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## ASSESSMENT OF USER AND PROVIDER EXPERIENCE, IDENTIFICATION OF APPROACHES TO INVOLVEMENT OF STAKEHOLDERS, AND COMPLEMENTARY OPTIONS

*Note by the Executive Secretary*

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## INTRODUCTION

1. The purpose of the present note is to assist the Panel of Experts on Access and Benefit-Sharing in its consideration of the substantive items of its provisional agenda (UNEP/CBD/EP-ABS/2/1), namely:

- (a) User and provider experience in access and benefit-sharing arrangements;
- (b) Approaches for the involvement of stakeholders in access and benefit-sharing arrangements;
- (c) Study of complementary options to address access and benefit-sharing in the framework of the Convention on Biological Diversity.

2. Section I outlines the mandate of the Panel of Experts, considers the broader context of the discussion of the issues by the Conference of the Parties and sets out the role of the Panel in preparing for the meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing — a body established by the Conference of the Parties at its fifth meeting — which will be held in October 2001 in Bonn.

3. Section II provides illustrations of user and provider experience on access and benefit-sharing and builds on the outcome of the first meeting of the Panel of Experts with a view to identifying elements which may serve as a basis for the development of international guidelines on access and benefit sharing. It also examines the involvement of stakeholders in access and benefit-sharing, by providing illustrations of stakeholder involvement, identifying some of their particular interests and/or concerns, and suggesting possible approaches for their involvement.

4. Section III outlines complementary options by providing an overview of approaches that may assist in the development of equitable access and benefit-sharing systems. Section IV provides an account of recent developments related to access and benefit-sharing, in other international organizations such as the Food and Agriculture Organization of the United Nations (FAO), the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO). Finally, the concluding section contains recommendations for the consideration of the Panel of Experts.

## I. BACKGROUND

5. The Panel of Experts on Access and Benefit-Sharing was established pursuant to decision IV/8, paragraph 3, in which the Conference of the Parties decided:

“To establish a regionally balanced panel of experts appointed by Governments, composed of representatives from the private and public sectors, as well as representatives of indigenous and local communities operating in accordance with decisions II/15, III/11 and III/15, under the Conference of the Parties... The mandate of this panel would be to draw upon all relevant sources, including legislative, policy and administrative measures, best practices and case-studies on access to genetic resources and benefit-sharing arising from the use of those genetic resources, including the whole range of biotechnology, in the development of a common understanding of basic concepts and to explore all options for access and benefit-sharing on mutually agreed terms including guiding principles, guidelines, and codes of best practices for access and benefit-sharing arrangements.”

6. During their first meeting, experts addressed options for access and benefit-sharing on mutually agreed terms and reached broad conclusions on: prior informed consent, mutually agreed terms, information needs and capacity building. The Panel, however, was not able to reach conclusions about the role of intellectual property rights in the implementation of access and benefit-sharing arrangements.

7. The second meeting of the Panel of Experts on Access and Benefit-sharing is being convened pursuant to decision V/26 A of the Conference of the Parties, which considered the report of the first meeting of the Panel. In paragraph 10 of that decision, the Conference of the Parties decided:

“[T]o reconvene the Panel of Experts on Access and Benefit-sharing with a concrete mandate and agenda. The Panel will conduct further work on outstanding issues from its first meeting, especially:

(a) Assessment of user and provider experience in access to genetic resources and benefit-sharing and study of complementary options;

(b) Identification of approaches to involvement of stakeholders in access to genetic resources and benefit-sharing processes;

and will include additional expertise. The Panel will submit its report to the Ad Hoc Working Group on Access and Benefit-Sharing referred to in paragraph 11 [of the decision];”

8. One of the outstanding issues from the first meeting of the Panel of Experts is that of intellectual property rights. In decision V/26 A, paragraph 15, the Conference of the Parties noted that the Panel of Experts was not able to come to any conclusions about the role of intellectual property rights in the implementation of access and benefit-sharing arrangements, and that the Panel developed a list of specific issues that require further study (UNEP/CBD/COP/5/8). The Conference of the Parties invited Parties and relevant organizations to submit to the Executive Secretary information on these issues by 31 December 2000. The COP further requested the Executive Secretary, on the basis of these submissions and other relevant material, to make available for the second meeting of the Panel *or* the first meeting of the Ad Hoc Open-ended Working Group, a report on these specific issues. The Executive Secretary had received no submissions from Parties and relevant international organizations at the time the present document was being finalized.

9. The conclusions of the Panel will be considered by the Open-ended Ad Hoc Working Group on Access and Benefit Sharing established by the Conference of the Parties at its fifth meeting. The mandate of the Working Group, as set out in decision V/26 A, paragraph 11, is to:

“[T]o develop guidelines and other approaches for submission to the Conference of the Parties and to assist Parties and stakeholders in addressing the following elements as relevant to access to genetic resources and benefit-sharing, inter alia: terms for prior informed consent and mutually agreed terms; roles, responsibilities and participation of stakeholders; relevant aspects relating to *in situ* and *ex situ* conservation and sustainable use; mechanisms for benefit-sharing, for example through technology transfer and joint research and development; and means to ensure the respect, preservation and maintenance of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity, taking into account work by the World Intellectual Property Organization on intellectual property rights issues.”

10. Against this background, the Panel of Experts may wish to identify elements for the development of international guidelines and other approaches for access and benefit sharing, which would provide a basis for the work of the Ad Hoc Open-ended Working Group.

## II. USER AND PROVIDER EXPERIENCE IN ACCESS TO GENETIC RESOURCES AND BENEFIT-SHARING, AND APPROACHES TO STAKEHOLDER INVOLVEMENT

11. At its first meeting, the Panel strongly endorsed the importance of preparing national strategies for access and benefit-sharing as part of national biodiversity strategies as a first step, prior to developing legislative, policy or administrative measures for access and benefit-sharing, in conformity with the needs of countries.

12. Access legislation is only as good as the process through which it is developed. It should allow stakeholders in the field of genetic resources to articulate their concerns and have them taken into consideration, to define the objectives of the legislation, and to develop capacity through the planning process. The national or regional planning process can either be built into an overall biological diversity strategy in accordance with Article 6(a) of the Convention or be established as a stand-alone process for access and benefit-sharing in relation to genetic resources.

13. Access legislation, administrative and policy measures have been central elements in user and provider experience. Although experience shows that a number of different approaches have been taken by countries either sub-nationally, nationally or regionally to regulate access and benefit-sharing, the first meeting of the Panel identified a number of common elements covered in access and benefit-sharing regimes, including definitions, scope and prior informed consent. User and provider experience is therefore illustrated on the basis of these common elements. Lessons learned with respect to these different elements during the first meeting of the Panel are also highlighted.

