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ACCESS AND BENEFIT-SHARING
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OVERVIEW OF RECENT DEVELOPMENTS AT NATIONAL AND REGIONAL LEVELS RELATING TO ACCESS AND BENEFIT-SHARING

Note by the Executive Secretary

I. INTRODUCTION

1. At the seventh meeting of the Conference of the Parties, by decision VII/19 D the Ad Hoc Open-ended Working group on Access and Benefit-sharing was mandated 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. An analysis of existing national, regional and international legal instruments relating to access and benefit-sharing was carried out for the third meeting of the Working Group on Access and Benefit-sharing, and made available as document UNEP/CBD/WG-ABS/3/2.

3. At its eighth meeting, in decision VIII/4 A, paragraph 3, the Conference of the Parties invited "Parties, Governments, indigenous and local communities, international organizations and all relevant stakeholders to provide information regarding the inputs on an analysis of existing legal and other instruments at national, regional and international levels relating to access and benefit-sharing to the Secretariat of the Convention four months prior to the fifth meeting of the Working Group on Access and Benefit-sharing". In paragraph 4, it requested the Secretariat to prepare a compilation of the information provided in accordance with paragraph 3 and to make it available for the work of the Working Group. Contributions provided to the Secretariat are compiled in document UNEP/CBD/WG-ABS/5/INF/1.

4. This document updates information related to regional and national measures contained in document UNEP/CBD/WG-ABS/3/2 on the basis of contributions provided by Parties and research carried out on recent developments. Section II addresses measures adopted by countries as providers of

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

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genetic resources under sub-section A and measures adopted by Parties as users of genetic resources under sub-section B. Section III provides an overview of the study commissioned by the Secretariat on access and benefit-sharing arrangements. The information provided in this document provides a basis for the analysis of gaps contained in document UNEP/CBD/WG-ABS/5/3.

5. Document UNEP/CBD/WG-ABS/5/4/Add.1 contains an update of recent developments in international instruments related to access and benefit-sharing.

II. OVERVIEW OF REGIONAL AND NATIONAL MEASURES RELATING TO ACCESS AND BENEFIT-SHARING

6. The following instruments related to access and benefit-sharing have been developed at the regional level: Andean Pact decision 391 on the Common Regime on Access to Genetic Resources; the draft Central American Agreement on Access to Genetic Resources and Bio-chemicals and related Traditional Knowledge; the draft ASEAN Framework Agreement on Access to Biological and Genetic Resources; and 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. An overview of these measures was included in document UNEP/CBD/WG-ABS/3/2. It examines how they address the establishment of competent national authorities, prior informed consent, mutually agreed terms including benefit-sharing, intellectual property rights and compliance measures. As the Secretariat was not aware of any recent developments relating to these regional measures at the time of drafting, readers are invited to refer to document UNEP/CBD/WG-ABS/3/2 for further details.

7. While Parties to the Convention are both providers and users of genetic resources, in order to facilitate the analysis of measures taken by Parties, sub-section A focuses on measures adopted by Parties as providers of genetic resources and sub-section B provides an overview of measures adopted by Parties as users of genetic resources. Sub-section A provides an update of the overview of national measures related to access and benefit-sharing contained in document UNEP/CBD/WG-ABS/3/2.

A. Access and benefit-sharing measures adopted by Parties as providers of genetic resources

1. National measures addressing access and benefit-sharing

8. The present section examines national access and benefit-sharing measures. The following analysis is based on measures included in the Secretariat database as well as measures in the process of drafting or adoption, which are not yet included in the database because of their unavailability or their provisional status. These measures although not finalized contribute to providing an overall picture of access and benefit-sharing developments and indicate developments to come. Therefore, these draft measures are mentioned to provide a better overview of the situation but are not taken into account in the detailed analysis of the existing national measures. According to official sources, at least 58 countries have initiated the process of developing, or have adopted, access and benefit-sharing measures.

9. A database containing administrative, legislative and policy measures to address the access and benefit-sharing provisions of the Convention was established by the Secretariat in response to decision VI/24 D, paragraph 6, by which the Conference of the Parties requested Parties and relevant organizations to make available to the Executive Secretary “detailed information on the measures adopted to implement access and benefit-sharing, including the text of any legislation or other measures developed to regulate access and benefit-sharing”. The purpose of the database is to facilitate access to this information by Parties and relevant stakeholders. The database is available at: http://www.cbd.int/programmes/socio-eco/benefit/measures.aspx

10. Although not all Parties forwarded information to the Secretariat on national measures related to access and benefit-sharing, research was carried out by the Secretariat to identify measures available from official sources, such as the national websites of Governments Parties to the Convention. These measures 1/ were included in the database, which, however, may not be comprehensive.

11. As of June 2007, the database included measures adopted in 39 countries. These countries are at different levels of implementation of access and benefit-sharing and have adopted different approaches to regulating access and benefit-sharing, reflecting their national administrative structures, priorities, cultural and social specificities.

a. Overview of access and benefit-sharing developments

12. For the purpose of this analysis, national measures relating to access and benefit-sharing have been divided into three main categories reflecting the level of development of the respective regimes adopted by Parties. This analysis considers countries that are planning to develop measures, countries which have taken steps to develop an access and benefit-sharing regime and, finally, countries which have established access and benefit-sharing measures.

(1) *Countries that are planning to develop access and benefit-sharing measures.*

13. As reflected in the third national reports received as of December 2006, 2/ a number of countries, such as Cameroon, China, Comoros, Congo, Finland and Lesotho are in the process of planning the development of access and benefit-sharing measures.

(2) *Countries that have initiated the development of an access and benefit-sharing regime*

14. Countries that have initiated the process of developing an access and benefit-sharing regime include the following:

(a) Some countries refer to access and benefit-sharing in their national biodiversity strategies, action plans or other administrative measures calling for the development of an access and benefit-sharing regime but have not yet regulated it in any detail (such as Canada, 3/ Central African Republic, Federated States of Micronesia, Honduras, Niue and Viet Nam).

(b) A number of countries have undertaken (some on the basis of a national strategy) to establish an access and benefit-sharing regime and have developed draft measures. These include Argentina, 4/ Bangladesh, 5/ Cambodia, 6/ Chile, 7/ Côte d'Ivoire, 8/ Estonia, 9/ Guatemala, 10/ Indonesia,

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1/ Copies of the measures included in the database were gathered from national governmental websites or official sources such as the FAO FAOLEX computerized legislative database which includes national laws and regulations on food, agriculture, and renewable national resources.

2/ The hereby study is based on the one hundred and eleven (111) 3rd National Reports received by the Secretariat by the end of December 2006.

3/ Canada has adopted, in October 2006, the *Guiding Principles and Features of ABS Policies in Canada* as a basis for further policy discussions within Canada. They have been developed by a Federal/Provincial/Territorial Group and have been endorsed by Federal, Provincial and Territorial Ministers responsible for Forests, Wildlife, Endangered Species and Fisheries and Aquaculture.

4/ http://www.diputados.gov.ar/ .

5/ Bangladesh's 3 rd National Report.

6/ Cambodia's 3rd National Report.

7/ Chile's 3rd National Report.

8/ Côte d'Ivoire's 3rd National Report.

9/ Estonia's 3rd National Report.

10/ Guatemala's 3rd National Report.

11/ Lebanon, 12/ Madagascar, 13/ Malaysia, 14/ Namibia, 15/ Nepal, 16/ Pakistan, 17/ Samoa, 18/ Seychelles, 19/ Saint-Lucia, 20/ Syrian Arab Republic, 21/ and Thailand. 22/

(3) *Countries that have established access and benefit-sharing measures.*

15. Finally access and benefit-sharing measures have entered into force in a number of countries:

(a) Some of these countries have legislative measures (focusing on environment and/or biodiversity) referring to access and benefit-sharing in general terms without addressing the access and benefit-sharing process in any detail. 23/ Among these, countries such as El Salvador, 24/ Cuba, 25/ Malawi, 26/ Mexico 27/ and Nicaragua 28/ are in the process of developing regulations or other specific measures to elaborate a more detailed access and benefit-sharing regime. However these have not yet been adopted.

(b) Several countries have addressed access and benefit-sharing in greater detail**.**

- Some countries have adopted a legislative measure (focusing on environment and/or biodiversity) referring to access and benefit-sharing in general terms and have also

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11/ Indonesia's 3rd National Report; Santiago Carrizosa, Stephen B. Brush, Brian D. Wright and Patrick E. Mcguire**,** (eds.) 2004. *Accessing Biodiversity and Sharing benefits: Lessons from implementation the Convention on Biological Diversity*, IUCN, Gland, Switzerland and Cambirdge, uk, p. 57.

