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REPORT OF THE PANEL OF EXPERTS ON ACCESS AND BENEFIT-SHARING

CONTENTS

* UNEP/CBD/COP/5/1.

REPORT OF THE PANEL OF EXPERTS ON ACCESS AND BENEFIT-SHARING

Introduction

1. At its fourth meeting, held in Bratislava from 4 to 15 May 1998, the Conference of the Parties to the Convention on Biological Diversity decided in its decision IV/8:

> "[T]o 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 and reporting to its next meeting. 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."

2. In the same decision, the Conference of the Parties requested the Inter-Sessional Meeting on the Operations of the Convention referred to in its decision IV/16, paragraph 2, inter alia, to explore options for access and benefit-sharing mechanisms. Accordingly, the Inter-Sessional Meeting, which was held in Montreal from 28 to 30 June 1999, considered the modalities of the meeting of the Panel of Experts and, in paragraph 3 of its recommendation 2, made specific recommendations regarding the preparations for the meeting, the composition of the Panel, and the items to be included in its agenda.

3. On the basis of nominations received from Governments, the Executive Secretary selected the experts for the meeting of the Panel, using a set of criteria to achieve, to the extent possible, balanced regional as well as sectoral distribution.

4. In accordance with recommendation 2 of the Inter-Sessional Meeting, representatives of competent intergovernmental organizations, including regional organizations, were invited to the meeting as observers.

5. The Panel of Experts on Access and Benefit-sharing met in San José, Costa Rica, from 4 to 8 October 1999. The meeting was co-hosted by the Governments of Costa Rica and Switzerland, which provided the financial support. Additional funding was provided by the Government of Norway.

Part One

PROCEEDINGS OF THE PANEL OF EXPERTS ON ACCESS AND BENEFIT-SHARING

I. OPENING OF THE MEETING

6. The meeting was opened at the Hotel Meliá Confort Corobicí, San José, at 10 a.m. on Monday, 4 October 1999.

7. Opening statements were made by Mr. Hamdallah Zedan, Executive Secretary of the Convention on Biological Diversity; Mr. Rodolph S. Imhoof, Ambassador of Switzerland to Costa Rica; Mr. Walter Niehaus, Vice-Minister for Foreign Affairs of Costa Rica, speaking on behalf of Mrs. Elizabeth Odio Benito in her capacity as Second Vice-President of Costa Rica; and Mr. Carlos Manuel Rodriguez, Minister Interim of Environment and Energy of Costa Rica, speaking on behalf of Mrs. Odio Benito in her capacity as Minister of Environment and Energy.

8. In his statement, Mr. Zedan welcomed participants and expressed his appreciation to the Government of Costa Rica for its warm hospitality and excellent arrangements for the meeting. He also expressed his deep gratitude to the Government of Switzerland for co-hosting the meeting and for providing the financial support that, together with the financial support received from Norway, had enabled the meeting to take place. Noting the complexity of the issues before the Panel, he said that many Parties to the Convention regarded progress on the issue of access and benefit-sharing as one of the keys to the success of the Convention as a whole. Work on the subject remained, however, at a very preliminary stage, namely, that of defining concepts and identifying the measures required to implement them. The Panel was the main tool that the Conference of the Parties had given itself to advance the process. Stressing that the meeting was not a negotiating session but a meeting of experts, he said that the work expected of the Panel, which was to further define the concepts and identify ways and means of putting them into practice in the real world, would constitute an important step forward in the implementation of the Convention.

9. Mr. Imhoof expressed his gratitude to the Government and people of Costa Rica for the hospitality they had shown in hosting the meeting. Costa Rica was one of the countries most committed to the conservation and sustainable use of biological diversity and had extensive experience with regard to access and benefit-sharing arrangements. The example of the partnership between Switzerland, as a user of genetic resources, and Costa Rica, as a country of origin, could contribute to the discussion on the crucial issue of access and benefit-sharing.

10. Mr. Niehaus welcomed all participants and said that he was gratified that Costa Rica had been chosen as the location of the meeting. He also expressed his gratitude to the Government of Switzerland for sponsoring the meeting and to the organizers for the arrangements made. Biological diversity was a matter of great importance to Costa Rica, which had undertaken many activities to preserve, investigate and utilize its genetic resources, working on the premise that the best means of conserving biological diversity was to turn it into an instrument of sustainable development. He recalled the 1991 agreement on bioprospecting between the National Biodiversity Institute (INBio) and Merck, Sharp and Dome, which constituted a precedent for access and equitable benefit-sharing arrangements. He stressed the importance of an open dialogue aimed at

building consensus among all stakeholders –the private sector, the public sector, intermediaries, and local communities –in order to arrive at arrangements that were satisfactory to all and which complied with the basic principles laid down by the Convention.

11. Mr. Rodriguez welcomed participants and said that the meeting provided the opportunity for a much needed exchange of information and experience on access and benefit-sharing arrangements, with a view to facilitating the application of Article 15 of the Convention on Biological Diversity. Costa Rica had made strenuous efforts to use its biological diversity in the development process and to provide for the needs of its people.

II. ORGANIZATIONAL MATTERS

A. Attendance

12. The meeting was attended by experts appointed by the following Governments and Parties to the Convention on Biological Diversity: Albania, Argentina, Armenia, Australia, Bolivia, Brazil, Cameroon, China, Congo, Cook Islands, Costa Rica, Cuba, Czech Republic, Denmark, Ecuador, Ethiopia, European Community, Finland, France, Germany, Hungary, India, Jamaica, Japan, Jordan, Kenya, Madagascar, Malaysia, Mexico, Morocco, Norway, Pakistan, Peru, Republic of Korea, Russian Federation, Slovakia, South Africa, Sri Lanka, Sweden, Switzerland, Syrian Arab Republic, United Kingdom of Great Britain and Northern Ireland, United States of America, Uruguay.

13. The following United Nations bodies and specialized agencies were represented by observers: Food and Agriculture Organization of the United Nations (FAO), Global Environment Facility (GEF), United Nations Conference on Trade and Development (UNCTAD), World Intellectual Property Organization (WIPO).

14. Observers from the following other international organizations were also present: COECOCEIBA-Friends of the Earth (Costa Rica), Consultative Group for International Agricultural Research (CGIAR), General Secretariat of the Andean Community, IUCN – The World Conservation Union, Indigenous People's Biodiversity Network, International Centre for Rain Forest Conservation and Development (Iwokrama), Max-Planck Institute of Foreign Public Law and International Law, Novartis Seed AG, World Resources Institute (WRI).

B. Election of officers

15. At the opening session, the Panel elected the following officers by acclamation:

Co-Chairs: Mr. Jorge Cabrera Medaglia (Costa Rica)
Mr. Martin Girsberger (Switzerland)

Rapporteur: Ms. Maureen Wolfson (South Africa)

C. Adoption of the agenda

16. At the opening session of the meeting, the Panel adopted the following agenda on the basis of the provisional agenda that had been circulated as document UNEP/CBD/EP-ABS/1:

1. Opening of the meeting.

2. Organizational matters:

2.1. Election of officers;

2.2. Adoption of the agenda;

2.3. Organization of work.

3. Options for access and benefit-sharing on mutually agreed terms:

3.1. Access and benefit-sharing arrangements for scientific and commercial purposes;

3.2. Review of legislative, administrative and policy measures at national and regional levels;

3.3. Review of regulatory procedures and incentive measures;

3.4. Capacity-building.

4. Other matters.

5. Adoption of the report.

6. Closure of the meeting.

D. Organization of work

17. After some discussion, the Panel agreed at the opening plenary session of the meeting, on 4 October 1999, that it would hear presentations from individual experts on each of the four sub-items under agenda item 3 (Options for access and benefit-sharing on mutually agreed terms). It was agreed that the individual experts responsible for those presentations would be: Mr. A. H. Zakri, expert from Malaysia, for agenda item 3.1 (Access and benefit-sharing arrangements for scientific and commercial purposes); Ms. Kerry ten Kate, expert from the United Kingdom, for agenda item 3.2 (Review of legislative, administrative and policy measures at national and regional levels); Mr. Jose Carlos Fernandez Ugalde, expert from Mexico, for agenda item 3.3 (Review of regulatory procedures and incentive measures); and Ms. Estherine Lisinge Fotabong, expert from Cameroon, for agenda item 3.4 (Capacity-building).

18. The Panel further decided that, after the presentations by individual experts, there would be a general exchange of views in plenary. The Panel would then split into four small, regionally balanced groups to conduct brainstorming sessions on each of the four sub-items, with a view to providing guidance and identifying the main issues for further consideration by the Panel. The experts responsible for the introductory presentations under the sub-items would also serve as the facilitators of the respective groups and would report back to plenary on the results of their group’s deliberations.