### *A. User and provider experience in access to genetic resources and benefit-sharing*

#### *1. Access legislative, administrative and policy measures*

14. The Executive Secretary has reported on measures taken by Parties and other stakeholders for access and benefit-sharing at previous meetings of the Conference of the Parties (see documents UNEP/CBD/COP/2/13, UNEP/CBD/COP/3/20, UNEP/CBD/COP/4/21, 22 and 23, UNEP/CBD/ISOC/3).

15. Policy measures, including legislation addressing access to genetic resources and the equitable sharing of benefits either have been adopted or are in the process of being developed in over 40 countries. <sup>1/</sup>

16. Based on an analysis of existing and draft legislation on access, the following typology for the classification of legislative frameworks has been suggested. <sup>2/</sup> It illustrates the diversity of approaches taken to address access and benefit-sharing and the difficulty in drawing general conclusions:

(a) Access provisions contained in general/framework environmental or sustainable development laws: The Gambia (1995), Malawi (1996), Republic of Korea (1991), Cameroun (1996), Fiji (1996), Uganda (1995);

(b) Access provisions in nature conservation or biodiversity laws: Costa Rica (Law No. 7788), Ecuador (1996), Peru (1997);

(c) Access provisions incorporated into existing laws through amendment: Western Australia (1993), Cameroon (1994);

(d) Specific access and benefit-sharing laws: Philippines (1995);

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<sup>1/</sup> Kerry ten Kate and Sarah A. Laird, "Biodiversity and business: coming to terms with the grand bargain", International Affairs 76, I (2000) 241-264.

<sup>2/</sup> Glowka, Lyle, "A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources", IUCN Environmental Law Centre, 1998.

(e) Regional legal frameworks for access and benefit sharing: decision 391 adopted in 1996 by the Andean Pact countries (Bolivia, Colombia, Ecuador, Peru, Venezuela) on access to genetic resources. Bolivia, Ecuador and Peru have promulgated the necessary regulations to implement decision 391. In March 1998, the Organization of African Unity adopted a Declaration and a Draft Model Law for the recognition and protection of the rights of local communities, farmers and breeders, and for the regulation of access to biological resources. Finally, the Association of South East Asian Nations (ASEAN) has developed a draft Framework Agreement on Access to Genetic and Biological Resources. <sup>3/</sup>

17. It was recognized during the first meeting of the Panel that such legislation should be clear and simple, to allow flexibility, transparency and reduce transaction costs, and will need to be tailored to the circumstances of individual countries. The development of international guidelines or principles for such measures could provide assurance to provider countries that their resources are used in accordance with the terms of the Convention.

18. It was also stressed that Parties should ensure that national legislation on access and benefit-sharing is consistent with existing international obligations, and does not restrict or undermine the position of Parties in ongoing international negotiations, including adherence to future agreements such as the International Undertaking on Genetic Resources for Food and Agriculture being negotiated under the auspices of the FAO (see section IV below).

(a) *Use of terms*

19. The Panel noted that a number of definitions are found in Article 2 of the Convention and that, in order to promote common understanding of these terms, it would be advisable for drafters of access legislation to adopt those terms as they are found in the Convention. Experience shows that such terms (e.g. biological resources, genetic resources) are generally used in national or regional systems.

20. However, those terms not defined in the Convention need to be defined in access legislation for the purposes of clarity. Some of the most important ones include: access, competent national authority, mutually agreed terms, benefit sharing, and prior informed consent.

(b) *Scope*

21. Experience has shown that the scope of national legislation is generally determined in the following terms:

- (a) Categories of genetic resources (e.g. plant, animal, microbial);
- (b) Geographical area (marine or terrestrial);
- (c) Legal status (public or private land);
- (d) Inclusion or not of *ex situ* collections (whether botanic gardens, culture collections and gene banks are covered by the convention);
- (e) Treatment of derivatives;
- (f) Treatment of knowledge, innovations and practices of indigenous and local communities.

(c) *Prior informed consent*

22. The Panel of Experts during its first meeting considered the following points as key elements of prior informed consent.

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<sup>3/</sup> At its tenth meeting, held in June 2000, the ASEAN Working Group on Nature Conservation and Biodiversity (AWGNCB) set the aim to finalize the Agreement at its next meeting, in 2001.

*Timing*

23. Prior informed consent must be sought adequately in advance to be meaningful both for those seeking and for those granting access (and to allow for adequate consideration of the information provided). A regular, predetermined and clearly understood deadline is critical.

*Specification of use*

24. Prior informed consent should be based on the specific uses for which consent has been granted. While prior informed consent may initially be granted for one set of uses, any intended change of use may require a new application for prior informed consent. Permitted uses should be clearly stipulated and further prior informed consent for changes or unforeseen uses should be required; alternatively, mutually agreed terms in prior informed consent should cover a broad enough range of circumstances to cover any possible future uses.

*Levels of requirement: national/subnational*

25. Prior informed consent may be required from different levels of government. It may be required by the government at the federal, state, departmental or regional level. It may also be required from agencies or organizations with whom this authority is shared or has been delegated. In federal countries, the federal/state relationship may influence the process. For example, in Malaysia, the State of Sarawak, through the Sarawak Biodiversity Council, established in February 1998, is responsible for regulating access to, collection of, study, research, experiment, protection, utilization and export of the state's biological resources. A "research permit system" has been set up to ensure the conservation and sustainable utilization of the state resources, and the fair and equitable sharing of benefits among stakeholders. <sup>4/</sup>

*Prior informed consent of indigenous and local communities*

26. Requirements to consult indigenous and local communities prior to access, and the obligation to seek prior informed consent for collection activities, have demonstrated the need for the identification and recognition of rights over traditional knowledge, innovations and practices.

27. As recognized by the Panel at its first meeting, experiences in the Philippines, Costa Rica and the Andean Community have clearly demonstrated that access legislation should recognize the rights of indigenous and local communities to decide on access to resources on their territories or lands, as well as to their knowledge, innovations and practices. Increasingly, countries that have adopted access legislation are in the process of developing *sui generis* legislation to define rights of local and indigenous communities over their knowledge, innovations and practices. Elements of *sui generis* legislation were provided for information in annex VI of the report of the first meeting of the Panel of Experts (UNEP/CBD/COP/5/8).

*(d) Monitoring and enforcement*

28. Access and benefit-sharing regimes generally contain provisions for monitoring and enforcement. However, since these systems are relatively recent, there is little experience to date with respect to their actual implementation.