12/ Lebanon's 3rd National Report.

13/ Madagascar's 3rd National Report.

14/ Malaysia's 3rd National Report; Santiago Carrizosa, Stephen B. Brush, Brian D. Wright and Patrick E. Mcguire**,** (eds.) 2004. *Accessing Biodiversity and Sharing benefits: Lessons from implementation the Convention on Biological Diversity*, IUCN, Gland, Switzerland and Cambirdge, uk, p. 10 and 13.

15/ Ministry of Environment and Tourism of Namibia <http://www.met.gov.na/programmes/legislation/legislation.htm>

16/ Nepal's 3rd National Report.

17/ Pakistan's 3rd National Report.

18/ Samoa's 3rd national Report.

19/ Robert J. Lewis-Lettington and Serah Mwanyiki, *Cases studies on Access and Benefit-Sharing*, IPGRI (International Plan Genetic Resources Institute), Rome, 2006, p. 4 <http://www.bioversityinternational.org/Publications/Pdf/1149.pdf>.

20/ Saint-Lucia's 3rd National Report.

21/ Syrian Arab Republic's 3rd National Report.

22/ Thailand submission (received 1/10/2007).

23/ This category of countries includes, for example, Cameroon, El Salvador, Gambia, Malawi, Mexico, Nicaragua and Zimbabwe.

24/ El Salvador's 3rd National Report; Robert J. Lewis-Lettington and Serah Mwanyiki, *Cases studies on Access and Benefit-Sharing*, IPGRI (International Plan Genetic Resources Institute), Rome, 2006, p. 15 <http://www.bioversityinternational.org/Publications/Pdf/1149.pdf>.

25/ Cuba's 3rd National Report.

26/ It should be noted that Malawi also has adopted *Procedures and Guidelines for Access and Collection of Genetic Resources in Malawi* (1996). However, according to Malawi's 3rd National Report, this measure is inadequate because it does not indicate the type of benefits to be shared and has not been promulgated into rules or regulations under existing legislation. Consequently, Malawi is currently drafting regulations on access and benefit-sharing.

27/ Mexico's 3rd National Report; Senate of Mexico website, <http://www.senado.gob.mx/sgsp/gaceta/index2.php?sesion=2005/05/11/1&documento=58>; Santiago Carrizosa, Stephen B. Brush, Brian D. Wright and Patrick E. Mcguire**,** (eds.) 2004. *Accessing Biodiversity and Sharing benefits: Lessons from implementation the Convention on Biological Diversity*, IUCN, Gland, Switzerland and Cambirdge, uk, p. 11.

28/ The section 63 of the Nicaraguan Ley General del Medio Ambiente y Recursos Naturales (Nicaraguan Act) is asking for the preparation of a specific regulation on access and benefit-sharing. This requirement is reiterated in section 43 of the Reglamento de la Ley General del Medio Ambiente y los Recursos Naturales (Nicaraguan Regulation) but no specific regulation addressing access and benefit-sharing has been adopted yet. However, according to the Nicaragua's 3rd National Report, a draft Law on Biological Diversity have been prepared.

adopted specific regulations, which have entered into force (such as Australia, Kenya, Uganda and Panama. 29/)

- Others have addressed access and benefit-sharing in greater detail directly through a legislative measure (focusing on environment and/or biodiversity). 30/ A subset of these countries is to adopt regulations to address in further detail specific elements of access and benefit-sharing relating to, for example, forms and procedures. 31/ Others, such as Brazil, 32/ Costa Rica, India and Philippines have already adopted complementary rules or regulations.

(c) Countries of the Andean Community (Bolivia, Colombia, Ecuador, Peru and Venezuela) have a Common Regime on Access to Genetic Resources established by the decision 391 of the Commission of the Andean Community. Although decision 391 became binding without requiring development of any new national law, national measures have been developed to assist with the implementation of decision 391 at national level. These countries have chosen various ways to proceed. Bolivia has adopted a detailed Regulation of decision 391 on the common regime for access to genetic resources. 33/ Venezuela has adopted a Biological Diversity Act covering access and benefit-sharing 34/ which addresses most issues of the regime but is to be completed by further regulations. Peru has also adopted several laws and regulations relating to access to genetic resources. 35/ However, these do not address procedures for access and benefit-sharing, with the exception of Law No. 27811, 36/ which addresses all aspects of an access and benefit-sharing regime but only applies to collective knowledge of Indigenous people. Ecuador has drafted a special law on conservation and sustainable use of biodiversity addressing access and benefit-sharing under its title IV, chapter VI. Finally, Colombia has adopted Decrees to establish a competent national authority to implement Decision 391. 37/

b. Analysis of access and benefit-sharing measures established at national level

16. Based on the examination of the measures adopted by countries of the 3rd category, which have adopted access and benefit-sharing measures, the following provides a comparative analysis of the main provisions of these measures which address the establishment of competent national authorities, prior informed consent, mutually agreed terms including benefit-sharing, intellectual property rights and

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29/ The Panamanian Ley General de Ambiente de la Republica de Panama (No. 41) (Panamanian General Law) provides for access and benefit-sharing (including PIC, MAT and Benefit-Sharing) but only for resources on Indigenous lands. Nevertheless, the Decreto Ejecutivo que Reglamenta el Articulo 71 de la Ley 41 de 1 Julio de 1998 (Panamanian Decree), entered into force in October 2006, has introduced a detailed access and benefit-sharing regime applying to genetic (and biological) resources and associated traditional knowledge.

30/ These countries include Afghanistan, Bulgaria, Bhutan, Brazil, Costa Rica, Ethiopia, India, Philippines, South Africa, and Vanuatu.

31/ Those countries include Bhutan, Bulgaria, Ethiopia, South Africa, and Vanuatu.

32/ In addition to the Brazilian Medida Provisoria No 2.186-16 (Brazilian Provisional Act), which is focusing on access and benefit-0haring, Brazil has adopted decrees addressing access and benefit-sharing and Genetic Heritage Management Council has also adopted several resolutions establishing rules and procedures for the ABS regime.

33/ See Bolivian Decreto Supremo 24676 - Aprueba reglamento de la decisión 391 de la comisión del acuerdo de Cartagena y el reglamento sobre biodiversidad (Bolivian Decree).

34/ See Venezuelan Ley de diversidad biologica (Venezuelan Biodiversity Law), under its title VII.

35/ See Peruvian Ley No. 26839 sobre la conservación y aprovechamiento sostenible de la diversidad biológica (1997); Decreto Supremo no 068-2001-PCM Aprueban el reglamento de la ley sobre la conservación y aprovechamiento sostenible de la diversidad biológica; Ley 28216, Ley de Protección al acceso a la Diversidad Biológica Peruana y los Conocimientos Colectivos de los Pueblos Indígenas; and Reglamento de la Ley de Protección al Acceso a la Diversidad biológica Peruana y los Conocimientos Colectivos de los Pueblos Indígenas, Decreto Supremo Nº 022-2006-AG..

36/ Peruvian Ley No 27811, Ley Que Establece El Régimen de Protección de los Conocimientos Colectivos de los Pueblos Indígenas Vinculados A los Recursos Biológicos.

37/ See Colombian Decree 730 of 1997, Resolution 620 of 1997 of the Ministry of Environment and Decree 2366 of 2004. See also the Decree 309 of 2000 about regulation of scientific investigation of biological diversity.

compliance measures. It is not necessarily exhaustive and is not intended to provide a detailed analysis of the different access and benefit-sharing systems adopted by each country.

17. It is difficult to draw general conclusions from the analysis of these measures because countries have adopted different approaches in terms of the types of measures adopted. While some countries have only adopted one measure, others have adopted a package of measures including, for example, a national strategy, a law and guidelines. A number of countries are still in the process of developing their national systems and therefore the package is often incomplete (e.g. a number of countries are in the process of developing guidelines or regulations to complement legislations). In addition, the national procedures and structures established are diverse. Some countries have different levels of government responsible for regulating access and benefit-sharing. For example, countries such as Argentina, Australia, Brazil and Malaysia have developed measures both at the national/federal level and at the State level.

