding the use of terms under the Bonn Guidelines.

8. Paragraph 8 of the Bonn Guidelines provides that:

> "The terms as defined in Article 2 of the Convention shall apply to these Guidelines. These include: biological diversity, biological resources, biotechnology, country of origin of genetic resources, country providing genetic resources, *ex situ* conservation, *in situ* conservation, genetic material, genetic resources, and *in situ* conditions."

9. In paragraph 8 (a) of decision VI/24 A, the Conference of the Parties decided that the issue of use of terms should be further considered by the Working Group on Access and Benefit-sharing at its second meeting, in order to determine the most appropriate way to address this issue. The Working Group was requested *inter alia*, to advise the Conference of the Parties on use of terms, definitions and/or glossary, as appropriate, in the Bonn Guidelines.

10. In a notification dated 27 June 2002, Parties were invited to communicate to the Secretariat their views with regard to the various issues that should be addressed by the Working Group on Access and Benefit-sharing, including use of terms. Reminders were sent out to Parties respectively on 25 September 2002, 15 October 2002 and 9 of April 2003. As of 22 April 2003, submissions on the "use of terms" had been received from Colombia, Ethiopia and the United States of America. 1/

11. In its submission, the Government of Colombia highlighted that the revision of definitions and use of terms in the Bonn Guidelines should be one of the main point of discussion at the second meeting of the Working Group.

12. Ethiopia stated that terms like "derivative", "access", "prior informed consent", "provider", "*in situ* source" and "user" need to be defined. It also stated that terms like "country of origin" and country providing genetic resources" need to be elaborated upon and that the terms "provider", "user" and "stakeholder" are neither defined in the Guidelines nor are they in use under the Convention. Therefore, they should be replaced by equivalent terms in the Convention or defined in a manner that is in keeping with the spirit of the Convention and enhances/facilitates the achievement of its objectives. Under paragraph 11 (d), Ethiopia suggested that "the term "stakeholder" should not be construed to mean only "providers" and "users" but such actors as States of providers and users".

13. The United States of America expressed the opinion that a glossary of terms would be of more value than adding definitions to the Bonn Guidelines, stating that such a glossary "would give Governments and stakeholders the flexibility that they will need to use effectively the Bonn Guidelines". The United States submission also contains both general and more specific comments, regardless of whether a glossary or definitions within the Bonn Guidelines are agreed upon. 2/

14. On the basis of information provided by experts in preparation for the sixth meeting of the Conference of the Parties and recent submissions by Parties on the use of terms, Parties may wish to consider the suggested definitions submitted by experts, available in document UNEP/CBD/COP/6/INF/40 and make a recommendation to the Conference of the Parties on whether definitions and/or a glossary would be the most appropriate, as well as on the process for drafting such a glossary or definitions.

III. OTHER APPROACHES AS SET OUT IN DECISION VI/24 B

15. In decision VI/24 B, paragraph 10, the Conference of Parties recognized that a package of measures may be necessary to address the different needs of Parties and stakeholders in the implementation of access and benefit-sharing arrangements. In paragraph 11, it also recognized that other approaches could be considered to complement the Bonn Guidelines, such as model contractual agreements, existing regional agreements and models laws on access to genetic resources and benefit-sharing. Finally, in paragraph 12, the Conference of the Parties requested the Executive Secretary to compile information on existing complementary measures and approaches, and experiences with their implementation, and to disseminate such information to Parties and relevant stakeholders through, inter alia, the clearing house mechanism of the Convention.

1/ See the compilation of submissions provided by Parties and relevant Governments (UNEPCBD/WG-ABS/2/INF/1).

2/ Ibid.

16. The following sections provide an overview of existing approaches and also points to potential additional approaches that could usefully assist Parties, Governments and relevant stakeholders in the implementation of access and benefit-sharing arrangements.

A. Existing approaches

17. A variety of approaches have been adopted by different actors, including Governments, institutions, professional associations, the private sector and inter-governmental organizations to manage access to genetic resources and benefit-sharing. These approaches include: regional instruments which provide guidance at the regional level; specific instruments elaborated for the agricultural sector which take into account the specificities of plant genetic resources for food and agriculture; codes of conduct and guidelines developed by specific user groups, such as botanical gardens, culture collections and certain professional associations which respond to the particular needs of their constituents. In addition, reference to corporate policies of certain private companies, reflecting their management practices in the area of access and benefit-sharing, are also included. The efficacy of these instruments in assisting with the implementation of access and benefit-sharing arrangements is difficult to assess, in part due to the fact that a number of these have still not entered into force or are relatively recent.

18. Initiatives undertaken by national Governments to assist users under their jurisdiction to comply with prior informed consent and mutually agreed terms are addressed under section IV below.

1. Agreements and model laws

Regional approaches

19. At the regional level, four instruments have been developed to provide a legal framework for the implementation of access and benefit-sharing arrangements. In decision 391, the Andean Pact countries 3/ adopted, in July 1996, a legally binding framework for access to genetic resources and benefit-sharing. Legal frameworks are also being developed in Central America and by the Association of South-East Asian Nations (ASEAN). Finally, in Africa, the African Model Law was developed by the Organisation of African Unity (OAU).

20. *Andean Pact decision 391 on the Common Regime on Access to Genetic Resources*, (1996, in force): One of the main objectives of the decision is to regulate access to genetic resources and derivatives in Andean Pact countries, in order to create the conditions for fair and equitable sharing of the benefits arising from such access (heading II). The decision sets out a number of principles, such as the sovereignty of member countries over genetic resources and their derivatives, and the recognition of traditional practices, knowledge and innovations (heading IV). It contains access procedures which include the terms, conditions and procedures of access. The access contract is to include an annex providing for the fair and equitable sharing of benefits arising from such access and supplementary contracts to the access contract address the benefit-sharing counterpart (headings V-VI). Failure to comply with the terms of benefit-sharing shall be grounds for termination and annulment of the access contract and consequently of the supplementary contract. Infractions and penalties are addressed under heading VIII.

21. *Central American Agreement on Access to Genetic Resources and Bio-chemicals and related Traditional Knowledge (2001, draft)*. This Agreement was developed by the Central American States and will enter into force when the fourth instrument of ratification is deposited. The draft agreement is meant to regulate access to genetic resources and related traditional knowledge, innovations and practices of Member States in order to ensure the fair and equitable sharing of benefits arising out of their utilization. The agreement covers the procedures for access, including conditions for access, such as benefit-sharing, terms and procedures (chapter II). It also covers the protection of traditional knowledge, innovations and practices (chapter III), and regional cooperation and institutional mechanisms (chapter IV).

