



CBD



CONVENTION ON
BIOLOGICAL
DIVERSITY

Distr.
GENERAL

UNEP/CBD/WGP-ABS/1/2
~~March 2001~~ April 2001

ORIGINAL: ENGLISH

AD HOC OPEN-ENDED WORKING
GROUP ON ACCESS AND
BENEFIT-SHARING

First meeting
Bonn, 22-26 October 2001
~~Item of the provisional agenda~~

REPORT OF THE PANEL OF EXPERTS ON ACCESS AND BENEFIT-SHARING ON THE
WORK OF ITS SECOND MEETING

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INTRODUCTION

1. The second meeting of the Panel of Experts on Access and Benefit-sharing was held at the headquarters of the International Civil Aviation Organization (ICAO) in Montreal from 19 to 22 March 2001, with financial support from the Governments of Switzerland and the United Kingdom. The meeting was convened pursuant to paragraph 10 of decision V/26 A, by which the Conference of the Parties to the Convention decided, *inter alia*:

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

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

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

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

2. Since decision V/26 A provides that the Panel of Experts was being “reconvened”, the government-nominated experts from the private and the public sectors, as well as from indigenous and local communities who participated in the first meeting, held in Costa Rica in October 1999, were invited to participate in the second meeting of the Panel. In accordance with decision V/26 A, additional experts were added to the composition of the Panel on the basis of nominations received from Governments. The Executive Secretary selected the additional experts for the meeting of the Panel, using the same set of criteria that were used for selection for the first meeting with a view to achieving, to the extent possible, a balanced regional as well as sectoral distribution.

3. In accordance with practice established at the first meeting of the Panel on the basis of recommendation 2 of the Inter-Sessional Meeting on the Operations of the Convention, representatives of competent intergovernmental organizations, including regional organizations, as well as representatives of indigenous and local communities were invited to attend the meeting as observers.

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Part One

PROCEEDINGS OF THE PANEL OF EXPERTS ON ACCESS AND BENEFIT-SHARING AT ITS SECOND MEETING

ITEM 1. OPENING OF THE MEETING

4. The meeting was opened at 10 a.m. on Monday, 19 March 2001, by Mr. Hamdallah Zedan, Executive Secretary of the Convention on Biological Diversity.

5. On the proposal of Mr. Zedan, the Panel agreed that Mr. Jorge Cabrera Medaglia (Costa Rica) and Mr. Martin Girsberger (Switzerland), Co-Chairs of the Panel at its first meeting, should continue to serve in that capacity for the current meeting.

6. Speaking on his own behalf and on that of his Co-Chair, Mr. Medaglia welcomed the experts to the meeting. He expressed his appreciation to the Executive Secretary for inviting the Panel of Experts to meet in Montreal and thanked the Secretariat for its support before and during the meeting. The first meeting had enabled the Panel of Experts to identify and reach some agreed conclusions on a number of concepts relating to access and benefit-sharing in line with the mandate from the Conference of the Parties. The second meeting provided the opportunity to go a step further by attempting to identify the mechanisms which should be developed under the framework of the Convention, in order to assist Parties and stakeholders in the implementation of access and benefit-sharing arrangements. He noted that the Open-Ended Working Group was expecting specific suggestions from the Panel for its first meeting in October 2001.

7. Mr. Zedan welcomed the participants and expressed his gratitude to the Governments of the United Kingdom and Switzerland for their financial support, which had enabled the meeting to take place. Mr. Zedan briefly recalled the history of the Panel since its establishment by the Conference of the Parties at its fourth meeting. He said that the current meeting would be pivotal to the work of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing, established by the Conference of the Parties in the same decision in which it had decided to reconvene the Panel. The outcome of the meeting was expected to assist Parties in the development of appropriate legislative, administrative and policy measures for the implementation of access and benefit-sharing arrangements, including, *inter alia*, prior informed consent and mutually agreed terms. He suggested that the Panel might wish to draw on tools such as codes of conduct and model agreements that had already been developed internationally. In order to assist the Panel, the Secretariat had prepared a background note (UNEP/CBD/EP-ABS/2/2) that built on the outcome of the first meeting of the Panel. Finally, he thanked those experts who had accepted the invitation to make presentations on their national experience or specific area of expertise, as an introduction to each of the substantive agenda items.