19. At the 2nd plenary session of the meeting, on 4 October 1999, the Panel agreed, on the proposal of the Co-Chair, that observers could participate in the proceedings of the plenary and any subgroups.

20. At the 3rd plenary session of the meeting, on 5 October 1999, after the small groups had completed their work and reported back to plenary, the Panel decided to establish two Working Groups: Working Group I, under the chairmanship of Mr. A. H. Zakri, expert from Malaysia, to consider agenda item 3.1 (Access and benefit-sharing arrangements for scientific and commercial purposes) and Working Group II, under the chairmanship of Mr. L. V. Kalakoutskii, expert from the Russian Federation, which would concurrently consider agenda items 3.2 (Review of legislative, administrative and policy measures at national and regional levels) and 3.3 (Review of regulatory procedures and incentive measures). Both Groups would take up agenda item 3.4, which concerned the cross-cutting issue of capacity-building, in the context of their discussions on their assigned agenda items. The initial membership of the two Groups would be determined by the Secretariat with a view to ensuring that all regions were equally represented in both Groups, although experts would be free to move from one Group to the other should they so desire.

III. OPTIONS FOR ACCESS AND BENEFIT-SHARING ON MUTUALLY AGREED TERMS

21. As agreed by the Panel when organizing the work of the meeting (see para. 17 above), introductory presentations on each of the four sub-items under agenda item 3 were made at the 1st plenary session of the meeting.

22. At the 2nd plenary session of the meeting, on 4 October 1999, the Panel held a general discussion on the main points raised in the presentations on the sub-items. Statements were made by experts from the following countries and Parties to the Convention: Argentina, Czech Republic, Denmark, Ecuador, Ethiopia, European Community, France, Germany, India, Kenya, Norway, Pakistan, Peru, Russian Federation, United States of America.

23. Following the general discussion, participants split into the four small groups envisaged during the organization of work (see para. 18 above). The facilitators of the groups reported on the outcome of the sessions at the 3rd plenary session of the meeting, on 5 October 1999.

24. Following the reports of the facilitators of the small groups, statements were made by experts from the following countries and Parties to the Convention: Argentina, Cameroon, China, Cook Islands, Cuba, Denmark, Ecuador, Ethiopia, European Community, Jamaica, Kenya, Peru, Russian Federation, Syrian Arab Republic, United States of America. Statements were also made by the observers from the IUCN Meso-American Regional Office and Friends of the Earth, Costa Rica.

25. As decided by the Panel at the first session of the meeting (see para. 20 above), the two Working Groups then proceeded to start work on their assigned agenda items, on the basis of the mandate provided by the Conference of the Parties and the recommendations of the Inter-Sessional Meeting on the Operations of the Convention and in the light of the issues identified for further elaboration in the report of the subgroups and the comments thereon.

3.1. Access and benefit-sharing arrangements for scientific and commercial purposes

26. As agreed by the Panel, sub-item 3.1 was considered by Working Group I, which met under the chairmanship of Mr. Zakri, expert from Malaysia.

27. The Working Group presented a progress report on its work at the 4th plenary session of the meeting, on 6 October 1999.

28. At the 5th plenary session of the meeting, on 7 October 1999, Mr. Zakri, Chair of Working Group I, reported the outcome of the work of that Group. He said that the Working Group had completed its assigned tasks, and its report was available as document UNEP/CBD/EP-ABS/L.2. He recalled that the Working Group had been allocated agenda item 3.1, together with the related aspects of item 3.4, on capacity-building. The Working Group had reviewed the scope of its mandate and had decided to consider four issues: mutually agreed terms and contractual approaches; benefit-sharing options and mechanisms; means of disclosure of country of origin; and prior informed consent. Capacity-building was considered as a cross-cutting issue within each of those broad areas and the results of the Working Group's consideration of agenda item 3.4 were therefore integrated into its text on mutually agreed terms and benefit-sharing options and mechanisms. With regard to disclosure of country of origin and prior informed consent, the Working Group, after reviewing the work being undertaken in Working Group II, had decided that those issues would be more appropriately taken up in the framework of that Working Group.

29. At the 6th plenary session of the meeting, also on 7 October 1999, the Chair of Working Group I drew attention to revisions to the report (UNEP/CBD/EP-ABS/L.2/Corr.1) that had been prepared on the basis of consultations held since the report had initially been circulated.

30. The Panel then took up, paragraph by paragraph, the report of the Working Group as revised by document UNEP/CBD/EP-ABS/L.2/Corr.1.

31. The report, with the exception of a number of paragraphs to be taken up in conjunction with the report of Working Group II, was approved with a number of amendments introduced by participants.

32. At the 8th session of the meeting, on 8 October 1999, the Panel took up a revised text of the report of Working Group I (UNEP/CBD/EP-ABS/L.2/Rev.1), which incorporated the earlier revisions introduced by the Chair of the Working Group and the oral amendments agreed upon by the Panel at the 6th session of the meeting. It also sought to eliminate duplications and inconsistencies with the report of Working Group II, as agreed by the Panel at its 6th plenary meeting (see para. 38 below).

33. The revised text was approved by the Panel with a number of amendments as part of its conclusions for submission to the Conference of the Parties (see paras. 50-90 below).

3.2. Review of legislative, administrative and policy measures at national and regional levels

and

3.3. Review of regulatory procedures and incentive measures

34. As agreed by the Panel, sub-items 3.2 and 3.3 were considered by Working Group II, which met under the chairmanship of Mr. L. V. Kalakoutskii, expert from the Russian Federation.

35. The Working Group presented a progress report on its work at the 4th plenary session of the meeting, on 6 October 1999.

36. At the 5th plenary session of the meeting, Mr. L. V. Kalakoutskii, Chair of Working Group II, reported on progress in the work of that Group. He said that the Working Group had set up the nucleus of a subgroup on intellectual property rights. A draft document had been prepared but needed further refinement before submission to plenary. The Working Group had identified areas requiring further clarification, such as the issue of nomenclature. It had also decided to refrain from tackling the question of economic valuation of genetic resources as it was an extremely large topic that required more consistent efforts. Issues and gaps identified by the Working Group were also outlined.

37. At the 6th plenary session of the meeting, on 7 October 1999, the Chair of Working Group II introduced the report of the Group as contained in document UNEP/CBD/EP-ABS/L.3. He said that the Group had had extensive discussions with a large and geographically balanced participation. Drawing attention to the format of the report, he said that it departed somewhat from the conventional style and used text boxes throughout the document to give examples of relevant activities.

38. After a discussion regarding the presentation of the report of the Working Group, it was agreed that members of the Panel, in consultation with the Secretariat, would look into ways to revise the format of the report in order to address various concerns expressed by some experts, while at the same time preserving the information value of the document. It was also agreed that an attempt should be made to consolidate the texts produced by the two Working Groups to reduce any overlaps and contradictions that might exist.

39. At the 7th plenary session of the meeting, on 8 October 1999, the Panel took up a revised text of the report of Working Group II, which had been reformatted in accordance with the decision taken by the Panel at its previous meeting (see para. 38 above).

40. The Chair of Working Group II explained that the revised text took into account the comments made by experts at the 6th plenary session and also sought to eliminate duplications and inconsistencies in the conclusions submitted by the two Working Groups. The material that had originally been presented in text boxes had been moved to annexes, with some editorial changes aimed at clarifying certain points. The intention of the Working Group was to bring the annexed material to the attention of the Conference of the Parties for information purposes.

41. At the 8th plenary session of the meeting, the Panel approved the revised report of Working Group II, with a number of amendments, for submission to the Conference of the Parties as its conclusions under the agenda items in question (see paras. 91-144 below).

42. The Panel also agreed that the annexes to the report of the Working Group should be forwarded without amendment to the Conference of the Parties as annexes to the Panel's report, on the understanding that they were being provided for illustrative purposes only and that their content had neither been discussed nor endorsed by the Panel as a whole. Likewise, cross-references to the annexes in the body of the Panel's conclusions were solely

for the purpose of providing the Conference of the Parties with additional background information on particular points.

3.4. Capacity-building

43. Sub-item 3.4 (Capacity-building) was taken up by Working Groups I and II as in the context of their discussions of the items allocated to them. The conclusions of the Panel on capacity-building are incorporated into its conclusions on sub-items 3.1, 3.2 and 3.3.

3.5. Key conclusions of the Panel under agenda item 3

44. At the 8th plenary session of the meeting, on 8 October 1999, the Panel adopted a number of key conclusions under agenda item 3 on the basis of a draft submitted by the Co-Chairs (UNEP/CBD/EP-ABS/L.4/Rev.1). The key conclusions, as adopted, are contained in paragraphs 145-173 below.