18. It is interesting to note that several regimes are expressly applicable to both *in situ* and *ex situ* genetic resources and that some of these regimes establish different procedures for each of these groups of genetic resources. 38/ Also, many countries explicitly mention the non application of their access and benefit-sharing regime to specific categories of resources, such as human genetic resources 39/, genetic resources accessed or exchanged for direct use or consumption or for traditional practices 40/ and genetic resources covered by the International Treaty on Plant Genetic Resources for Food and Agriculture of the Food and Agriculture Organization of the United Nations. 41/

19. *Competent national authorities*. Most countries with detailed regimes have established competent national authority(ies) (CNA). In some cases, the competent national authority is an organization already in existence, while in other cases a new organization is created by the access and benefit-sharing measure. Some countries have established more than one competent authority (such as Philippines) or have created a new specific unit within an existent body (such as Panama). Some countries have chosen, as competent national authority(ies), a general environmental body (such as Afghanistan, Kenya and Nicaragua), when others have created a specific body to address biodiversity (such as Costa Rica, Ethiopia, India and Vanuatu) or access and benefit-sharing issues in particular (such as Brazil). A number of these measures also provide indications with respect to the composition and the tasks of the competent national authorities (e.g. Bolivia, Brazil, Ethiopia, Kenya, India, Panama and Vanuatu).

20. *Prior informed consent*. In each access and benefit-sharing regimes, 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 42/ and the

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38/ Such as Bhutan, under section 6 of the Biodiversity Act; Bolivia under title III, chapter IV of its Decree; and Brazil under sections 16 and 18 of the Provisional Act.

39/ For example, see Australia under section 8A.03 (3) of Environment Protection and Biodiversity Conservation Regulations (Australian Regulations); Bhutan, under section 4 (c) of Biodiversity Act; Brazil under section 4 of the Provisional Act; Kenya under section 3 (c) of Access to Genetic Resources and Benefit-Sharing Regulations 2006 (Kenyan Regulations); South Africa under section 80 (2) (b) of National Environmental Management: Biodiversity Act (South African Biodiversity Act); and Uganda under section 4 (2) (d) of National Environment (Access to Genetic Resources and Benefit-Sharing) Regulations, 2005 (Ugandan Regulations).

40/ For example, see section 61 (2) of Afghanistan Environment Act; section 8A.03 (3) of the Australian Regulations; section 4 (a)(b) of the Bhutan Biodiversity Act; section 4 of the Ethiopian Proclamation to Provide for Access to Genetic Resources and Community Knowledge and Community Rights of 2006 (Ethiopian Proclamation); section 3 of the Bolivian Decree; section 4 of the Brazilian Provisional Act; section 3 (a) of the Kenyan Regulations; and section 4 (2) (b) of the Ugandan Regulations.

41/ Such as Bhutan under section 4 (d) of Biodiversity Act and South Africa under section 80 (2) (b) of Biodiversity Act.

42/ See, for example, Bhutan (section 7 of the Biodiversity Act) and Afghanistan (section 63 of the Environment Act).

procedure leading to approval or refusal. 43/ In certain countries, application or collection fees are also requested. 44/ 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, 45/ 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. 46/ Many countries also provide for the protection of traditional knowledge associated to genetic resources within their national regime. 47/ In this respect, some of these countries require to obtain the prior informed consent from the owners/holders of the traditional knowledge. 48/

21. Some regimes require the prior informed consent of relevant stakeholders and/or that evidence of PIC is provided to competent national authority(ies) before the granting of the permit of access or signature of the contract of access (such as Afghanistan, Panama, South Africa, Uganda and Vanuatu). 49/ In addition, some countries have adopted different requirements for access depending on the type of applicant. For example, the Indian, 50/ Bolivian, 51/ Brazilian 52/ and Philippines 53/ regimes provide for

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43 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).

44/ 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 Accesso a los Elementos y Recursos Geneticos y Bioquimicos 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.

45/ Such as Bhutan and Ethiopia (except in cases of access to traditional knowledge).

46/ 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).

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

48/ 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.

49/ In Afghanistan, an access permit can only be issued if the Competent national authority is satisfied of the achievement of the prior inform 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).

50/ 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.

51/ 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.

52/ 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".

different procedures for nationals and foreigners who wish to obtain access to genetic resources. Other countries, such as Australia, 54/ Bhutan, 55/ Costa Rica, 56/ the Philippines 57/ and South Africa, 58/ have established different requirements depending on whether access is to be granted for commercial or non-commercial purposes. Some countries, such as Ethiopia, 59/ Kenya 60/ and Uganda 61/ 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. 62/

22. *Mutually agreed terms including benefit-sharing.* A majority of existing national systems provide that mutually agreed terms for access and benefit-sharing are to be set out in an agreement. Measures generally provide for benefit-sharing with the State (or the competent national authority), or with indigenous and local communities or other resource providers, 63/ and in most cases for both. 64/ Benefit-sharing terms can be set out in different kinds of agreements. Depending on the regime, they can be established in a contract of access or a material transfer agreement with other mutually agreed terms

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53/ 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.

54/ 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.

55/ See section 6 of the Bhutan Biodiversity Act.

56/ See article 71 of the Costa Rican Law.

57/ 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.

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

59/ 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.

60/ 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)).

61/ Ugandan Regulations does not apply to approved research activities intended for educational purposes by Ugandan institutions recognized 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)).

62/ 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).

63/ 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).

64/ 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).

(regarding access conditions, use of collected resources, commitment to report, etc.) or in a specific benefit-sharing agreement. In some countries, the agreement containing benefit-sharing arrangements is negotiated by the competent national authority(ies) 65/ while in others, the competent national authority(ies) is only to approve the agreement negotiated by indigenous and local communities or any relevant stakeholder and the applicant. 66/ Some measures also provide for the consultation of relevant stakeholders by the competent national authority(ies) before entering into an agreement 67/ or the possibility of parallel agreements between the applicant and both of the competent national authority(ies) and relevant stakeholders (local communities, providers). 68/ It should be noted that many countries also provide that owners/holders of traditional knowledge associated to genetic resources shall get a share of benefits arising from the use of their traditional knowledge. 69/

23. Some measures provide for different types of agreements, depending on whether the genetic resources are being accessed for research or for commercial purposes. 70/ Most of the measures also provide in more or less detail for a minimum number of clauses to be included in the contract. 71/ Standard clauses include: the geographical area where the genetic resources are to be accessed, the quantity to be accessed, the purpose of the access, the duration of the contract and several commitments of the applicant such as supplying duplicates of samples collected and keeping the competent national authority informed of subsequent research and developments.

24. 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. 72/ 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. 73/ Some measures also require the

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65/ 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).

66/ 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).

67/ 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.

68/ Such as in Bhutan Biodiversity Act, section 10 and in Panamanian Decree, sections 38 and 41.

69/ 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).

70/ For example, in Mexico, collection of flora and fauna species or other biological resources for scientific research purpose require that the results of the investigation be available to the public and is subject to the terms and conditions established in the Official Mexican Standards NOM-126-SEMARNAT-2000 while, for a biotechnological purpose, it is subject to a fair sharing of benefits derived with owners and legitimate holders of resources: Environmental Protection Law, sections 87 and 87BIS. For other examples, see Australian Regulations, divisions 8A.2 and 8A.3; Brazilian provisional Act, section 16 (4); Costa Rican Decree, articles 9 (4) (5)); Panamanian Decree, section 24; and South African Biodiversity Act, sections 83-84.

71/ For example, see section 8A.08 of the Australian Regulations; articles 15, 36 and 37 of the Bolivian regulation; section 28 of the Brazilian Provisional Act; sections 16 and 17 of the Ethiopian Proclamation; section 15 of the Kenyan Regulations; sections 15.1-15.11 of the Philippines Implementing Rules and Regulation; sections 83-84 of the South African Biodiversity act; section 15 of Ugandan Regulations; and section 74 of the Venezuelan Biodiversity Law.

72/ 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.

73/ 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

disclosure of origin of genetic resources or traditional knowledge referred to in publications or other uses and disseminations. 74/ However, it is interesting to note that some countries only focus on monetary 75/ or non-monetary 76/ benefits. While some countries only address equitable benefit-sharing on a case-by-case basis, 77/ others establish the minimum or maximum percentage of their participation in benefits. 78/ 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. 79/ 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. 80/ 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. 81/

25. *Certificate of origin/source/legal provenance*. Several countries require the issuance of a certificate of origin by the competent national authority for genetic resources to certify that conditions under which the access was granted have been satisfied. 82/ Furthermore, some countries, such as Afghanistan, require a certificate of origin (or the equivalent) for export or import of any genetic resources. 83/

26. *Intellectual property rights* as they relate to access and benefit-sharing are addressed by a majority of the access and benefit-sharing systems examined, in different ways and to various extents. 84/ A number of measures consider intellectual property rights in the context of benefit-sharing through the sharing of royalties 85/ or provide that the agreement is to recognise the joint ownership of intellectual

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Provisional Act of Brazil mentions that research on genetic resources should preferably be carried out on Brazilian territory (section 16 (7)).

74/ 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.

75/ Such as South Africa, under section 85 of the Biodiversity Act.

76/ Such as Venezuela, under section 74 (4) of the Biodiversity Law. .

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

78/ 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 activites in the Philippines, section 16).