ITEM 2. ORGANIZATIONAL MATTERS

2.1. Attendance

8. The meeting was attended by Panel members nominated by the following Governments and Parties to the Convention: Argentina, Armenia, Australia, Benin, Belarus, Bolivia, Canada, China, Congo, Cook Islands, Costa Rica, Cuba, Czech Republic, Denmark, Ecuador, European Community, France, Germany, Honduras, Hungary, India, Iran (Islamic Republic of), Jamaica, Japan, Jordan, Kenya, Lebanon, Madagascar, Malawi, Malaysia, Mexico, Morocco, Nigeria, Pakistan, Philippines, Poland, Republic of Korea, Russian Federation, Slovakia, Spain, Sri Lanka, South Africa, Sweden, Switzerland,

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Syrian Arab Republic, Ukraine, United Kingdom of Great Britain and Northern Ireland, United States of America, Venezuela, Zimbabwe.

9. 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), United Nations Environment Programme (UNEP), United Nations University (UNU), World Intellectual Property Organization (WIPO), World Trade Organization (WTO).

10. Observers from the following other organizations were also present: Arab Center for the Studies of Arid Zones and Dry Lands (ACSAD), Asociacion Ixacavaa De Desarrollo e Informacion Indigena, Biodiversity Strategies International (BSI), Consultative Group on International Agricultural Research (CGIAR), DuPont, Indigenous People's Biodiversity Network (IPBN), Instituto Agronomico per l'Oltremare (IAO), IUCN-The World Conservation Union, Novartis Seed AG, Organisation for Economic Co-operation and Development, Organization of American States (OAS), South Pacific Regional Environment Programme (SPREP), Third World Network (TWN).

2.2. Officers

11. As decided at the opening session of the meeting, on 19 March 2001, the officers elected at the first meeting of the Panel (UNEP/CBD/COP/5/8, para. 15) continued to serve in their respective capacities for the second meeting, namely:

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

Rapporteur: Ms. Maureen Wolfson (South Africa)

2.3. Adoption of the agenda

12. 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/2/1:

1. Opening of the meeting.
2. Organizational matters:
 - 2.1 Officers;
 - 2.2 Adoption of the agenda;
 - 2.3 Organization of work.
3. Assessment of user and provider experience, identification of approaches to involvement of stakeholders, and complementary options:
 - 3.1 Assessment of user and provider experience in access to genetic resources and benefit-sharing;
 - 3.2 Identification of approaches to involvement of stakeholders in access to genetic resources and benefit-sharing processes;

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- 3.3 Study of complementary options to address access and benefit-sharing in the framework of the Convention on Biological Diversity.
4. Other matters.
5. Adoption of the report.
6. Closure of the meeting.

2.4. Organization of work

13. At the opening session of the meeting, the Panel decided that it would first hear all the introductory presentations that had been arranged under each substantive item of the agenda (see UNEP/CBD/EP-ABS/2/1/Add.2). The Panel would therefore have the opportunity to hear the issues raised under all the agenda items before splitting into two working groups: Working Group I to consider agenda item 3.1 (Assessment of user and provider experience in access to genetic resources and benefit-sharing) and Working Group II to consider agenda item 3.2 (Identification of approaches to involvement of stakeholders in access to genetic resources and benefit-sharing processes). Having heard the reports of the working groups, the Panel would continue its work in plenary to consider agenda item 3.3 (Study of complementary options to address access and benefit-sharing in the framework of the Convention on Biological Diversity). The remaining items would also be taken up directly in plenary on the last day of the meeting.

ITEM 3. ASSESSMENT OF USER AND PROVIDER EXPERIENCE, IDENTIFICATION OF APPROACHES TO INVOLVEMENT OF STAKEHOLDERS, AND COMPLEMENTARY OPTIONS

14. As an introduction to the item, at the 1st plenary session of the meeting, on 19 March, the meeting heard a statement from a representative of the World Intellectual Property Organization (WIPO), outlining recent developments on intellectual property and genetic resources at WIPO. Main programme 11 of the WIPO programme and budget contained a subprogramme on biological diversity and biotechnology, and the Working Group on Biotechnology had recommended the establishment of nine projects relating to the protection of inventions in the fields of biotechnology. The WIPO General Assembly had set up an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore to provide a forum for discussions on intellectual property and genetic resources including four main aspects: contractual agreements for access to genetic resources; legislative, administrative and policy measures to regulate access to genetic resources and benefit-sharing; multilateral systems for facilitated access to genetic resources; and the protection of biotechnological inventions.