22. *ASEAN Framework Agreement (2000, draft)*: Objectives of the draft ASEAN Framework Agreement on Access to Biological and Genetic Resources include: ensuring that access regulations

3/ The member States of the Andean Community include Bolivia, Colombia, Ecuador, Peru and Venezuela.

within the ASEAN region are uniform and consistent with minimum requirements set out in the Agreement; setting minimum standards in regulating access to biological and genetic resources and strengthening national initiatives towards this objective, and promoting technology transfer and capacity-building at the regional, national and community levels. Elements covered by the agreement include: the establishment of competent national authorities, the settlement of disputes, prior informed consent and the participation of key stakeholders, the fair and equitable sharing of benefits and the creation of a Common Fund for Biodiversity Conservation.

23. *African Model Law:* The African Model Law for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources (2000) was developed by the Organization of African Unity (OAU). The African Model Law "aims to protect Africa's common biological diversity and the livelihood systems dependent on it with a common tool". The African Model Law is meant to be adapted to national priorities and needs of each African nation. With respect to access and benefit-sharing, the Model Law covers the conditions for access to genetic resources, (including the prior informed consent of both the State and the local communities affected) and the fair and equitable sharing of both monetary and non-monetary benefits, including the establishment of a Community Gene Fund for financial benefit-sharing, and the establishment of national competent national authorities and other relevant institutional arrangements. In addition, the Model Law addresses Farmers' Rights, plant breeders' rights and, community rights and responsibilities. It also contains provisions addressing sanctions and penalties and possible appeals.

The sectoral approach: an international agreement for plant genetic resources for food and agriculture

24. *International Treaty on Plant Genetic Resources for Food and Agriculture*. The Conference of the Food and Agriculture Organization of the United Nations (FAO) adopted the International Treaty on Plant Genetic Resources for Food and Agriculture in November 2001. This legally binding treaty covers all plant genetic resources for food and agriculture. Its objectives are "the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of benefits derived from their use, in harmony with Convention on Biological Diversity, for sustainable agriculture and food security". The centrepiece of this Treaty is the Multilateral System of Facilitated Access and Benefit-sharing that supports the work of breeders and farmers. The Multilateral System can be seen as a particular way of applying Article 15, paragraph 2, of the Convention, which states that "Parties shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention". In its article 10, the Treaty roots the establishment of multilateral system in the exercise of sovereign rights and carefully balances access and benefit-sharing. 4/ The Multilateral System applies to more than 60 plant genera, which include 64 major crops and forages. A "Material Transfer Agreement" to be established by the Governing Body will set out the conditions for access to these genetic resources and benefit-sharing. Access will be provided for utilization and conservation in research, breeding and training. The treaty also provides for payment of an equitable share of the monetary benefits derived from the commercialization of a product that uses plant genetic resources from the system. The treaty makes provisions for benefit-sharing through information-exchange, access to and transfer of technology, and capacity-building. The treaty will enter into force after it has been ratified by 40 countries. As of 10 September 2003, the treaty had been ratified by 31 countries.

2. Policy guidelines and codes of conduct related to access and benefit-sharing

25. Specific guidelines have been developed for the agricultural sector. Additionally, a growing number of organizations such as botanic gardens, culture collections and even some genebanks are developing institutional policies in response to the Convention on Biological Diversity, according to the needs of their specific user groups.

4/ Cooper, D., "The International Treaty on Plant Genetic Resources for Food and Agriculture", RECIEL 11 (1), 2002.

Agricultural sector

26. *International Code of Conduct for Plant Germplasm Collecting and Transfer*. The International Code of Conduct adopted by the FAO Conference in 1993 is a voluntary instrument. It provides a framework for Governments in developing national regulations or formulating bilateral agreements for the collection of germplasm. Among other elements, it sets out minimum responsibilities of collectors, sponsors, curators and users of collected germplasm, in the collection and transfer of germplasm. At its next regular meeting in 2004, the Commission on Genetic Resources for Food and Agriculture will consider the need to update elements of the Code in light of the adoption of the International Treaty and other developments.

27. *The international network of ex situ collections of plant genetic resources*. The international network of *ex situ* collections of plant genetic resources under the auspices of the FAO comprises most of the collections held by the International Centres for Agricultural Research (IARCs) according to an agreement signed between each of the Centres and FAO in 1994. The agreement sets out policies by which genetic resources are held and transferred. The agreement is to be "construed and applied in a manner consistent with the provisions for the Convention on Biological Diversity and the International Undertaking on Plant Genetic Resources" (article 1). In implementing the agreement, the IARCs make genetic resources available according to a standard Material Transfer Agreement (MTA), which has been approved by the FAO Commission on Genetic Resources for Food and Agriculture. In 2002, a revised MTA was endorsed by the Commission and recommended for use by the Centres. 5/ Upon entry into force of the International Treaty on Plant Genetic Resources for Food and Agriculture, it is envisaged that the Centres will sign agreements with the Governing Body of the Treaty, and new MTAs, to be adopted by the Governing Body, will be used.

Botanical gardens

28. *Principles and Common Policy Guidelines on Access to Genetic Resources and Benefit-sharing for Participating Institutions* (botanic gardens and herbaria). This project involved 28 botanic gardens and herbaria from 21 countries in the development of a common approach on access and benefit-sharing and includes: Principles on Access to Genetic Resources and Benefit-sharing for Participating Institutions; Common Policy Guidelines; and an explanatory text. 6/ The Principles promote the sharing of benefits arising from the use of genetic resources acquired prior to the entry into force of the Convention, in the same manner as for those acquired thereafter. The group also designed two model material transfer agreements (a Written Acquisition Agreement and a Written Supply Agreement) to assist participating institutions negotiate the transfer of biological material, which are included in annex.

29. *The Code of Conduct and Access and Benefit-sharing system for botanic gardens.* According to the thematic report on access and benefit-sharing submitted under the Convention on Biological Diversity by the European Community, 7/ following the initiative of German Ministry of Environment, "representatives of 34 botanic gardens from Austria, Germany and Switzerland took part and developed a 'Code of Conduct for Botanic Gardens and Similar Collections governing the Acquisition, Maintenance and Supply of Living Plant Material'. An exchange circuit has been established for botanic gardens that have endorsed the code. The circuit facilitates the exchange of genetic resources for non-commercial purposes between these gardens. The list of botanic gardens that have endorsed the code are available at www.biologie.univulm.de/verband/cbd/list.html. The concept of an international circuit has been endorsed by members of the European Consortium of Botanic Gardens, the platform for official representatives of national botanic gardens networks in the EU."

5/ See CGRFA-9/02/REP, appendix E, available at www.fao.org/ag/cgrfa.

6/ Latorre Garcia, F., Williams, C., ten Kate, K. &Cheyne, 2001 (based on contributions from 36 individuals from 28 botanic gardens and herbaria from 21 countries). *Results of the Pilot Project for Botanic Gardens: Principles on Access to Genetic Resources and Benefit-sharing, Common Policy Guidelines to assist with their implementation and Explanatory Text*. Royal Botanic Gardens, Kew.