79/ 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).

80/ 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.

81/ 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).

82/ For example, see Afghanistan Environment Act, section 66 (2); Bhutan Biodiversity Act, section 10.1; and Costa Rican Decree, section 19.

83/ Article 66 (3) (4) of Afghanistan Environment Act.

84/ 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.

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

property rights 86/ or establish mutually agreed conditions for determination of the owner/holder of these rights. 87/ In addition to Andean Pact countries, through decisions 391 and 486, countries such as Brazil, Costa Rica, Ethiopia, India and Panama, 88/ have established measures including specific references to the requirement for the disclosure of origin of genetic resources and associated traditional knowledge in intellectual property applications for products or processes based on genetic resources or associated traditional knowledge. However, it should be noted that certain countries, including some which have not developed specific measures related to access and benefit-sharing, have addressed the issue of disclosure through their patent legislation. 89/

27. In addition, a number of specific requirements related to intellectual property rights have been included in access and benefit-sharing measures. For example, the Costa Rica legislation 90/ provides that the competent authority on intellectual property rights must consult the competent national authority before granting intellectual property protection to innovations involving components of biodiversity to ensure that the proper requirements for access have been met. Ethiopia, India and Uganda provide that prior approval of the competent national authority (National Biodiversity Authority) must be obtained before applying for intellectual property rights for an invention based on a biological resource obtained from their territory, 91/ while Bhutan requires a notification to the competent national authority. 92/ Other countries provide that relevant authorities may oppose the grant of intellectual property rights (such as India 93/) or review patents and other intellectual property rights registered outside their respective country, on the basis of national genetic resources or collective knowledge of indigenous community, in order to either claim their nullity or benefits arising from their utilization (such as Peru 94/ and Venezuela 95/).

28. *Compliance measures*. The measures examined generally include provisions dealing with compliance. These provisions may cover, depending on the country, monitoring, reporting, enforcement, infractions/offences, penalties/sanctions and dispute resolution.

86/ Such as Bhutan Biodiversity Act, section 10 (e) and Ugandan Regulations, section 20 (2) (i).

87/ 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).

88/ The Brazilian Provisional Act, in article 31, provides that "the person or institution applying for the property rights must inform the origin of the genetic material, the genetic knowledge and the associated traditional, as appropriate" and the Costa Rican Biodiversity Law, in article 80, states that prior to awarding intellectual property protection for inventions which involve elements of biodiversity, intellectual property authorities must obtain the certificate of origin issued by the access and benefit-sharing competent national authority and prior informed consent. Opposition of the competent national authority will prevent the registration of a patent or protection of the innovation. According to the 3rd National Report of India, its amended Patent Act also "provides for mandatory disclosure of the source and geographical origin of the biological material in the specification when used in an invention. Further, non-disclosure or wrongful disclosure of the source of biological material and any associated knowledge will result in opposition to grant of patent or revocation of patents." Furthermore, the disclosure of origin of genetic resources is also require in Panama and Ethiopia (this one also cover traditional knowledge) in application for commercial property protection (Panamanian Decree, section 23 (f) and Ethiopian Proclamation, section 17 (14)).

89/ For example Denmark (according to its 3rd National Report and Nordic Council of Ministers, *Access and Rights to genetic resources, A Nordic Approach*, 2003:16, p. 94), Egypt, Norway and Sweden. According to the Swedish 3rd National Report, "The current Swedish Patent legislation (Patentkungörelse 1967:838) requires that the origin of the genetic resources used in an invention shall be disclosed in patent applications. If the origin is unknown it should be indicated. The failure to provide this information does not affect the handling of the patent application by the authorities or the rights conferred by a patent. The requirement does not, however, have any material effects on e .g. the validity of granted patents".

90/ Article 80 of the Costa Rican Biodiversity Law and article 25 of the Decree.

91/ See section 17 (13) of the Ethiopian Proclamation, sections 6(1) and 19(2) of the Indian Biological Diversity Act and section 18 of the Biodiversity Rules; and section 15 (1) (e) of the Ugandan Regulations.

92/ Bhutan Biodiversity Act, section 9 (e).

93/ Indian Biological Diversity Act, section 18 (4).

94/ See article 4 c) of the Peruvian Ley de proteccion al acceso a la diversidad biologica peruana y los conocimientos colectivos de los pueblos indígenas.

95/ See article 83 of the Venezuelan Biodiversity Law.

29. 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. 96/

30. 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-respect of the clauses 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 a collection permit (such as State of Queensland (Australia), Ethiopia, Panama, South Africa and Uganda 97/) and/or creates obstruction to an inspector in the exercise of his powers or duties (such as Afghanistan. 98/)

31. The sanctions have many similarities from one measure to the other. They range from a written warning, 99/ to a fine (in some cases, a scale of fines is included), 100/ a seizure of samples, 101/ the suspension of the sale of product, 102/ the revocation/cancellation of the permission or license of access

96/ For example, 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. The Costa Rica, in article 20 of the Decree, provide that the Technical Office will carry out 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 alias, 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 alias, 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.

97/ 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.

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

99/ 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.

100/ 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.

101/ 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.

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

or of the agreement, 103/ a ban on undertaking prospecting of biological and genetic resources 104/ and, finally, imprisonment. 105/

32. It is interesting to note that some countries, such as South Africa 106/, provide for a higher fine when offences involve specimen of threatened or protected species, which can be, in this specific case, up to 3 times of the commercial value of the specimen. Brazil 107/ also requires a higher fine in case of violation committed by a corporation. Furthermore, in case of second or subsequent offences, India and Brazil 108/ require additional fine, which can be higher. Many measures also provide for the possibility of cumulating fine and imprisonment. 109/ It is interesting to mention that without prejudice to administrative sanctions, the Brazil Provisional Act provides that the economic use of a product or process developed from genetic resources or associated knowledge accessed in a manner contrary to this act, shall be subject to the payment of, at least, 20 percent of the gross income obtained from commercialization or royalties, whether or not they are protected by intellectual property. It should also be noted that the India Biological Diversity Act provides different penalties depending on whether they are applying to foreigners or locals. 110/

33. Certain provisions also address dispute settlement mechanisms, such as the Philippines Guidelines. 111/ In this respect, some countries give power to the competent national authority to apply sanctions 112/ and have designated judicial instance(s) with jurisdiction to hear dispute related to the access and benefit-sharing regime. 113/ 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. 114/

34. 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. 115/

35. *Others.* Some national regimes also provide rules and procedures to promote public awareness of the access and benefit-sharing process, such as a public register of access permits delivered. 116/

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

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

105/ 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.

106/ South African Biodiversity Act, section 102.

107/ Brazilian Provisional Act, section 30 par. 5.

108/ Indian Biological Diversity Act, section 56 and Brazilian Provisional Act, section 30 par. 6.

109/ Such as Afghanistan Environment Act, section 73 par.1; Bhutan Biodiversity Act, section 44 (a); Ethiopian Proclamation, section 35; Indian Biological Act, section 55; Kenyan Regulations, section 24; South African Biodiversity Act, section 102; Ugandan Regulations, section 26; Vanuatu Environmental Act, section 32.

110/ See section 55 of the Biological Diversity Act of India.

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

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

113/ Such as Afghanistan Environment Act, sections 73-74; Bhutan Biodiversity Act, section 48; Indian Biological Diversity Act, sections 52-53; South African Biodiversity Act, sections 94-96; and Ugandan Regulations, section 27.

114/ For example, see section 57 of the Indian Biological Diversity Act and section 75 of the Afghanistan Environment Act.

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

Many measures also provide standard forms for applications, prior informed consent, permit of access, contract of access, material transfer agreements, benefit-sharing agreements, etc. 117/

36. While a number of countries have adopted measures on access and benefit-sharing, a majority of Parties to the Convention have not yet addressed the issue of access and benefit-sharing through national measures. In certain countries, access and benefit-sharing is being regulated by measures adopted prior to the entry into force of the Convention to regulate the access and management of biological resources, (though they were not adopted with access and benefit-sharing provisions of the Convention in mind). However, these measures have been actually found to provide useful solutions to address situations of access and benefit-sharing. They generally provide for collection or research permits as conditions for access only, and rarely address benefit-sharing. It should be mentioned that a few countries have adopted measures regarding specific resources or resources located in specific areas which also address access and benefit-sharing. For example, Guatemala is regulating protected areas for access to wildlife resources and requires the sharing of benefits arising from patentability or commercialization of the results, which shall not be inferior to 50 percent of the profit made. 118/ For its part, Nigeria has established a regime for bioprospecting within national parks "incorporating the concepts of prior informed consent, benefit-sharing, mutually agreed terms, and access to technology". 119/

B. Access and benefit-sharing measures adopted by Parties as users of genetic resources

37. This section examines measures to support compliance with the prior informed consent of the contracting Party providing genetic resources and mutually agreed terms on which access was granted. Sub-section 1 provides an overview of government initiatives and measures and sub-section 2 addresses codes of conducts and guidelines adopted by different sectors.