15. The Panel also heard a presentation from a representative of the Food and Agriculture Organization of the United Nations (FAO), outlining progress made in the negotiations on the revision of the International Undertaking on Plant Genetic Resources for Food and Agriculture. The Undertaking had been adopted by the FAO Conference in 1983 as an instrument to promote international harmony in matters regarding access to plant genetic resources for food and agriculture. In 1992, Agenda 21 had called for the strengthening of the FAO Global System on Plant Genetic Resources and its adjustment in line with the Convention on Biological Diversity. Resolution 3 of the Nairobi Final Act, adopted by the Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity, had recognized the need to seek solutions to outstanding matters concerning plant genetic resources, in particular access to *ex situ* collections not addressed by the Convention and the question of Farmers' Rights and that those matters be addressed within the FAO forum. Negotiations on the revision of the Undertaking, in harmony with the Convention on Biological Diversity, had started in 1994. The Conference of the Parties to the Convention on Biological Diversity had consistently given its support to

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the negotiation of the International Undertaking, most recently at its fifth meeting, in decisions V/5 and V/26. A number of new and creative ideas had been introduced and negotiated by countries for the articles on facilitated access; sharing of monetary benefits on commercialization and financial resources; the governing body; the secretariat of the International Undertaking; and amendment of the Undertaking and of the annexes. There was now a coherent negotiating text for the overall Undertaking. — The intention was to complete the negotiations by the time of the FAO Conference in the current year. The revised International Undertaking would be a major international legally-binding instrument reflecting the significance of access and benefit-sharing as the basis for continued and sustainable utilization of plant genetic resources for food and agriculture.

3.1. Assessment of user and provider experience in access to genetic resources and benefit-sharing

16. At the 1st plenary session of the meeting, on 19 March, the Panel heard presentations under this item from:

(a) Ms. Sally Petherbridge (Australia), on the Environmental Protection and Biodiversity Conservation Act 1999 and relevant findings of the Commonwealth Public Inquiry on access to biological resources in Commonwealth areas;

(b) Ms. Beatriz Zapata Ferrufino (Bolivia), on the implementation of Decision 391 of the Andean Pact, establishing a common system throughout the Andean Community for access to genetic resources; and on the inclusion of access and benefit-sharing in the national biodiversity strategy of Bolivia; and

(c) Mr. Shri R. H. Khwaja (India), on access and benefit-sharing in India, in the context of the National Biodiversity Strategy and Action Plan.

17. In her presentation, Ms. Petherbridge said that to date, generally only inadequate provisions were in place to cover benefit-sharing as it related to the use of genetic resources, and Australia was now attempting to establish a nationally consistent approach to access. Following conclusion of the Commonwealth public inquiry, a scheme was proposed that would include both an access permit and a benefit-sharing contract. The scheme would apply only to areas under Commonwealth jurisdiction, and had been designed to be simple, flexible and transparent and to take into account the concerns both of indigenous communities and of industry and research organizations.

18. Ms. Zapata began her presentation by giving the historical background to Decision 391, going on to describe the steps that had been taken to establish the common system. She also covered property rights as they related to genetic resources, as well as the scope of and exceptions to the system. She explained that human genetic resources, and those used by the indigenous populations in their traditional practices, were excluded from the coverage of the system. After describing the formalities to be observed under the system, she concluded by describing Bolivia's national strategy for conservation and sustainable use of biodiversity, including the genetic resources component.

19. In his presentation, Mr. Khwaja described the Indian national policy and the macro-level action strategy, and the salient features of the biological diversity legislation. He went on to describe other initiatives, and outlined how the legislative measures worked in practice, using as examples the Kani experience and the Honey Bee Network. He concluded by giving a brief description of the National Innovation Foundation, the Peoples' Biodiversity Registers and the Traditional Knowledge Digital Library.

20. The item was taken up by Working Group I.

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21. At the 3rd plenary session of the meeting, on 21 March 2001, Mr. L.V. Kalakoutskii (Russian Federation), Chair of Working Group I, reported on the outcome of the work of that Group and introduced a text that it had prepared for the consideration of the Panel (UNEP/CBD/EP-ABS/2/L.2). He said that the Working Group had held four meetings, on 19 and 20 March, to consider examples of user and provider experience with regard to access and benefit-sharing. The Working Group had built on the outcome of the first meeting of the Panel and on the note prepared by the Executive Secretary for the current meeting. It had identified elements that could serve as the basis for the development of international guidelines and other approaches for access and benefit-sharing. The Working Group had met predominantly in plenary session but had established several drafting groups to prepare draft text on individual topics, such as capacity-building, legislative, administrative or policy measures, prior informed consent and intellectual property rights. The reports of the drafting groups had been considered in plenary session and approved in the form of the text that was now before the Panel. He then outlined the main points in the text with regard to capacity-building, legislative, administrative and policy measures, prior informed consent, mutually agreed terms and intellectual property rights, traditional knowledge and access and benefit-sharing.

22. The report of Working Group was subsequently incorporated into the draft report of the meeting (UNEP/CBD/EP-ABS/2/L.3) and adopted, with amendments, by the Panel as part of the present report at the final session of the meeting, on 22 March 2001 (see part two, paras. 44-82 below).