29. Decision 391 adopted by Andean Pact countries provides for penalties in case of infractions such as unauthorized access activities. The competent national authority may apply administrative sanctions based on its internal statutes.

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<sup>4/</sup> Paper presented by Malaysia at the UNCTAD Expert Meeting on Systems and National Experiences for Protecting Traditional Knowledge, Innovations and Practices, held in Geneva, from 30 October to 1 November 2000.

30. In order to ensure that access legislation is properly implemented at the national level, appropriate measures should be considered to ensure the enforcement of the legislation, such as control at the borders. Controls may involve the need to develop national capacities through i.e. training of customs officials. The issue of capacity-building is further considered under section III below.

(e) *National authority*

31. At its fifth meeting, the Conference of the Parties requested Governments to designate national focal points and one or more competent national authorities, as appropriate. The national focal points or competent national authorities should be able to indicate to applicants for access from whom prior informed consent is required. Competent national authorities, where countries choose to establish them, should have the legal power to grant prior informed consent and to develop national procedures for access and benefit-sharing for different types, sources and uses of genetic resources.

32. As of 10 December 2000, the Executive Secretary had received nominations for national focal points or competent national authorities from only 13 countries. These nominations are accessible through the clearing house mechanism in two databases, listing respectively national focal points and competent national authorities nominated by Governments.

33. Their role has included the following:

- (a) Advising on the requirements for access on mutually agreed terms;
- (b) Ensuring mutually agreed terms (by participating in the negotiating process or endorsing agreements reached by institutions according to national policy);
- (c) Providing legal certainty and lowering transaction costs;
- (d) Providing information.

*2. Access and benefit-sharing arrangements*

34. While legislative, administrative or policy frameworks have been recognized as essential to ensure that access and benefit-sharing arrangements serve national policy goals and assist Parties in implementing the objectives of the Convention, contractual arrangements are presently the main mechanism for concluding access agreements and implementing benefit-sharing.

35. During the first meeting of the Panel of Experts, consensus was reached on a number of elements that should be taken into consideration. Instruments developed to assist in the elaboration of fair and equitable contractual arrangements, such as guidelines or model agreements for example, could take these elements into account to ensure their fairness and equity.

36. The following sub-section highlights the elements identified by experts during the first meeting of the Panel.

(a) *Mutually agreed terms and contractual approaches*

37. Although it was deemed premature to develop principles for contractual arrangements in view of the enormous differences in circumstances of access and benefit-sharing cases and the evolving legal framework, it was agreed that a common understanding had emerged on a number of aspects of contractual arrangements and mutually agreed terms which could provide the basis for guidelines for such terms and arrangements, such as the following:

- (a) Legal certainty and clarity facilitate access to and use of genetic resources and contribute to mutually agreed terms in line with the aims of the Convention. In order to achieve this, Governments



may define roles, ownership and authority to determine access, taking due account of community interests, tenure and other property rights;

(b) Transaction costs have a significant impact on actual use of genetic resources. High transaction costs diminish value by reducing the interest of users and the net value of providers. In order to decrease transaction costs, measures could be taken for:

- (i) Establishment and the promotion of awareness of Governments' requirements for contractual arrangements;
- (ii) Ensuring awareness of existing mechanisms;
- (iii) Umbrella arrangements, under which repeat access under expedited arrangements can be made;
- (iv) Standardized material transfer agreements, which should prove valuable;

(c) Mutually agreed terms should also include provisions on user obligations, such as those derived from Article 15, paragraph 7, Article 16, paragraph 2, and Article 19, paragraph 2, of the Convention;

(d) Different resources and uses require different contractual arrangements. Therefore, to the extent possible, commercial arrangements should be anticipated at the outset. If this is not possible, arrangements should be made to accommodate changes through key steps;

(e) Benefits are often generated from the commercialization of derivatives that use genetic resources as a source of innovation, such as synthesized products. In these instances, for fair and equitable benefit-sharing, it is important that the scope of contracts include the full range of biotechnology applications in addition to biological resources accessed;

(f) In order to reflect the increasing role of intermediaries in contractual arrangements and access-permitting mechanisms, flexible and simple approach to protect the interests of all parties should be elaborated in such a way that relevant rights and responsibilities survive the duration of the contract, and are transferred to the third parties, as appropriate;

(g) Parties should be aware of relevant agreements that may pre-date an agreement under development.

*(b) Benefit-sharing options and mechanisms*

38. At its first meeting, the Panel recognized that, depending on the use made of genetic resources, benefits arising from the utilization of genetic resources can be either monetary or non-monetary. A number of examples were put forward of these two types of benefits (UNEP/CBD/COP/5/8, paras. 74-76).

39. Case-studies show that financial compensation may include up-front payments and medium term benefit-sharing as progress is made on research. Equity, profit sharing and joint venture opportunities may also be offered by companies. However, it has been suggested that royalties alone should not be relied upon as they only occur if and when a drug is marketed. <sup>5/</sup>

40. Other types of non-monetary benefits often overlooked in benefit-sharing discussions were also put forward by the Panel of Experts, such as:

- (a) Biological inventories and taxonomic studies;

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<sup>5/</sup> K. Moran "Bioprospecting: lessons from benefit-sharing experiences", International Journal of Biotechnology, Vol.2, Nos. 1/2/3, 2000.

(b) Contributions to the local economy through “value-added” activities such as the cultivation of a species that is needed in large quantities for natural-products research, development and production as a commercial commodity;

(c) Public-health benefits for source countries, in cases where access and benefit-sharing agreement encompass a commitment by a firm seeking genetic resources to invest in or support research in locally important diseases for which there is relatively little private sector investment. For example, in the context of a benefit-sharing arrangement in Nigeria between Shaman Pharmaceuticals and Nigerian scientific institutions, social benefits included the development of low-cost phytomedicines and conserving the primary source of health care in the country. Participation of nationals in research on tropical diseases through technology transfer, training, and joint research publications contributed to building the technical capacity of nationals during the discovery process; <sup>6/</sup>

(d) Institutional and personal relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities;

(e) Human and material resources to strengthen the capacities of personnel responsible for the administration and enforcement of access regulations.

