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ANALYSIS OF EXISTING NATIONAL, REGIONAL AND INTERNATIONAL LEGAL INSTRUMENTS RELATING TO ACCESS AND BENEFIT-SHARING AND EXPERIENCE GAINED IN THEIR IMPLEMENTATION, INCLUDING IDENTIFICATION OF GAPS

Note by the Executive Secretary

I. INTRODUCTION

1. In decision VII/19 D, the Conference of the Parties decided to mandate the Ad Hoc Open-ended Working Group on Access and Benefit-sharing, to elaborate and negotiate an international regime on access to genetic resources and benefit-sharing with the aim of adopting an instrument/instruments to effectively implement the provisions in Article 15 and Article 8(j) of the Convention and the three objectives of the Convention” and recommended that the Working Group on Access and Benefit-sharing “should operate in accordance with the terms of reference contained in the annex to this decision. 1/

2. In the preamble to decision VII/19 D, the Conference of the Parties noted “that there is a need for further analysis of existing national, regional and international legal instruments and regimes relating to access and benefit-sharing and experience gained in their implementation, including gaps and their consequences”. In addition, the terms of reference of the Working Group contained in the annex to the same decision provide that the negotiation of the international regime should 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”.

3. Accordingly, the present note provides an analysis of existing legal and other instruments at national, regional and international levels relating to access and benefit-sharing, taking into account existing instruments listed in the annex to decision VII/19 D, under section (d) sub-paragraph (xxiii) of the terms of reference as elements for consideration by the Working Group for inclusion in the international regime.

* UNEP/CBD/WG-ABS/3/1.

1/ Decision VII/19 D, paragraphs 1 and 2.

II. OVERVIEW OF EXISTING INSTRUMENTS RELATED TO ACCESS AND BENEFIT-SHARING

A. *International legal instruments*

4. This section provides a general description of the international instruments identified by the Conference of the Parties to be considered for inclusion in the international regime as well as an examination of their relevance to access and benefit-sharing.

1. *FAO International Treaty on Plant Genetic Resources for Food and Agriculture*

General description of the instrument

5. The International Treaty on Plant Genetic Resources for Food and Agriculture was adopted by the Conference of the Food and Agriculture Organization of the United Nations (FAO) in November 2001 and entered into force on 29 June 2004. As of 1 November 2004, 61 countries and the European Community had ratified the Treaty. This legally binding treaty covers all plant genetic resources for food and agriculture. Its objectives are “the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of benefits derived from their use, in harmony with Convention on Biological Diversity, for sustainable agriculture and food security”.

Access and benefit-sharing component

6. One of the main components of this Treaty, the Multilateral System of Facilitated Access and Benefit-sharing addresses access and benefit-sharing and supports the work of breeders and farmers. The Multilateral System applies to more than 60 plant genera, which include 64 major crops and forages. The list of crops covered under the Multilateral System is listed in annex I of the Treaty. The Multilateral System can be seen as a particular application of the principles of Article 15, paragraph 2, of the Convention to the plant genetic resources for food and agriculture covered by the Multilateral System. In its article 10, the Contracting Parties to the Treaty recognize the sovereign rights of States over their own plant genetic resources for food and agriculture and agree to establish a multilateral system to facilitate access to these resources, and to share, in a fair and equitable way, the benefits arising from their utilization. The mechanism for facilitated access and benefit-sharing is a standard Material Transfer Agreement (MTA) to be adopted by the Governing Body which will set out the conditions for access to these genetic resources and benefit-sharing. The Treaty establishes a number of mandatory terms and conditions to be included in the MTA but leaves a number of issues for negotiation within the Governing Body. Access will be provided for utilization and conservation in research, breeding and training for food and agriculture. The treaty provides for benefit-sharing through the payment of monetary and other benefits of commercialization; information-exchange; access to and transfer of technology; and capacity-building.

7. An Expert Group has been established, pursuant to FAO Conference Resolution 3/2001 that adopted the Treaty, to prepare recommendations for the first meeting of the Governing Body regarding the form and content of a standard Material Transfer Agreement.

2. *The WTO Agreement on Trade-related Aspects of Intellectual Property Rights*

General description of the instrument 2/

8. The TRIPs Agreement came into force on 1 January 1995 as a result of the Uruguay Round of multilateral trade negotiations. It covers areas of intellectual property such as copyright and related rights, trademarks, geographical indications, patents including the protection of new varieties of plants, the layout designs of integrated circuits and undisclosed information including trade secrets and test data.

9. The Agreement establishes the minimum standards of protection to be provided by Members in each of the main areas of intellectual property covered by the TRIPs Agreement. It also deals with domestic procedures and remedies for the enforcement of intellectual property rights and makes disputes

^{2/} For further details see www.wto.org.

between WTO Members about the respect of the TRIPs obligations subject to the WTO dispute-settlement procedures. The Agreement also provides for the applicability of basic GATT principles, such as most favoured nation and national treatment.

10. The main goals of the TRIPs Agreement include the reduction of distortions and impediments to international trade, promotion of effective and adequate protection of intellectual property rights, and ensuring that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade. Article 7 of the Agreement sets out as one of its objectives that the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

11. With respect to patents, article 27(1) of the Agreement defines the formal requirements regarding patentable subject matter and provides that patents shall be available for inventions that are “new, involve an inventive step and are capable of industrial application”.

12. Article 27, paragraph 3 (b) of the Agreement provides that Members may exclude from patentability plants and animals other than micro-organisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, any country excluding plant varieties from patent protection must provide an effective *sui generis* system of protection. Members may therefore decide whether or not to grant patents for plants, animals or biological processes. The agreement calls for a review of the provisions of Article 27.3 (b) four years after the agreement entered into force. Such a review is ongoing. In addition, it should be noted that paragraph 19 of the 2001 Doha Declaration has broadened the discussion. It provides that the TRIPS Council should also examine the relationship between the TRIPs Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore and other relevant new developments raised by Members pursuant to article 71.1. It also provides that the work of the TRIPS Council on these topics is to be guided by the Agreement’s objectives (Article 7) and principles (Article 8), and must take development issues fully into account.

Relevance to access and benefit-sharing

13. A number of issues have been addressed in the TRIPs Council with respect to the revision of article 27.3(b), the relationship between the Convention on Biological Diversity and the TRIPs Agreement, and the possibility of broadening the criteria for patentability with respect to inventions based on genetic material or associated traditional knowledge.

14. While certain members have expressed the opinion that the TRIPs Agreement and the Convention on Biological Diversity are already compatible, others have argued that the TRIPs Agreement should be amended in order to ensure its compatibility with the Convention on Biological Diversity. More specifically, it has been suggested that the TRIPs Agreement should be amended so that patent applicants are required to disclose the origin of genetic resources and associated traditional knowledge in patent applications where the subject matter of the application is based on genetic resources or related traditional knowledge. It is also suggested that evidence of prior informed consent and benefit-sharing be provided by the applicant. Others are of the opinion that the TRIPs Agreement should prohibit the patenting of all life forms. Other countries have suggested addressing the issue of disclosure of origin of genetic resources and related traditional knowledge as a stand alone requirement and another has suggested to address the issue of disclosure by amending the Patent Cooperation Treaty adopted under the aegis of WIPO. No consensus has been reached, as yet, on this issue. The latest proposal, available as document IP/C/W/429, dated 20 September 2004, was submitted by Brazil, India, Pakistan, Peru, Thailand, and Venezuela and considered at the TRIPs Council meeting on 21 September 2004. The proposal explores disclosure requirements relating to the origin of genetic resources and any traditional knowledge used in an invention. It discusses the rationale for such a requirement and provides suggestions for the form it could take and the consequences of non-compliance. No substantive progress was made at that meeting.

3. *WIPO conventions and treaties*

15. WIPO administers 23 international treaties dealing with different aspects of intellectual property protection and it counts 180 countries as Member States. Treaties of relevance to the international patent system are those of most relevance to the issue of access to genetic resources and benefit-sharing.

16. In September-October 2001, at the thirty-sixth series of meetings of the Assemblies of the Member States of the WIPO, Member States agreed that WIPO should begin consultations with a view to preparing a strategic blue print for change in the international patent system. ^{3/} Developments of various aspects of the patent system were already being addressed in a number of forums within WIPO, such as those relating to the Patent Law Treaty (PLT), the draft Substantive Patent Law Treaty (SPLT), the reform of the Patent Cooperation Treaty (PCT) and the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. The WIPO Patent Agenda is to ensure, *inter alia*, the effectiveness of these processes and instruments and their mutual consistency.