3.2. *Identification of approaches to involvement of stakeholders in access to genetic resources and benefit-sharing processes*

23. At the 1st plenary session of the meeting, on 19 March, the Panel heard a presentation under this item from Ms. Maureen Wolfson (South Africa) on the national consultation process in South Africa, in the development of the 1997 White Paper for the conservation and sustainable use of biodiversity, and present consultations and partnerships being developed in terms of access and benefit-sharing.

24. Ms. Wolfson began her presentation by describing the formation of a 28-person multi-stakeholder Reference Group, a series of stakeholder briefings held throughout the country, and a national consultative conference, going on to explain that the consultation process had helped to raise awareness; strengthen capacity; improve networking and coordination; and bring new perspectives to the biodiversity debate. However, despite the broad support for the biodiversity policy and the process, a concrete action plan to implement the policy had not yet been developed, partly owing to budgetary and other constraints. It was expected, however, that the Biodiversity Bill would pass through the parliamentary process towards the end of the current year.

25. The item was taken up by Working Group II.

26. At the 3rd plenary session of the meeting, on 21 March 2001, Ms. Anoja Wickramasinghe (Sri Lanka), Chair of Working Group II, reported on the outcome of the work of that Group and introduced a text that it had prepared for the consideration of the Panel (UNEP/CBD/EP-ABS/2/L.1). She said that the Working Group had held three meetings, on 19 and 20 March. The text that had emerged from the Group's discussions dealt with the identification of stakeholders, examples of stakeholder involvement and identification of approaches for the involvement of stakeholders. She then drew attention to the main points made in the text, noting, in particular, the view of the Working Group that the wide variety of stakeholders, their divergent interests and the broad range of processes meant that it was not feasible to identify general approaches to promote the full involvement of stakeholders and that approaches would therefore need to be designed on a case-by-case basis. Finally, she expressed the hope that the key points raised by the Working Group would be incorporated into the Panel's discussion under agenda item 3.3.

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27. The report of Working Group was subsequently incorporated into the draft report of the meeting (UNEP/CBD/EP-ABS/2/L.3) and adopted, with amendments, by the Panel as part of the present report at the final session of the meeting, on 22 March 2001 (see part two, paragraphs 83-89 below).

3.3. *Study of complementary options to address access and benefit-sharing in the framework of the Convention on Biological Diversity*

28. At the 2nd plenary session of the meeting, on 19 March, the Panel heard presentations under this item from:

(a) Mr. Alwin Kopse (Switzerland), on the draft Guidelines on Access and Benefit-sharing regarding the Utilization of Genetic Resources prepared by Switzerland; and

(b) Ms. Kerry ten Kate (United Kingdom), on guidelines and complementary measures in access and benefit-sharing.

29. Mr. Kopse began his presentation by giving the historical background to the draft Guidelines, then went on to describe their main features. They were intended to serve as a facilitating tool for the consideration of access and benefit-sharing under the Convention, to be a point of reference for all stakeholders involved in access and benefit-sharing, to give guidance to governments in implementing their obligations under the Convention on Biological Diversity and to be voluntary in nature. Additionally, they had the twofold aim of ensuring fair and equitable sharing of the benefits arising from the use of genetic resources and of promoting appropriate access to those resources. They were designed to be process-based, and at the same time took an across-the-board approach to the responsibilities of the stakeholders involved in the process, regardless of the sector to which the stakeholder belonged. He concluded by describing the features of the system of prior informed consent.

30. In her presentation, Ms. ten Kate recalled that one of the themes from the first meeting of the Panel had been that any proposed measures on access and benefit-sharing should demonstrate simplicity, clarity and flexibility, and went on to put forward some ideas on how these goals might be achieved. Stressing that any laws promulgated had to be workable, she listed some of the complementary measures that might be appropriate to support these. She suggested that the most successful approach might be based on creation of a "package" comprising an access and benefit-sharing strategy, laws, guidelines, indicators, a variety of illustrative model agreements and capacity-building programmes. To reach that stage, it was necessary to identify the nature of the guidelines needed, to outline elements of overarching guidelines, to identify the "package" of measures needed, and to recommend how the Open-ended Working Group or the Conference of the Parties should develop them. She then outlined the Principles and the Common Policy Guidelines on Access and Benefit-sharing developed by 28 botanical gardens and herbaria from 21 countries.