IV. OTHER MATTERS

45. No other matters were raised by participants.

V. ADOPTION OF THE REPORT

46. At the 9th plenary session of the meeting, on 8 October 1999, the Panel adopted the present report on the basis of a consolidated draft text (UNEP/CBD/EP-ABS/L.5/Rev.1), which incorporated:

(a) The draft report of the meeting that had been circulated under the symbol UNEP/CBD/EP-ABS/L.1 and Add.1;

(b) The Panel's conclusions under agenda item 3, as approved on the basis of the reports of Working Groups I and II (UNEP/CBD/EP-ABS/L.2/Rev.1 and UNEP/CBD/EP-ABS/L.3/Rev.1);

(c) The key conclusions of the Panel, as approved on the basis of the text submitted by the Co-Chairs (UNEP/CBD/EP-ABS/L.4/Rev.1).

47. The report was adopted on the understanding that the Rapporteur and Co-Chairs, with the assistance of the Secretariat, would be responsible for introducing any required editorial corrections and for finalizing the report to reflect the proceedings of the final day of the meeting and the amendments made at the time of its adoption.

VI. CLOSURE OF THE MEETING

48. After an exchange of courtesies, the Co-Chairs declared the meeting closed at 9.30 p.m. on Friday, 8 October 1999.

Part Two

RESULTS OF THE MEETING OF THE PANEL OF EXPERTS ON ACCESS AND BENEFIT-SHARING

VII. CONCLUSIONS OF THE PANEL OF EXPERTS

49. In its consideration of the substantive elements of its agenda, the Panel focused on:

(a) Mutually agreed terms and contractual approaches;

(b) Benefit-sharing options and mechanisms;

(c) Access legislation;

(d) The concept and procedure of prior informed consent;

(e) Intellectual property rights;

(f) Regulatory and incentive measures;

and the related capacity-building aspects of the above.

A. Mutually agreed terms and contractual approaches

50. Based on the expertise and experience of the participants, the Panel identified the following as key lessons with respect to promoting mutually agreed terms in access and benefit-sharing arrangements in line with the Convention.

51. The Panel agreed that, because of the enormous differences in the circumstances of particular cases of access and benefit-sharing, as well as the evolving nature of the legal regimes to implement the Convention, it would be premature for the Conference of the Parties to develop principles for contractual arrangements.

52. Nevertheless, the Panel felt that there were a number of aspects of contractual arrangements and mutually agreed terms for which a common understanding has emerged, which could be the basis for any guidelines for such terms and arrangements.

53. Contractual arrangements, for the moment, are the main mechanism for gaining access to genetic resources and delivering benefits.

54. 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. To this end, Governments should define roles, ownership and authority to determine access. In this regard, attention needs to be paid to community interests, tenure and other property rights. In addition, countries should be aware of other relevant legal obligations.

55. Furthermore, 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.

56. The following decrease transaction costs:

(a) Establishment and awareness of Governments' requirements for contractual arrangements;

(b) Awareness of existing mechanisms;

(c) Umbrella arrangements, under which repeat access under expedited arrangements can be made;

(d) Situations where standardized Material Transfer Agreements should prove valuable.

57. 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.

58. Governments should appoint national focal points and competent authorities, which may or may not be different entities with separate functions. These should be capable of advising on the requirements for access on mutually agreed terms, among other functions (see, for example, annex I below). These authorities have an important role to play in ensuring equitable mutually agreed terms. This can be achieved by either directly participating in the negotiating process or endorsing agreements reached by institutions according to national policy. Authorities have an especially important role in providing legal certainty and lowering transaction costs. They also have an important role in providing information. It is therefore important that they have adequate resources to carry out these tasks.

59. There is a critical balance between the need for transparency and confidentiality. This means balancing the need for confidentiality and the need for access to information by the stakeholders in order to guarantee, under market conditions, fair and equitable benefit-sharing.

60. Proper stakeholder participation is critical to successfully achieving mutually agreed terms that promote the objectives of the Convention on Biological Diversity. The participation of indigenous and local communities is very important in the negotiation process, where their knowledge or territories are involved. In order for these communities to be able to participate effectively in the process, their ability to negotiate in a legal and commercial context frequently needs to be developed. Their capacity to understand the value of their knowledge and practices in commercial terms also needs to be further developed.

61. The link between access and the benefits arising from the use of genetic resources and conservation and sustainable use of biodiversity is important. An important aspect of this link is that the stakeholders take into account the relevant national biodiversity strategies and action plans.

62. Many countries have made significant progress in developing the legal basis of their access and benefit-sharing regime. Nevertheless, while most countries are still at an early stage in the development of their regimes, access and benefit-sharing is taking place. Even in the absence of national access legislation, contracts can be negotiated to reflect the spirit of the Convention, and achieve its objectives. Countries should consider continuing work to develop legislative, administrative or policy frameworks for access to genetic resources in a timely manner.

63. Different resources and uses require different contractual arrangements. To the extent that it is possible, it is important that commercial arrangements be anticipated at the outset. Nevertheless, where a commercial use cannot be predicted at the outset, arrangements can accommodate changes through key steps. For example, the application for a

patent might provide the basis for clarifying or renegotiating the terms of contract.

64. In line with decision II/15 of the Conference of the Parties, the Panel recognizes the uniqueness of genetic resources for food and agriculture and has identified the following distinct characteristics of those resources:

(a) They are essential for food security;

(b) They are developed by humans to satisfy their basic needs;

(c) Intra-species diversity is important;

(d) There is a high degree of interdependence among countries.

65. The Panel agreed that in the search for distinct solutions for genetic resources for food and agriculture, the development of multilateral regimes may play a role.

66. Benefits are often generated from the commercialization of derivatives that use genetic resources as a source of innovation, such as synthesized products. Accordingly, 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 (as respectively defined in Article 2 of the Convention).

67. Most genetic-resource exchanges are not limited to a simple user/provider relationship. Research and development on genetic resources for both scientific and commercial purposes frequently involves numerous parties with different contributions to the end-product (for additional information on the role of non-end-users, see annex II below). Any given project may include more than one academic, governmental and industrial partner in multiple countries.

68. The number of such collaborators has increased in recent years as activities have become more specialized. For example, collection, preparation and distribution of samples, as well as testing, analysis, product development and marketing may each involve one or more organizations.

69. Contractual agreements and access-permitting mechanisms need to anticipate this complexity with flexible and simple approaches that protect the interests of all parties, in such a way that relevant rights and responsibilities survive the duration of the contract, and are transferred to the third parties, as appropriate. In this regard, it is important for parties to be aware and informed of relevant agreements that may pre-date an agreement under development.

70. Information and the capacity to engage in negotiations are vital to ensuring equitable mutually agreed terms.

71. Further development of skills and capacity regarding all aspects of mutually agreed terms and contractual arrangements is required, particularly in government, academic institutions and indigenous communities.

72. A great deal of relevant information about access and benefit-sharing already exists. Many stakeholders are not in a position to properly use this information. Therefore, there is a critical need to consider its accessibility and mechanisms for delivering this information. More user-friendly documents are needed. Better access to examples of actual

contracts, codes of conduct and voluntary guidelines would assist those involved in the process of achieving mutually agreed terms. The Convention Secretariat should facilitate access to this information through its clearing-house mechanism.

73. Increased awareness about user institutions is an important need. In particular, companies should be encouraged to provide information regarding the commercial details to the relevant stakeholders in the access and benefit-sharing arrangements. The Secretariat could assist in promoting awareness in this respect by establishing a list of institutions, companies and other relevant organizations active in using genetic resources.

B. Benefit-sharing options and mechanisms

74. Benefits arising from the utilization of genetic resources can be either monetary or non-monetary.

75. Examples of monetary benefits include:

(a) "Up-front" payments;

(b) Milestone payments;

(c) Royalties;

(d) Research funding;

(e) Licence fees; and

(f) Salaries.

76. Examples of non-monetary benefits include:

(a) The participation of nationals in research activities;

(b) The sharing of research results;

(c) A set of voucher specimens left in national institutions;

(d) Support for research for the conservation and sustainable use of biological diversity;

(e) Strengthening capacities for technology transfer, including biotechnology;

(f) Strengthening the capacities of local and indigenous groups to conserve and use their genetic resources and, in particular, to negotiate the benefits arising from the use of the intangible associated components of genetic resources and their derivatives;

(g) Reasonable access by nationals of countries of origin to duplicates or, as appropriate, originals of specimens deposited in international ex situ collections;

(h) The receipt by providers, without payment of a royalty, of all technologies developed from research on endemic species;

(i) Donation to national institutions of equipment used as part of research;

(j) Reasonable access to technology and products resulting from the agreement;

(k) Information exchange;

(l) Protection of local existing applications of intellectual property rights;

(m) Building capacities in controlling aspects of bioprospecting methods, such as collection and preparation of samples, biodiversity monitoring, socio-economic monitoring, and/or nursery and agronomic techniques (increased conservation capacity);

(n) Institutional capacity-building; and

(o) Intellectual property rights.