17. A Diplomatic Conference adopted the Patent Law Treaty (PLT) on 1 June 2000. The PLT aims at harmonizing formal requirements set by national or regional patent offices for the filing of national or regional patent applications. It was then decided by the WIPO's Standing Committee on the Law of Patents (SCP) to initiate work on harmonization of substantive patent law. At the November 2001 meeting, the SCP agreed on an approach of establishing a seamless interface between the SPLT, the PLT and the Patent Cooperation Treaty (PCT). A draft of the Substantive Patent Law Treaty is now under consideration. In addition, a reform of the Patent Cooperation Treaty began in October 2000 and is ongoing. The Patent Cooperation Treaty is an international instrument that allows for the processing of a single international patent application for patents in multiple member countries of the Patent Cooperation Treaty rather than having to process applications in the national office of each country. An international patent application is subjected to an "international search" carried out by one of the major patent offices appointed by the PCT Assembly with respect to prior art, novelty and inventive step.

18. In addition, the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) was established by the WIPO General Assembly in October 2000 as a forum for debate and dialogue concerning the relationship between intellectual property (IP), and traditional knowledge, genetic resources and traditional cultural expressions. It was considered that these themes cut across the conventional branches of intellectual property law and therefore did not fit into other WIPO bodies. ^{4/}

Relationship to access and benefit-sharing

19. Issues related to access and benefit-sharing have been addressed essentially by the IGC. However, certain member States have expressed the view that issues related to access and benefit-sharing, such as the disclosure of origin of genetic resources and related traditional knowledge should be addressed in the context of the reform of the PCT and the development of the SPLT.

20. Among issues examined by the IGC, the issue of disclosure of origin of genetic resources and related traditional knowledge in patent applications is of particular relevance to the negotiation of an international regime. A technical study on disclosure requirements related to genetic resources and traditional knowledge was carried out by WIPO in response to the invitation of the Conference of the Parties to the Convention on Biological Diversity, ^{5/} and made available to the Conference of the Parties at its seventh meeting (UNEP/CBD/COP/7/INF/17). At this meeting, the Conference of the Parties invited WIPO to carry out additional work on this issue in decision VII/19 E, paragraph 8.

21. This invitation was considered by the IGC at its sixth session in March 2004. At this meeting, the Committee agreed that the invitation should first be considered by the WIPO General Assembly to be held in September-October 2004 in order to determine which WIPO forum was the most appropriate to

^{3/} For further details see WIPO website regarding WIPO Patent Agenda.

^{4/} For further details see www.wipo.int/tk/en/igc/

^{5/} See decision VI/24 C, paragraph 4.

address this issue. While certain countries were of the opinion that the IGC was the most appropriate body to respond to such an invitation, other countries expressed the view that the protection of genetic resources and traditional knowledge against misappropriation must be addressed in patent-related legal instruments and, in particular, by introducing the necessary changes to those instruments so as to ensure that they provided for the declaration of source of genetic resources or traditional knowledge. These countries therefore suggested that the issue of disclosure should be addressed in the context of the PCT reform and of the discussions regarding the SPLT.

22. At the fourth session of the Working Group on Reform of the Patent Cooperation Treaty (PCT), held from 19 to 23 May 2003, Switzerland submitted proposals regarding transparency measures under patent law in the area of genetic resources and traditional knowledge. ^{6/} The essence of the proposals was to enable the national patent legislation to require the declaration of the source of genetic resources and traditional knowledge in patent applications, if the invention was directly based on such resources and traditional knowledge. Additional comments on these proposals were submitted to the sixth session of this Working Group (3-7 May 2004) with the aim of enabling the Working Group to have a more substantive discussion on its proposals. ^{7/} These comments covered the use of terms, the source of genetic resources and traditional knowledge, the scope of the obligation to declare this source in patent applications, and the possible legal sanctions for failure to disclose or the wrongful disclosure of the source. Divergent views were expressed in response to these proposals and the Working Group agreed to discuss the issue again at its next session, at the end of November 2004. ^{8/} The views expressed at this meeting reflected the lack of consensus among WIPO Member States with regard to the appropriate forum to discuss matters related to the issue of disclosure of source of genetic resources and related traditional knowledge in patent applications.

23. At its fifteenth extraordinary session, in September/October 2004, the WIPO General Assembly considered the invitation of the Conference of the Parties at its seventh meeting, regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications. The General Assembly decided that WIPO should respond positively to the invitation from the Conference of the Parties and established a timetable and modalities for addressing the issue, including the holding of an ad hoc intergovernmental meeting in May 2005 to consider a draft document and the submission of a revised draft thereof to the General Assembly at its ordinary session in September 2005.

4. *International Convention for the Protection of New Varieties of Plants*

General description

24. The International Convention for the Protection of New Varieties of Plants was signed in Paris in 1961 and entered into force in 1968. It was revised in 1972, 1978 and 1991. The 1991 Act of the UPOV Convention entered into force in 1998. The purpose of the UPOV Convention is “to ensure that the members of the Union acknowledge the achievement of breeders of new varieties of plants, by granting to them an intellectual property right, on the basis of a set of clearly defined principles”. Thus, the Convention provides a *sui generis* form of intellectual protection specifically adapted to the process of plant breeding and developed with the aim of encouraging breeders to develop new varieties of plants. To be eligible for protection, varieties have to be: (i) distinct from existing, commonly known varieties; (ii) sufficiently uniform; (iii) stable; and (iv) new in the sense that they must not have been commercialized prior to certain dates established by reference to the date of the application for protection. ^{9/} The Convention offers protection to the breeder, in the form of a “breeder’s right”, if his plant variety satisfies the above conditions. The scope of the breeder’s right is, however, limited by two important exceptions

^{6/} WIPO document PCT/R/WG/5/11.

^{7/} These comments were submitted to the SCBD by the Government of Switzerland and are also available as WIPO document PCT/R/WG/6/11.

^{8/} See Report of the meeting in WIPO document PCT/R/WG/6/12.

^{9/} UPOV Publication No. 437 (E), November 10, 2003 edition.

(Article 15). The first exception, known as the “breeder’s exemption” allows the use of the propagating material of the protected variety, without prior authorization, for the purpose of breeding other varieties. The breeder’s exemption optimizes variety improvement by ensuring that germplasm sources remain accessible to all breeders. The second exception concerns the right of farmers to use farm-saved seed for replanting. This is known as the “farmers’ privilege” and seeks to safeguard the common practice of farmers saving their own seed for the purpose of re-sowing. However, the Convention requires that the farmers’ privilege be regulated “within reasonable limits and subject to safeguarding of the legitimate interests of the breeder”. As of 1 August 2004, 55 States were a Party to the UPOV Convention. The mission of UPOV is “to provide and promote an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants, for the benefit of society”. ^{10/}

Relationship to access and benefit-sharing

25. In response to notifications by the Executive Secretary inviting relevant international organizations to contribute to the work on access and benefit-sharing, the Vice Secretary-General of UPOV provided detailed replies highlighting the access and benefit-sharing aspects of the UPOV Convention. The UPOV submission is included in the compilation of submissions by Parties, international organizations and other relevant stakeholders (UNEP/CBD/WG-ABS/3/INF/1).

26. In these communications, UPOV highlighted the importance of access to genetic resources to ensure progress in plant breeding. It also pointed to the concept of the breeder’s exemption in the UPOV Convention which reflects the view of UPOV that the worldwide community of breeders needs access to all forms of breeding material to sustain progress in plant breeding and hence maximize the use of genetic resources for the benefit of society. The communications also include reference to the inherent benefit-sharing principles of the UPOV Convention, in the form of breeder’s exemption and other exceptions to the breeder’s right. Concern is expressed with respect to any other measures for benefit-sharing that could introduce unnecessary barriers to progress in breeding and the utilization of genetic resources. Finally, UPOV urges the Working Group on Access and Benefit-Sharing to recognize these principles in its work and to ensure that any measures it develops are supportive of these principles and of the UPOV Convention.

5. United Nations Convention on the Law of the Sea

General description

27. The United Nations Convention on the Law of the Sea was adopted in 1982 and entered into force on 16 November 1994. The Convention currently has 145 Parties. As set out in its preamble, the Convention was adopted in order to establish “with due regard to the sovereignty of all States, a legal order for the seas and oceans which will facilitate international communication, and will promote the peaceful uses of the seas and oceans, the equitable and efficient utilization of their resources, the conservation of their living resources, and the study, protection and preservation of the marine environment”. The Convention establishes a general framework to govern all activities on the oceans. It establishes specific regimes for living resources in the high seas and mineral resources of the deep seabed beyond the limits of national jurisdiction (“the Area”) as well as for marine scientific research. Part XII of the Convention contains general provisions regarding the protection and preservation of the marine environment. It provides for measures to prevent, reduce and control marine pollution; the prevention and control of the introduction of alien species; the global and regional cooperation for the protection and preservation of the marine environment; and the monitoring and assessment of environmental impacts of activities. The regime of the Area established in Part XI is based on the principle that the Area and its resources are the common heritage of mankind. The definition of the term “resources”, however, refers only to mineral resources, thus leaving biological resources outside the ambit of the regulatory regime. Part XIII of the Convention establishes the regime for marine scientific research and affirms the right of all States and competent international organizations to conduct marine scientific research, including in the Area. It provides that such research shall be conducted exclusively for peaceful purposes and in

^{10/} Ibid.

compliance with relevant regulations adopted under the Convention, including those for the protection and preservation of the marine environment.