31. At the 3rd plenary session of the meeting, on 21 March 2001, the Panel began its consideration of the agenda item. Introducing the discussion, the Co-Chair said that the task of the Panel was to produce a package of complementary options to address the different requirements of the various parties. One of the main objectives was to identify elements for guidelines to be developed by the Ad Hoc Working Group on Access and Benefit-sharing. He suggested that the Panel might wish to draw on the texts produced by the working groups under agenda items 3.1 and 3.2 (see paras. 21 and 26 above) and focus on the characteristics of possible guidelines and elements that they might contain.

32. The Panel then engaged in an exchange of views, focusing firstly on the potential characteristics of the guidelines and then on their requisite elements.

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33. On the subject of the potential characteristics, statements were made by the experts from the following countries and Parties to the Convention: Argentina, Canada, Cuba, Denmark, European Community, France, Islamic Republic of Iran, Kenya, Malawi, Russian Federation, Switzerland, United Kingdom of Great Britain and Northern Ireland, United States of America, and Venezuela.

34. Statements on the potential characteristics were also made by the observers from the Asociación Ixacavaa de Desarrollo e Información Indigeni, and the South Pacific Regional Environment Programme (SPREP).

35. On the subject of the elements that the guidelines might contain, statements were made by the experts from the following countries and Parties to the Convention: Argentina, Bolivia, Canada, Cook Islands, Cuba, Denmark, Ecuador, Islamic Republic of Iran, Kenya, Switzerland, United Kingdom of Great Britain and Northern Ireland and Venezuela.

36. Statements on the elements were also made by the observers from the Asociación Ixacavaa de Desarrollo e Información Indigeni, the Consultative Group for International Agricultural Research (CGIAR), DuPont, the Global Environment Facility (GEF), the Organisation for Economic Co-operation and Development (OECD), the South Pacific Regional Environment Programme (SPREP) and the World Intellectual Property Organization (WIPO).

37. Following the exchange of views, the Panel decided to establish an open-ended drafting group to develop a text based on the comments made during the discussion, with a core composition of the experts from Argentina, Canada, Denmark, Indigenous People's Biodiversity Network, India, Malawi, Russian Federation, South Africa, Sri Lanka, Switzerland and United Kingdom. The drafting group would be chaired by the expert from Canada.

38. In response to a request for clarification from the floor, the Co-Chair suggested that, if time permitted, the drafting group might also consider other approaches to access and benefit-sharing.

39. At the 4th plenary session of the meeting, on 21 March 2001, the Panel took up the report of the drafting group. Various amendments were made, and the revised text was subsequently incorporated into the draft report of the meeting (UNEP/CBD/EP-ABS/2/L.3) and adopted, with amendments, by the Panel as part of the present report at the final session of the meeting, on 22 March 2001 (see part two, paras. 90-114 below).

40. It was noted by the Panel that further work was needed on complementary options, which had not been discussed in detail because of lack of time.

AGENDA ITEM 4. OTHER MATTERS

41. There were no other matters.

AGENDA ITEM 5. ADOPTION OF THE REPORT

42. The present report was adopted at the 5th plenary session of the meeting, on 22 March 2001 on the basis of the draft report that had been circulated under the symbol UNEP/CBD/EP-ABS/2/L.3. The two texts previously circulated by the chairs of the working groups as documents UNEP/CBD/EP-ABS/2/L.1 and 2 were incorporated into that draft report.

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AGENDA ITEM 6. CLOSURE OF THE MEETING

43. After the customary exchange of courtesies, the Co-Chair declared the second meeting of the Panel of Experts on Access and Benefit-sharing closed at 2.20 p.m. on Thursday, 22 March 2001

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Part Two

CONCLUSIONS OF THE PANEL OF EXPERTS

Agenda item 3.1. Assessment of user and provider experience in access to genetic resources and benefit-sharing

44. The Panel of Experts considered examples of user and provider experience on access and benefit-sharing, building on the outcome of the first meeting of the Panel and the note by the Executive Secretary prepared for the current meeting (UNEP/CBD/EP-ABS/2/2), and identified elements that may serve as a basis for the development of international guidelines and other approaches on access and benefit-sharing.

45. The Panel adopted the following conclusions, taking into consideration that they are complementary to the conclusions of the first meeting of the Panel contained in the report of the Panel to the fifth meeting of the Conference of the Parties (UNEP/CBD/COP/5/8).

A. Capacity-building

46. The Panel of Experts felt that high priority should be placed on capacity-building.

47. Capacity-building should be the *essence of the work* on access and benefit-sharing under the Convention on Biological Diversity and should be operationalized. The approaches should be based on a needs assessment for individual countries, and should aim to strengthen the ability of relevant stakeholders in the following areas:

(a) Legislation; administrative and policy measures; negotiations; mutually agreed terms; intellectual property rights;

(b) Protection of genetic resources and associated traditional knowledge, innovations and practices of indigenous and local communities;

(c) Scientific and technical areas, including technology transfer, enabling countries to conserve and undertake sustainable use of their own biological resources, such as molecular biology, natural product chemistry, taxonomy, maintenance of culture collections, intellectual property rights, among others.