7/ The report is available at: http://www.biodiv.org/world/reports.asp?t=abs#E.

30. *Plant Net Conservation policy*: The thematic report of the European Community also states that "Plant Net is the national network of botanic gardens, arboreta and other documented plant collections for Britain and Ireland. It seeks to promote botanical collections as a national resource for research, conservation and education, as well as to facilitate networking and training. Plant Net has made a general policy commitment to implementing the CBD. The Plant Net conservation policy states that 'while botanic gardens have much to offer and gain from the CBD, there are also obligations (such as gaining government permission to access genetic resources) which botanic gardens must honour.' Amongst others, Plant Net aims seeks to ensure that plant collections are collected, maintained and managed in accordance with the CBD by providing information on the Convention to its members and promoting understanding of its provisions."

Micro-organisms culture collections

31. *Micro-Organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC)*. 8/ MOSAICC is a voluntary code of conduct. Its development was initiated by the Belgian Coordinated Collections of Micro-organisms (BCCM) in 1997, with the support of the Directorate General XII for Science, Research and Development of the European Commission, and involved twelve partners from various sectors in both developed and developing countries. Its purpose is to facilitate access to microbial genetic resources in conformity with the Convention on Biological Diversity and other applicable national and international law, and to help partners to make appropriate arrangements when transferring microbial genetic resources. MOSAICC covers the terms of access to microbial genetic resources, which include the terms of agreement on benefit-sharing, access to and transfer of technology, scientific and technical cooperation as well as technology transfer.

32. *CAB International (CABI) Policy on Access to Ex Situ Genetic Resources:* CABI, an intergovernmental organization, addresses the receipt and supply of microbial strains and the sharing of benefits arising from their use, in conformity with national and international law in its policy on access to *ex situ* genetic resources. It has also developed a model material transfer agreement and a position statement on patenting, intellectual property rights and ownership issues under the Convention on Biological Diversity. 9/

Professional societies or organizations

33. A number of professional societies and international organisations, such as the Society of Economic Botany, the International Society of Ethnobiology, the Society for Applied Anthropology have developed codes of conduct to encourage their members to obtain prior informed consent and to share benefits with source country institutions and communities. 10/

The private sector

34. A number of companies have developed policies in response to the Convention. Five companies that have introduced public policies, or have drafted documents outlining their "best practice" in response to the Convention are GlaxoSmithKline, Novo Nordisk, Xenova, Shaman Pharmaceuticals, and Bristol-Myers Squibb.

35. In 1995, Novo Nordisk A/S, a Danish company, developed a policy for the acquisition of natural resources for pharmaceutical and enzyme development. In 1997, the company developed guiding principles for Novo Nordisk's implementation of the Convention. Both the policy and guiding principles were developed by a joint environmental and bioethics committee covering the company's health-care and industrial-enzymes businesses. According the thematic report of the European Community, although the company's health-care and industrial-enzymes businesses have subsequently demerged into Novo Nordisk and Novozymes, they remain committed to the Convention on Biological Diversity and its

8/ Further information is available at: www.belspo.be/bccm/mosaicc.

9/ Op.cit. footnote 7, p. 32.

10/ Ten Kate, K., Laird S., "The Commercial Use of Biodiversity - Access to Genetic Resources and Benefit-sharing", Earthscan, London, 1999, p. 309.

provisions on access and benefit-sharing, including efforts to obtain prior informed consent on mutually agreed terms, even in countries where national access and benefit-sharing systems have not been established. 11/

36. Another example drawn from the thematic report of the European Community is the GlaxoSmithKline (GSK) public policy position on the Convention on Biological Diversity approved in February 2002. 12/ Although the company now has apparently limited interest in access and screening natural materials, 13/ natural product screening still takes place under outsourced programmes with collaborative partners in countries such as Brazil and Singapore. It would appear that the company has taken a number of steps to implement the provisions of the Convention, including getting the prior informed consent of national Governments for any proposed material-collecting programme, while taking measures to ensure biodiversity protection and sustainable use of the materials. GSK also works exclusively with organizations and suppliers with the expertise and legal authority to collect plant and other natural material samples, such as botanic gardens, universities and research institutes. Benefit-sharing may include local training in collecting and screening skills and direct or indirect benefits to the country of origin in the event that a commercial product based on a natural material is developed by GSK.

37. The Japan Bioindustry Association has developed a "Statement of Policy on Access to Genetic Resources and Benefit-sharing". 14/ This association is a non-profit organization representing a large proportion of the users of genetic resources in Japan. 15/

3. Model forms, clauses and contractual agreements related to access to genetic resources and benefit-sharing

38. A number of codes of conduct, policies and guidelines described above also include model agreements or model forms. The Principles and Common Policy Guidelines on Access to Genetic Resources and Benefit-sharing for Participating Institutions (botanic gardens and herbaria) include model material transfer agreements to assist participating institutions to negotiate the transfer of biological material. MOSAICC proposes a model transfer agreement for the transfer of microbial genetic resources, a prior informed consent application model form for access to *in situ* microbial genetic resources and a model of prior informed consent for access to *in situ* microbial genetic resources. CABI has also developed a model material transfer agreement for microbial strains.

39. Model contractual agreements have also been developed by certain government agencies, such as the National Cancer Institute, a Government Agency of the United States of America, which has developed a model Memorandum of Understanding and letter of collection. Model contractual agreements developed by government agencies are further addressed under section IV below, which addresses measures to support compliance with prior informed consent and mutually agreed terms in Contracting Parties with users of genetic resources under their jurisdiction.

40. Finally, the WIPO on-line searchable database of biodiversity-related access and benefit-sharing agreements, with a particular emphasis on the intellectual property aspects of such agreements 16/ provides a list of model contractual agreements developed by Governmental bodies, research institutes and private individuals which could also assist Parties in the implementation of access and benefit-sharing arrangements.

11/ Thematic report on access and benefit-sharing of the European Community, October 2002, p. 34-35, box 4.

12/ Further information is provided in the European Community's thematic report, p.35, box 5.

13/ According to the European Community's thematic report, since the merger of SmithKline Beecham and Glaxo Wellcome in January 2001, there has been increasing focus on drug discovery using high-throughput screening of synthetic chemical compounds.

14/ www.jba.or.jp/jbl/vol-16/8-5.html.

15/ UNU/IAS, "User Measures – Options for Developing Measures in User Countries to Implement the Access and Benefit-sharing Provisions of the Convention on Biological Diversity", March 2003, p.15.

16/ Available at www.wipo.int/globalissues/databases/contracts/background/index.html

B. Additional approaches for further consideration

41. In addition to existing approaches examined above, the following approaches may prove useful in ensuring the implementation of access and benefit-sharing provisions and may usefully complement the Bonn Guidelines.