41. During its first meeting, the Panel highlighted a number of points with respect to benefit-sharing options and mechanisms from which elements for guidelines or other approaches could be drawn:

(a) It was recognized that identifying and rewarding the beneficiaries in a particular access and benefit-sharing arrangement are crucial elements in implementing fair and equitable benefit-sharing;

(b) With respect to indigenous and local communities, the Panel recognized that fair and equitable benefit-sharing strategies could focus on non-monetary benefits such as improving local food security, supporting continued vitality of traditional agricultural practices, soil conservation and integrated pest management inputs. Arrangements should not restrict or interfere with existing traditional ecological and technological knowledge systems and contemporary innovations for exchange of genetic resources and benefit-sharing employed by indigenous and local communities;

(c) Recognizing that benefits, beneficiaries and the specific conditions of different countries and communities vary widely and may involve a number collaborating parties, the Panel felt that parties to access and benefit-sharing agreements must be allowed flexibility to negotiate fair and equitable benefit-sharing arrangements;

(d) With respect to benefit-sharing methods, trust funds are considered to be one method of using monetary benefits while avoiding the problems associated with direct cash payments to individuals or communities, provided that their activities are approved by the host country, so that they are not considered as a threat by the Government. A trust fund is nevertheless an independent authority operating autonomously. The legal status of the fund depends on the laws of the host country where the fund is established. If the fund is able to obtain benefits normally associated with non-profit and charitable entities, such as exemption from taxation, it may also be able to attract other sources of funds; <sup>7/</sup>

(e) Joint ventures are innovative approaches to sharing benefits, involving the development of commercial products and the equally sharing in their ownership and benefits, and deserve further study and development.

(c) *User and provider experience relating to benefit-sharing arrangements*

42. In attempting to analyse user and provider experience, the benefit-sharing experience of different industry sectors provides the opportunity to identify their respective characteristics: <sup>8/</sup>

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<sup>6/</sup> Ibid.

<sup>7/</sup> Ibid.

<sup>8/</sup> Kerry ten Kate and Sarah A. Laird, *Op. cit.*

(a) *The pharmaceutical sector* is the largest industry sector using genetic resources in terms of market, research budgets and profit margins. With respect to the sharing of benefits, the situation has evolved over the past decade, and it has now become usual for pharmaceutical companies to pay royalties on net sales. A number of factors, reflected by specific clauses in supply contracts, generally have an impact on the magnitude of the royalties. These factors include:

- (i) The current market rate for royalties;
- (ii) The likely market share of a given product;
- (iii) The relative contribution of the partners to the discovery and its development;
- (iv) The degree of derivation of the final product from the genetic resource supplied;
- (v) The provision of ethnobotanical data with the sample;

Benefit-sharing arrangements are often composed of a package of monetary and non-monetary measures delivered across time. With the increasing capacity of source countries to carry out quality research in a cost-effective manner, companies have become more open to collaborations with provider-country institutions;

(b) In the area of *botanical medicines, personal care products and cosmetics*, benefit-sharing has essentially been carried out through the supply of raw materials by provider countries for the manufacture of products. In certain cases, these benefit-sharing arrangements have taken place through partnerships that have included technology transfer and capacity building. Developments in scientific and technological capacity for the study and testing of natural products have encouraged the demand for access to new species. Closer relationships may therefore be envisaged between these companies and source countries. Benefit-sharing could then include commercial research and product development activities thereby assisting in the development of local capacity and institution building;

(c) In the *biotechnology sector*, outside of health care and agriculture, companies are generally not familiar with the scope and coverage of the Convention on Biological Diversity. They often obtain samples free of charge through collaboration with academic researchers or obtain their materials from intermediary organizations, such as culture collections, in exchange for a license fee or a purchase price. In rare cases of benefit-sharing with provider countries, the company will generally collect the genetic resources itself or will establish an arrangement with an intermediary institution in the source country;

(d) In the *agricultural seed industry* for major crops, an informal system of exchange is still generally in place, permitting reciprocal access to genetic resources. It is common for many seed companies to obtain genetic resources free of charge or in exchange of a small handling fee, particularly if the germplasm acquired is unimproved. A number of actors are involved from initial access, through pre-breeding and commercial development, to sale of the final product to the farmer or consumer. Agreements are more common towards the end of the chain, for example with the use of license agreements when seeds are patented. The increasing use of intellectual property rights is said to influence partnerships in the industry to a greater extent than the development of policies and legislation on access to genetic resources;

(e) In the *horticultural sector*, and more specifically in the field of commercial ornamental horticultural development, there exists commercial arrangements that involve:

- (i) Royalties;
- (ii) Payment of fees;

- (iii) In kind benefits: e.g. reciprocal access to plant material between non-commercial organizations;
- (iv) Acknowledgement of the name of the provider of the genetic resources in the name of the plant variety subsequently developed by a breeder;
- (v) Sponsorship of student placements within the company or enrolment on courses of higher education.

43. The need for access and benefit-sharing systems to be flexible is underscored by differences in benefit-sharing between and within sectors.

### *3. Intellectual property rights*

44. Although the Panel was not able to reach consensus on issues related to intellectual property rights during its first meeting, specific issues were nevertheless identified for further consideration (UNEP/CBD/COP/5/8, paras.127-138). These issues include:

(a) *The role of intellectual property rights in prior informed consent:* The Panel stated that application procedures for intellectual property rights could require that the applicant submit evidence of prior informed consent, thereby creating an incentive for users to effectively comply with obligations to seek prior informed consent. Therefore, if bioprospectors use traditional knowledge they would need to obtain the prior informed consent of the holders of this traditional knowledge;

(b) *Intellectual property and traditional knowledge related to genetic resources:* The Panel identified a number of issues for further consideration by the Conference of the Parties. In essence, the issue raised is whether traditional intellectual property rights regimes adequately address the issue of traditional knowledge. Certain Governments have felt that there is a need to develop *sui generis* systems for the protection of traditional knowledge and, therefore, options for their development are to be considered;

(c) *Intellectual property rights and access and benefit-sharing arrangements:* The Panel set out the following issues to be considered as guiding parameters for contractual agreements:

- (i) The use of resources should be regulated in order to take into account ethical concerns;
- (ii) Provisions should be made to ensure the continued customary use of genetic resources and related knowledge;
- (iii) Provision should be made for the exploitation and use of intellectual property rights including joint research and the obligation to work any right on inventions obtained or provide licenses;
- (iv) The possibility of joint ownership of intellectual property rights should be taken into account. Benefit-sharing arrangements must include provisions on how benefits are shared with the holders of knowledge used for the development of a product;
- (v) Traditional knowledge could be protected as a trade secret or as a form of know-how as appropriate and may be subject to licensing;
- (vi) Licenses to secure continued control by providers over genetic resources could be considered by potential parties to an access and benefit-sharing agreement.