Relationship to access and benefit-sharing

28. In paragraph 12 of decision II/10, the Conference of the Parties requested the Executive Secretary, in consultation with the Division for Ocean Affairs and the Law of the Sea of the Office of Legal Affairs of the United Nations, to undertake a study of the relationship between the Convention on Biological Diversity and the UNCLOS with regard to conservation and sustainable use of genetic resources on the deep sea bed, to enable SBSTTA to address the scientific, technical and technological issues relating to bioprospecting of genetic resources of the deep seabed. The issue of access to genetic resources on the deep seabed and benefit-sharing was addressed by this study (UNEP/CBD/SBSTTA/8/INF/3/Rev.1). A synthesis of this study, (UNEP/SBSTTA/8/9/Add.3/Rev.1) was considered at the eighth meeting of SBSTTA and provides a useful overview of the relationship between the Convention on Biological Diversity and the UNCLOS with respect to the conservation and sustainable use of deep seabed genetic resources beyond national jurisdiction and also addresses the issue of marine genetic resources in the Area. ^{11/}

29. The study notes that whereas the provisions of the UNCLOS and the Convention on Biological Diversity are complementary and mutually supportive regarding the conservation and sustainable use of marine and coastal biodiversity, an important legal lacuna exists with respect to commercially oriented activities relating to genetic resources in the Area. While UNCLOS contains provisions for marine scientific research, including in areas beyond national jurisdiction, it is unclear about bioprospecting. With respect to the Convention on Biological Diversity, in areas beyond the limits of national jurisdiction, the provisions of the Convention only apply to activities and processes carried out under a Party's jurisdiction or control which may have adverse impacts on biological diversity. Thus, the provisions of the Convention relating to access to genetic resources and benefit-sharing do not apply to genetic resources in areas beyond national jurisdiction. Article 15 of the Convention on Biological Diversity, which addresses the issue of access to genetic resources and benefit-sharing, is based on the principle of State sovereignty over genetic resources. The provisions of Article 15 apply only to genetic resources provided by Contracting Parties that are countries of origin of such resources or by Parties that have acquired them in accordance with the Convention. Genetic resources located in areas beyond the limits of national jurisdiction are therefore outside the scope of Article 15.

30. The study concludes that the two conventions contain useful principles, concepts, measures and mechanisms that could provide the building blocks for a specific legal regime focusing on the conservation and sustainable use of marine genetic resources in the deep seabed beyond the limits of national jurisdiction. The common-heritage-of-mankind principle under the United Nations Convention on the Law of the Sea could provide an important underlying conceptual construct for genetic resources of the deep seabed. In addition, the two conventions share certain principles and concepts, such as the responsibility of States for activities under their jurisdiction and control; the ecosystem approach; the establishment of marine protected areas; information exchange, consultation and notification regarding activities; environmental impact assessment; sustainable use; and fair and equitable sharing of benefits. These principles would provide useful tools in addressing conservation and equity considerations in the management of genetic resources of the deep seabed beyond national jurisdiction.

31. The Conference of the Parties considered issues arising from the study of the relationship between the Convention on Biological Diversity and the UNCLOS in decision VII/5 on marine and coastal biodiversity. ^{12/} The Conference of the Parties recognized that further work was needed on this issue and requested the Executive Secretary in consultation with Parties and relevant organizations to compile information, for consideration by SBSTTA, on the following issues: information on the methods for the identification, assessment and monitoring of genetic resources of the seabed and ocean floor and

^{11/} Where the water column becomes the high seas, the seabed becomes "the Area".

^{12/} The relevant sections of decision VII/5 are included in paragraphs 54 to 56.

subsoil thereof, in areas beyond the limits of national jurisdiction; information on the status and trends of these genetic resources including identification of threats and the technical options for their protection.

32. In addition, the Conference of the Parties invited “the Parties to raise their concerns regarding the issue of conservation and sustainable use of genetic resources of the deep seabed beyond limits of national jurisdiction at the next meeting of the General Assembly”. It also invited the “General Assembly to further coordinate work relating to conservation and sustainable use of genetic resources of the deep seabed beyond the limits of national jurisdiction”. Finally, Parties and other States were invited “to identify activities and processes under their jurisdiction or control which may have significant adverse impact on deep seabed ecosystems and species beyond the limits of national jurisdiction, in order to address Article 3 of the Convention”.

6. *The Convention on International Trade in Endangered Species of Wild Fauna and Flora*

General description 13/

33. The Convention on International Trade in Endangered Species of Wild Fauna and Flora entered into force in 1975 and now has 166 Parties. Its aim is to ensure that international trade in specimens of wild animals and plants does not threaten their survival.

34. In order to do so, CITES regulates international trade in specimens of species of wild fauna and flora, including the export, re-export and import of live and dead animals and plants and of parts and derivatives thereof, based on a system of permits and certificates which can be used if certain conditions are met and that have to be presented before consignments of specimens are allowed to leave or enter a country.

35. Each Party to the Convention is to designate one or more Management Authorities responsible for issuing these permits and certificates, subject to the advice from one or more Scientific Authorities designated for that purpose.

36. The species covered by CITES are listed in three Appendices, according to the degree of protection they need:

(a) Appendix I includes species threatened with extinction. Trade in specimens of these species is permitted only in exceptional circumstances;

(b) Appendix II includes species not necessarily threatened with extinction, but in which trade must be controlled in order to avoid utilization incompatible with their survival;

(c) Appendix III contains species that are protected in at least one country, which has asked other CITES Parties for assistance in controlling the trade.

37. A specimen of a CITES-listed species may be imported into or exported (or re-exported) from a State party to the Convention only if the appropriate document has been obtained and presented for clearance at the port of entry or exit.

Relationship to access and benefit-sharing

38. CITES does not address specifically the issue of access to genetic resources and benefit-sharing. However, in the context of discussions related to access and benefit-sharing, and more specifically of approaches to assist Parties and stakeholders with the implementation of the access and benefit-sharing provisions of the Convention on Biological Diversity, it has been suggested that the permit system established by CITES to regulate the trade of endangered species could provide useful experience to draw from when examining the possibility of developing an international certificate of origin/source/legal provenance and the implications of such a certificate. This issue is examined in document UNEP/CBD/WG-ABS/3/5.

7. *The Antarctic Treaty*

General description

39. The Antarctic Treaty System is the whole complex of arrangements made for the purpose of regulating relations among States in the Antarctic. At its heart is the Antarctic Treaty itself. The original Parties to the Treaty were the 12 nations active in the Antarctic during the International Geophysical Year of 1957-58. The Treaty was signed in Washington on 1 December 1959 and entered into force on 23 June 1961. The Antarctic Treaty Consultative Parties comprise the original 12 States and a further fourteen States that have become parties by acceding to the Treaty and demonstrating their interest in Antarctica by carrying out substantial scientific activity there.

40. The primary purpose of the Antarctic Treaty is to ensure “in the interests of all mankind that Antarctica shall continue forever to be used exclusively for peaceful purposes and shall not become the scene or object of international discord.”^{14/} To this end, it prohibits military activity, except in support of science; prohibits nuclear explosions and the disposal of nuclear waste; promotes scientific research and the exchange of data; and holds all territorial claims in abeyance. In furtherance of the principles and objectives of the Treaty, contracting parties undertake to put in place measures regarding the use of Antarctica for peaceful purposes only; the facilitation of scientific research; the facilitation of international cooperation; questions relating to the exercise of jurisdiction in Antarctica; and the preservation and conservation of living resources in Antarctica. The Treaty applies to the area south of 60°S, including all ice shelves and islands. It is, however, affirmed that nothing in the Treaty shall prejudice or in any way affect the rights, or the exercise of the rights, of any State under international law with regard to the high seas within that area. The Treaty is augmented by recommendations adopted at Consultative Meetings, by the Protocol on Environmental Protection to the Antarctic Treaty (Madrid, 1991), and by two separate conventions dealing with the Conservation of Antarctic Seals (London 1972), and the Conservation of Antarctic Marine Living Resources (Canberra 1980). The Convention on the Regulation of Antarctic Mineral Resource Activities (Wellington 1988), negotiated between 1982 and 1988, will not enter into force.

41. The Convention on the Conservation of the Antarctic Marine Living Resources, 1980, provides a framework for the conservation of marine living resources, including measures to control and regulate the harvesting of such resources. It seeks to ensure that harvesting and associated activities are in compliance with basic conservation principles (Article II). It also establishes a Commission for the Conservation of Antarctic Marine Living Resources (Article VII), whose mandate includes the facilitation of research and studies of Antarctic marine living resources and of the marine ecosystem; the monitoring and assessment of such resources; the identification of conservation needs; and the formulation and adoption of conservation measures (Article IX).