77. Some other important non-monetary benefits are often overlooked in benefit-sharing discussions. These include:

(a) Biological inventories and taxonomic studies, integral components of many bioprospecting activities, which can provide important benefits for conservation and sustainable use of biological diversity;

(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 agreements encompass a commitment by a firm seeking genetic resources to invest in or support research on locally important diseases for which there is relatively little private-sector investment;

(d) The institutional and personal relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities under it – between a local university and an international research centre, for example – are in themselves an extremely important non-monetary benefit. Often these relationships lead to important follow-on scientific collaboration and increased access to international funding sources; and

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

78. Appreciation of the value of non-monetary benefits would increase if efforts were made to place credible monetary values on non-monetary benefits. Appreciation of the value of relative contributions in collaboration would also contribute to fair and equitable benefit-sharing. In this regard, stewardship of genetic resources may also be considered a contribution in addition to those activities mentioned in paragraph 76 above.

79. Identifying and rewarding the beneficiaries in a particular access and benefit-sharing arrangement – those with a just claim to the sharing of benefits according to the respective contribution made – are crucial elements in implementing fair and equitable benefit-sharing. Different beneficiaries in a particular case should in turn influence the choice of the type of benefits included in the agreement.

80. Benefits vary, for example, in the time of their delivery, ranging from immediate to quite long-term. Different beneficiaries will desire benefits in different time-frames.

81. In the case of local and indigenous communities, for example, experience has shown that payment of monetary benefits – cash exchanging hands – can have negative impacts on local values and cultures, and be a divisive influence within the community. Where indigenous and other local communities are involved in access and benefit-sharing arrangements, 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.

82. Also with respect to indigenous communities, it is important to ensure that benefit-sharing arrangements negotiated as part of access and benefit-sharing agreements do 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.

83. The range and scale of potential benefits also vary with the sector that is involved.

84. Benefits, beneficiaries and the specific conditions of different countries and communities vary widely. Bioprospecting activities involve a complex array of collaborating parties, as reflected in paragraphs 67-69 above. Therefore, parties to access and benefit-sharing agreements must be allowed flexibility to negotiate fair and equitable benefit-sharing arrangements.

85. The mechanisms for delivering benefits are very diverse and in many cases unique to particular agreements. Trust funds are one method of employing monetary benefits while avoiding the problems associated with direct cash payments to individuals or communities.

86. The establishment of joint ventures (between, for example, a government agency and a foreign pharmaceutical firm) to develop commercial products and share equally in their ownership and benefits is an innovative approach that deserves further study and development.

87. Source countries need better market information in order to play a more proactive role in identifying potential "users" of genetic resources and negotiating fair and equitable benefit-sharing terms. In this regard, it would be very helpful to establish an "international roster" of users of genetic resources and market data companies and others familiar with the economics and the risks involved in product discovery and development – including case-studies on each users' sub-sectoral speciality, countries of operation and the like.

88. Monitoring the implementation of benefit-sharing terms of access and benefit-sharing agreements is a difficult task, particularly in cases where benefits are long-term and product development occurs outside of the country of origin. This is often easier to achieve where parties from provider counties remain active partners in the research and development process.

89. Indicators may address both procedural and substantive aspects of benefit-sharing, and some possible indicators are described for information purposes in annex III below.

90. The multipartite nature of many access and benefit-sharing arrangements – involving various parties and transfers of resources to third parties – complicates monitoring.

C. Access legislation

1. Preamble

91. In order to support the objectives of the Convention on Biological Diversity, access legislation needs to be designed with the goals of the conservation and sustainable use of biological diversity in mind, as much as with those of access and benefit-sharing. For example, access legislation needs to ensure that access activities create minimum adverse environmental impact and foster the sustainable use of genetic resources and that fair and equitable benefit-sharing is designed to contribute to conservation measures and to improve the living standards of communities.

92. To ensure that legislative, administrative and policy measures meet the objectives of the Convention on Biological Diversity, they need to be based upon a clear national strategy. The Panel strongly endorsed the importance of preparing national strategies on access and benefit-sharing as part of national biodiversity strategies, prior to developing legislative, policy or administrative measures on the same, in conformity with the needs of countries.

93. The Panel therefore submits that Parties should address access and benefit-sharing measures in their national biodiversity strategies.

94. Although contractual arrangements are at present the main mechanism for gaining access to genetic resources and delivering benefits, legislation is essential to ensure that contractual arrangements serve national policy goals and implement the access and benefit-sharing objectives of the Convention on Biological Diversity. 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 degree of legislative simplicity in countries providing genetic resources will increase to the extent that countries and organizations receiving genetic resources take the legislative, administrative or policy measures to offer security to providers that these resources are utilized in accordance with the terms of the Convention. In this regard, the Conference of the Parties may wish to consider developing international guidelines or principles for such measures.

95. Legislative, administrative and policy measures on access can only succeed in a broader legal framework, clarifying property rights (including ownership of genetic resources, knowledge and innovations), conservation and biosafety.

96. Parties should ensure that national legislation on access and benefit-sharing is consistent with existing international obligations, and does not restrict or undermine Parties' positions in ongoing international negotiations, and foreclose options, including, possibly, the option of adhering to future agreements such as the one on plant genetic resources for food and agriculture being negotiated within FAO.

2. Scope

97. Genetic resources, as defined in the Convention on Biological Diversity, offer a suitable starting point for the scope of access legislation, but in order to ensure appropriate and efficient coverage in national legislation or other measures to regulate access, Parties may wish to consider the following aspects of scope:

(a) Categories of genetic resources, such as plant, animal and microbial genetic resources;

(b) Geographical area, for instance, marine or terrestrial areas;

(c) Legal status, for example, public or private land;

(d) Ex situ collections, such as botanic gardens, culture collections or gene banks; and

(e) Associated information, including the knowledge, innovations and practices of indigenous and local communities.

98. Attention was given to the inclusion in existing access legislation and legislative proposals of requirements for prior informed consent for access to derivatives. The Panel considered that requiring prior informed consent for access to derivatives may, in the majority of cases, prove counter-productive because of the impracticability of the implementation of such measures in view of the infinite range of derivatives that exist or may be produced, and their distribution.

99. However, it was stressed that derivatives intended for utilization for scientific and commercial purposes should be subject to mutually agreed terms in benefit-sharing arrangements relating to the genetic resources from which they are derived.

100. Considering the complexity of the issue and the lack of official definition of derivatives, the Panel suggests further consideration be given to this issue.

3. Definitions

101. The Panel observed that a number of definitions are to be found in Article 2 of the Convention on Biological Diversity and that, in order to promote common understanding of these terms, it would be advisable for those drafting access legislation to adopt those terms as they are found in the Convention. For clarity, a number of other terms that do not appear in the Convention need to be defined in access legislation. It was noted that definitions often have implications that are not immediately apparent and, for this reason, the Panel felt that it could be useful to invite a team of scientists and lawyers to comment on the implications of definitions such as genetic resources, derivatives and country of origin. This list is not complete, and the Conference of the Parties, in considering the item, may wish to decide on other terms that need to be defined.

4. Flexibility

102. Appropriate mutually agreed terms in contractual agreements may vary according to whether the use of genetic resources is scientific or commercial, and, within each of these categories, according to the specific nature of the use. If measures to regulate access are to facilitate access

and benefit-sharing, different requirements for prior informed consent and/or mutually agreed terms in contracts may be needed for uses by different users. Indeed, given the almost limitless combination of users, uses and potential uses of genetic resources as a result of the rapid developments in science and technology, there is a pressing need for flexibility in requirements for mutually agreed terms in contracts. The Panel felt that prescribing minimum standards for these mutually agreed terms would not achieve the level of flexibility necessary. In such circumstances, where specific benefits would not be prescribed in access legislation, a number of supporting measures, including indicators and guidelines, could assist Parties to ensure that mutually agreed terms supported the fair and equitable sharing of benefits.

103. Guidelines establishing standards for both providers and users of genetic resources, such as those described for information purposes in annex IV below, and voluntary industry measures and guidelines could also assist Parties to supplement access legislation and support fair and equitable partnerships. The guidelines could differentiate between the possible uses of genetic resources (i.e., education, research and development, and commercialization) and would contain possible elements for mutually agreed terms associated with these uses. The Panel encourages organizations to submit such guidelines to the Secretariat of the Convention.

104. It is suggested that legislation under development take into account and allow for the development of a multilateral system for access and benefit-sharing for plant genetic resources for food and agriculture currently being considered in intergovernmental negotiations at FAO. There is a risk that access legislation under consideration in a number of countries might foreclose or restrict the option of multilateral approaches that those same countries may be pursuing in international forums. Parties developing national legislation/regulations may wish to include provisions for facilitated access to materials, including those for food security, which are now, or may in the future, be covered under international agreements to which the Parties adhere.