1. Government Initiatives/Measures

a. Awareness raising/Public outreach/Information exchange and gathering

Surveys

38. Studies have been carried out respectively in Belgium, Germany and the United Kingdom with a view to assessing the level of awareness of users of genetic resources to the access and benefit-sharing provisions of the Convention and the Bonn Guidelines and their practical implementation: 120/

39. In 2006, the Belgian DG Environment of the Federal Public Service Health, Food Chain Security and Environment funded a survey on the extent of knowledge and use of the provisions of the Convention on Biological Diversity on access and benefit-sharing (and in particular the Bonn Guidelines) by Belgian users of genetic resources. The study was carried out in 2006 by the Research Unit on Biodiversity of the Centre for Philosophy of Law of the Catholic University of Louvain (specialized in ABS issues). Its objective was to consolidate the Belgian access and benefit-sharing national and international policy, and to know the exact situation regarding access and benefit-sharing provisions and

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116/ For example, see the Australian Regulations, section 8A.18; the Costa Rican Decree, sections 15, 16 (3) and 17; the Kenyan Regulations, sections 10 and 17; and the Ugandan Regulations, sections 28 and 29.

117/ For example, see Indian Biological Diversity Rules; Kenyan Regulations; Philippines Guidelines for bioprospecting; and Ugandan Regulations.

118/ Reglamento de Ley de Areas Protegidas, Acuerdo Gubernativo No. 759-90, article 26 e).

119/ According to Kent Nnadozie et al., *African Perspectives on Genetic Resources*, Washington, Environmental Law Institute, 2003, p. 188-189, the National Parks Service Decree 1999 is unique since it is permitting the "full incorporation of the basic principles of the CBD with respect to access – prior informed consent, mutually agreed terms, and benefit-sharing of both monetary and other benefits. These provisions cover not only the biological material but also the associated knowledge". See also Robert J. Lewis-Lettington and Serah Mwanyiki, *Cases studies on Access and Benefit-Sharing*, Rome, 2006, p. 121-122.

120/ UNEP/CBD/WG-ABS/3/5, par. 21 to 23

users of genetic resources in Belgium. This aimed at identifying specific measures that need to be taken in order to improve the involvement of stakeholders, on the basis of information gathered from all potential Belgian actors involved in the exchange of genetic resources. The main results of the study indicate that the Convention on Biological Diversity is well known in the collections and research sectors and that the implementation seems more spread for acquisition of PIC than for benefit-sharing.121/

40. In early 2005, the United Kingdom communicated to the Secretariat of the Convention on Biological Diversity and made available to the Parties at the third meeting of the Working Group on Access and Benefit-sharing, copies of the 'Review of the Experience of Implementation by the United Kingdom Stakeholders of Access and Benefit-sharing Arrangements under the Convention on Biological Diversity'. The Review's recommendations relate in particular to the advantages in the short to medium term of awareness raising of the concept of access and benefit-sharing and its requirements, and they were endorsed by UK Environment Ministers. 122/

41. In 2005, the German Ministry for the Environment published a study on "Users of genetic resources in Germany", which was made available to participants of the third meeting of the Working Group on Access and Benefit-sharing. The study is an analysis of the level of awareness and knowledge of access and benefit-sharing regulations of users of genetic resources in Germany and gives recommendations on how to improve the involvement of stakeholders. 123/

Web-portals

42. The European Community established an internet-based portal providing information on access and benefit-sharing 124/ as an integral part of the EC Biodiversity Clearing-House Mechanism. The EC ABS Portal is used to disseminate information relevant to the implementation of the Bonn Guidelines to access and benefit-sharing focal points in Member States and to a growing group of registered stakeholders from Governments, research institutes, private companies and NGOs.125/

43. Further, Member States of the European Community, such as the United Kingdom, The Netherlands and Germany 126/, as well as the Government of Canada 127/ and Australia have established national web-portals dedicated to Access and Benefit-sharing issues.

Use of the Bonn Guidelines

44. In the context of their cooperation amongst the Nordic countries, Denmark, Finland, Norway and Sweden contributed in 2006 to a guide introducing and explaining the Bonn Guidelines and their implications for both users and providers of genetic resources. This guide has been translated into the four Nordic languages (Swedish, Danish, Finnish and Norwegian). The full text is available at: http://www.norden.org/pub/ovrigt/orvrigt/US2006448.pdf"128/

45. The Bonn Guidelines were translated in Japanese in September 2002 and disseminated through a series of public seminars and international symposia in major cities throughout Japan. User specific guidelines were then developed by Japan's Ministry of Economy, Trade and Industry (METI). The "Guidelines on Access to Genetic Resources for Users in Japan" were published on 1 April 2005. To

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121/ Contribution of the EC and its Member States in preparation for WG-ABS5.

122/ Contribution by EC and its Member States to WG-ABS4.

123/ Contribution by EC and its Member States to WG-ABS4.

124/ The EC ABS Portal can be accessed at: http://abs.eea.eu.int.

125/ Contribution by EC and its Member States to WG-ABS4.

126/ Contribution by the EC and its Member States to WG-ABS5. Webportals for Germany: http://www.abs.biodiv-chm.de; United Kingdom: http://www.defra.gov.uk/science/geneticresources

127/ See www.ec.gc.ca/apa-abs.

128/ Contribution by EC and its Member States to WG-ABS5.

promote their dissemination METI in cooperation with the Japan Bioindustry Association (JBA) held public seminars in 6 major cities throughout Japan. 129/

Workshops/dialogues/consultations

46. Working groups and/or consultations with stakeholders have been organised in a number of countries such as Finland, Denmark, Spain, Sweden and Norway in order to increase awareness to the provisions on access and benefit-sharing of the Convention on Biological Diversity and the Bonn Guidelines and also to assess the existing level of awareness amongst potential users/stakeholders and increase their involvement in activities related to access and benefit-sharing . 130/

47. Specific activities within the European Community and its Member States have included the following 131/:

- Member States such as Belgium or France have undertaken extensive consultations with users of genetic resources to enhance awareness of Access and Benefit-sharing issues.

- In November 2005, Germany held an international user workshop bringing together representatives from the research community, *ex-situ* collections and botanical gardens. At this meeting, different access and benefit-sharing compliance measures and activities adopted by botanical gardens and academic research institutions were presented. This meeting also demonstrated the need to consider existing instruments when designing new access and benefit-sharing policies.

- In November 2006, a Nordic workshop was held for users from the Nordic Countries. The workshop concluded that further information as well as the development of tools to facilitate compliance with access rules is needed. A Nordic project to follow up on these conclusions will be considered in 2007.

48. Furthermore, expert meetings organised by the Commission and Member States involving users of genetic resources in the EU have become a regular feature of EU preparations prior to meetings of the Convention on Biological Diversity on Access and Benefit-sharing.

49. In Japan, bilateral workshops have been organised with other countries, such as Australia, Indonesia, Malaysia, Mongolia, Myanmar, Thailand and Vietnam with a view to sharing information and experiences concerning the respective national policies, laws and regulatory systems relevant to the Convention on Biological diversity and access and benefit-sharing, and thereby deepening mutual understanding. 132/

50. In Switzerland, "a national working group on ABS was set up in early 2003 by the Swiss Federal Office for the Environment (FOEN) and the Federal Office for Agriculture (FOA). This working group is composed of representatives from governmental and non-governmental stakeholders, including academic research, private sector, seed producers, botanical gardens and NGOs. The major tasks of this working group are to:

- identify the specific needs and activities of each particular stakeholder;
- help the stakeholders in the development of sector-based measures;
- support the coordination of information exchange (through the CHM) and promote public and professional awareness on topics related to access and benefit-sharing;
- develop a national strategy on ABS with coordinated measures;

129/ "Japan's Activities to Implement the CBD and the Bonn Guidelines – Highlights", made available at COP8, in Curitiba, Brazil, March 18, 2006.

130/ Further details regarding initiatives in these respective countries are included in UNEP/CBD/WG-ABS/3/5, section II.A.1.

131/ Contribution by EC and its Member States to WG-ABS5.

132/ "Japan's Activities to Implement the CBD and the Bonn Guidelines – Highlights", made available at COP8, in Curitiba, Brazil, March 18, 2006.