48. *Awareness is a prerequisite.* The Panel of Experts wishes to draw attention to the fact that, within countries, the urgency and need for capacity-building will not be appreciated without a substantial increase in the awareness of the importance of this area. Awareness-raising is required at all levels, from government to local communities.

49. *Funding is a necessity.* The funding here should be both institutional, such as through the Global Environment Facility (GEF) and multilateral, regional, bilateral and national organizations, such as individual donor development programmes, and case-by-case, covered by users.

50. *Action plan needed.* Recalling decision V/26 A, paragraph 11, to address fully the needs outlined above related to the objectives of access and benefit-sharing, the Ad Hoc Open-ended Working Group should consider the need to draw up action plans for capacity-building on access and benefit-sharing with specific indicators, identified milestones, time-frames, roles, donors, drivers, etc. Progress in building capacity needs to be monitored and evaluated.

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B. Legislative, administrative or policy measures on access and benefit-sharing

51. Legislative, administrative or policy measures on access and benefit-sharing should be based on a clear national strategy on access and benefit-sharing, coordinated with a national biodiversity strategy and action plan or other relevant planning process related to biological diversity. The strategy should consider how different approaches to the regulation of access may affect the strategy's objectives.

52. Legislative, administrative or policy measures need to be clear, simple, flexible and enforceable, and tailored to the circumstances and needs of individual countries. These measures need to take account of different institutional frameworks (e.g., national/state/territorial) and sectoral competencies (e.g., health, biotechnology). The development of international guidelines or principles for such measures could help provide assurance to Parties that their resources are used in accordance with the terms of the Convention.

53. The distinctive nature of various categories of genetic resources suggests that these should be considered in the design of a country's approach or approaches to regulating access. There is a need for:

(a) Increased knowledge and understanding of the relationship between access regulations and existing and/or potential markets for those resources;

(b) A distinction to be made between academic and commercial use with possible different access and benefit-sharing requirements such as prior informed consent, mutually agreed terms and different benefit-sharing arrangements;

(c) A distinction to be made between end-users and intermediaries in creating access-and-benefit-sharing contractual arrangements;

(d) Increased understanding of what is a cost-effective regulatory framework and how this can be developed. In developing their policy on access and benefit-sharing, countries may wish to examine what national or international measures might already exist that could be supplemented or further improved to address access and benefit-sharing;

(e) Better understanding of ways and means of addressing the requirements of Article 8(j) in access legislation.

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

C. Prior informed consent

Key elements

55. The Panel was of the view that the following elements of prior informed consent should be considered in international guidelines and other approaches.

National focal point

56. The national focal point in each country should have the responsibility for providing two-way information flow on correct procedures and identification of competent authorities for particular transactions (at the national, provincial or local levels).

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57. The functions of focal points for countries, acting in their capacity as users, need to be clarified. National focal points should address the activities of their entities as both providers and users of genetic resources.

Competent national authorities

58. The competent national authorities may have:

(a) The responsibility for advising on the requirements for access on mutually agreed terms;

(b) The responsibility for ensuring mutually agreed terms (by participating in the negotiating process or endorsing agreements reached by institutions according to national policy and legislation).

59. These two functions may be performed by separate institutions in some countries and one institution in others.

Identifying who gives consent

60. The focal point in each country should inform access applicants (both domestic and foreign) from whom prior informed consent should be secured, both within government and among local stakeholders, and should indicate the competent national authorities.

61. The Panel emphasized that prior informed consent involves both national enabling measures by Parties and bottom-up approaches that identify those relevant stakeholders whose prior informed consent is required.

62. National procedures should facilitate the involvement of all appropriate stakeholders from the community to the government level, aiming at simplicity and clarity.

63. Permission to access genetic resources does not necessarily imply permission to use associated traditional knowledge and vice versa.

User responsibility

64. Those who have accessed genetic resources and/or traditional knowledge should be responsible for demonstrating that they have satisfied the requirements for prior informed consent. To this end, they need to document carefully the source and origin of materials accessed and the terms under which they were acquired.

Prior informed consent and capacity-building

65. In order to make access-and-benefit-sharing arrangements operational, capacity-building for prior informed consent is needed at all levels, from national to local – including administrative capacity.

66. At community level, capacity-building and strengthening of capacity-building is needed for giving prior informed consent, including adequate knowledge (in particular, the state of conservation of resources with the legal and commercial contexts of genetic resources) and skills when negotiating prior informed consent.