42. The 1991 Protocol on Environmental Protection to the Antarctic Treaty, establishes a comprehensive regime for the protection of the Antarctic environment and its dependent and associated ecosystems and designates Antarctica as a natural reserve, devoted to peace and science. The Protocol requires that activities in the Antarctic Treaty area shall be planned and conducted so as to limit adverse impacts on the Antarctic environment and dependent and associated ecosystems (Article 3). Adverse impacts are defined to include detrimental changes in the distribution, abundance or productivity of species or populations of species of fauna and flora; further jeopardy to endangered or threatened species or their populations; and degradation of, or substantial risk to areas of biological or wilderness significance. Annex II to the Protocol establishes a permit system regarding harvesting of Antarctic fauna and flora. Permits are to be issued only for the provision of specimens for scientific study or scientific information and for the provision of specimens to museums, herbaria, zoological and botanical gardens, or other educational or cultural institutions or uses.

^{14/} Preamble to the Antarctic Treaty.

Relationship to access and benefit-sharing

43. The access and benefit-sharing provisions of the Convention do not apply to the Antarctic region, since this territory is beyond the limits of national jurisdiction. However, bioprospecting is becoming an issue in the Antarctic Region. According to a study carried out by the Institute of Advanced Studies of the United Nations University (UNU/IAS), “An increasing amount of scientific research on the flora and fauna of Antarctic is being done with a view to identifying commercially useful genetic and biochemical resources, and this trend is likely to increase. ^{15/}

44. As noted in this study, bioprospecting was first discussed in the Treaty System in 1999 and has since then received regular attention at meetings of the Scientific Committee on Antarctic Research (SCAR), the Committee for Environmental Protection (CEP) and the Antarctic Treaty Consultative Meeting (ATCM).

45. Unregulated commercial research in Antarctica is now creating concern among researchers that patented products may become unavailable for basic research and that the unregulated harvesting of samples may cause ecological damage. ^{16/}

46. Although the Antarctic Treaty System does not directly regulate bioprospecting activities, provisions relevant to the consideration of the issue exist, as demonstrated above, in the Antarctic Treaty, its Protocol on Environmental Protection and the Convention on the Conservation of Antarctic Marine Living Resources (CCAMLR). The Convention on the Regulation of Antarctic Mineral Resources Activities (CRAMRA) may also provide some guidance for developing measures for regulating bioprospecting activities. These provisions are examined in more detail by the UNU/IAS study.

47. It has been suggested by the Scientific Committee on Antarctic Research that the Antarctic Treaty System may need to be revised in order to include the regulation of bioprospecting. It has also been suggested that UNCLOS and the Convention on Biological Diversity should be examined in order to help find solutions to the issue of bioprospecting in the Antarctic.

48. Parties to the Antarctic Treaty System are considering the issue of bioprospecting in the governing body, the Antarctic Treaty Consultative Meeting (ATCM). Biological prospecting in Antarctica was on the agenda of the twenty-seventh ATCM, held in Cape Town, South Africa, from 24 May to 4 June 2004 and the final report of the meeting should be available soon.

8. *Human rights instruments*

General description

49. The Conference of the Parties included in the list of existing international instruments to be examined, the following human rights instruments: the Universal Declaration of Human Rights, the International Covenant on Civil and Political Rights; and the International Covenant on Economic, Social and Cultural Rights. The following provides a general description of each of these instruments and others of potential relevance and highlights potential linkages to access and benefit-sharing as applicable to genetic resources and traditional knowledge. More importantly, these human rights instruments provide a context for the continuing development of standards by the international system. Copies of these human rights instruments and others are available through the website of the Office of the High Commissioner for Human Rights at <http://www.ohchr.org/english/law/index.htm>

50. The Universal Declaration of Human Rights was adopted by the General Assembly of the United Nations on 10 December 1948. As set out in its preamble, the General Assembly proclaimed the Universal Declaration of Human Rights “as a common standard of achievement for all peoples and all

^{15/} Dagmar Lohan and Sam Johnston, “Bioprospecting in Antarctica: Existing Activities, Policies and Emerging Issues for the Treaty System”, United Nations University, Tokyo, p.1.

^{16/} See the article in *Nature*, 11 August 2004, on the outcome of meeting of the Scientific Committee on Antarctic Research.

nations ... to promote respect for these rights and freedoms and by progressive measures, national and international, to secure their universal and effective recognition and observance”.

51. The International Covenant on Civil and Political Rights (ICCPR) was adopted and opened for signature, ratification and accession by General Assembly resolution 2200 A (XXI) of 16 December 1966 and entered into force on 23 March 1976. It details the basic civil and political rights of peoples and individuals. Among the rights of peoples are: the right to self-determination; the right to own, trade, and dispose of their property freely; and not be deprived of their means of subsistence. Among the rights of individuals are: the right to legal recourse when their rights have been violated (even if the violator was acting in an official capacity); the right to life; the right to liberty and freedom of movement; the right to equality before the law; the right to presumption of innocence until proven guilty; the right to appeal a conviction; the right to be recognized as a person before the law; the right to privacy and protection of that privacy by law; freedom of thought, conscience, and religion; freedom of opinion and expression; freedom of assembly and association.

52. The International Covenant on Economic, Social and Cultural Rights (ICESCR) was adopted and opened for signature, ratification and accession by General Assembly resolution 2200 A (XXI) of 16 December 1966 and entered into force on 3 January 1976. Similar to the International Covenant on Civil and Political Rights, articles 1 and 2 (part 1) also focus on the right of self-determination as the right of all peoples and notes that States have an obligation to promote self-determination. It describes the basic economic, social and cultural rights of individuals and nations including the right to: self-determination; equal pay for equal work; equal opportunity for advancement; form trade unions; strike; paid or otherwise compensated maternity leave; free primary education and accessible education at all levels; and copyright, patent, and trademark protection for intellectual property.

Relationship to access and benefit-sharing

53. Whereas there is no direct linkage with access and benefit-sharing, the development and implementation of an access and benefit-sharing regime under the Convention may have a positive or negative impact on the respect for and exercise of the rights embodied in these instruments, particularly as regards the protection of traditional knowledge of indigenous and local communities.

54. The Universal Declaration is underpinned by the principle of non-discrimination (article 7). Given the historic discrimination and social disadvantage that affect indigenous and local communities, non-discrimination (with the exception of positive discrimination measures) should underpin the development of standards established to protect them and/or their property (i.e. traditional knowledge). It could be further inferred that traditional knowledge should be protected to at least the same standards as other forms of intellectual property, whether it is expressed individually or collectively. Furthermore, article 29 (1) of the Declaration states that “everyone has duties to the community in which alone the free and full development of his personality is possible”. This is supportive of the indigenous concept that individual holders of collective knowledge are responsible to the community for the safe keeping, use of and passing on of that knowledge and, therefore, it is relevant to access and benefit-sharing regimes.

55. Article 47 of the International Covenant on Civil and Political Rights states: “Nothing in the present Covenant shall be interpreted as impairing the inherent right of all peoples to enjoy and utilize fully and freely their natural wealth and resources.” This article as well as article 25 of the International Covenant on Civil and Political Rights recognizes one basic principle regarding access to genetic resources, which is the recognition of sovereign rights over natural resources.

56. In addition, the phrase “to enjoy and utilize fully and freely their natural wealth and resources”, would seem to imply that Governments would control and manage their natural resources, which will logically carry with it the establishment of mechanisms in order to avoid misappropriation of natural wealth and resources, regulate access and ensure benefit-sharing arrangements that are fair and equitable.

57. Article 1, paragraph 2, of the International Covenant on Economic, Social and Cultural Rights states:

“All peoples may, for their own ends, freely dispose of their natural wealth and resources without prejudice to any obligations arising out of international economic cooperation, based upon the principle of mutual benefit, and international law. In no case may a people be deprived of its own means of subsistence.”

Should the concept of “natural wealth and resources” and “mutual benefit” and “means of subsistence” include and be applied to access and benefit-sharing regimes, indigenous and local communities should be afforded the right to freely determine the use of their traditional knowledge and genetic resources and that access and benefit-sharing regimes should be built upon this principle. Furthermore, the concepts contained within Article 15 of the Covenant, such as the right of everyone to take part in a cultural life, to enjoy the benefits of scientific progress and its applications and to benefit from the protection of moral and material interests resulting from any scientific, literary or artistic production of which he is the author may also be taken into account in the context of access and benefit-sharing to ensure a balance between the rights of those providing knowledge and/or genetic resources and the rights of the broader community.

58. It is also worth noting that the International Labour Organization Convention No.169 (ILO 169) remains the only international instrument that deals specifically with indigenous and local communities. Its relevance to the construction of access and benefit-sharing regimes is in providing a minimal rights context and in identifying minimal standards for the participation of indigenous and local communities in their own affairs and in its promotion of special measures to ensure the full protection of their rights.