International certificate of origin

42. In its submission to the Secretariat, Mexico 17/ refers to the establishment of a certificate of legal origin. It suggests that in order to ensure compliance with the prior informed consent of the providing country, a certificate of legal origin should be developed. This certificate would ensure compliance with requirements for access to genetic resources of provider countries and would minimize risks of illegal access to genetic resources. The certificate would need to contain information on the origin of genetic resources and related traditional knowledge and proof of prior informed consent with respect to the material accessed and related traditional knowledge, innovations and practices.

43. Little analysis has been carried out on the possible characteristics of such a certificate of origin. UNU/IAS has suggested that "the documentation utilized in such a system might incorporate a standard permit or 'certificate of origin' including information concerning: particulars of the provider and user; particulars of indigenous and local communities parties to the agreement; details of genetic resources or traditional knowledge; details of the approved use which may be made of the resources; details of any restrictions on use; period of the agreement; conditions relating to transfer of rights to third parties."18/

44. The certificate or permit would therefore be awarded by the competent national authority in the provider country and follow the genetic resource along the access and benefit-sharing process, as a guarantee that the genetic resource has legally been obtained, in conformity with the access and benefit-sharing provisions of the Convention.

45. For example, if in a particular country, patent applications require the disclosure of the source of genetic resources when the product or process to be patented is based on a genetic resource, the certificate of origin could be used to demonstrate that the genetic resource was obtained legally, without the need for any additional verification process. 19/

46. The establishment of such an international system would involve a number of steps to be undertaken both at the national and international levels. At the national level, steps may include for the providing country, the establishment of competent national authorities and institutional mechanisms to issue the certificate of origin based on the prior informed consent of relevant national authorities, and for the importing country, the establishment of adequate mechanisms to ensure recognition of the certificate of origin at relevant stages of the life of the genetic resource.

47. At the international level, this may involve the establishment of an internationally harmonized system, including a set of minimum criteria for obtaining the certificate, such as the identification of the source of genetic resources and/or related traditional knowledge and prior informed consent of relevant national authorities in the providing country. It may also involve the development of a model certificate.

48. It has been argued that the establishment of such an internationally harmonised system would facilitate the tracking of genetic resources; harmonize procedures for identifying the existence of prior informed consent; protect the confidentiality of contracts; reduce transaction costs; promote increased

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17/ A compilation of submissions provided by Parties is being circulated as an information document (UNEP/CBD/WG-ABS/2/INF/1).

18/ See footnote 15 above.

19/ This issue is also addressed in the technical study on implementation issues related to disclosure of origin and prior informed consent for applications of intellectual property rights based on genetic resources being circulated as an information document for the second meeting of the Working Group on Access and Benefit-sharing (UNEP/CBD/WG-ABS/2/INF/2).

trade in genetic resources and by establishing a more transparent system, provide an incentive for countries of origin to develop more flexible access and benefit-sharing provisions. 20/

49. The permit system established by the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) and the experience acquired with its implementation could certainly provide useful assistance in establishing an efficient system.

50. In view of the foregoing, an international certificate of origin system could be considered as another approach to assist Parties to the Convention and other Governments with the implementation of the access and benefit-sharing provisions of the Convention.

Interregional or bilateral arrangements

51. It has also been suggested that existing mechanisms, such as bilateral or regional partnership agreements, which include sectoral agreements covering environmental issues and natural resources could also include measures related to access and benefit-sharing.

52. The thematic report of the European Community on access and benefit-sharing, provides the following example: 21/

> "The Partnership Agreement between the Members of the African, Caribbean and Pacific (ACP) States and the European Community and its Member States (Cotonou Agreement), could also enable technology transfer under ABS partnerships between EU institutions and countries that provide genetic resources and related traditional knowledge. The Compendium on Co-operation Strategies provides for scientific, technical and research co-operation.
>
> "Specifically, the Co-operation Strategy aims to support:
>
> (a) the development and implementation of R&D projects and programmes established by ACP States
>
> (b) activities aimed at consolidation of appropriate indigenous technology and the acquisition and adaptation of relevant foreign technology;
>
> (c) scientific and technical co-operation between ACP States themselves and between ACP States and other developing countries and the EU; as well as
>
> (d) the design of policies, incentive structures and institutions that enable the development of innovative capacity and competitiveness
>
> "The Co-operation Strategy also specifies that ACP/EC collaboration shall continue to stimulate partnerships between both users and generators of knowledge, based on a step by step refined analysis of existing research capacities and needs. The Strategy highlights development of ACP capacity to manage science and technology for sustainable economic and social development, and for protecting and conserving the environment and natural resources. This includes the development of the infrastructure, skills and knowledge base necessary for ACP states to acquire, adapt and generate environmentally sound technologies.
>
> "Sectoral agreements on environment and natural resources are also developed in bilateral or regional agreements of the EU with third countries, for instance in the EU-Mexico agreement."

53. Access and benefit-sharing considerations could thus be addressed more specifically in this type of agreement.

20/ Ibid.

21/ Thematic report on access and benefit-sharing of the European Community, October 2002, p.8-9

IV. MEASURES, INCLUDING CONSIDERATION OF THEIR FEASIBILITY, PRACTICALITY AND COSTS, TO SUPPORT COMPLIANCE WITH PRIOR INFORMED CONSENT OF THE CONTRACTING PARTY PROVIDING SUCH RESOURCES AND MUTUALLY AGREED TERMS ON WHICH ACCESS WAS GRANTED, IN CONTRACTING PARTIES WITH USERS OF GENETIC RESOURCES UNDER THEIR JURISDICTION

A. Background

54. Several provisions of the Convention address the legal obligations of Parties with users of genetic resources under their jurisdiction to ensure the fair and equitable sharing of benefits arising from the utilization of genetic resources.

55. Article 15, paragraph 7 provides that:

> "Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms."

56. In addition, Article 16, paragraph 3, provides that:

> "Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, 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, through the provisions of Articles 20 and 21 and in accordance with international law and consistent with paragraphs 4 and 5 below."

57. Paragraphs 1 and 2 of Article 19 also highlight the importance of measures to be taken by Contracting Parties to ensure the fair and equitable sharing of benefits with Contracting Parties providing the resources:

> "1. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties.
>
> "2. Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms."

58. The focus of discussions on access to genetic resources and benefit-sharing under the Convention process and also experience in the implementation of access and benefit-sharing provisions of the Convention have so far focused on measures to be taken by provider countries to develop national access and benefit-sharing systems to facilitate access to genetic resources within their countries and to ensure mutually agreed terms. However, the issue of balance between the obligations of users and providers and the need for Contracting Parties with users under their jurisdiction to take appropriate measures to ensure compliance with prior informed consent and mutually agreed terms was raised during the final negotiations of the Bonn Guidelines at the sixth meeting of the Conference of the Parties and was finally reflected in the text of the Guidelines, more specifically under paragraph 16 (d), which 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:

(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."