67. There is a priority need for capacity-building in information technology including databases, Internet access and skills development for information management. This information should be accessible at all levels.

68. Other possible elements of guidelines on prior informed consent include:

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- (a) Traceability and tracking of sources and origins of genetic material;
- (b) Timing involved in obtaining prior informed consent, including that related to change in use;
- (c) Specification of use;
- (d) Levels of requirement: national/provincial/local;
- (e) Prior informed consent of indigenous and local communities.

D. Mutually agreed terms and benefit-sharing arrangements

69. A number of aspects of contractual arrangements and mutually agreed terms have emerged which could provide the basis for guidelines for such terms and arrangements, such as the following:

- (a) Legal certainty and clarity;
- (b) Minimizing transaction costs, by, e.g.:
 - (i) Establishment and promotion of awareness of Governments' requirements for prior informed consent and contractual arrangements;
 - (ii) Ensuring awareness of existing mechanisms for applying for access, entering into arrangements and sharing benefits;
 - (iii) Framework agreements, under which repeat access under expedited arrangements can be made;
 - (iv) Standardized material transfer agreements;
- (c) Mutually agreed terms, which should include provisions on user and provider obligations;
- (d) Different contractual arrangements for different resources and uses;
- (e) The sharing of benefits arising from the commercialization of derivatives of the genetic resources.

70. Examples of a variety of model contractual arrangements/agreements may assist the negotiation of fair and equitable access and benefit-sharing arrangements.

71. Monetary benefits can be shared in the short, medium and long terms, e.g. up-front payments, milestone payments and royalties. It has been suggested that royalties alone should not be relied upon. Equity, profit-sharing and joint-venture opportunities may also be offered by companies. The guidelines could address the different kinds of monetary benefits.

72. Types of non-monetary benefits, aimed, *inter alia*, at conserving genetic resources, that could be covered in guidelines include:

- (a) Capacity-building and the transfer of technology, including biotechnology;
- (b) Scientific information relevant to conservation and sustainable use, including biological inventories and taxonomic studies;

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- (c) Contributions to the local economy, including at the village levels, such as livelihood improvements;
- (d) Health benefits for source countries and countries of origin;
- (e) Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities;
- (f) Human and material resources to strengthen the capacities of personnel responsible for the administration and enforcement of access regulations;
- (g) Participation in research processes;
- (h) Benefits for conservation and restoration of biodiversity by the providers;
- (i) Food security benefits, consistent with the work of FAO.

73. Elements for guidelines or other approaches on benefit-sharing options and mechanisms could also address:

- (a) Non-monetary benefits, arrangements that 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;
- (b) Trust funds;
- (c) Joint ventures;
- (d) User and provider experiences relating to benefit-sharing arrangements;
- (e) Economic and regulatory instruments.

74. Incentive measures offer a potential mechanism to promote benefit-sharing, particularly benefit-sharing that contributes to the conservation and sustainable use of biological diversity.

75. The need for access and benefit-sharing systems to be flexible is underscored by differences in benefit-sharing between and within sectors. The benefit-sharing experiences of different industry sectors demonstrates that there is considerable variation, both within and between sectors, on the nature and value of benefits shared and familiarity with the provisions of the Convention on Biological Diversity and requirements of relevant national law.

E. Intellectual property rights, traditional knowledge and access and benefit-sharing

76. Recalling decision V/26 A, in which the Conference of the Parties invited Parties and relevant organizations to submit information on the role of intellectual property rights in the field of access to genetic resources and the sharing of benefits, the Panel of Experts emphasizes the importance of Parties and relevant organizations submitting such information to the Executive Secretary.

77. The Panel of Experts further examined the following issues:

- (a) Introducing requirements into existing intellectual property rights procedures, such as in the filing of patent applications (e.g. specification of the country of origin or source of the genetic materials and resources), may be a possible way to track compliance with prior informed consent and

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mutually agreed terms on the basis of which access was granted. In this regard, seeking intellectual property rights may be one indicator of commercial intent;

(b) Protection measures for traditional knowledge, innovations and practices must be further explored to guarantee the rights of traditional knowledge holders. Further work is needed for the protection of traditional knowledge by means of intellectual property rights, *sui generis* systems, and other approaches, taking into account the work of the Ad Hoc Working Group on Article 8(j) and the World ~~Property~~-Intellectual ~~Property~~ Organization (WIPO);

(c) In order to build trust among providers and users of genetic resources, the current intellectual property rights system must be properly applied to avoid the inappropriate granting of intellectual property rights. Various measures can be taken in this regard including placing such information in the public domain and/or protection through traditional knowledge registers. However, it should be taken into account that some of these measures may result in the loss of novelty and the waiving of the possibility to acquire exclusive rights to commercial exploitation;

(d) Contractual agreements are currently the main legal mechanism to facilitate access and benefit-sharing arrangements and intellectual property rights clauses also play a fundamental role in such agreements. There is therefore a need for awareness and capacity-building at all levels, as well as a need to develop up-to-date model intellectual property rights clauses. WIPO may be a relevant organization to assist in this regard for these purposes.