45. Emerging practice with respect to intellectual property rights is illustrated by the legislation developed by the Andean Community. It adopted decision 486, a new intellectual property rights system,

on 14 September 2000 which came into force on 1 December 2000. <sup>9/</sup> The new regime is meant to bring the IPR systems of the five countries of the Andean Pact in line with the WTO TRIPs Agreement. <sup>10/</sup> In essence, the decision ensures that the grant of patents is conditional upon the provision of evidence that the prior informed consent of relevant stakeholders was obtained, including local, indigenous and Afro-American communities, for the use of their knowledge.

46. In Australia, according to the 1990 Patents Act, the intellectual property rights in any processes or products derived from or developed from *ex situ* collections of biological resources held by Commonwealth agencies will belong to the inventor, regardless of the ownership of any resources from which those processes or products are derived, or where those resources may be held. However, a Commonwealth agency may decide, for instance, to permit access only on the condition that intellectual property rights in any products derived from these resources are granted jointly to the inventor, the Commonwealth and a representative of the traditional owners. <sup>11/</sup>

47. In its decision V/26 A, the Conference of the Parties recognized that the Panel of Experts was not able to come to any conclusions about the role of intellectual property rights. It also invited Parties and relevant organizations to submit information on these issues by 31 December 2000. Although no new information has been brought to the attention of the Executive Secretary at the time the present paper was drafted, these issues could be further considered by the Panel of Experts during its second meeting, to determine how they can best be addressed under the framework of the Convention with a view to assisting the Ad Hoc Open Ended Working Group.

## ***B. Approaches for the involvement of stakeholders in access to genetic resources and benefit-sharing processes***

### *1. Identification of stakeholders*

48. In order to identify approaches for the involvement of stakeholders it is first important to identify the stakeholders who may be involved in the process. A note on the subject prepared for the fourth meeting of the Conference of the Parties (UNEP/CBD/COP/4/23) identified a list of stakeholders that could be involved in the development of access and benefit-sharing systems.

49. Stakeholders in user and provider countries may include the following:

- (a) Ministries, and government agencies concerned with natural resources, agriculture, economic issues including fisheries and forestry, customs, protected areas, health, research, justice;
- (b) The industrial sector, in particular pharmaceutical, plant-health horticultural, personal care and cosmetics, flavoring and fragrance, food and beverage, and other biotechnological companies;
- (c) The scientific and academic communities or their representative organizations;
- (d) People's organizations;
- (e) Traditional healers or their associations;
- (f) Local and indigenous communities and their organizations;
- (g) Non-governmental organizations working in the field of genetic resources.

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<sup>9/</sup> This regime replaces the one defined in the 1993 decision 344 of the Community.

<sup>10/</sup> <http://www.grain.org/publications/reports/andean.htm>, "Andean Community Adopts New IPR Law", 5 October 2000.

<sup>11/</sup> John Voumard – Inquiry Chair, *Access to Biological Resources in Commonwealth Areas*, Commonwealth Public Inquiry, July 2000.

## *2. Examples of stakeholder involvement*

50. National consultative processes have been carried out in a number of countries in the preparation of a national biodiversity strategy (e.g., South Africa) or in the development of national systems for access and benefit-sharing (e.g., Philippines, Costa Rica). <sup>12/</sup> Experience demonstrates that the stakeholders involved, the level of their involvement and the stages during which they are involved vary on a case-by-case basis.

51. In South Africa, no legislation has been adopted to date to regulate access and benefit-sharing. However a consultative process was carried out, involving a range of stakeholders, in the development of the national biodiversity policy and strategy contained in a White Paper published in 1997. One of the objectives of this consultation process was to ensure that benefits derived from the use and development of South Africa's genetic resources serve national interests. The issue of access to genetic resources and the equitable sharing of their benefits was addressed during this process and taken into consideration in the elaboration of the national strategy, but no access and benefit-sharing system has yet been established.

52. In the Philippines, Executive Order No.247 "Prescribing a Regulatory Framework for the Prospecting of Biological and Genetic Resources, and their By-Products and Derivatives, for Scientific and Commercial Purposes, and for Other Purposes", which became law in 1995 is the result of a democratic consultative process. The development of the legislation was first initiated by the scientific community and involved academics, university scientists, government officials and departments, non-governmental organizations and, finally, organizations representing the indigenous communities, and the private sector.

53. In the case of Costa Rica, the Biodiversity Law was passed in April 1998. The elaboration of this legislation involved a wide participation of stakeholders, including indigenous and local communities at different stages of its development. Consultations were first carried out before drawing the first draft involving indigenous people, small farmer groups, legal experts, scientists, civil servants and representatives of the private sector, with the purpose to establish the basic content of the legislation. Once the first draft had been circulated and comments and suggestions had been received, a more substantive draft was drawn up. However, there was no further progress due to a wide and conflicting range of views. A Special Joint Subcommission was then established to draw up another draft of the law, including a broad range of institutions and stakeholders. <sup>13/</sup> The draft was finally completed in November 1997, passed by legislative assembly in April 1998 and became Law No. 7788 in May 1998.

## *3. Diverging interests and concerns of stakeholders*

54. Stakeholders have diverging interests and different perceptions of the value of genetic resources. Consequently, access and benefit-sharing arrangements have raised different concerns that need to be addressed and reconciled in access and benefit-sharing systems.

55. The need to involve indigenous and local communities has been a particular concern of the Conference of Parties and is set out under Article 8(j) of the Convention. Experts recognized during the first meeting of the Panel that proper stakeholder involvement is critical to achieving the objectives of the Convention and that, therefore, indigenous and local communities should be involved in the negotiation process, where their knowledge or territories are involved.

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<sup>12/</sup> Examples provided in a paper prepared by Graham Dutfield for the UNCTAD Expert Meeting on Systems and National Experiences for Protecting Traditional Knowledge, Innovations and Practices, held on 30 October-1 November 2000, in Geneva.

<sup>13/</sup> National Indigenous Forum; Federation for Environmental Conservation; National Small Farmers Forum; University of C-R; National University; Union of Chambers for Private Business; National Biodiversity Institute; Advisory Council to the Minister of the Environment and Energy; National Liberation Party; Christian Socialist Unity Party.

56. At its fifth meeting, the Conference of the Parties, under element 4, task 7, of the programme of work on the implementation of Article 8(j) and related provisions of the Convention (decision V/16, annex) mandated the Working Group on Article 8(j) “to develop guidelines for the development of mechanisms, legislation or other appropriate measures to ensure: (i) that indigenous and local communities obtain a fair and equitable share of benefits arising from the use and application of their knowledge, innovations and practices; (ii) that private and public institutions interested in using such knowledge, practices and innovations obtain prior informed approval of the indigenous and local communities; (iii) advancement of the identification of the obligations of countries of origin, as well as Parties and Governments where such knowledge, innovations and practices and the associated genetic resources are used”.