B. Regional agreements

59. The note by the Executive Secretary on use of terms, other approaches and compliance measures (UNEP/CBD/WG-ABS/2/2) prepared for the second meeting of the Working Group on Access and Benefit-sharing, provides an overview of the four regional agreements related to access and benefit-sharing: 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.

60. Out of these four instruments, it should be noted that Andean Pact decision 391 is a legally binding instrument and is more elaborate than the other instruments. Andean Community decisions are binding on the member countries ^{17/} as of the date of their approval by the Commission. The ASEAN and the Central American agreements are both still in draft form. Finally, the African Model Law provides a model for the development of access and benefit-sharing legislation in African countries and also addresses issues such as Farmers’ Rights, plant breeders’ rights and, community rights and responsibilities. The following provides a general overview of how these agreements have addressed the establishment of competent national authorities, prior informed consent, mutually agreed terms including benefit-sharing, intellectual property rights and compliance measures. ^{18/} It should be noted that it is not intended to address the peculiarities of each of these instruments.

61. *Competent national authorities.* Each of the agreements provide for the establishment of a competent national authority by their member States. Their obligations are set out in various degrees of detail. In addition, each of the agreements, with the exception of the African Model Law, provide for the establishment of a regional committee composed of representatives from the national competent authority

^{17/} These include: Bolivia, Colombia, Ecuador, Peru and Venezuela.

^{18/} The text of these measures is included in the database on ABS measures available at: <http://www.biodiv.org/programmes/socio-eco/benefit/measures.aspx>

and, in certain cases, other relevant stakeholders. ^{19/} Their obligations are also set out by each agreement in more or less detail and generally include regional coordination and exchange of information.

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

63. *Mutually agreed terms, including benefit-sharing*. The regional instruments provide for the development of access and benefit-sharing agreements and include a minimum list of terms which are to be covered by the agreement (Article 11 of the draft ASEAN agreement, decision 391, chapter III, article 17, Central American agreement, article 19, African Model Law, article 8). Decision 391 is distinguishable in that it provides for the signature of both an access contract between the competent national authority and the applicant requesting access (chapter III) and for the signing of an ancillary contract between the applicant and the provider of the genetic resources (title IV, article 41). It is also worth noting that both the African Model Law and the ASEAN agreement provide that indigenous and local communities are to be involved in the negotiation of access and benefit-sharing agreements. ^{20/} As set out in these regional instruments, access and benefit-sharing contracts are to include non-monetary benefits and monetary benefits, as appropriate (e.g. decision 391, articles 17 and 35).

64. The transfer of biological or genetic resources to third parties is addressed by decision 391 (article 17), the Central American agreement (article 19) and the African Model Law (article 8). Whereas the Andean decision and the Central American agreement provide for the terms of transfer to a third party to be included in the access contract, the African Model Law provides that the transfer to a third party of biological resources, its derivatives, or traditional knowledge, innovations and practices is subject to the authorization of the competent national authority and of the relevant local community.

65. Decision 391 (article 21) and the Central American agreement (article 23) provide for the establishment of registries by competent national authorities to include information related to access applications and access and benefit-sharing agreements.

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

67. *Intellectual property rights* are covered by all of the regional agreements with the exception of the ASEAN agreement. The draft Central American Agreement (article 26) provides that the presentation of the legal certificate of origin establishing the legality of access is to be requested by relevant intellectual property authorities prior to the registration of products and processes which may involve the use of genetic resources and traditional knowledge. If the certificate of origin is not presented or access laws or the conditions of the access contract are not respected, the delivery of any approval or registration to the applicant shall be prevented.

68. The Andean Pact decision 391, under the section on “Complementary provisions” provides that “Member countries shall not acknowledge rights, including intellectual property rights, over genetic resources, by- products or synthesized products and associated intangible components, that were obtained or developed through an access activity that does not comply with the provisions of this decision.

^{19/} See article 51 of decision 391, article 39 of the draft Central American agreement, article 8 of the draft ASEAN agreement.

^{20/} See article 7 of African Model Law and article 11 of the draft ASEAN agreement for further details.

Furthermore, the Member country affected may request nullification and bring such actions as are appropriate in countries that have conferred rights or granted protective title documents.”^{21/} In addition, “the competent national offices on intellectual property shall require the applicant to give the registration number of the access contract and supply a copy of it as a prerequisite for granting the respective right, when they are certain or there are reasonable indications that the products and processes whose protection is being requested have been obtained or developed on the basis of genetic resources or their by-products which originated in one of the Member Countries”.^{22/} These provisions are reinforced by decision 486 of the Andean Community, 2000, on the common intellectual property regime, which also provides that a patent may be declared null or void if copy of the access contract was not submitted or if the prior informed consent of indigenous and local communities was not obtained, in the case of a product or process based on genetic resources or traditional knowledge (chapter IX, article 75).

69. Finally, the African Model Law does not recognize patents over life forms and biological processes.^{23/}

70. The draft Central American agreement contains a chapter dealing with the protection of traditional knowledge, innovations and practices of indigenous and local communities.

71. *Compliance measures.* The regional instruments generally provide for sanctions in specific circumstances, such as access to genetic resources without authorization or prior informed consent, and the non-respect of the terms of the contract or of the legislation on access and benefit-sharing. Depending on the agreement, sanctions may include the revocation of the authorization to access (article 14 of African Model Law), the termination/nullification of a contract (article 39 of decision 391, article 19 of Central American Agreement), fines and other civil and criminal sanctions.

72. The draft ASEAN agreement provides that disputes between a resource user and a member State shall be settled at the national level in accordance with the provisions of the national access regulation. (article 9)

73. In the draft Central America Agreement, appropriate legal mechanisms to prevent biopiracy of genetic resources, biochemicals and associated traditional knowledge are to be established by member States at the national level to implement administrative, civil and criminal sanctions. (article 27)

1. *Experience with implementation*

74. Experience with respect to the implementation of regional approaches is limited. As noted above, both the Central American and the ASEAN Framework Agreements are still in draft form. With respect to decision 391 of the Andean Community and the African Model Law, the following paragraphs provide some information on their implementation.

75. Case-studies carried out in Pacific Rim countries provide some information with respect to the implementation of decision 391 of the Andean Community. According to the authors of these studies, Andean countries had no access and benefit-sharing policies before decision 391 was adopted in 1996. When adopted, the decision became binding and was automatically integrated into national legislation. Decision 391 did not require the development of any new national law; however, “technical ambiguities, social protest, political concerns, and institutional limitations, among other factors, forced Bolivia, Ecuador, Peru, and recently Colombia to develop national policies to facilitate the implementation of decision 391 into their national context”.^{24/}

^{21/} Second provision under “Complementary provisions”.

^{22/} Third provision under “Complementary provisions”.

^{23/} Article 9(1) of the African Model Law.

^{24/} Carrizosa, Santiago, Stephen B. Brush, Brian D. Wright, and Patrick E. Mc Guire (eds) 2004. *Assessing Biodiversity and Sharing the Benefits: Lessons from Implementation of the Convention on Biological Diversity*. IUCN, Gland, Switzerland and Cambridge, UK, Chapter 1, p. 9.

76. According to an analysis of the African Model Law and its implementation,^{25/} the development and adoption of the African Model Law was critical to the development of access and benefit-sharing legislation in the region. It has been suggested that African countries in the process of developing legislation and adapting the Model Law framework can be generally classified into four categories:

(a) Countries with *sui generis* legislation embodying various components of the Model Law and having internal capacity for their implementation. This group includes Egypt, Namibia, and Zimbabwe;

(b) Countries with draft *sui generis* legislation patterned after the Model Law and pending enactment into law. This group includes, *inter alia*, Ethiopia, Nigeria, South Africa, Uganda and Zambia;

(c) Countries of Francophone West and Central Africa (members of the African Intellectual Property Organisation (OAPI)), which, through revision and ratification of the Bangui Accord, acceded to a UPOV-style *sui generis* system for plant variety protection;

(d) Countries without TRIPs/CBD-compliant legislation that are only now contemplating the possibility of developing a *sui generis* system of protection predicated on the Model Law or other legal instruments. The majority of African countries belong in this category. While most prefer the Model Law, many are under external pressure not to conform to it.”^{26/}

77. According to the same analysis, a number of factors have contributed to the slow response by African countries in developing national legislation, taking into account the Model Law. These include the lack of national capacity, skill, and expertise in legal drafting to transpose the Model Law into national legislation, constraints in implementation capacity, lack of information on the utility of protecting traditional knowledge, and incoherent interpretations of the meaning of the Law among countries.

C. National measures addressing access and benefit-sharing

78. The present section examines access and benefit-sharing measures included in the database established by the Secretariat and highlights lessons learned from country case-studies examining access and benefit-sharing developments in some regions.

79. Measures taken by Governments with users under their jurisdiction to ensure compliance with the prior informed consent of the Contracting Party providing genetic resources and mutually agreed terms on which access was granted are examined in a separate note by the Executive Secretary (UNEP/CBD/WG-ABS/3/5).