- follow international activities within the Convention on Biological Diversity (especially on the development of an "international regime on ABS") and the FAO International Treaty". 133/

51. Canada has also undertaken a stakeholder outreach exercise in which the views and interests of a broad range of Canadian stakeholders were gathered. These dialogues with stakeholders are helping policy-makers understand the context in which genetic resources are currently being used and provided in Canada and the potential positive and negative impacts of prior informed consent and mutually agreed terms. 134/

52. Developments in Canada are at the stage of policy discussions at the federal, provincial and territorial levels:

> "As a first step, the Federal/Provincial/Territorial Working Group on Access and Benefit-sharing (FPTWGABS) has developed a scoping paper which sets out the policy questions that arise when implementing Access and Benefit-sharing, including some applicable to PIC and MAT.
>
> Building on this document, and mindful of the Bonn Guidelines, the group recently undertook an in-depth discussion and exploration of the many legal and socio-economic aspects associated with the elaboration of a PIC system and the negotiation of MAT.
>
> At the heart of this discussion are considerations around ownership of genetic resources and associated traditional knowledge in Canada and question of who would have the authority to grant PIC and negotiate MAT. The group also discussed issues such as how PIC might relate to existing land claim agreements, what the appropriate role of governments in determinations of MAT might be, and the need to ensure the transparency and efficiency of PIC and MAT systems.
>
> The contribution of a number of Canadian jurisdictions, either at the federal, provincial or territorial level, is crucial for ensuring the relevancy of the system and the ability of all involved in the system to comply with it."135/

b. Support to stakeholder initiatives

53. As reflected in submissions of the EC and its Member States to previous meetings of the Working Group, the European Commission has lent its support to the implementation of institutional policies and codes of conduct on access and benefit-sharing by stakeholder groups, including for ex situ collections. For example, the Commission supported the development of the Micro-organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC) 136/ by the Belgian Co-ordinated Collections of Micro-organisms (BCCM), together with 16 other organizations from around the world. 137/

54. In addition, in part as a consequence of the awareness raising activities mentioned above, users of genetic resources, like the pharmaceutical industry, the biotechnology sector, the botanical gardens and *ex-situ* collections have already developed or are in the process of developing and implementing codes of conduct that establish best practices on access and benefit-sharing for their respective areas of activity. 138/

55. In Switzerland, "the Swiss Federal Office for the Environment commissioned and sponsored the Swiss Academy of Sciences (SCNAT) to raise the awareness of stakeholders involved in academic research related to access and benefit-sharing issues with emphasis on the implementation of the Bonn

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133/ Submission by Switzerland to WG-ABS5.

134/ Submission by Canada to WG-ABS5.

135/ Contribution by Canada to WG-ABS5.

136/ http://www.belspo.be/bccm/mosaicc.

137/ European Community submission, p. 3, available in document UNEP/CBD/WG-ABS/3/INF/1.

138/ Contribution by EC and its Member States to WG-ABS5.

Guidelines. As a first step, a survey was conducted to determine the level of awareness of the stakeholders with regards to access and benefit-sharing issues and to evaluate the number of research projects involving the use of genetic/biological resources and/or traditional knowledge. As a second step, stakeholders involved in projects dealing with access and benefit-sharing issues were asked more specific questions regarding access and benefit-sharing situation. The outcome of these two studies showed that a vast majority of stakeholders were not aware of the provisions of the Convention on Biological Diversity, in particular those dealing with access and benefit-sharing issues.

56. Therefore a manual aiming to inform the academic community about the system governing the access and benefit-sharing procedure was developed in the context of an iterative and participative process, and various drafts were evaluated at different stages by members of the Swiss academic community. The resulting manual "Access and Benefit-Sharing - Good practice for academic research on genetic resources" was widely distributed among the Swiss scientific community and also presented and distributed at several international meetings and workshops. Finally, a website dedicated to the access and benefit-sharing issues was launched during the Summer 2006 (http://abs.scnat.ch/)". 139/

57. In addition, at national level, an initiative was developed and supported with the aim to integrate all the Swiss botanic gardens in the International Plant Exchange Network (IPEN), by assisting them in the development of databases to keep track of all relevant materials coming in and out of the gardens. By the end of 2006, all Swiss botanic gardens of importance had integrated the IPEN mechanism. Further information on IPEN is provided below under the section addressing codes of conduct and guidelines.

58. In Switzerland, also the State Secretariat for Economic Affairs supported the development of the "ABS Management Tool" by the International Institute for Sustainable Development and Stratos Inc., as an instrument to support the implementation of the Bonn Guidelines. The ABS Management Tool is further examined below under "codes of conduct and guidelines".

59. Considering that other potential sectors are concerned by access and benefit-sharing issues including industry (agro-food, agro-chemicals, pharmaceuticals and cosmetic industry), as well as horticulture and garden centers, several other projects are underway in Switzerland to evaluate the precise involvement and awareness of these sectors in relation with access and benefit-sharing issues. First data will be available at the end of 2007.

60. Finally, in the frame of economic development co-operation, the Swiss State Secretariat for Economic Affairs (SECO) supports the BioTrade Facilitation Programme (BTFP) UNCTAD, which brings together sustainable economic use and protection of biodiversity. The genetic resource should have an economic value and the local community should profit from the international trade of their genetic resource. Pilot programs are currently implemented in Bolivia, Peru, Colombia, Southern Africa and Vietnam. The SECO in Switzerland launched a pilot case in this context. Between a Swiss retailer and the government of Bolivia an agreement was settled, that farmers in Switzerland plant a variety of potatoes from Bolivia and sell them to the retailer. Five percent of the benefits from the sales will be reimbursed to the local community in Bolivia (cultivator of the potato varieties), the national potato institute and the national directorate for natural reserves. The first sales of these potatoes are expected to take place in spring 2008.

c. Access and benefit-sharing requirements and public funding

61. Denmark and Sweden provide examples of situations where access and benefit-sharing requirements are to be met as a prerequisite for funding. In Denmark, providers of funding for research and development projects are to be contacted to include the application of the Bonn Guidelines as parts of the conditions for funding. In Sweden, a policy adopted by the Swedish International Development Cooperation Agency requires the establishment of a material transfer agreement between the provider

139/ Contribution by Switzerland to WG-ABS-5.

and receiver of genetic material in research cooperation activities financed by the Agency that involve genetic material. 140/

62. Public research funders in Germany and France are also undertaking work to request acceptance of guidance on access and benefit-sharing formulated within the Convention on Biological Diversity. 141/

d. Disclosure of origin/source/legal provenance

63. Measures to support compliance with prior informed consent and mutually agreed terms in Contracting Parties with users under their jurisdiction have also included measures to require the disclosure of the origin/source/legal provenance of genetic resources in applications for intellectual property rights. These requirements have taken various forms.

64. At the national level, countries have taken different approaches to address the requirement for disclosure of the country of origin of genetic resources and relevant traditional knowledge in relevant intellectual property rights applications. Certain countries have chose to amend their patent law, others have chosen to include the disclosure requirement in their biodiversity or access and benefit-sharing laws, and others still have included reference to the requirement in both laws on patents and laws on biodiversity or access and benefit-sharing. The following illustrates the various approaches taken by countries in relation to the disclosure requirement.

65. Recital 27 of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions provides that the patent application should, where appropriate, include information on the geographical origin of biological material if known. This is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.

66. The directive did not create a legally enforceable obligation, therefore not all European countries adopted legislation on this issue. Within the European Union, Belgium, Denmark, Germany and Sweden adopted a disclosure requirement, as follows:

- Belgium amended its patent laws with the aim to contribute to transparency with regard to the geographic origin of the genetic source on which inventions are directly based. The amended law includes a new formal requirement "that patent applications must contain the geographic source of the plant or animal material, if known, that formed the basis for the development of the invention"142/.

- Denmark has revised its Patent law with a provision requiring that patent applicants provide information on the origin of the genetic resources used in the invention for which a patent is applied for. In cases of non-compliance, no sanctions are provided in the patent system, however under criminal law, sanctions are established regarding the provision of false information to public authorities. 143/

- The German Patent Law from 16 December 1980, Article 34a, was modified through the Law on the Implementation of the EU Directive on biotechnological inventions and came into force on 28 February 2005 144/.

140/ See document UNEP/WG-ABS/3/5.

141/ Contribution by EC and its Member States to WG-ABS5.

142/ Submission provided in preparation for WG-ABS4.

143/ Submission by Denmark in annex to the European Community submission for WG-ABS3.

144/ Dr. Ana Maria Pacon, "Possible effects of a certificate on the Disclosure of Origin process in patent appications", in European Regional Meeting on an Internationally Recognised Certificate of Origin/Source/Legal Provenance, Report of an International Workshop hosted by the German Federal Agency for Nature Conservation, Isle of Vilm, Germany, 24-29 October 2006.