59. In addition, section V of the Guidelines on "other provisions" also includes reference to measures which could assist Contracting Parties with users under their jurisdiction to ensure compliance with prior informed consent and mutually agreed terms, such as: incentive measures; accountability in implementing access and benefit-sharing arrangements; national monitoring and reporting; means for verification; dispute settlement and remedies.

60. While section III of the Guidelines, on other approaches, includes measures developed by a variety of actors involved in access and benefit-sharing, this section examines more specifically measures to be applied in Contracting Parties with users under their jurisdiction, to ensure compliance of users with prior informed consent of the Contracting Party providing such resources and mutually agreed terms on which access was granted.

B. Possible measures for consideration

61. Measures to support compliance with prior informed consent and mutually agreed terms by Contracting Parties with users under their jurisdiction could be used at various stages, including at the point of entry, through the research and development process until commercialization or other use of a product or process which was based on a genetic resource.

62. It should be noted that genetic resources may be used by different types of users, ranging from universities, research institutes, gene banks, botanical gardens to biotechnological companies. These different types of users each have different mechanisms in place, and different objectives, needs and priorities when accessing genetic resources. Measures to support compliance will therefore need to be adapted to this diversity of ways of "doing business". Measures will also need to be adapted to the intended use of the genetic resources, whether for basic research or potential commercialization.

63. A large range of legal, administrative and policy measures could be developed to ensure compliance with prior informed consent and mutually agreed terms, but little analytical work has been carried out to date on these measures. Therefore the following is not exhaustive but rather attempts to provide an illustration of measures which could be further considered by Contracting Parties with users under their jurisdiction in order to ensure compliance with prior informed consent and mutually agreed terms. In view of the numerous differences in resources, users and possible uses of genetic resources, these measures may not be applicable to all circumstances and may need to be adapted.

64. In order to facilitate consideration of possible measures to ensure compliance with prior informed consent and mutually agreed terms, the present paper looks at the following categories:

(a) Measures to encourage compliance with prior informed consent and mutually agreed terms in Contracting Parties with users under their jurisdiction

(b) Measures to *monitor and enforce* compliance with prior informed consent and mutually agreed terms in Contracting Parties with users under their jurisdiction

(c) Measures to *address violations* of prior informed consent and mutually agreed terms in Contracting Parties with users under their jurisdiction

1. Measures to encourage compliance with prior informed consent and mutually agreed terms in Contracting Parties with users under their jurisdiction:

Provision of information by users to providers

65. Providing information to providers on the nature of legislative, administrative and policy measures addressing access and benefit-sharing in Contracting Parties with users under their jurisdiction and also on the type of users located in their jurisdiction could contribute to greater transparency and help to build mutual trust among user and provider countries.

66. This information can be provided by national focal points and national clearing house mechanisms, as illustrated by the websites of the United Kingdom (www.defra.gov.uk/science/GeneticResources) and the Netherlands focal points for access to genetic resources and benefit-sharing (www.absfocalpoint.nl).

Awareness raising/public outreach

67. Measures could also be considered by Contracting Parties with users under their jurisdiction to provide information to users on obligations regarding access to genetic resources and benefit-sharing.

68. Measures of this type have already been undertaken by certain Governments. For instance:

> "The U.S. Government has been actively engaged in informing U.S. scientists and U.S. funded scientists, either working for the U.S. Government or academia or the private sector or otherwise, about the importance of obtaining prior informed consent and mutually agreed terms for obtaining access to genetic resources outside the United States and providing monetary and/or non-monetary benefit-sharing. The U.S Government has been conveying this message at conferences, meetings and electronically through the Internet."22/

69. National focal points and competent national authorities for access and benefit-sharing could have an important role to play in raising awareness amongst users. For example, the websites set up by the United Kingdom and the Netherlands, as mentioned above, provide relevant information to users on access to genetic resources and benefit-sharing, including relevant policies and other measures.

Incentive measures

70. Incentives are the opportunities and constraints that influence the behaviour of individuals and organisations in a society. Incentive measures are specific inducements for companies, communities and individuals to undertake certain activities in the interest of public policy. 23/ Importantly, such an inducement does not rely on an outright prescription or prohibition of specific activities. Incentive measures are designed to encourage users to engage in access and benefit-sharing activities on their own initiative (as opposed to complying with an external norm or law).

71. The following types of incentive measures could be envisaged by Governments to encourage users to comply with prior informed consent and mutually agreed terms:

22/ United States submission in the compilation of submissions (UNEP/CBD/WG-ABS/2/INF/1).

23/ UNEP/CBD/COP/3/24, paras. 7 and 8.

(a) *Direct incentive measures* seek to change the relative costs and benefits of specific activities. They include *positive incentive measures*, that is, economic, legal or institutional measures designed to encourage beneficial activities, and *negative incentives* or *disincentives*, that is, mechanisms designed to discourage harmful activities;

(b) *Indirect incentive measures* seek to change the relative costs and benefits of specific activities in an indirect way, by creating or improving markets. Examples include certification and eco-labelling initiatives;

(c) *Perverse incentive measures* induce behaviour to not comply with prior informed consent and mutually agreed terms, often as unanticipated side effects of policies designed to attain other objectives. In consequence, their removal or the mitigation of their negative impacts through appropriate means is warranted.

Direct incentive measures

72. A number of direct incentive measures could be envisaged by Governments to encourage users to comply with prior informed consent and mutually agreed terms:

(a) The tax systems of many countries foresee tax breaks or deferrals for charitable activities. The related legal frameworks could be adapted to provide adequate incentives for private companies and research institutions to comply with voluntary guidelines or codes of conduct on access and benefit-sharing, and in particular on prior informed consent and mutually agreed terms;

(b) Several countries have programmes in place to offer subsidized export credits or loan guarantees in order to encourage private companies to engage in high-risk export markets. Requirements for eligibility to such programmes could be adapted to provide incentives to such companies to comply with access and benefit-sharing requirements related to prior informed consent and mutually agreed terms;

(c) Requirements for eligibility for publicly sponsored research grants could be adapted to reflect access and benefit-sharing provisions. The public support of research that makes use of genetic resources could be made contingent on compliance with prior informed consent and mutually agreed terms;

(d) Private research funds could be encouraged to apply similar requirements. Again, adequate adaptations of the tax system could be envisaged to provide incentives for private research funds to apply such requirements for compliance with prior informed consent and mutually agreed terms;

(e) The funding of relevant public institutions in general, in particular academic research institutions could be made contingent on their adoption of and compliance with such requirements.