5. Capacity-building

105. Access legislation will only be feasible and implementable if it is developed with the full participation of all those who will be affected by and administering it, such as certain industry sectors, universities, scientific research organizations, ex situ collections and local and indigenous communities.

106. To involve all the necessary stakeholders in the development and implementation of access legislation, particularly weak and vulnerable groups, their awareness of the significance of access and benefit-sharing will need to be raised. The capacity of certain stakeholders, particularly community-based organizations, may need to be raised in order to facilitate their participation in the development of access legislation.

107. Capacity-building is also required for institutions involved in administering access, such as the national focal points, competent national authorities and other institutions with designated functions in the role of access and benefit-sharing. These functions may include the transfer of technology in fields such as taxonomy; collection methods; facilitation of negotiations between stakeholders; assisting in the establishment of national libraries of genetic resources; monitoring activities on access and benefit-

sharing; and the provision of information on access and benefit-sharing in national reports.

108. Upon request, to the extent possible, Governments should assist individuals, communities and organizations at the local level, whose consent is being sought, so they are not subject to undue influence and to help with equality of bargaining power.

6. Regional cooperation

109. Regional cooperation among countries may help to streamline access procedures internationally and also promote capacity-building through shared efforts. Where genetic resources are shared between countries, regional cooperation in the formulation of legislative, administrative and policy measures, as well as information exchange may be useful to ensure that providers of genetic resources do not "undercut" each other, by accepting benefit-sharing agreements on less favourable terms.

D. The concept and procedure of prior informed consent

1. Key elements of prior informed consent

110. Concerning the meaning of the term "prior" in the context of prior informed consent, the following points need to be considered:

(a) Timing. 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 the adequate consideration of the information provided). While this period needs to be adequate to allow all the stakeholders properly to assess the information, too long a period of review will be an impediment to potential users seeking access. In this regard, a regular, pre-determined and clearly understood deadline is critical;

(b) Change of use. Prior informed consent should be based on 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 will require a new application for prior informed consent.

111. In order for those whose consent is sought in applications for access to be able to take a fully informed decision, those seeking access must provide them with certain information. The information provided should serve a number of purposes. First, it should be sufficient to enable the provider to decide whether to grant access to the applicant. Second, it should enable the provider to monitor compliance with the terms for which the consent was granted. It is useful if prior informed consent covers the permitted uses of the material and whether the recipient is entitled to transfer the material to third parties.

112. It is possible that the ultimate use and value of materials meant for research cannot be predicted when prior informed consent is sought. For example, the potential commercial uses of material may emerge during research initially regarded as of purely academic interest.

113. Prior informed consent should be granted based on the best current knowledge at the time access is granted and either:

(a) Stipulate clearly the permitted uses with a requirement for further prior informed consent for changes or unforeseen uses; or

(b) Ensure that mutually agreed terms in prior informed consent cover a broad enough range of circumstances to cover any possible future uses.

114. Parties to access and benefit-sharing arrangements should, in mutually agreed terms, make provision for access to dispute resolution in conformity with national and international law. The nature of such a mechanism must be such that it does not preclude access to relief for economic, jurisdictional or proximity constraints.

115. The Panel considers that:

(a) Parties should create an educational document to highlight the wide variety of potential uses and indicate how these may have implications on the terms of prior informed consent;

(b) Parties should raise awareness of donor agencies and research councils of the implications of the Convention on Biological Diversity for their work; and

(c) The Conference of the Parties may wish to invite academies of science to raise awareness among their members on the issues relating to access and benefit-sharing.

116. Applicants for access should obtain the prior informed consent of such parties as are required by applicable national law. Prior informed consent should provide access applicants with legal certainty, such that they are confident that all necessary consents have been acquired. The scope of the consent granted should be clearly stated. Contracting Parties should assist applicants for access to determine from whom consent is required.

117. Prior informed consent may be required at different levels:

(a) National level. Whether prior informed consent is required from government and, if so, whether from government at the federal, State, departmental/regional levels, or from agencies or organizations to whom this authority has been delegated or with whom it is shared;

(b) Subnational level. Identification of the categories or individuals, organizations and/or communities from whom prior informed consent is required, and thereafter the mechanisms to contact the specific stakeholders concerned.

118. The prior informed consent provisions of access legislation should be flexible enough to accommodate different types, sources and uses of genetic resources and to allow for the development of multilateral solutions on access and benefit-sharing. Some examples of flexible approaches to prior informed consent are described for information purposes in annex V below.

119. Until full and clear access legislation is in place, voluntary measures, such as the Common Policy Guidelines for Participating Botanic Gardens on Access to Genetic Resources and Benefit-sharing, the Micro-Organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC), the Swiss Draft Guidelines on Access and Benefit-sharing regarding the Utilisation of of Genetic Resources, the report commissioned by the Swedish Scientific Council on Biological Diversity on fair and equitable sharing of benefits from the use of genetic resources and traditional knowledge (UNEP/CBD/EP-ABS/Inf.1), etc., (for further information, see annex IV below) could be adopted by individual Parties as appropriate, and the

experience gained in implementing them analysed and used to shape access legislation.

120. With regard to interim measures, the Panel considers that, in the absence of national access legislation, countries desirous of encouraging users to access resources in accordance with the objectives of the Convention, may consider identifying a body of guidelines compliance with which would lead to a presumption of conformity with those objectives.

2. Procedural aspects of prior informed consent

Indigenous and local communities and prior informed consent

121. Emerging experience with the development of access legislation, as well as international human rights legislation pertaining to indigenous peoples has –in those countries where such legislation is enforced –reinforced and extended the obligations of Article 8(j) of the Convention on Biological Diversity. Requirements to consult indigenous and local communities prior to access, and obligations to seek prior informed consent for collection activities, signifies the need for identification and recognition of rights over traditional knowledge, innovations and practices. Experiences in the Philippines, Costa Rica and the Andean Community have clearly demonstrated that access legislation must 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 which have adopted access legislation have commenced processes for development of sui generis legislation to define the rights of local and indigenous communities over their knowledge, innovations and practices. Possible elements of sui generis legislation are provided for information purposes in annex VI below. Within the Andean Community, in accordance with decision 391, Bolivia, Ecuador and Colombia have commenced participatory processes with a view to development of indigenous proposals on the recognition and protection of their knowledge, innovations and practices. In Peru, draft legislation on the protection of indigenous knowledge has already been the subject of wide discussion, and processes are under way to bring it to consideration by stakeholders at the national level.

National focal points and competent national authorities

122. The Panel considered that, as a matter of urgency, each Government should establish a national focal point and one or more competent national authorities, as appropriate, on access an benefit-sharing. National focal points should be able to indicate to applicants for access, from whom prior informed consent is required. Competent national authorities should have the legal power to grant prior informed consent and to develop national procedures for access and benefit-sharing concerning different types, sources and uses of genetic resources. The functions of each of these kinds of body are addressed for information purposes in annex I below.

Capacity-building

123. As a matter of priority, the capacity-building needs of both national focal points and competent national authorities for the administration of the procedures, including the procedure for prior informed consent, need to be identified and appropriate capacity-building measures instituted.

124. In establishing national procedures for access and benefit-sharing, individual countries should pay due attention to and should consult local community groups, and identify the traditional regulatory measures that could be integrated in acquiring access and utilizing the genetic resources. Local community groups/organizations could become the agents that could facilitate and control access for different uses and help competent national authorities to monitor and evaluate the impacts.

3. International measures to support prior informed consent

User measures

125. National jurisdictions may impose certain limitations on the implementation of prior informed consent. As a result, there may be a need to explore multilateral mechanisms to support prior informed consent internationally. Parties should explore possible measures to support, in user countries, prior informed consent requirements in provider countries. Such measures could be regulatory or incentive-based, some of which relates to intellectual property rights, and are considered in the relevant section of this document. Parties may consider, inter alia, the following options:

(a) Improved means for the identification of the existence of prior art;

(b) Monitoring of intellectual-property-rights applications;

(c) Development of mechanisms for the control of importation of genetic resources;

(d) Certification schemes for institutions abiding by rules on access and benefit-sharing;

(e) Product approval and certification processes;

(f) Clearing-house mechanism;

(g) Establishment of processes for conflict resolution and arbitration concerning access and benefit-sharing.

Voluntary guidelines, including those for ex situ collections

126. The Panel considers that the Parties should support the development of international guidelines regarding access to genetic resources and benefit-sharing to ensure consistency with the objectives of the Convention. In this respect, the Panel considers that Parties should study available initiatives such as the Common Policy Guidelines for Participating Botanic Gardens, and the Swiss draft guidelines (see, for information purposes, annex IV below), the MOSAICC code, the report commissioned by the Swedish Scientific Council on Biological Diversity and the FAO Code of Conduct for Collecting and Transfer of Plant Germplasm.