1. Database from the Convention on Biological Diversity on access and benefit-sharing measures

80. 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.

81. Although very few Parties forwarded information to the Secretariat on their national measures related to access and benefit-sharing, research was carried out by the Secretariat to identify measures

^{25/} J. A. Epkere, “African Model Law on the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources”, Chapter 19 available in Kent Nnadozie, Robert Lettington, Carl Bruch, Susan Bass, Sarah King (eds), *African Perspectives on Genetic Resources – A Handbook on Laws, Policies and Institutions*, Environmental Law Institute, 2003.

^{26/} Ibid, page 283.

available from official sources, such as the national websites of Governments Parties to the Convention. These measures ^{27/} were included in the database, which, however, may not be comprehensive.

82. As of 20 October 2004, the database included measures adopted in 26 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.

83. In a number of these countries, general laws on environment, sustainable development or biodiversity address access and benefit-sharing in varying degrees of detail and provide for the establishment of guidelines or regulations on access and benefit-sharing. Some of these guidelines or regulations have already been adopted (e.g., Costa Rica, India, Malawi), while others are in draft form (e.g. Australia, Philippines) and others still have not yet been drafted (e.g., Bulgaria, Gambia, Kenya, Peru, Uganda, Venezuela).

84. For the purpose of the following analysis, the countries with national measures included in the database of the Convention on Biological Diversity have been divided into the following three categories:

(a) Countries that refer to access and benefit-sharing in their national biodiversity strategy or their environmental or biodiversity legislation but have not yet regulated access and benefit-sharing in any detail. These measures generally provide for the development of access and benefit-sharing regulations and include some general specifications regarding elements to be addressed by the regulation. Countries in this category include: Argentina, Cameroon, Cuba, Gambia, Kenya, Panama and Uganda.

(b) Countries that have a biodiversity or environmental law with some general provisions on access to genetic resources or biological resources, which may include a provision for the establishment of a regulation on access and benefit-sharing. The countries included in this category are: Bulgaria, Ecuador, Mexico and Nicaragua;

(c) Countries which have addressed access and benefit-sharing in greater detail. ^{28/} Based on the examination of the measures adopted by countries in this category, 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 compliance measures.

85. However, 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 Australia and Brazil, have developed measures both at the national/federal level and at the State level.

2. *Overview of measures at national level*

86. Against this background, the following paragraphs provide an overview of how elements of access and benefit-sharing regimes, such as competent national authorities, prior informed consent, mutually agreed terms including benefit-sharing, intellectual property rights and compliance measures have been addressed by countries. 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.

^{27/} 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.

^{28/} The measures examined were adopted by the following countries: Australia, Bolivia, Brazil, Costa Rica, Guyana, India, Malawi, Philippines, Peru, South Africa, Vanuatu and Venezuela.

87. *Competent national authorities.* These measures each provide for the establishment of one or more competent national authority(ies). 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. A number of these measures also provide indications with respect to the composition and the tasks of the competent national authorities (e.g. India).

88. *Prior informed consent.* In each country, 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 and the procedure leading to approval or refusal. In certain countries, application or collection fees are also requested. ^{29/} The approval or the refusal to grant access is determined by the competent national authority. However, 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. ^{30/} Hence, without the prior informed consent of the relevant stakeholder, the competent national authority cannot grant access to the applicant.

89. In addition, some countries have adopted different requirements for access depending on the type of applicant. For example, the Indian Biological Act provides for different procedures for nationals and foreigners who wish to obtain access to genetic resources. ^{31/} Other countries, such as Costa Rica and the Philippines, have established different requirements depending on whether access is to be granted for commercial or non-commercial purposes. ^{32/} Finally, some countries issue a certificate once prior informed consent has been obtained or for permission to export. ^{33/}

90. *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. Some measures ^{34/} also provide for different types of agreements, depending on whether the genetic resources are being accessed for research or for commercial purposes. The measures generally provide that the agreement is to be approved by the competent national authority. However, some measures provide that the contract is to be negotiated between indigenous and local communities or any relevant stakeholder and the applicant. ^{35/} Most of the measures also provide in more or less detail for a minimum number of clauses to be included in the contract. ^{36/} 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. Measures also generally provide for benefit-sharing with the competent national authority, or with indigenous and local communities or other resource providers, and in most cases for both. ^{37/}

^{29/} For example: Malawi, section D(3), India, Chapter X, 41(3); draft Philippines guidelines on bioprospecting Chapter IV, section 10, section 14; Costa Rica, article 76 of legislation, article 4 of the rules; India, section 41(3).

^{30/} For example, see article 63 of Costa Rica Biodiversity Law, Malawi, section E(8), South Africa Biodiversity Act, article 82.

^{31/} For example, the prior informed consent of the National Biodiversity Authority is requested for foreigners as defined under Chapter II, section 3(2) of the Biological Diversity Act, 2002. Different procedures are established for Indian nationals under Chapter IV of the same act.

^{32/} For example, see article 71 of the Costa Rica legislation and section 14-15 of the Philippines Republic Act 9147.

^{33/} For example, the draft Philippines guidelines on bioprospecting, under section 12.2 (C) and Annex IV, provide for the issuance of a PIC certificate once prior informed consent has been obtained. The regulation of Costa Rica, 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. The Guyana regulation, in article 33, provides that a certificate of export has to be obtained from the competent national authority before exporting any specimen from Guyana.

^{34/} For example, see South Africa National Environmental Management: Biodiversity Act, 2004, articles 83-84.

^{35/} For example, see Vanuatu Act, article 34 (6) (a), and South-Africa Act, article 82 (3) (b).

^{36/} For example, see article 37 of the Bolivian regulation and articles 83-84 of the South African Biodiversity act.

^{37/} Philippines draft guidelines, under section 15, provides for sharing of benefits between the national Government and the resource providers in the case of bioprospecting.

Indications regarding the types of benefits to be shared vary depending on the measures. Some measures appear to focus on non-monetary benefits, such as the involvement of a local institution in the research, collection and the technological development of the products derived from the biological and genetic resources, ^{38/} while others focus on monetary benefits derived from the commercial utilization of the resources accessed, through the sharing of royalties. Some countries ^{39/} also provide for the establishment of funds, in which the benefits not allocated to stakeholders will be kept. Finally, some measures also establish conditions with respect to the transfer of genetic resources to third parties. ^{40/}

91. *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. ^{41/} A number of measures consider intellectual property rights in the context of benefit-sharing through the sharing of royalties. ^{42/} In addition to Andean Pact countries, through decisions 381 and 486, only few of the measures examined ^{43/} include 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. ^{44/}

92. 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 ^{45/} 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. The Indian Biodiversity Act provides 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 India. ^{46/} Other countries, such as Peru ^{47/} and Venezuela, ^{48/} provide for relevant authorities to 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.

93. *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.

^{38/} For example, the Malawi guidelines, section H(1), E(2)(3), and the Venezuela legislation, article 74(4) address non-monetary benefits.

^{39/} For example, India Biological Diversity Act 2002, Chapter V, section 21(3) and Chapter VII, section 27(2) and South Africa National Environmental Management: Biodiversity Act, 2004, article 85.

^{40/} For example, see India, Chapter V, article 20, the Venezuela Biodiversity Law, article 74-3, the South Africa Biodiversity Act, article 84 VII.

^{41/} See measures adopted by Brazil, Costa Rica, Guyana, India, Peru, Philippines, 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.

^{42/} For example, article 5 of the Costa Rica Rules provide for the obligation to pay up to 50% of royalties.

^{43/} 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 and 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 ABS 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.

^{44/} For example Denmark, Egypt and Norway.

^{45/} Article 80 of the Costa Rica Biodiversity Law.

^{46/} See section 6(1) and 19(2) of the Indian Biological Diversity Act, 2002.

^{47/} See article 4 c) of the Peruvian Ley de proteccion al acceso a la diversidad biologica peruana y los conocimientos colectivos de los pueblos indigenas

^{48/} See article 83 of the Venezuela Biodiversity Law.

94. 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. [49/](#)

95. 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, such as the Biodiversity Act of the State of Queensland [50/](#) and the South Africa [51/](#) Biodiversity Act provide for sanctions in the case where a person gives false or misleading documents or information in an application for a collection permit.