73. In order to assist potential applicants in the fulfilment of these requirements, instruments such as guidelines, model proposals or model contractual agreements between the applicant and the funding institution could be developed in order to provide guidance to potential users of genetic resources provided by foreign countries (countries of origin). Illustrations of guidelines, codes of conduct and model contractual agreements developed by specific user groups are described in section III of this note.

74. The United States submission provides further examples, stating that:

> "The Agriculture Research Service (ARS) of the U.S. Department of Agriculture (USDA) administers one of the strongest national programs for conserving plant genetic resources and making them available for crop improvement and sustainable use. The USDA/ARS model contractual agreement is in the form of a Plant Exploration Proposal between USDA/ARS and the plant explorer. This agreement underscores the importance of collaborating with the host governments scientists, helping to build the host government's capacity to conserve plant genetic resources, and sharing equitably the results of research with the host government."

75. The submission also states that the Agriculture Research Service (ARS) funds foreign and domestic plant explorations to acquire plant germplasm for inclusion in the United States National Plant

Germplasm System. Plant exploration proposals may be submitted by any qualified scientist. Guidelines for plant exploration proposals have been developed and are revised annually. These include a "plant exploration proposal format" and "guidelines for conduct of foreign plant explorations", which contain specific references to access and benefit-sharing considerations.

76. Principles for accessing genetic resources, the treatment of intellectual property and the sharing of benefits have also been developed for research sponsored by the International Cooperative Biodiversity Groups (ICBG). ICBG are a grants programme developed by the National Institutes of Health (NIH), USDA and the National Science Foundation (NSF). According to the submission, the principles are incorporated in the contractual agreements used by the ICBG in carrying out its activities. These principles cover: disclosure to and informed consent of host country stakeholders; clear designation of the rights and responsibilities of all partners; protection of inventions using patents or other legal mechanisms; sharing of benefits with the appropriate source country parties; information flow that balances proprietary, collaborative and public needs; and, respect for and compliance with relevant national and international laws, conventions and other standards.

77. The absence of a mechanism for independent verification of their implementation may be considered as a shortcoming of such measures.

78. Similar incentive measures as enumerated in paragraph 72 above could also be designed and implemented to foster the transfer of relevant proprietary technology by private and public institutions as a means to share benefits. 24/ They could encourage private companies to carry out research and development activities in the provider country, thereby facilitating the transfer of technology to provider countries and the building of capacity, through training of local scientists and researchers. Incentive measures could also aim at encouraging joint ventures, involving joint research programmes with institutions in provider countries and eventually joint patents if the research leads to commercialization.

Indirect incentive measures

79. Voluntary certification programmes are an example of indirect incentives. A voluntary certification programme could apply to the users of genetic resources and provide the basis for provider countries to feel more confident about their potential partners. Certification could be a means to demonstrate that users have respected basic requirements related to access to genetic resources and benefit-sharing, such as prior informed consent and mutually agreed terms.

80. Paragraph 16 (d) (v) of the Bonn Guidelines refers to "voluntary certification schemes for institutions abiding by rules on access and benefit-sharing", as measures for consideration by Parties with users of genetic resources under their jurisdiction to support compliance with prior informed consent and mutually agreed terms. Under section V Dof the Bonn Guidelines, on means for verification, it is also provided in paragraph 58 that:

> "A system of voluntary certification could serve as a means to verify the transparency of the process of access and benefit-sharing. Such a system could certify that the access and benefit-sharing provisions of the Convention have been complied with."

81. A study was undertaken on behalf of the Government of Switzerland in order to explore the feasibility of establishing a certification system and assist further deliberations in this field. 25/

82. According to this study:

> "Certification is a market based concept that verifies an organisation's practices. In its highest form, an independent third party assesses the operation of a private or public

24/ See the discussion in the note by the Executive Secretary on incentive measures prepared for the ninth meeting of the Subsidiary Body on Scientific, Technical and Technological Advice (UNEP/CBD/SBSTTA/9/7).

25/ L. Glowka, "Towards a Certification System for Bioprospecting Activities", study commissioned by the State Secretariat for Economic Affairs, Bern, 2001.

organisation against a standard set of criteria. A certificate of conformity is issued as written evidence of verification." 26/

83. Certification is a market-based instrument, which has been widely used to encourage sustainable management practices in the environmental area. Certification systems have already been set up internationally in specific environmental fields, such as forestry (Forest Stewardship Council) and marine resources (Marine Stewardship Council) in order to encourage environmentally sustainable management practices.

84. UNU/IAS in its paper on "Options for Developing Measures in User Countries to implement the Access and Benefit-sharing Provisions of the Convention on Biological Diversity" 27/ argues that users of genetic resources may have an incentive to participate in a certification programme for the following reasons:

(a) A credible certification scheme may lessen the chances of restrictive legal measures;

(b) A certification system may be considered useful when genetic resources are obtained from countries that do not have an access and benefit-sharing system in place;

(c) Public relations gains to being certified;

(d) Certification may help to attract investors who use social and environmental criteria to make investment decisions.

85. The study carried out for the Swiss Government concludes that, although there is nothing to suggest that certification could not be applied to bioprospecting activities, outstanding issues, such as cost and demand, need to be reviewed more closely in order to determine whether a bioprospecting certification system would be feasible to create and operate in practice.

Removal or mitigation of perverse incentives

86. Government could also undertake to remove or mitigate policies or programmes that create incentives not to comply with prior informed consent and mutually agreed terms. For instance, illegal side-payments to foreign officials in exchange for favourable regulatory decisions or procurement contracts are in some countries tax-deductible for private companies. Such provisions for tax exemption may provide perverse incentives to circumvent national access and benefit-sharing legislation and not to comply with prior informed consent and mutually agreed terms requirements. Consequently, the abolishment of such provisions, in accordance, for instance, with the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, would remove such perverse incentives.

Model contractual agreements

87. Model contractual agreements are addressed under section III above on other approaches. They are also relevant to this section when developed by government agencies to set out conditions for international access to genetic resources in order to support compliance with prior informed consent and mutually agreed terms. The National Cancer Institute (NCI), a government agency of the United States of America, which seeks genetic resources of possible interest to cancer researchers, provides examples of such model agreements. The NCI model contractual agreement (either a memorandum of understanding or a letter of collection) operates as an agreement between NCI and a foreign partner. According to the submissions of the United States of America., over two dozen foreign partners, from Latin America, Africa, Asia, Australia and Europe have concluded such agreements with the NCI.

88. As highlighted in the United States submission, the NCI has adopted a two-stage approach to benefit-sharing:

26/ Ibid, p. iii.

27/ See footnote 15 above.