E. Intellectual property rights

1. The role of intellectual property rights in prior informed consent

127. Intellectual property rights application procedures could require that the applicant submit evidence of prior informed consent. Such a system may create incentives for users to effectively comply with obligations to seek prior informed consent.

128. The effectiveness of such measures should be further evaluated. Other alternatives or complementary instruments such as user-country legislation or multilateral information systems, must also be explored regarding their effectiveness to promote the objectives of the Convention. In doing so, other international legal instruments need to be taken into consideration.

129. The Conference of the Parties needs to explore this matter in greater depth.

2. Intellectual property and traditional knowledge related to genetic resources

130. The Panel considers that, in relation to the protection of traditional knowledge, the Conference of the Parties should consider how to facilitate progress in relation to the following issues:

(a) How to define relevant terms including subject matter of traditional knowledge and scope of existing rights;

(b) Determining whether existing intellectual property rights regimes can be used to protect traditional knowledge;

(c) Options for the development of sui generis protection of traditional knowledge rights.

131. The Panel also felt that there was:

(a) A need to study the relationship between customary laws governing custodianship, use and transmission of traditional knowledge, on the one hand, and the formal intellectual property system, on the other;

(b) A need for pilot projects by means of which holders of traditional knowledge, including indigenous peoples, may test means of protection of traditional knowledge based on existing intellectual property rights, sui generis possibilities, and customary laws;

(c) A need to ensure that granting intellectual property rights does not preclude continued customary use of genetic resources and related knowledge;

(d) A need to take into account the work of all relevant bodies, including at the community, national, regional and international levels, and in particular the work of bodies under the Convention on Biological Diversity, such as the Ad Hoc Open-ended Working Group on Article 8(j) and Related Provisions and the clearing-house mechanism, and the work of other international organizations such as the United Nations Educational, Cultural and Scientific Organization (UNESCO), WIPO, the World Trade Organization (WTO) and FAO.

3. Intellectual property rights and access and benefit-sharing agreements

132. The Panel acknowledges that intellectual property rights may have an influence on the implementation of access and benefit-sharing agreements. The Panel considers that when entering into such agreements, it must be on mutually agreed terms. It also has to be taken into account that contractual arrangements must be consistent with national and international law.

133. In particular, the following issues could be considered as guiding parameters for contractual agreements:

(a) Regulating the use of resources in order to take into account ethical concerns;

(b) Making provision to ensure the continued customary use of genetic resources and related knowledge;

(c) Provision for the exploitation and use of intellectual property rights include joint research, obligation to work any right on inventions obtained or provide licenses;

(d) Taking into account the possibility of joint ownership of intellectual property rights.

134. Traditional knowledge may be protected as a trade secret or as a form of know-how as appropriate and may be subject to licensing.

135. Potential parties to an access and benefit-sharing agreement may consider the usefulness of licenses to secure continued control by providers over genetic resources.

4. Scope, prior art and monitoring

136. Some Panel members expressed concerns regarding the obtaining of intellectual property rights where there is potential misapplication of the formal requirements for protection.

137. Some Panel members expressed concerns that the scope of protection under intellectual property rights regimes may prejudice the legitimate interests of indigenous and local communities in respect of their knowledge, innovations and practices.

138. Panel members agreed that the development of registers of traditional knowledge could promote the identification and accessibility of prior art.

F. Regulatory and incentive measures

139. Incentives created by specific mechanisms need to be evaluated along with an assessment of the effectiveness of alternative regulatory measures. This assessment must be based on:

(a) The identification of specific objectives to be achieved by specific measures, for example:

(i) Fair and equitable benefit sharing;

(ii) Conservation;

(iii) Sustainable use; and

(iv) Facilitating access;

(b) The evaluation of the costs of implementation (monitoring and enforcement).

140. It was noted that different objectives may require different instruments. Over-emphasis on single-instrument approaches, such as access regulations, may run counter to some objectives such as fair and equitable benefit-sharing and facilitating access. A richer set of measures must be considered in an integrated regulatory package. This may include user, provider and multilateral measures.

141. More integrated incentive-measure approaches, involving user, provider and multilateral approaches, are desirable to the extent that they may contribute to:

(a) Altering the monitoring and enforcement costs, including the burden of proof in case of disputes;

(b) Enhancing confidence between parties;

(c) Reducing costs of compliance; and

(d) Fostering the credibility of the measures.

142. Activities related to but distinct from access to genetic resources, for example, ecotourism, can provide incentives for access activities, and vice versa, as the following example shows. It has been the experience of the Iwokrama International Centre for Rain Forest Conservation in Guyana that information resulting from access to genetic resources by scientists studying in the Centre has enhanced the interpretative value of the site for tourism, thus acting as an incentive for ecotourism. The Panel noted that ecotourism (which does not, per se, involve access to genetic resources) nonetheless can give rise to substantial benefits, which should be shared with the appropriate stakeholders.

143. The Panel submits to the Conference of the Parties that this aspect should be considered in the work of the Subsidiary Body on Scientific, Technical and Technological Advice on the subject.

144. Taking into account that the issue of economic valuation was not discussed due to time constraints, the Panel suggests that the Conference of the Parties consider the best approach to continue working on the issue.

VIII. KEY CONCLUSIONS OF THE PANEL

145. The Panel of Experts on Access and Benefit-sharing reviewed access and benefit-sharing arrangements in line with its terms of reference as contained in decision IV/8 of the Conference of the Parties and recommendation 2 of the Inter-Sessional Meeting on the Operations of the Convention.

146. On the basis of this review, the Panel suggests that the Conference of the Parties may wish to consider the following elements.

A. General conclusions

147. Parties should establish a national focal point and one or more competent national authorities, as appropriate, for access and benefit-sharing arrangements.

148. To ensure that legislative, administrative and policy measures on access and benefit-sharing meet the objectives of the Convention on Biological Diversity, they need to be based on a clear national strategy. Access and benefit-sharing strategies should be a component of national biodiversity strategies.

149. In addition, access and benefit-sharing arrangements must be developed within the context of national biodiversity strategies and action plans, so as to ensure that such arrangements are linked to conservation and sustainable-use objectives.

150. Legislative, administrative and policy measures for access and benefit-sharing need to promote flexibility, while balancing the need for regulation of access to genetic resources sufficient to promote the objectives of the Convention.

151. Flexibility in providing countries is related to the extent that user countries and organizations implement measures that provide incentives or establish control mechanisms in order to secure the interest of providers over their resources. To this end, Parties are urged to pay particular attention to their obligations under paragraph 7 of Article 15 of the Convention.

152. Legal certainty and clarity facilitates access to and use of genetic resources and contributes to mutually agreed terms in line with the aims of the Convention. In the absence of full and clear legislation and national strategies for access and benefit-sharing, voluntary measures and guidelines may be adopted by Parties to help ensure they meet the objectives of the Convention. Alternatively, this can be achieved by endorsement of individual access and benefit-sharing agreements by Governments.

153. In developing national legislation on access, Parties should take into account and allow for the development of a multilateral system to facilitate access and benefit-sharing for plant genetic resources for food and agriculture.

154. The Conference of the Parties may wish to consider the development of guidelines with respect to prior informed consent and mutually agreed terms based on the common understandings described below. To this end, the Secretariat is requested to prepare a proposal along these lines for consideration by the Conference of the Parties.

155. The Panel considered intellectual property rights in line with item 3.2 of its agenda. The Panel acknowledged that intellectual property rights may have an influence on the implementation of access and benefit-sharing arrangements and may have a role in providing incentives for users to seek prior informed consent. The Panel was not able to come to any conclusions about these issues, and therefore suggests that the Conference of the Parties consider these matters further. To guide this further consideration the Panel developed a list of specific issues that require further study, which are contained in paragraphs 127-138 above.

B. Prior informed consent

156. Prior informed consent is the core requirement of effective access and benefit-sharing measures. The following principles should guide development of prior informed consent procedures:

157. An applicant must supply sufficient information to allow for informed consent, including the best scientific and commercial information, and information regarding relevant social, cultural and environmental issues.

158. The provider must be allowed to request further particulars.

159. The information should be provided in a manner and language comprehensible to the provider.

160. Consent should be construed strictly.

161. Prior informed consent of indigenous and local communities is dependent on clear recognition and protection of their rights, knowledge and innovation and practices. For this reason the development of sui generis legislation may need to be considered.

C. Mutually agreed terms

162. Contractual arrangements are presently the main mechanism for concluding access agreements and implementing benefit-sharing, and mutually agreed terms are at the heart of the contracting process. Nevertheless, legislative, administrative or policy frameworks are essential to ensure that contractual arrangements serve national policy goals and implement the access and benefit-sharing objectives of the Convention.

163. The negotiation of mutually agreed terms must respect the legal policy and administrative arrangements of the provider country.

164. Mutually agreed terms should include provisions on user obligations such as those derived from Articles 15, paragraph 7, 16, paragraph 2, and 19, paragraph 2, of the Convention on Biological Diversity.