57. These issues will be addressed by the Working Group on Article 8(j) at its meeting in February 2002. In order to avoid duplication of work and in order to benefit from the expertise of the Working Group, the Panel of Experts on Access and Benefit-sharing may wish to defer specific consideration of benefit-sharing issues of direct relevance to indigenous and local communities to the Working Group on Article 8(j). The conclusions of the Panel of Experts will feed into the preparations of the Working Group on Article 8 (j).

58. The involvement of the private sector has received limited attention to date and may deserve further consideration. It may be useful for the Panel to take into account the results of studies recently carried out which have highlighted the particular concerns of the private sector with respect to access and benefit-sharing arrangements. They include the following: <sup>14/</sup>

- (a) Lack of clarity in the Convention on Biological Diversity and national access and benefit-sharing measures;
- (b) Difficulty in keeping up with the diversity of measures adopted by countries;
- (c) Bureaucracy and delay involved in following access procedures;
- (d) Unrealistic expectations on the part of Governments and provider-country institutions; <sup>15/</sup>
- (e) Perception that the Convention on Biological Diversity rejects scientific traditions of research collaboration and exchange of specimens (therefore damaging research on biodiversity and new product development);
- (f) Belief that the Convention on Biological Diversity and access legislation create a disincentive to conduct research on natural products;
- (g) Unreasonable transaction costs and cumbersome procedures.

59. Consequently, changes in business practices have included:

- (a) Decrease in corporate collecting activities, consolidation of collecting programmes into fewer countries and in some cases concentration on domestic collections;
- (b) Greater recourse to material from *ex situ* collections rather than samples acquired through collecting activities;
- (c) Increased role of intermediaries as brokers of access and benefit-sharing (for obtaining permits and negotiating access and benefit-sharing arrangements) and suppliers of samples;
- (d) Increasing use of material transfer agreements.

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<sup>14/</sup> Kerry ten Kate and Sarah A. Laird, “ The Commercial Use of Biodiversity – Access to Genetic Resources and Benefit Sharing”, Earthscan Publication Ltd, London, 1999.

<sup>15/</sup> Certain private sector representatives are of the opinion that Governments misconceive the role of the private sector and their demand for genetic resources and the benefits they can offer.

60. Overall, few companies have developed policies in response to the Convention, but a number of pharmaceutical companies have introduced corporate policies to clarify their approach to requirements of prior informed consent and benefit-sharing.

61. These concerns highlight the importance of involving stakeholders from the start in the development of access and benefit-sharing regimes in order to develop systems that take into account, to the greatest extent possible, the diverging interests of stakeholders. International guidelines on access and benefit-sharing could assist in harmonizing to a certain extent access and benefit-sharing regimes and provide greater clarity and legal certainty.

#### *4. Identification of approaches for the involvement of stakeholders*

62. As demonstrated above, initiatives have been taken to ensure the involvement of various stakeholders in access and benefit-sharing. However, in order to ensure that their interests and views are taken into account it may be useful to consider a more systematic approach to their involvement.

63. Approaches for the involvement of stakeholders need to be considered in the following three instances:

- (a) In the development of national measures regulating access and benefit sharing;
- (b) When access to genetic resources is requested by a user, provider country stakeholders should be consulted;
- (c) In the establishment of benefit-sharing arrangements.

64. The following elements are meant to assist the Panel in identifying more systematic approaches for the involvement of stakeholders in decision-making and the sharing of benefits. The establishment of appropriate procedures in provider countries could ensure that stakeholders take part in the process:

- (a) Rules and requirements for Governments (competent national authorities) to disclose information to the public (relevant stakeholders), i.e. the application for obtaining access to genetic resources should be publicized to ensure transparency;
- (b) A consultative committee formed of a broad range of stakeholder representatives could be established and consulted by the competent national authority following each request for access to genetic resources;
- (c) A reasonable and specific time period could be allocated for stakeholders to provide their comments and views and to provide an analysis of the potential impacts for their group of allowing the exploitation of the concerned resource;
- (d) The extent of participation of stakeholders in the decision-making process should be determined. At the least, their comments and views should be taken into consideration to the greatest extent possible;
- (e) If their views are not taken into consideration the competent national authority should provide justification upon request by the concerned stakeholder;
- (f) In parallel, the prior informed consent of relevant stakeholders should be sought;
- (g) The decision-making authority should be clearly established and the main criteria based on which the competent national authority will decide to authorize access should be set out in the procedure, taking into account the national biodiversity strategy and its objectives;
- (h) Stakeholders should have the right to be informed of the reasons why their views and interests were not taken into account in the final decision;
- (i) Stakeholders should have the right to seek judicial remedy for non-compliance with the terms of the agreement or relevant national legislation;



(j) Relevant stakeholders should be included in the sharing of benefits arising from the use of genetic resources.

65. In the context of benefit-sharing arrangements, model agreements could help to promote the involvement of stakeholders. In addition, capacity-building initiatives may be necessary to ensure the proper involvement of stakeholders.

### **III. STUDY OF COMPLEMENTARY OPTIONS TO ADDRESS ACCESS AND BENEFIT-SHARING IN THE FRAMEWORK OF THE CONVENTION ON BIOLOGICAL DIVERSITY**

66. In order to assist Parties to develop appropriate legislative, administrative, or policy measures and contractual arrangements on access and benefit-sharing, a package of complementary measures or approaches could be considered to address the different needs which have been expressed by Parties and stakeholders, such as the need for guidance, information and capacity building.

67. The Panel of Experts has been invited to study complementary options. The following are different approaches that may be considered by the Panel of Experts to address the needs of Parties. The Panel may wish to discuss these approaches, establish priorities and identify the appropriate forum to address them.

#### ***A. Guidelines, codes of conduct, indicators and model agreements***

68. A number of instruments could provide guidance and assist Parties in the development of access legislation and benefit-sharing arrangements. Certain of these instruments, such as guidelines, may be appropriate in the development of access legislation, while others such as model agreements or indicators, may assist in the establishment of contractual arrangements.

69. Different types of guidelines could be established to assist in the development of fair and equitable systems for access and benefit-sharing, as illustrated below.

70. The Panel may wish to consider which type of guidelines or other approaches would be most usefully developed by the Ad Hoc Open-ended Working Group in order to best assist Parties through international consensus.