> "In the first stage, the NCI collaborates with foreign partners in the exchange of results, the support of short-term and long-term visitors to discuss further collaboration and undertake training in drug discovery, respectively, and technology transfer. If, after analysis of genetic resources covered by the first stage of an agreement, the NCI decides to proceed to the second stage of patenting the product of its research and seeks to license it for development and possible production and marketing, then it will require the licensee to return to the foreign partner to negotiate an agreement concerning royalties and other forms of compensation, as appropriate. The parties conduct negotiations on monetary benefit-sharing only where there is a reasonable possibility of commercialization of a product and at a time when there is more information about the likely value of the product."

89. The model memorandum of understanding and letter of collection, which are being used internationally, are included in the submission provided by the United States. 28/

2. Measures to monitor and enforce compliance with prior informed consent and mutually agreed terms in Parties with users under their jurisdiction

Import regulations

90. The regulation of imports of genetic resources and their control at the point of entry could be a means to ensure that importers of genetic resources have obtained access to these resources with the prior informed consent of the Party providing such resource and that access was granted on mutually agreed terms.

91. Elaborate controls on the importation of biological material have been established by national authorities in many countries for different purposes including the protection of human, plant, animal health, and the protection of the environment according to national standards. Governments also regulate imports in order to implement international obligations, such as those under CITES which was established to control the international trade of endangered species.

92. The above-mentioned paper prepared by UNU/IAS 29/ provides examples of national customs controls for the importation of biological material and reviews the measures adopted by certain countries in order to implement CITES. Existing procedures such as those undertaken to implement CITES may deserve further examination when determining the feasibility, practicality and costs of similar measures to control the terms of access to genetic resources.

93. Import/export regulations would presumably apply to all genetic resources regardless of their potential use by the importer. The main objective of the border control would be to ensure that the appropriate permit has been issued by the exporting country and that therefore relevant conditions for import have been met.

94. Measures which could be envisaged, include the following: 30/

(a) A requirement that imported genetic resources have export permits as evidence of prior informed consent from the providing Party (e.g. Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, article VI);

(b) A requirement that importers, within national jurisdiction, maintain records of imported genetic resources, showing origin, date of receipt and other information; 31/

28/ Compilation of submissions by Parties and Governments (UNEP/CBD/WG-ABS/2/INF/1).

29/ See footnote 15 above.

30/ UNEP/CBD/COP/2/13, para. 87.

31/ An analogy may be found with the UNESCO Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property, adopted 14 November 1970. Article 10 requires each Party to require domestic antique dealers to maintain registers of items of cultural property in stock and to impose penal or administrative sanctions for violations of this requirement.

(c) Designation of a governmental authority to administer the regulation of imports of genetic resources from other Parties.

95. In order to determine the feasibility, practicality and costs of such customs and regulatory controls, a number of elements should be considered:

(a) Control of genetic resources at the borders may be difficult in practice due to the fact that genetic resources can be easily dissimulated due to their small size;

(b) Establishment of such as system may be quite costly for both exporting and importing countries, as it would involve setting up appropriate infrastructures in both exporting and importing countries and training of personnel, such as customs officials;

(c) The costs involved in setting up appropriate mechanisms at the borders will need to be assessed in order to determine whether they are proportional to the benefits;

(d) Import regulations and border controls may create increased administrative burden and additional costs for users in importing countries and thereby act as a disincentive to the use of imported genetic resource;

(e) In certain cases, research may be carried out in the providing country and the results forwarded electronically to the user country in which case border controls would be of no assistance to ensure compliance with prior informed consent and mutually agreed terms.

Disclosure of origin in intellectual property rights applications

96. 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 were referred to in paragraph 16 (d) (ii) of the Bonn Guidelines as one type of measure to support compliance with prior informed consent and mutually agreed terms.

97. In paragraphs 1 and 2 of decision VI/24 C, the Conference of the Parties invited Parties and Governments to encourage the disclosure of country of origin of genetic resources and traditional knowledge in applications for intellectual property rights, where the subject-matter of the application concerns or makes use of genetic resources and/or traditional knowledge in its development. However, the Conference of the Parties also recognised that further work was needed on this issue. The note by the Executive Secretary on the role of intellectual property rights in access and benefit-sharing arrangements, including national and regional experiences (UNEP/CBD/WG-ABS/2/3) and the above-mentioned technical study on issues of implementation relating to Disclosure of Origin and Prior Informed Consent for Applications of Intellectual Property Rights Based on Genetic Resources (UNEP/CBD/WG-ABS/2/INF/2) further address issues related to the disclosure of origin of genetic resources and relevant traditional knowledge in applications for intellectual property rights. In addition, the World Intellectual Property Organization, in response to the invitation of the Conference of the Parties, in paragraph 4 of decision VI/24 C, has also prepared a technical study addressing the issue of disclosure within patent applications, which will be considered by the WIPO General Assembly in September 2003 for onward transmission to the Conference of the Parties to the Convention on Biological Diversity.

98. It has been argued that the disclosure of origin of the source of genetic resources in applications for intellectual property rights could help ensure that the genetic resource was accessed with the prior informed consent of the country of origin and that benefit-sharing arrangements have been agreed.

99. In cases of commercial use of genetic resources, for example in pharmaceuticals, royalties generally arise between seven and twenty years after the original access to the genetic resources in question. In addition, the probabilities of an individual sample succeeding to the market are very small.

Therefore, only a small portion of individual access transactions would give rise to benefits such as royalties. 32/

100. Nevertheless, it has been suggested that "scientific, commercial and industrial users will not invest large sums of money in the research, development and marketing of any product unless they can secure IPR protection for their investment." 33/ Therefore, since the intention of these users is to patent the product in the event that the research proves successful, if a requirement for the disclosure of origin is established in patent applications, it will be in their interest to obtain prior informed consent and mutually agreed terms when they obtain access to the resource. Therefore in the majority of cases where no patent applications will be filed because the research has not been conclusive, the disclosure requirement will in any case have created an incentive for users to seek prior informed consent and to agree on mutually agreed terms that may involve not only monetary but also non-monetary benefits, such as technology transfer and capacity-building, through, for example, training of local researchers.

101. The note by the Executive Secretary on the role of intellectual property rights in access and benefit-sharing arrangements, including national and regional experiences (UNEP/CBD/WG-ABS/2/3) provides an overview of existing national and regional experiences related to the issue of disclosure of origin of genetic resources in intellectual property rights applications.

Disclosure of country of origin in relevant publications

102. The disclosure of origin of genetic resources could also be a requirement for relevant publications. For example, a scientist could acknowledge the country of origin of genetic resources that are the subject of a publication in a professional journal.