165. Legislative, administrative and policy measures that provide the legal basis for mutually agreed terms should seek to minimize transaction costs.

D. Information needs

166. Information is a critical aspect of providing the necessary parity of bargaining power for stakeholders in access and benefit-sharing arrangements.

167. In this respect, there is a particular need for more information regarding:

(a) User institutions;

(b) The market for 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".

168. More user-friendly documents are required. Better access to examples of actual contracts, codes of conduct, voluntary guidelines, including those used by the private sector, is also required.

169. The Secretariat is requested to prepare for the Conference of the Parties a proposal to begin to address these information needs.

E. Capacity-building

170. Further development of capacities regarding all aspects of access and benefit-sharing arrangements is required for all stakeholders, in particular, local governments, academic institutions, and indigenous and local communities.

171. Four of the most critical capacity-building needs are:

(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; and

(d) Development of *sui generis* regimes for the protection of traditional knowledge associated with genetic resources.

172. The Secretariat in consultation with the secretariat of the Global Environment Facility should develop a proposal for the consideration of the Conference of the Parties regarding how to address these needs, which would include support from the financial mechanism and other relevant organizations and the private sector.

173. The Conference of the Parties should consider guidance to the financial mechanism, bilateral and multilateral donors to provide support for developing the capacities of national focal points and competent national authorities.

Annex I

FUNCTIONS OF THE NATIONAL FOCAL POINT AND COMPETENT NATIONAL AUTHORITY

The role of the focal point in a country will likely vary according to whether that country does or does not have a competent national authority or authorities regulating access and benefit-sharing. Some Governments may designate or create the same institution to serve as both the focal point and the competent national authority. The minimum functions of the national focal point and competent national authority/authorities should be the following.

The national focal point

- Provide basic information for those seeking access to genetic resources (whether domestic or foreign applicants) as to access and benefit-sharing procedures and identification of, or means to identify, the competent national authorities and other stakeholders involved in the access and benefit-sharing procedures.

- Provide basic information to national stakeholders, such as local and indigenous communities, research institutions and companies, on legal, administrative and policy measures within the country that may entitle them to benefit from access activities and on notification procedures related to access applications.

- A focal point could also provide information on organizations involved in the conservation and sustainable use of genetic resources in the country, since these organizations could be potential partners in access and benefit-sharing arrangements or could introduce applicants to a network of other potential collaborators.

- Through the clearing-house mechanism, focal points could develop links or form a network, facilitating identification of those involved in the regulation of access around the world.

- Increase public awareness of the implications of the implementation of the Convention on Biological Diversity at the national level. This awareness-raising should be particularly targeted to key stakeholders, such as academics and commercial users of genetic resources.

The competent national authority

- Process and determine applications for access to genetic resources.

- Liaise with individuals, communities, organizations within the country to facilitate the processing of access applications, including the identification of those from whom prior informed consent is required and the evaluation of access applications.

- Produce, as required, detailed guidelines, rules and regulations on access procedures.

- Clarify the role of government in the negotiation and approval of individual access and benefit-sharing agreements.

- Coordinate with other legislative, administrative and policy bodies with functions involving genetic resources (for example, national committees on biosafety).

- Increase public awareness of the implications of the implementation of the Convention on Biological Diversity at the national level. This awareness-raising should be particularly targeted to key stakeholders, such as academics and commercial users of genetic resources.

- Perform such other functions as may be necessary to apply these implementing rules and regulations.

Some of the functions described here for competent national authorities may be exercised by the national focal point.

Annex II

THE GROWING ROLE OF "INTERMEDIARY" ENTITIES IN THE COMMERCIAL EXPLORATION AND USE OF GENETIC RESOURCES

1. As markets for genetic resources have grown and diversified over the past decade, a wide range of entities have come into being which provide specialized services to the commercial end-users of genetic resources. Such services include the collection and provision of genetic-resource samples, extracts, and associated information, as well as assistance in assuring that access and benefit-sharing laws and procedural requirements in provider countries have been met with respect to the samples provided. These entities, sometimes termed "intermediaries", are appearing in a wide range of institutional forms. They may be for-profit private-sector firms operating in multiple countries, small domestic firms working in their own country, or local universities. In several biodiversity-rich countries, specialized parastatal institutions have been established to fulfil these functions, Costa Rica's National Biodiversity Institute (INBio) being the most well-known.

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

(a) Add value to the resource; and

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

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

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

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

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

Annex III

POSSIBLE INDICATORS OF THE FAIRNESS AND EQUITY OF BENEFIT-SHARING ARRANGEMENTS IN THE CONTEXT OF MUTUALLY AGREED TERMS*

Process indicators

- Were the benefits identified and defined jointly by the provider of genetic resources and the user?
- Was there prior informed consent for access?
- Were all affected parties (e.g., government, research institutions, local communities) represented in the provider's granting of consent?
- Are the provider and user clear which variables affect the type and value of benefits agreed?
- Is it clear from the agreement which benefits were precisely defined at the time that the agreement was made, and which benefits must be defined later in the partnership once the use of the genetic resources becomes clear?
- If some of the benefits are to be defined after the initial agreement is made, is there a process stipulated in the initial agreement for reaching agreement during discovery and development on the type and value of benefits?
- Was the agreement based on full disclosure by the users of how they initially intend to use the genetic resources, and a process determined by which other uses might be approved by the provider?
- Did both the provider and the user of genetic resources have available to them the information enabling them to assess the likely value of the results of access (including the probability of success of a commercial product and the likely size and value of the market for the product)?
- Did both the provider and the user of genetic resources have available to them the negotiating skills and legal assistance needed to reach agreement?

Content indicators

- Are both monetary and non-monetary benefits included in the agreement?
- Are benefits shared at different points in time, from initial access, through discovery and development, and for the duration of sale of a product?
- Are benefits distributed to a range of stakeholders?
- Does the agreement include a "package" of different benefits?

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* Source: Kerry ten Kate and and Sarah A. Laird, Access to Genetic Resources and Benefit-sharing (prepared for the European Commission by the Royal Botanic Gardens, Kew, United Kingdom) (Earthscan Publications Ltd., London, 1999).

- Is the agreement based on the standard terms of either the provider or the user of genetic resources, or was it tailored to the specific needs of both parties?

- Does the magnitude/value of benefits vary according to degree of exclusivity of access?

- Does the magnitude/value of benefits vary according to the value added to the genetic resources by the provider (whether by supplying derivatives of the raw genetic resources, such as purified compounds, or by providing information concerning the raw genetic resources, such as ethnobotanical information or data on traits)?

- Is a mechanism established for the distribution of benefits within the provider country over time?

- Is benefit-sharing linked to a set of objectives or principles (e.g. conservation of biodiversity, sustainable development) that address wider national as well as local and institutional priorities?

Annex IV

GUIDELINES

A. Swiss draft guidelines on access and benefit-sharing regarding the utilization of genetic resources

For many years, Switzerland has been actively involved in the discussion on access to genetic resources and benefit-sharing. In order to gather useful information and to better understand the issues at a practical level, a survey had been conducted with the private sector and the research community regarding possible benefit sharing mechanisms used in connection with genetic resources. The results of this survey were reported to the Conference of the Parties to the Convention on Biological Diversity at its fourth meeting (see document UNEP/CBD/COP/4/Inf.16). The survey showed that one possible solution to address these issues is the elaboration of a set of guidelines. The draft guidelines have been drawn up with the active collaboration of the partners that were already involved in the above-mentioned survey. They are intended to serve as a starting point in the discussion on access to genetic resources and benefit-sharing.

The guidelines can be described as follows:

- Their primary function is to serve as a point of reference for all stakeholders involved in access to genetic resources and their utilization, and in the fair and equitable sharing of benefits arising from their utilization.

- They aim at: (i) prompting the appropriate access to genetic resources; and (ii) the fair and equitable sharing of benefits arising from the utilization of these resources.

- They are based on the sovereignty of States over their genetic resources.

- They set standards and contain principles that should be observed by those stakeholders that adhere to it.

- Because of their voluntary nature, the draft guidelines can be applied not only by States, but also by all other stakeholders involved in access to genetic resources and the sharing of the benefits arising from their utilization.

- They are based on an approach that differentiates the various steps involved in access to genetic resources and the sharing of the benefits arising from their utilization, that is, they differentiate all steps from the collection of genetic resources to the commercialization of the results of scientific research and development. The draft guidelines thus follow a process-based approach and list the responsibilities of all stakeholders involved in access to genetic resources and benefit-sharing.