96. The sanctions have many similarities from one measure to the other. They range from a written warning, to a fine (in some cases, a scale of fines is included), a seizure of samples, the suspension of the sale of product, the revocation/cancellation of the permission or license of access, the revocation of the agreement, a ban on undertaking prospecting of biological and genetic resources and, finally, imprisonment. Certain provisions also address dispute settlement mechanisms, such as the draft Philippines guidelines. [52/](#)

97. Most of these measures are relatively recent. Therefore, lessons learned or experience gained from their implementation is limited. However, the Philippines provide an interesting case as it was one of the first countries to regulate access and benefit-sharing, with the development and implementation of Executive Order 247 on Access to Genetic Resources, and to have adopted a new legislation to address access and benefit-sharing, the Wildlife Resources Conservation and Protection Act (enacted on 30 July 2001), and developed new draft implementing guidelines on bioprospecting. Provisions of the Executive Order 247, that are clearly contradictory to and irreconcilable with the Wildlife Act, are deemed repealed. [53/](#) One of the main characteristics of the new legislation is that distinct procedures have now been established for genetic resources depending on whether they are to be used for research or for commercial purposes. According to certain authors who have examined the Philippines experience, the following lessons can be drawn: stakeholder participation is essential in developing, enacting and implementing access and benefit-sharing policies, laws, rules and regulations; defining the scope and coverage of a national access and benefit-sharing regulation is a priority concern; the potential impacts on scientific research activities must be carefully considered when designing and implementing national access and benefit-sharing measures; creative approaches to obtaining consent from, and sharing benefits with, local communities, including indigenous peoples, need to be explored and developed; an efficient and effective institutional system should be put in place; and, in regions where countries share genetic resources, regional mechanisms may be required. [54/](#)

[49/](#) In Australia, the Biodiversity Act of the State of Queensland Act, 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 Rules, in article 20, provide that the Technical Office will carry out verification and control duties through inspections on the site where access is granted. In the case of the Philippines, the draft bioprospecting guidelines, under section 26, indicate that the Government encourages the role of civil society in monitoring the implementation of bioprospecting undertaking. It also states, under section 22, that the resource user shall submit an Annual Progress report to the implementing agencies concerned.

[50/](#) See article 52 of the Queensland Biodiversity Act.

[51/](#) See article 93 a) of the South Africa Biodiversity Act.

[52/](#) Section 30 of the draft Philippines Guidelines covers conflict resolution.

[53/](#) For further details see paper by Paz Benavidez entitled “The Challenges in the Implementation of the Philippines ABS Regulations: Monitoring and Enforcement of Bioprospecting Activities in the Philippines” presented at the International Expert Workshop on Access to Genetic Resources and Benefit sharing, held in Cuernavaca, Mexico, from 24 to 27 October 2004.

[54/](#) See « Developing and implementing national measures for genetic resources access regulation and benefit-sharing » by Charles V Barber, Lyle Glowka and Antonio G M La Vina, in « Biodiversity and Traditional Knowledge – Equitable Partnerships in Practice », edited by Sarah Laird, Peoples and Plant Conservation Series, Earthscan, 2002, p. 404 et al.

98. 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, which were not adopted with access and benefit-sharing in mind. These measures have been found to provide useful solutions to address situations of access and benefit-sharing. However, although they generally provide for collection or research permits as conditions for access, they rarely address benefit-sharing.

3. Case-studies

99. Although experience regarding existing access and benefit-sharing regimes is scarce, recent projects carried out in twelve African countries ^{55/} and in Pacific Rim countries ^{56/} have examined developments in countries that are in the process of or have elaborated frameworks for access and benefit-sharing. The following draws from these case-studies and highlights some of the lessons drawn from them. It illustrates the difficulties faced by a number of countries in the development of access and benefit-sharing regimes and their implementation.

100. It is generally recognized that the development of national access and benefit-sharing measures has proven difficult for many countries due to a number of factors: lack of technical expertise, budgetary constraints, weak government structures and political support, local social conflicts, and conflicts over ownership of genetic resources. ^{57/}

101. According to the case-studies carried out in twelve African countries, ^{58/} the current regimes governing access to genetic resources and benefit-sharing in these countries are largely sectoral and patchy. A common approach has been to adapt existing structures and legal frameworks in relevant sectors such as protected areas, forestry and science and technology to address access and benefit-sharing. This approach has led to a lack of coherence and coordination. Access and benefit-sharing policies and regulations, however, seem to be evolving in a number of these countries towards more harmonized centralised structures. Regulatory frameworks developed in Ethiopia, South Africa and Uganda are illustrations of this trend. In the twelve African countries examined, it is interesting to note that agriculture overwhelmingly dominates access and benefit-sharing policies.

102. In the absence of legislation or regulatory measures to address specific circumstances of access and benefit-sharing, contracts for access have been developed to supplement the existing permit and fee structure. In countries, such as Kenya, the Seychelles and South Africa, model or standardized contracts are often used.

103. Authors of these case-studies point to strengths and weaknesses highlighted by the studies. ^{59/} Weaknesses include: inadequate or nonexistent legal frameworks and institutions, lack of capacity, awareness and participation. Inadequate or nonexistent legal frameworks and institutions were stressed in all countries with the exception of Ethiopia. Depending on the country, the factors responsible for this weakness were the absence of coordinated and harmonized approaches to access and benefit-sharing, a

^{55/} For detailed information on the twelve African country case studies, see Kent Nnadozie, Robert Lettington, Carl Bruch, Susan Bass, Sarah King (eds) *African Perspectives on Genetic Resources – A Handbook on Laws, Policies, and Institutions*, Environmental Law Institute, 2003.

^{56/} For detailed information on country case-studies carried out in Pacific Rim countries, see Carrizosa, Santiago, Stephen B. Brush, Brian D. Wright, and Patrick E. Mc Guire (eds) 2004. *Assessing Biodiversity and Sharing the Benefits: Lessons from Implementation of the Convention on Biological Diversity*. IUCN, Gland, Switzerland and Cambridge, UK.

^{57/} Conclusions of International Workshop on “Accessing Genetic Resources and Sharing the Benefits: Lessons from Implementing the Convention on Biological Diversity”, held in Davis, California, from 29 to 31 October 2003.

^{58/} For further discussion on the access and benefit-sharing approaches adopted in Cameroon, Egypt, Ethiopia, Ivory Coast, Kenya, Madagascar, Nigeria, Senegal, Seychelles, South Africa, Uganda, and Zambia see publication referred to in footnote 55.

^{59/} See publication referred to in footnote 55, pages 72-73.

failure to optimize the use of the capacity and resources of national institutions, limited enforcement capacity and ineffective sanctions, and absence of coordination with broader national policies. Lack of capacity was raised in all countries examined by the project. While the most common lack of capacity is administrative, legal and policy capacity, in certain countries the lack of capacity is isolated to particular skills such as taxonomy or the ability to conduct independent research on genetic resources. With respect to awareness and participation, the study highlights the need to increase the awareness and participation of rural communities as the custodians of genetic resources, in order to effectively implement access and benefit-sharing strategies.

104. Strengths relating to genetic resources in these countries include a large diversity of species and capacity through a network of research institutions, particularly in the agricultural sector. It is suggested that non-monetary benefits such as technology transfer, training and infrastructure, could further assist Africa in developing value-added products based on their genetic resources.

105. In order to address the challenges faced by neighbouring countries that share genetic resources, it has been suggested that national approaches to access and benefit-sharing may be inadequate and regional mechanisms may be required in order to facilitate enforcement of access and benefit-sharing requirements, cooperation at a technical level and exchange of information. In the absence of a regional framework, the differences in access and benefit-sharing requirements among neighbouring countries could disadvantage certain countries over others. For instance, users of genetic resources will likely be attracted to countries with a system which is considered more flexible or easier to deal with. ^{60/}

106. According to case-studies carried out in Pacific Rim countries, of the 41 countries that are party to the Convention on Biological Diversity, only nine (22 per cent) have developed a national access and benefit-sharing law or policy, 26 (63 per cent) are in the process of developing these laws and policies, and six (15 per cent) are not engaged in any process leading to the development of such frameworks. ^{61/}

107. According to the authors, part of the complexity and challenges in addressing access and benefit-sharing lies in the diverse social, economic, ethical and political implications of access and benefit-sharing policies and the consequent need to involve a wide variety of stakeholders, such as agricultural research centers, environmental non-governmental organizations, indigenous and farmer communities, government agencies, biotechnology firms and universities. Because of the wide variety of stakeholders involved, there is a danger of advantaging some over others. ^{62/}

108. The conclusions reached by the authors of the Pacific Rim country case-studies include the following: ^{63/}

(a) The broad scope of access and benefit-sharing policies has impaired their effective and efficient implementation. Most of them cover genetic (DNA and RNA), biological (specimens or parts of specimens) and biochemical resources (molecules, combination of molecules, and extracts) found in both *in situ* and *ex situ* conditions;

(b) Access to pre or post-Convention on Biological Diversity *ex situ* collections is not clearly defined by the access and benefit-sharing policies developed in the Pacific Rim countries examined;

(c) Most access and benefit-sharing policies promote the conservation of biological diversity, but in practice as demonstrated by the Costa Rican experience, bioprospecting has not been a significant source of funding for biodiversity conservation compared to other sources of funding;

^{60/} For further discussion on the benefits of regional approaches to access and benefit-sharing, see publication referred to in footnote 55, p. 79-80 and “Developing and implementing national measures for genetic resources access regulation and benefit-sharing” by Charles V Barber, Lyle Glowka and Antonio G M La Viña in “Biodiversity and Traditional Knowledge – Equitable Partnerships in Practice”, edited by Sarah Laird, People and Plants Conservation Series, Earthscan, 2002.