Joint patents when joint research between users and providers

103. The possibility of joint ownership of intellectual property rights could be given further consideration, when research is conducted jointly by researchers in the provider country and the user country. In certain countries, such as Switzerland, existing intellectual property rights already take into account the possibility of joint ownership. 34/ In India, The Biological Diversity Bill, 2002, provides that the National Biodiversity Authority (NBA), will impose terms and conditions to secure equitable sharing of benefits, including the granting of joint ownership of intellectual property rights to the NBA, or where benefit claimers are identified, to such benefit claimers.

104. Such intellectual-property-rights-related mechanisms for the sharing of benefits may provide important avenues for the transfer and diffusion of biotechnologies, not only through joint patents with stakeholders in countries of origin of genetic resources, but also through joint research programmes with institutions in such countries. Countries could engage in adapting their legal, regulatory and policy frameworks to encourage the use of such mechanisms.

Product approval process

105. Product approval procedures could include requirements of prior informed consent and mutually agreed terms. All sectors that use genetic resources must comply with specific product approval regulations. A product will need to be certified and approved by the relevant regulating agencies, prior to its production or distribution. In the pharmaceutical and botanical sectors, for example, products are generally regulated to meet human-health safety standards. Inclusion of requirements for prior informed consent and mutually agreed terms may deserve further consideration.

32/ UNEP/CBD/COP/4/21, para. 28.

33/ B. Tobin, 1997, "Certificates of origin: A role for IPR regimes in securing prior informed consent", in *Access to genetic resources – Strategies for sharing benefits*, ACTS Press, 1997.

34/ Thematic report on access and benefit-sharing submitted by Switzerland (available at http://www.biodiv.org/world/reports.asp?t=abs#S).

106. It has been suggested that "as many products not subject to patents are commercially exploited at an industrial scale, it is important that mechanisms be developed to control all major commercialisation of genetic resources, collective property, and products developed with use of such resources". 35/

3. Measures to address violations of prior informed consent and mutually agreed terms in Parties with users under their jurisdiction

Measures facilitating access to justice

107. In cases of infringements to access and benefit-sharing arrangements, difficulties may be encountered by the provider in obtaining access to justice, when the resource accessed has been exported to a foreign country by the user of the resource.

108. Cooperation between Contracting Parties to address alleged infringements of access and benefit-sharing agreements could take various forms. The above-mentioned UNU/IAS paper suggests that a number of measures deserve to be further considered to address alleged infringement of access and benefit-sharing agreements, such as "investigation of claimed breaches, facilitating access to information on user of resources and knowledge; notification of patent applications; assisting service of court documents; identifying the location of defendants; flexibility of rules for accepting evidence by affidavit or audio/visual recordings; recognition of standing; provision of legal aid; provision of visas; and alternative, reduced-cost dispute resolution mechanism, including arbitration". It is also suggested that the designation of an ombudsman could be considered. The ombudsman could "provide a point of contact for receipt of ABS claims, carry out preliminary investigation of alleged infringements of rights over genetic resources and traditional knowledge, and monitor breaches of contractual obligations". 36/

Administrative or judicial penalties

109. Administrative or judicial penalties could be considered to address violations of requirements to comply with prior informed consent and mutually agreed terms. Other international instruments, such as CITES (article VIII), the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (article 9, paragraph 5) and the UNESCO Cultural Property Convention (article 10) require each Party to introduce appropriate national/domestic legislation to prevent and punish illegal trafficking.

35/ B. Tobin, op. cit., p.338.

36/ See footnote 15 above.

V. NEEDS FOR CAPACITY-BUILDING IDENTIFIED BY COUNTRIES TO IMPLEMENT THE BONN GUIDELINES

110. At its fifth meeting, in 2000, the Conference of the Parties noted, in paragraph 14 of decision V/26 A "that further development of capacities regarding all aspects of access and benefit-sharing arrangements is required for all stakeholders, including local governments, academic institutions, and indigenous and local communities". At its second meeting, in March 2001, the Panel of Experts on Access and Benefit-sharing recommended that high priority should be placed on capacity-building and underlined that capacity-building should be the essence of the work on access and benefit-sharing under the Convention on Biological Diversity and should be operationalized. As suggested by the Panel of Experts and in response to paragraph 11 of decision V/26 A, the Ad Hoc Open-ended Working Group on Access and Benefit-sharing considered issues of capacity-building at its first meeting in October 2001. The Working Group requested the Executive Secretary to convene an open-ended expert workshop on capacity-building for access and benefit-sharing in order to further develop draft elements for an action plan on capacity-building for access and benefit-sharing, for consideration by the Conference of the Parties at its sixth meeting. Because of lack of funds, the workshop could not be held prior to the sixth meeting of the Conference of the Parties.

111. At its sixth meeting, the Conference of the Parties, in decision VI/24 B, recognized the need to assess ongoing capacity-building activities for access and benefit-sharing in view of elaborating an action plan for capacity-building for access and benefit-sharing. In paragraph 1 of the same decision, the Conference of the Parties decided to convene an open-ended expert workshop on capacity-building for access to genetic resources and benefit-sharing opened to participation by representatives, including experts, nominated by Governments and regional economic integration organizations; as well as representatives of relevant intergovernmental organizations (including donor organizations), non-governmental organizations, and indigenous and local communities.

112. Pursuant to that decision, the workshop was held from 2 to 4 December 2002, in Montreal, in order to further develop the draft elements for an Action Plan on Capacity-building for Access and Benefit-sharing.

113. The draft Action Plan on Capacity-building for Access to Genetic Resources and Benefit-sharing, elaborated by the expert workshop is included in annex I of the report of the Workshop (UNEP/CBD/ABS/EW-CB/1/3) for adoption by the Conference of the Parties at its seventh meeting.

114. As set out in section A of the draft Action Plan:

> "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, and in particular the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits arising out of their Utilization, taking into account their voluntary nature."

VI. CONCLUSIONS AND RECOMMENDATIONS

Use of terms

115. With respect to the use of terms, the Working Group may wish to make appropriate recommendations to the Conference of the Parties on whether a glossary and/or definitions would be appropriate, as well as on the process to draft such glossary or definitions.

Other approaches

116. Taking into account existing approaches, the Working Group is invited to give further consideration to additional approaches, complementary to the Bonn Guidelines, which may assist Parties and stakeholders with the implementation of the access and benefit-sharing provisions of the Convention.

Measures to ensure compliance with prior informed consent and mutually agreed terms

117. The Working Group is invited to consider possible measures by Parties with users under their jurisdiction to ensure compliance with prior informed consent of the Contracting Party providing genetic resources and mutually agreed terms on which access was granted. The Working Group may wish to make recommendations to the Conference of the Parties on the need for further work to advance this issue.

Capacity-building

118. The Working Group may wish to take note of the draft Action Plan on Capacity-building for Access and Benefit-sharing (UNEP/CBD/ABS/EW-CB/1/3, annex I) and recommend it for adoption by the Conference of the Parties at its seventh meeting.