- In Sweden, a new provision on the disclosure of origin of biological material of plant or animal origin in patent applications came into force on 1 May 2004, in accordance with article 5 of the Patents Regulations (SFS 2004:162) under the Patent Act. The article provides that if the origin is unknown, it shall be stated. It is also provided that "lack of information on the geographical origin or on the knowledge of the applicant regarding the origin is without prejudice to the processing of the patent application or the validity of rights arising from a granted patent." 145/

67. Norway also adopted a disclosure requirement:

"The Norwegian Patent Law was amended in 2003. The amendments entered into force the 1st of February 2004. A new para. 8 b) was included to address disclosure of origin. It states that the patent application shall include information on the country from which the inventor collected or received the biological material (the providing country). If it follows from national law in the providing country that access to biological material shall be subject to prior consent, the application shall inform on whether such consent has been obtained.

If the providing country is not the same as the country of origin of the biological material, the application shall also inform on the country of origin. The country of origin means the country from which the material was collected from in-situ sources. If it follows from national law in the country of origin that access to biological material shall be subject to prior consent, the application shall inform on whether such consent has been obtained. If information dealt with under this subsection is not known, the applicant shall state this in the application.

Infringement of the duty to provide information is subject to penalty in accordance with the General Civil Penal Code § 166. The duty to provide information is without prejudice to the processing of patent applications or the validity of granted patents." 146/

68. Andean Community decision 486 on the Common Industrial Property Regime also includes a disclosure requirement. It involves disclosure of the access contract, prior informed consent of indigenous and local communities and acquisition of material in accordance with national, Andean Community and international law. A patent may be declared null or void if copy of the access contract was not submitted or if the prior informed consent of relevant indigenous and local communities was not obtained, in the case of a patent granted for a product or a process based on genetic resources or traditional knowledge.

69. In Brazil, the Provisional Measure 147/ requires the disclosure of origin of the genetic material and the associated traditional knowledge as a condition to the grant of industrial property rights.

70. In India, the disclosure of the source and geographical origin of the biological material used for the invention is required. 148/

71. In Costa Rica, the Biodiversity Law requires a certificate of origin and prior informed consent before granting protection of intellectual or industrial property to innovations involving components of biodiversity. 149/

72. The disclosure requirement is a condition of patentability for the following countries: Member States of the Andean Community, Brazil, Costa Rica and India. In other countries, such as Sweden, Norway and Denmark, lack of disclosure does not affect processing of patent applications or the validity

145/ Submission by Sweden in annex to the European Community submission for WG-ABS3.

146/ Contribution provided by Norway for the fourth and fifth meetings of the Working Group on Access and Benefit-sharing.

147/ Article 31 of Provisional Measure No. 2.186-16 of 23 August 2001.

148/ Patents Act 1970 as amended by the Patents Second Amendment Act (2002).

149/ Biodiversity Law No. 7788 of Costa Rica, 1998, article 79 and 80.

of rights arising from such patents. However, in Denmark and Norway, the absence of disclosure could be considered a breach to obligations punishable under the Penal Code.

e. Technology transfer and cooperation

73. 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."

74. 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 document UNEP/CBD/COP/8/INF/9.

75. The guidelines for the third national report contain 9 questions on access to and transfer of technology (questions 117 to 125). On question 118 addressing Article 16(3), less than one third of responding Parties claimed to have some (25) or comprehensive (3) measures in place, while 33 countries indicated that there are no such measures in place and 19 Parties indicated that potential measures are under review. A total of 13 countries indicated that the question does not apply to them. No further comments were provided on this question. 150/ On question 119 on Article 16(4), almost two thirds (54) of countries indicated that no such measures were taken (41) or that potential measures are under review (13). 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.

76. 32 Parties provided further comments to question 119. A few countries referred to general policies or measures, while concrete examples of public-private-partnerships were provided by 4 Parties. As regards specific sectors, agriculture took the lead, with 6 Parties making reference to private sector engagement in this sector. Forestry was mentioned by four Parties, fisheries management by three Parties, and pharmaceutical research by two Parties. General references to the development of markets for biodiversity-based products were made by four Parties.

77. The thematic reports on technology transfer and technological cooperation, as well as the recent submissions provided by Parties 151/ 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. 152/ In addition, in a number of countries, incentives for the private sector for enhancing the transfer of technology are also

150/ Figures are as of March 2007.

151/ 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.

152/ See UNEP/CBD/COP/8/INF/ 9, paragraph 82.

implemented in form of tax concessions, refunds or deferrals for R&D investments and relating them to the commercialization of technology; however, it is not clear whether and to what extend these measures are specifically geared towards technologies of relevance to the Convention.

78. 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.

79. 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:

- Beyerlee and Fisher point to a joint venture between the multi national company Dupont and the Applied Genetic Engineering Research Institute (AGERI), an Egyptian public research institute. The project aims to jointly develop Bt maize, whereas AGERI gains access to expertise to develop the local strain of Bt (the innovation) and to train its staff. Dupont in turn, has access to the new Bt strain for use in markets outside of Egypt. 153/

- Austria reported on a research project on sweet potato germplasm diversity assessment, under which unlimited use of all results for the CGIAR system and partners in developing countries is ensured. 154/

- The United Kingdom reports that the training of developing country scientists in the application of new technologies for the conservation and utilization of genetic resources takes place in various institutions including universities, Kew, the John Innes Centre in Norwich and CABI. In collaboration with Institutes in several Central Asian countries, new systems of production, which conserve biodiversity of rangelands, have been developed. Current work in South America is developing systems with local organizations for the sustainable management of vicunas.

80. In the third national reports, 155/ 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. For instance, Belgium provided four good practice case studies covering: inter alia (i) the Belgian Federal Science Policy Office; (ii) the Plant Biotechnology Institute for Developing Countries; (iii) the International Network for the Improvement of Banana and Plantain.

81. 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 labeling 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

153/ Beyerlee and Fischer (2000): *Accessing Modern Science: Policy and Institutional Options for Agricultural Biotechnology in Developing Countries*, AKIS Discussion Paper.

154/ Thematic report on technology transfer and cooperation from Austria.

the third national reports,

155/ See boxes LV and LVI of the questionnaire.

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.

2. Codes of conduct/guidelines

82. Specific guidelines have been developed for the agricultural sector. A number of voluntary codes of conduct and guidelines have also been developed by organisations, such as botanic gardens, culture collections, the academic research community and professional associations. These codes of conduct and guidelines were generally developed to assist with the implementation of the access and benefit-sharing provisions of the Convention by responding to the particular needs of their constituents.

a. The Agricultural Sector

83. The International Code of Conduct for Plant Germplasm Collecting and Transfer, negotiated by the FAO Commission on Genetic Resources for Food and Agriculture and 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, its sets out minimum responsibilities of collectors, sponsors, curators and users of collected germplasm, in the collection and transfer of germplasm.

b. Botanic gardens

84. As highlighted in the contribution by Switzerland, "Botanic gardens are particularly concerned by issues related to access and benefit-sharing. Indeed, one of the main activities of botanical gardens is the collection of plants for the purposes of scientific research, conservation, display and education. Thus botanic gardens are used to collect, document, distribute and exchange a great amount of various biological materials (living plants, seeds, cuttings, bulbs, etc.). This makes botanic gardens stakeholders in the implementation of provisions of the Convention on Biological Diversity. In order to facilitate these activities and to comply with the Convention on Biological Diversity, several instruments were developed at the international level, such as the "Principles on ABS" of the Royal Botanic Gardens, Kew and the "Code of Conduct" of the German Ministry of Environment. A mechanism to implement both instruments, called the "International Plant Exchange Network, IPEN)" was developed under the control of the BGCI (Botanic Gardens Conservation International, http://www.bgci.org/worldwide/home)."

85. *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. 156/ 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. 157/

86. The International Plant Exchange Network (IPEN) was established by European botanic gardens in order to comply with the access and benefit-sharing provisions of the Convention. It covers the non-commercial exchange of plant material between botanic gardens. As of May 2007, IPEN included

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156/ 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.

157/ See UNEP/CBD/WG-ABS/2/2, section III.A.2 on "Policy guidelines and codes of conduct related to access and benefit-sharing".