^{61/} See publication in footnote 56, Chapter 1, page 1.

^{62/} See publication in footnote 56, p. 295.

^{63/} For further details, see publication in footnote 56, Chapter 13, pages 296-297.

(d) Monitoring of bioprospecting activities has proven to be a difficult, expensive and resource consuming task and no Pacific Rim country has established a monitoring system;

(e) The issue of State intervention in the negotiation of benefit-sharing agreements has proven to be a complex and controversial question, some advocating the need for the direct involvement of the State while others are rather in favour of leaving the negotiation to the direct providers of genetic resources and associated traditional knowledge in order to avoid high transaction costs and burdensome bureaucratic procedures;

(f) The complex nature of access and benefit-sharing policies make it difficult to anticipate problems which may arise from their implementation and explain the need for their improvement over time.

109. On the basis of these conclusions, recommendations put forward to assist countries in developing more effective access and benefit-sharing policies include; ^{64/}

(a) Clear ownership rights over genetic, biological and biochemical resources as a condition to the development of access and benefit-sharing policies;

(b) Clearly established competent national authorities to process access applications;

(c) The type of activities that constitute utilization of genetic resources, biological and biochemical resources and are to be regulated by ABS policies should be clearly established to avoid confusion;

(d) Differentiated access procedures for low-tech and small commercial users may be worth considering. Although some access and benefit-sharing policies have differentiated between access for commercial and non-commercial purposes, no distinction has been established depending on the potential users of genetic resources (e.g. biotechnology, pharmaceutical, seed, agrochemical, ornamental, botanical medicine, the food industry);

(e) Access procedures for resources available in *ex situ* conditions deserve clarification;

(f) Prior informed consent procedures are to be clearly delineated in order to avoid time consuming and costly procedures and should be simplified for non-commercial users;

(g) With respect to benefit-sharing standards, rather than applying minimum standards, it is suggested that a range of standards may be more appropriate in order to adapt to the variety of bioprospecting activities;

(h) Regional access and benefit-sharing policies could clarify access rules for bioprospectors and in countries sharing the same genetic resources avoid favouring one country over another on the basis of their access procedures.

110. Finally, with respect to the implementation of access and benefit-sharing laws and policies, according to the authors, five following lessons can be drawn from the review of Pacific Rim countries: ^{65/}

(a) Agreements are most likely to succeed when the number of parties to the agreement is kept to a minimum;

(b) The determination of a competent authority or local focal point in granting access is critical, and ambiguity in this respect can create problems;

(c) The determination of clear access procedures and particularly prior informed consent requirements are essential to expedite the approval of applications and the negotiation of benefits;

^{64/} For further details regarding recommendations, see publication in footnote 56, pages 297-298.

^{65/} For further details see publication referred to in footnote 56, Chapter 3, pages 73-74.

(d) Governments need to build local capacity to facilitate the effective and efficient implementation of access and benefit-sharing laws and policies;

(e) Creating a forum for balanced discussion of controversial access and benefit-sharing concepts and implications may facilitate the application process and accomplishment of bioprospecting projects.

III. ISSUES FOR CONSIDERATION BASED ON THE REVIEW OF EXISTING NATIONAL, REGIONAL AND INTERNATIONAL INSTRUMENTS

A. The role of international instruments

111. In essence, the relationship of existing international instruments with access and benefit-sharing can be synthesized as follows:

(a) Apart from the Convention on Biological Diversity, the FAO International Treaty on Plant Genetic Resources for Food and Agriculture is the only international instrument to directly address access and benefit-sharing by establishing a Multilateral System of Facilitated Access and Benefit-sharing for a list of crops contained in annex 1 to the Treaty;

(b) Although instruments, such as some WIPO treaties, the WTO TRIPs agreement and the UPOV Convention, do not address access and benefit-sharing directly, they are of relevance to specific aspects of access and benefit-sharing such as intellectual property issues related to access and benefit-sharing;

(c) The United Nations Conventions on the Law of the Sea and the Antarctic Treaty are relevant international instruments when examining access to genetic resources beyond areas of national jurisdiction;

(d) Other instruments not directly related to access and benefit-sharing, such as CITES, may provide useful lessons in the elaboration of the international regime. For example, useful lessons could be drawn from the international permit system established by CITES to regulate international trade in endangered species;

(e) Finally, human rights instruments provide broad political, economic and social rights for indigenous and local communities and establish an overarching framework under which the preservation, maintenance and protection of traditional knowledge, innovations and practices associated to biological resources should be considered.

B. Challenges at the national level

112. As demonstrated above, on the basis of the information available, it appears that a majority of Parties to the Convention on Biological Diversity have yet to adopt specific access and benefit-sharing measures. Some countries have adapted existing frameworks while others have either adopted or are in the process of adopting measures. In a number of these countries the national systems are therefore incomplete.

113. In the absence of specific access and benefit-sharing provisions, the scope of resources and activities regulated by law are often unclear. Certain legislations adopted for other purposes, prior to the Convention on Biological Diversity may apply to access to genetic resources. Consequently the body of law within a country may be incomplete, difficult to identify and national competent authorities may vary depending on the location of the resource and property rights within a specific country. ^{66/}

114. In those countries that have adopted access and benefit-sharing measures, the approaches in terms of the types of measures adopted, the actual procedures set up, including the sequence of procedures to follow, and the institutional frameworks established are diverse.

^{66/} Kerry ten Kate & Sarah A Laird, "The Commercial Use of Biodiversity – Access to Genetic Resources and Benefit-sharing", Earthscan, 1999.

115. According to some experts, the lack of clear national access regimes and the lack of harmonization between countries which have developed access and benefit-sharing regimes raises serious concerns among users. They find it difficult to comply with legal requirements in different provider countries, because such requirements differ from one country to the other.

116. With respect to compliance measures, it is worth noting that few countries have set up monitoring and verification systems to ensure that access and benefit-sharing arrangements are being respected, such as inspections or reporting systems. While sanctions or penalties are generally established to address situations of infraction or breach of contract, it is not clear how these in practice will be applied once the genetic resources have left the country.

117. Finally, the lack of experience with implementation makes it difficult to draw conclusions at this stage. It is generally recognized that the development of national measures has proven difficult for many countries due to a number of factors: lack of technical expertise, budgetary constraints, weak government structures, and political support, local social conflict, conflict over ownership of genetic resources. ^{67/}

118. Challenges faced by countries are often due to a lack of capacity in various areas, ^{68/} including in negotiations at the international and bilateral levels, in the formulation and implementation of national access and benefit-sharing policies and legislations. Also due to the lack of scientific and technical capacity, a number of countries are limited to providing raw materials. Strengthened capacity could hence assist in adding value to genetic resources in the provider country. The lack of awareness to access and benefit-sharing issues among national stakeholders, such as local communities, has also been an obstacle.

C. The value of regional approaches

119. As suggested above, regional approaches to access and benefit-sharing may provide a useful response to some of the current challenges, such as the issue of transboundary genetic resources. Regional approaches would facilitate both cooperation among countries at the technical level and the exchange of information. In addition, the harmonization of requirements for access and benefit-sharing at the regional level would have the benefit of creating similar conditions for access and benefit-sharing in countries across the region. This would prevent countries within the region from competing with neighbouring countries to attract foreign investments on prejudicial terms. It would also provide users with greater predictability through streamlined processes for obtaining access to genetic resources. Finally, regional institutions could play an important role in enabling countries with no specific expertise at the national level to benefit from expertise in the region.

D. The role of intermediaries

120. According to a recent publication, “Almost without exception, every biodiversity-prospecting collection effort undertaken on behalf of companies is done through intermediaries”. ^{69/} A number of guidelines, codes of conduct and codes of ethics have been developed by associations of botanic gardens, microbial collections and professionals, to provide guidance to their constituents in implementing the objectives of the Convention on Biological Diversity and more specifically its access and benefit-sharing provisions. However, taking into account the role played by these intermediaries in access and benefit-sharing arrangements, consideration may need to be given to the need for Governments to regulate these activities.

^{67/} See footnote 57.

^{68/} See reference of publication in footnote 55, p.81.

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

121. Although in most cases intermediaries are research institutions, botanic gardens and universities with expertise in collection techniques, taxonomy and other relevant fields, firms specialized in providing genetic resources to the private sector have also appeared in recent years. These intermediary institutions provide a valuable service and could possibly contribute to ensuring that access and benefit-sharing is carried out under terms beneficial to both providers and end-users of genetic resources, in accordance with the Convention. Therefore, it has been suggested that the importance of such intermediaries may need to be considered by Governments in the development of their access and benefit-sharing regimes.^{70/} Awareness-raising efforts with respect to access and benefit-sharing requirements could also be targeted towards intermediaries with a view to ensuring that their actions are in compliance with access and benefit-sharing requirements.

^{70/} For further discussion see the publication referred to in footnote 69 above.