71. On the basis of existing experience in the development of access legislation and in order to assist Parties still in the process of developing their national regime, the development of international guidelines containing basic standards for national access regimes could be developed. These guidelines should provide for sufficient flexibility in order for each Party to develop a system that responds to specific national or regional priorities or needs. It should also ensure a certain level of harmonization of systems across countries in order to provide legal clarity and certainty.

72. The following are existing approaches that could either be considered as part of a package of measures or from which elements could be drawn for the development of an international framework.

#### ***1. Draft international guidelines on access and benefit-sharing***

73. The Swiss Draft Guidelines on Access and Benefit Sharing Regarding the Utilisation of Genetic Resources (UNEP/CBD/COP/5/INF/21) were drawn up following a survey conducted with the private sector and the research community to serve as a starting point in the discussion on access to genetic resources and benefit sharing. They were made available to the Panel of Experts at its first meeting and are summarized in section A of annex IV to the report of that meeting (UNEP/CBD/COP/5/8).

74. The Swiss guidelines take into account the series of steps involved in access to genetic resources and the sharing of benefits that arise from their utilization, from the collection of the resources to the commercialisation of the findings of scientific research and development. The guidelines are based on a commitment to assist the fulfilment of the objectives of the Convention. They do not cover genetic resources falling under the FAO Global System for the Conservation and Utilization of Plant Genetic Resources.

75. A number of innovative steps are suggested in these guidelines:

- (a) Stakeholders are encouraged to create a system of certification (article 14);
- (b) Stakeholders involved in a transaction of genetic resources are encouraged to seek support by a mediator for the negotiation of mutually agreed terms. (article 15);
- (c) To take into account the particular needs of developing countries and economies in transition, governments are to promote institutional, procedural, technical and scientific cooperation for the sustainable use of genetic resources and the conservation of biodiversity (article 16);
- (d) Stakeholders are encouraged to report periodically to the clearing-house mechanism on actions taken regarding the application of the guidelines. It is also suggested that these reports may be integrated in the national reports submitted in accordance with Article 26 of the Convention (article 17).

## 2. *Existing guidelines/codes of conduct addressing access to genetic resources and benefit-sharing*

76. Numerous professional and institutional guidelines and codes of conduct relevant to access and benefit-sharing have been developed. These guidelines generally apply to specific types or uses of genetic resources such as the Micro-Organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC), the Common Policy Guidelines for Participating Botanical Gardens on Access to Genetic Resources (UNEP/CBD/ISOC/Inf.2; see also annex IV, section B, of the report of the Panel of Experts on the work of its first meeting) and the International Code of Conduct for Plant Germplasm Collecting and Transfer.

77. MOSAICC is a voluntary code of conduct to facilitate access to microbial genetic resources. It is meant to facilitate the implementation of the Convention on Biological Diversity at the microbial level and combines the need for easy transfer of microbial genetic resources and the need to monitor the transfer of such resources.

78. The Common Policy Guidelines for Participating Botanical Gardens on Access to Genetic Resources were developed to harmonize policies, practices and agreements of participating botanic gardens with a view to facilitate access to genetic resources from countries of origin and through exchange with other botanic gardens. The project now involves 28 botanic gardens and herbaria from 21 countries, coordinated by the CBD Unit of the Royal Botanic Gardens, Kew.

79. It is interesting to note that both of these sets of guidelines distinguish between different possible uses of genetic resources and provide a range of illustrative documents.

80. The International Code of Conduct for Plant Germplasm Collecting and Transfer was negotiated by the FAO Commission on Genetic Resources for Food and Agriculture and adopted in 1993 by the FAO Conference as a voluntary instrument. It provides a framework that Governments may use in developing national regulations or formulating bilateral agreements for the collection of germplasm. It provides guidelines for the requesting of permits by collectors and for the issuance of these permits by national authorities. It also sets out minimum responsibilities of collectors, sponsors, curators and users of collected germplasm, in the collection and transfer of germplasm. <sup>16/</sup>

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<sup>16/</sup> <http://www.fao.org/ag/agp/agps/pgr/icc.htm>

### 3. Indicators

81. The role of indicators in addressing both procedural and substantive aspects of benefit-sharing was highlighted by the Panel of Experts during its first meeting. Possible indicators of the fairness and equity of benefit-sharing arrangements in the context of mutually agreed terms were provided for information in annex III of the report of that meeting and could be considered as part of a package of complementary approaches.

### 4. Model agreements

82. It is interesting to note that both the guidelines developed for microbial culture collections and those developed for botanical gardens contain model documents and/or agreements for the supply and acquisition of genetic resources.

83. Model agreements could be useful tools to provide guidance in the development of access and benefit-sharing contractual agreements. A series of models could be developed for different types of genetic resources and their different possible uses.

### ***B. Information exchange mechanisms***

84. In paragraph 12 of decision V/26 A, the Conference of the Parties noted:

“[T]hat information is a critical aspect of providing the necessary parity of bargaining power for stakeholders in access and benefit-sharing arrangements, and that, in this respect, there is particular need for more information regarding:

- (a) User institutions;
- (b) The market of genetic resources;
- (c) Non-monetary benefits;
- (d) New and emerging mechanisms for benefit-sharing;
- (e) Incentive measures;
- (f) Clarification of definitions;
- (g) *Sui generis* systems; and
- (h) ‘Intermediaries’”.

85. Following the fifth meeting of the Conference of the Parties, Parties were invited to provide the following:

- (a) Information on the role of intellectual property rights in the implementation of access and benefit-sharing arrangements;
- (b) Information on any recent developments related to access and benefit sharing, including texts of any legislative, administrative or policy measures;
- (c) Information regarding the issues listed above from paragraph 12 of decision V/26 A.

86. On the basis of information provided by Parties, the Secretariat will develop a database on existing legislative texts and policy decisions in this field as soon as the information is provided by Parties. Thematic reports on benefit-sharing are being made available through the clearing-house mechanism as Parties forward them to the Secretariat.

87. The Secretariat, through the clearing house mechanism, should serve as a centre for information exchange among Parties. Although information has been recognized as an essential tool for Parties and

stakeholders, the information-gathering process has been rather slow. Experts may wish to suggest mechanisms that could improve this exercise.

### ***C. Capacity building***

88. The Conference of the Parties also noted “that further development of capacities regarding all aspects of access and benefit-sharing arrangements is required for all stakeholders, including local governments, academic institutions, and indigenous and local communities, and that key capacity-building needs include:

- (a) Assessment and inventory of biological resources as well as information management;
- (b) Contract negotiation skills;
- (c) Legal drafting skills for development of access and benefit-sharing measures;
- (d) Means for the protection of traditional knowledge associated with genetic resources”.