67 member gardens from Germany, the Netherlands, Austria, Switzerland, Luxembourg, France, Sweden, United Kingdom, Greece and Italy. Botanic gardens that want to join the network must adopt the IPEN Code of Conduct and use its common documents for plant material transfer. The IPEN Code of Conduct covers acquisition, maintenance and supply of living plant material by the gardens as well as benefit-sharing. Only botanic gardens that commit themselves to act according to the Code of Conduct can become member of the IPEN network.

c. Micro-organisms culture collections

87. With respect to microbial genetic resources, the Micro-organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC) 158/ was developed by the Belgian Coordinated Collections of Micro-organisms (BCCM) in 1997, with the support of the European Commission, and involved twelve partners from various sectors in both developed and developing countries. It is a voluntary code of conduct which covers the terms of access to microbial genetic resources, including the terms of agreement on benefit-sharing, access to and transfer of technology, scientific and technical cooperation as well as technology transfer. 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. (see UNEP/CBD/WG-ABS/2/2, par. 31)

88. *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.159/ (UNEP/CBD/WG-ABS/2/2, par. 32)

d. Academic research community

89. In 2006, the Swiss Academy of Sciences made available a brochure to respond to the needs of academic researchers entitled "Access and Benefit-sharing – Good Practice for academic research on genetic resources". 160/ In order to create awareness among the academic research community to the access and benefit-sharing provisions of the Convention, the brochure provides information on the access and benefit system and explains the necessary steps to follow when accessing biological resources for research purposes and possibilities for benefit-sharing from an academic research perspective.

e. Professional societies or organisations

90. A number of professional research societies in fields such as anthropology, ethnobiology, pharmacognosy and ecology have developed documents to articulate ethical values embedded in research and set standards for best practice. These documents are variously referred to as codes of ethics, voluntary codes, codes of practice, statements on ethics, guidelines and research protocols. Elements of these codes of ethics and research guidelines generally address prior informed consent, research behaviour including benefit-sharing and the publication and distribution of data. 161/

158/ For further information, see http://bccm.belspo.be/projects/mosaicc/.

159/ For further information, see www.cabi.org.

160/ For further information see: abs@scnat.ch

161/ For further information see "Professional society standards for biodiversity research: codes of ethics and research guidelines" by Sarah A Laird and Darrell A Posey, Chapter 2 of the publication by S. Laird entitled "Biodiversity and Traditional Knowledge – Equitable Partnerships in Practice", Conservation Series, Peoples and Plants, Earthscan Publications, 2002. See also, Ten Kate, K., Laird, S., "The Commercial Use of Biodiversity – Access to Genetic Resources and Benefit-sharing", Earthscan, London, 1999, p. 309.

f. Private sector

91. In the private sector, some associations have also developed guidelines for their members involved in access and benefit-sharing activities, such as the Guidelines for International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) Members on Access to Genetic Resources and Equitable Sharing of Benefits Arising out of their Utilization, issued 7 April 2006 162/ and the Guidelines for Biotechnology Industry Organization (BIO) 163/ Members Engaging in Bioprospecting.

92. As stated in the contribution of IFPMA to the Secretariat, "These guidelines reflect our Council's decision that IFPMA is firmly against the taking of genetic resources without prior authorization. The guidelines reaffirm IFPMA members' support of all three objectives of the Convention on Biological Diversity, as well as our full engagement and participation in discussions relating to the development of an international regime on Access and Benefit-sharing."

93. As pointed out by BIO, the Guidelines for BIO Members Engaging in Bioprospecting "were developed with the goal of educating BIO members as to relevant issues that can arise in the conduct of bioprospecting activities, and in providing assistance to those BIO member companies seeking guidance in this area." They "identify certain "best practices" that can be followed by companies that elect to engage in these activities."

94. In addition, it should be noted that some companies have developed access and benefit-sharing policies, such as GlaxoSmithKline and Novo Nordisk 164/.

95. Also of relevance to the private sector is the ABS Management Tool, a voluntary instrument, also developed with the support of the Swiss State Secretariat for Economic Affairs (SECO). Its aim is to support the implementation of the principles of the Bonn Guidelines. It provides practical guidance for providers and users of genetic resources and facilitates mutually beneficial relationships between them. It helps the providers and users in the negotiation of agreements and their implementation, as well as monitoring.

96. A first phase consisted in the elaboration of the ABS Management Tool available at http://www.iisd.org/pdf/2005/standards_abs_mt_user_guide.pdf. During the second phase, the tool was tested in Australia, Malaysia, Cameroon and Bolivia in order to assess its practicability. The results of the tests will be reflected in the new edition of the ABS Management Tool, which will be available within the next few months. 165/

III. ACCESS AND BENEFIT-SHARING ARRANGEMENTS IN DIFFERENT SECTORS

97. In order to assess existing practice with respect to access and benefit-sharing, an analytical study is being carried out of access and benefit-sharing arrangements in different sectors. The final outcomes of this project will be available at the sixth meeting of the Working Group on Access and Benefit-sharing, in January 2008. This study aims to identify common or diverging practices among sectors in carrying out access and benefit-sharing partnerships. The analysis should also assist in determining whether there are gaps in the existing system which should be addressed by an international regime.

162/ These guidelines are contained in the compilation of submissions provided by Parties and relevant organizations, in document UNEP/CBD/WG-ABS/5/INF/2.

163/ BIO is the national trade association for the biotechnology industry, based in Washington, DC, representing more than 1000 biotechnology companies, academic institutions and biotechnology centers in the United States and 33 countries. BIO members are involved in the research and development of health care, agricultural and environmental biotechnology products. For further information on BIO see http://bio.org.

164/ See GlaxoSmithKline's Position on the Convention on Biological Diversity, November 2006 and www.novonordisk.com.

165/ Contribution by Switzerland for the fifth meeting of the Working Group on Access and Benefit-sharing.

98. Despite a flurry of interest in these arrangements in the 1990s, few studies have tracked their evolution. Addressing this gap is essential to ensure that ongoing negotiations to develop an international regime are informed by best practice and lessons learnt from implementation.

99. A wide range of sectors undertake research and develop commercial products from genetic resources. They include the pharmaceutical, biotechnology, seed, crop protection, horticulture, cosmetic and personal care, fragrance and flavor, botanicals, and food and beverage industries. Each sector is part of a unique market, undertakes research and development in distinct ways, and uses genetic resources and demands access to these resources very differently. They also enter into partnerships with providers of genetic resources in distinct ways, have specific sets of stakeholders, negotiate prior informed consent in diverse ways, and have different approaches through which they reach mutually agreed terms with regard to benefit-sharing and intellectual property. Agreements within and across sectors also vary considerably with regard to the legal remedies they use for compliance and enforcement.

100. The scope of this study will be primarily focused on genetic resources – genetic material of actual or potential value - as part of the access and benefit-sharing component of the Convention on Biological Diversity. However, a number of the sectors that make use of genetic resources may also use biological resources – a broader category that includes genetic resources, but also organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity. Increasingly, there is an overlap in the contractual agreements around use of genetic and biological resources, and different understandings as to the application of access and benefit-sharing under these circumstances. It is also often difficult to distinguish between these categories of resources, and a number of national access and benefit-sharing laws go beyond the Convention on Biological Diversity to address, for example, both biological and genetic resources (e.g. The Philippines EO, the South African Biodiversity Act 10 of 2004) or biochemical and genetic elements (e.g. Costa Rica Law 7788). Because of these divergent interpretations and practices, the study will also examine case studies that illustrate some of these definitional complexities and further our understanding of current practice.

Methodology for study

101. The study will examine access and benefit-sharing partnerships, collaborations and contractual agreements in a range of sectors using genetic resources, including: pharmaceutical, biotech, seed, crop protection, horticulture, botanical medicine, and the personal care, cosmetic and food/nutraceutical industries. It will examine at the nature of these relationships, and whether and how they achieve the objectives of sustainable use and equitable benefit-sharing. One or two partnerships/case-studies will be profiled for each sector, and an additional two to three cases referenced in discussions in order to provide a picture of common practices in the sectors discussed.

102. The characteristics and procedures common to different sectors seeking access, and sharing benefits, will be examined. These include: prior informed consent; mutually-agreed terms, including benefit-sharing packages (non-monetary and monetary, and capacity-building associated with partnerships), and intellectual property; legal agreements/contracts employed; and compliance and legal remedies if contracts are breached. The study will also explore the nature of these procedures and arrangements for different stages of the research, development and commercialization process; will examine how access and benefit-sharing arrangements are implemented and monitored; and will analyse constraints towards implementation. A comparative analysis will be done across sectors to elucidate practices that are working well, and those requiring attention, and to extract lessons learnt for best practice. A summary of key conclusions and recommendations will be developed to enable effective incorporation of findings into the documentation of the Convention on Biological Diversity, and thus aid the negotiation process.

103. Initial research has included a review of recent literature on the subject, the collection of contracts and agreements, and interviews with individuals from industry, government, NGOs,

international agencies, and others. A second phase of more intensive interviews is currently being undertaken with individuals involved in selected case studies. The final outcomes of this project will be available for the sixth meeting of the Working Group on Access and Benefit-sharing.