B. The Common Policy Guidelines for Participating Botanic Gardens on Access to Genetic Resources and Benefit-sharing

For the ex situ collections held in botanic gardens to be of value to science and conservation, they must be maintained and improved. To achieve

this, continued access to plant and microbial genetic resources is essential, and botanic gardens generate and share a number of benefits. The exchange of genetic resources between botanic gardens is necessary to facilitate taxonomic and other scientific research and to ensure that the levels of diversity held in ex situ collections are adequate for conservation. Additionally, botanic gardens act as an important "clearing-house", as the genetic resources they collect may be supplied to a wide range of organizations including other botanic gardens, universities, research institutions and industry.

The Convention on Biological Diversity and national laws on access to genetic resources and benefit-sharing have introduced certain legal obligations with which botanic gardens must comply. However, in some important respects – for example, in countries where there are no laws pertaining to access to ex situ genetic resources, and with respect to access to collections made prior to the entry into force of the Convention on Biological Diversity – there is little legal or policy guidance for botanic gardens on access and benefit-sharing. By taking a voluntary, proactive approach in order to find a clear and practical way to operate in this situation, botanic gardens can help devise solutions that meet the requirements of the Convention on Biological Diversity and applicable national law and are appropriate to their activities. As there are some 1,800 botanic gardens in the world, the exchange of materials could become extremely complicated and time-consuming if each garden were to adopt its own approach to access to genetic resources and different material transfer agreements. In order to facilitate access to genetic resources directly from countries of origin and through exchange with other botanic gardens, it is highly desirable that botanic gardens harmonize their policies, practice and agreements.

With this in mind, 17 botanic gardens, from Australia, Brazil, Cameroon, Canada, China, Colombia, Malaysia, Germany, Ghana, Mexico, Morocco, the Russian Federation, South Africa, the United Kingdom and the United States of America worked together in a project coordinated by the Convention on Biological Diversity Unit of the Royal Botanic Gardens, Kew, in the United Kingdom. The project was funded by the United Kingdom Department for International Development. Botanic Gardens Conservation International and the International Association of Botanic Gardens also took part. The objectives of the project were to develop a harmonized approach for the participating gardens on access to genetic resources and benefit-sharing that implemented the letter and spirit of the Convention on Biological Diversity; to produce model material transfer agreements for the acquisition and supply of genetic resources by botanic gardens; and to prepare a publication explaining the choices made and their implications.

The resulting Common Policy Guidelines (which are available on the World Wide Web at www.rbg.ca/cbcn/cpg_index.html) were finalized in May 1999. Participating gardens subscribing to these Common Policy Guidelines will, as far as possible and as appropriate:

- Obtain prior informed consent for the acquisition of genetic resources from in situ conditions from the Government of the country of origin and other stakeholders;

- Obtain the prior informed consent for the acquisition of genetic resources from ex situ conditions from the body governing the ex situ

collection concerned, and such other consents as that body indicates are required;

- Acquire and supply genetic resources, their progeny or derivatives under material-acquisition and material-supply agreements that satisfy these principles;

- Maintain records and mechanisms to track the acquisition and supply of genetic resources, their progeny and derivatives, and the benefits that arise from their use; and

- Share the benefits arising from the use of genetic resources, their progeny and derivatives fairly and equitably with the country of origin and other stakeholders.

The Common Policy Guidelines contain a preamble, sections on objectives, definitions, principles, acquisition, records, tracking and management, supply, benefit-sharing, implementation, and model material-acquisition and supply agreements.

The botanic gardens that developed the Common Policy Guidelines hope that, in order to promote the objectives of the Convention on Biological Diversity, other organizations - which could include not only botanic gardens but other kinds of ex situ collections - will become involved in the implementation and refinement of the Common Policy Guidelines.

Annex V

FLEXIBILITY IN PRIOR INFORMED CONSENT REGIMES

Flexibility may be needed in prior informed consent regimes for a number of reasons. Flexibility could be built into prior informed consent regimes in a number of ways.

Particular uses of genetic resources

Access legislation could anticipate particular prior informed consent regimes for certain categories of genetic resources or for particular uses.

- Plant genetic resources for food and agriculture. For example, access legislation under development should anticipate the possible conclusion of a revised International Undertaking on Plant Genetic Resources for Food and Agriculture, and the need for a particular prior informed consent regime in the context of plant genetic resources for food and agriculture, which may differ from regimes for other categories and uses of genetic resources.

- Special circumstances/emergencies. There may be a need to provide for "fast-track" or "simplified" prior informed consent procedures to respond to emergencies, for example in the field of health. Outbreaks of disease sometimes require rapid access to type and reference strains to different causative agents of disease, including viruses and bacteria. The Micro-Organisms Sustainable Use and Access Regulation International Code of Conduct (the "MOSAICC code") provides for a special category of simplified procedure for such circumstances.

- Small-volume transfers for educational purposes. A simplified prior informed consent procedure, with appropriate material transfer agreements, could be used to facilitate access to single or a small numbers of specimens for educational purposes, such as use by biology students on a course or by a Ph.D. student in taxonomy.

Particular categories of recipient

Depending on the adoption of guidelines, codes of conduct or institutional standards by specific categories of recipient, prior informed consent authorities may consider the following particular categories of recipient eligible for fast-track or simplified prior informed consent procedures.

- Organizations adhering to policies, guidelines and codes of conduct. By virtue of adopting codes of conduct or other standards on access, certain organizations may qualify for a simplified prior informed consent procedure. In some cases, such standards may be developed or endorsed by government, whether in the absence of or to supplement access legislation. For example, following experience in endeavouring to regulate each access application by all domestic academics, the Philippines has initiated a decentralized system for its university community. Filipino universities are now encouraged by the competent national authorities for access in the Philippines to adopt a code of conduct embodying the requirements of the Philippines Executive Order 247 and Implementing Regulations on Bioprospecting, under which they are obliged to ensure compliance with the Executive Order by their faculty

and students. In other cases, such standards may be developed and adopted voluntarily by these organizations, independently of government. For example, the Common Policy Guidelines for Participating Botanic Gardens were developed on the initiative of a group of botanic gardens worldwide, who hope that this will facilitate simple procedures for exchange of genetic resources among participating gardens;

- Registered institutions. In the future, a system of registered institutions could be established. To be eligible for registration, these would meet independently established criteria (similar to ISO standards but, in this case, for access and benefit-sharing), demonstrating their commitment and institutional capacity to implement access and benefit-sharing obligations. Such institutions could be accorded access on a "fast-track" basis. Experience might be drawn from the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), under which CITES-registered institutions can exchange specimens with minimal documentation, instead of needing to apply for licences for import and export.

Some draft access regimes have considered different prior informed consent procedures for a variety of circumstances. For example, those developing Andean Pact decision 391 considered separate procedures for access to genetic resources from the wild; access to genetic resources from the territories of indigenous peoples; and access to genetic resources obtained from certain ex situ collections.

Transfer to third parties

It is important to be aware that certain intergovernmental agreements require genetic resources to be made accessible to third parties. This may need to be borne in mind by those granting prior informed consent, particularly with respect to the terms for transfer of material to third parties in prior informed consent provisions. For example, the International Convention for the Protection of New Varieties of Plants (the UPOV Convention) requires plant breeders to grant access to varieties protected by plant variety rights. Similarly, the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure requires patented strains to be deposited in internationally recognized culture collections ("international depositary authorities") and specifies access procedures to such strains for authorized third parties. Conditions for obtaining funding from donor agencies may require the transfer of the results of research and development (such as technology) and access by third parties.

Prior informed consent that allows for a broad range of uses

Companies often screen against a large range of targets –each with different economic implications –and, in large, multi-disciplinary life-science companies, products may emerge in a range of different industry sectors, from pharmaceuticals to crop protection to plant breeding. One possibility would be to develop a number of protocols containing a range of benefits to be shared that would be appropriate for each sector, enabling provider and user to be aware in advance of their potential rights and obligations. The precise benefits within this range could be mutually agreed at a later stage in product discovery and development.

Annex VI

POSSIBLE ELEMENTS OF *SUI GENERIS* LEGISLATION TO PROTECT THE KNOWLEDGE, INNOVATIONS AND PRACTICES OF LOCAL AND INDIGENOUS COMMUNITIES

- Recognition of ancestral community rights over knowledge, innovations and practices related to genetic resources.

- Recognition that such rights exist even where information may be in the "public domain".

- Establishment of the principle that such rights may be collective in nature.

- Distinction between rights over genetic resources (where vested in the State) and rights over knowledge associated with such resources (vested in local and indigenous custodians.)

- Presumption that use of genetic resources implies use of associated knowledge, innovations and practices.

- Establishment of administrative and judicial review processes to resolve disputes regarding the granting of access on the basis of potential environmental, economic, cultural or social impacts.

- Creation of benefit-sharing mechanisms/obligations to ensure equitable distribution of benefits amongst custodians, whether parties to access agreements or not.

- Establishment of local and centralized registers of traditional knowledge, innovations and practices of local and indigenous communities.

- Creation of programmes and processes for the strengthening of traditional knowledge systems.