89. The capacity-building needs of national focal points, competent national authorities and others involved in the implementation of the access system will need to be identified and measures taken to address them as a priority. In addition, the capacity of stakeholders to engage in negotiations is vital to ensuring equitable mutually agreed terms. Further development of skills and capacity regarding all aspects of mutually agreed terms and contractual arrangements is required and should be supported, particularly in government, academic institutions and local and indigenous communities.

90. Capacity building could therefore be considered as a complementary option and could be addressed as part of a package.

## **IV. RELEVANT DEVELOPMENTS IN OTHER INTERNATIONAL FORUMS**

### ***A. Developments in the Food and Agriculture Organization of the United Nations (FAO) on the International Undertaking on Plant Genetic Resources***

91. The process of revising the International Undertaking to harmonize it with the Convention on Biological Diversity has been under way since 1993. At its eighth session, in April 1999, the Commission on Genetic Resources for Food and Agriculture (CGRFA), decided to continue negotiations on the revision of the International Undertaking using a composite draft text, and the Chair was authorized to convene sessions of the Chair’s Contact Group to advance negotiations on the basis of the “Chairman’s elements” derived from an expert meeting held in Montreux, Switzerland, in January 1999. The draft text provides for the development of a multilateral system addressing the issue of access to plant genetic resources for food and agriculture on mutually agreed terms and benefit-sharing, a financial strategy and other support measures. The Contact Group, composed of 41 countries, selected according to regional representation, was established to address the most contentious issues under discussion.

92. Although the Contact Group had made progress with a provisional package agreement on intellectual property rights and commercial benefit-sharing during its third meeting, in Tehran in August 2000, a number of issues were left unresolved at the end of its fourth meeting, held in Neuchâtel, Switzerland, from 12 to 17 November 2000. On the basis of the latest developments, the FAO Council, which met in Rome, from 20 to 25 November 2000, called for a final text of the revised International Undertaking to be submitted to the thirty-first session of the FAO Conference, scheduled for November 2001. A fifth session of the Contact Group will be held in Rome from 5 to 10 February 2001.

## ***B. Developments in the World Intellectual Property Organization (WIPO)***

93. Since 1998, WIPO has been addressing issues of relevance to the Convention on Biological Diversity in the context of its work programme on global intellectual property issues, which contains a sub-programme on biological diversity and biotechnology. Recent developments directly relevant to the issue of access and benefit-sharing include:

(a) *Three case-studies carried out in collaboration with UNEP presented at the fifth meeting of the Conference of the Parties.* <sup>17/</sup> These studies focus on cases where intellectual property rights were used as a tool for benefit-sharing in India, Mali and Nigeria. They are part of a larger study undertaken jointly by WIPO and UNEP on the role of intellectual property rights in benefit sharing of biological resources and associated traditional knowledge. Lessons learned on the basis of these case-studies will be made available to the Panel of Experts at its second meeting.

(b) *Establishment of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore:* At its twenty-sixth session, held in Geneva, from 26 September to 3 October 2000, the WIPO General Assembly, decided to establish an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. The three primary themes to be addressed by this committee are intellectual property rights that arise in the context of (i) access to genetic resources and benefit sharing; (ii) protection of traditional knowledge, whether or not associated with those resources; and (iii) the protection of expressions of folklore. The first meeting should be held in the second quarter of 2001. Participants could include WIPO member States and representatives from relevant intergovernmental organizations, accredited international and regional non-governmental organizations will be invited to participate in an observer capacity.

## ***C. Developments in the World Trade Organization (WTO)***

94. As requested by the Conference of the Parties at its fifth meeting, the Executive Secretary applied for observer status for the Convention Secretariat in the WTO Council for the Trade-related Aspects of Intellectual Property Rights (TRIPs). The request was discussed alongside the outstanding requests from 14 other intergovernmental organizations at its meeting on 21-22 September 2000. The issue of the granting of observer status was then the subject of discussion in the context of the WTO General Council's work on implementation issues and concerns. At its special session on 18 October 2000, the General Council urged the TRIPs Council to give positive consideration to granting observer status to the Secretariat on an ad hoc basis pending the conclusion of wider discussions on observer status for international organizations in the General Council. During its meeting at the end of November 2000, the TRIPs Council took up this question both formally and informally and was unable to reach a consensus.

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<sup>17/</sup> UNEP/CBD/COP/5/INF/26, "The Role of Intellectual Property Rights in the Sharing of Benefits Arising from the Use of Biological Resources and Associated Traditional Knowledge: Selected Case-Studies", 10 May 2000.

95. Also as suggested by Conference of the Parties, in , paragraph 2 of its decision V/26 B, on access to genetic resources, WTO is further exploring the relationship between the TRIPs Agreement and the Convention on Biological Diversity. During the above-mentioned November meeting of the TRIPs Council , informal consultations on the issue of the relationship between the TRIPs Agreement and the Convention revealed differences of views among WTO members: some consider the two agreements to be mutually supportive, but others are of the view that there is a potential conflict and that they may need to be harmonized. Yet others were not prepared to take position on this issue. It was agreed that the Council is to continue consideration of the relationship between the two agreements at its next meeting. <sup>18/</sup>

## V. CONCLUSIONS AND/OR RECOMMENDATIONS

96. The present note has reviewed recent developments in user and provider experience, highlighted lessons learned during the first meeting of the Panel of Experts, suggested approaches for the involvement of stakeholders, and put forward a series of complementary options, including the development of international guidelines that could assist Parties in establishing access and benefit-sharing regimes.

97. On the basis of this review, with a view to facilitating the work of the Ad Hoc Open-ended Working Group, the Panel of Experts may wish to, :

(a) Identify the types of guidelines and other approaches that would be best suited to achieve the objectives of the Convention with respect to access and benefit-sharing arrangements;

(b) Identify elements for international guidelines and other approaches, taking into account the conclusions of the first meeting of the Panel of Experts;

(c) Further examine the issue of intellectual property rights with a view to determine whether consensus may be reached on the role of intellectual property rights in the implementation of access and benefit-sharing arrangements;

(d) Suggest mechanisms that could assist the Executive Secretary in the gathering of information on access and benefit-sharing in the most efficient manner.

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<sup>18/</sup> WTO, Council for Trade-Related Aspects of Intellectual Property Rights, *Implementation Issues Referred to the Council for TRIPs, Report by the Chairman of the Council on his own Responsibility*, IP/C/21, 4 December 2000.