78. The Panel of Experts recognizes that the protection of traditional knowledge and access to genetic resources and benefit-sharing are related, and recalls that the issue of traditional knowledge is being addressed by the Ad Hoc Working Group on Article 8(j).

79. In examining the above-mentioned issues, the Panel of Experts recognizes that access-and-benefit-sharing issues related to plant genetic resources for food and agriculture are best dealt with by FAO.

80. The Panel of Experts invites the Executive Secretary to present the reports of the first and second meetings of the Panel to the first session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore of WIPO.

81. The Panel of Experts recommends that ~~the~~ Executive Secretary invites WIPO to share its expertise by exploring options for addressing the above-mentioned issues and to report back to the Ad Hoc Open-ended Working Group on Access and Benefit-sharing.

82. The Panel of Experts invites the Executive Secretary, in consultation with the Bureau of the fifth meeting of the Conference of the Parties, to ensure a continued flow of information between the Convention on Biological Diversity and the World Trade Organization on matters related to access and benefit-sharing.

Agenda item 3.2. Identification of approaches to involvement of stakeholders in access to genetic resources and benefit-sharing processes

A. Identification of stakeholders

83. Because there are a wide variety of access-and-benefit-sharing situations, it is important first to identify the stakeholders who may be involved in the process in order to identify approaches for their involvement.

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84. The major types of stakeholders are users and providers. Clearly identifying the type of users or providers as the relevant stakeholders in any situation can be done only on a case-by-case basis. Nevertheless, users and providers may include, but are not limited to, the following:

- (a) Ministries, and government agencies concerned with natural resources, environment, agriculture, rural development, social welfare, culture, economic issues including fisheries and forestry, customs, protected areas, health, research, justice, finance;
- (b) Regional and provincial level government agencies;
- (c) National and international organizations involved in genetic-resources conservation;
- (d) The industrial sector, in particular seed, pharmaceutical, plant-health horticultural, personal care and cosmetics, flavouring and fragrance, food and beverage, and other biotechnological companies;
- (e) The scientific and academic communities or their representative organizations;
- (f) People's organizations;
- (g) Farmers, foresters and their organizations;
- (h) Traditional healers or their associations and communities;
- (i) Local and indigenous communities and their organizations;
- (j) Non-governmental organizations working in the field of genetic resources;
- (k) Elements of civil society that are not organized; and
- (l) Media.

B. Examples of stakeholder involvement

85. National consultative processes have been carried out in a number of countries in the preparation of a national biodiversity strategy (e.g., South Africa, Australia, Bolivia, India) or in the development of national systems for access and benefit-sharing (e.g., Philippines, Costa Rica). Experience demonstrates that the stakeholders involved, the level of their involvement and the stages during which they are involved vary from case to case.

86. Some lessons from this experience of general relevance to most access-and-benefit-sharing arrangements are:

- (a) Stakeholder involvement is directly related to the facilitation of access to genetic resources and benefit-sharing: the more that all stakeholders are involved in the process the more effective and sustainable the results;
- (b) Increased stakeholder involvement however results in increased transaction costs;
- (c) Balancing the competing aims of minimizing transaction costs, whilst at the same time maximizing stakeholder involvement is a difficult task. It requires iterative, flexible approaches to management and decision-making, and proactive leadership within government agencies, and effective support for marginalized stakeholders;

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(d) Preliminary activities such as carefully preparing for a process, identifying all relevant stakeholders and considering how to integrate stakeholders in the process are important in ensuring the most effective involvement of stakeholders.

C. Identification of approaches for the involvement of stakeholders

87. Two groups of stakeholders that generally require further attention in order to ensure adequate stakeholder involvement are indigenous and local communities and the private sector. With respect to the former, it is important that the community and its decision-making structures be included in the process.

88. The wide variety of stakeholders, their divergent interests and the broad range of processes mean that it is not feasible to identify general approaches to promote full involvement of stakeholders; rather, approaches will need to be designed on a case-by-case basis. The number of relevant stakeholders may vary at different stages in the process, with a broad range of involvement in the development of the national biodiversity strategies and action plans and regulations, for example, but a more limited number in actual contractual negotiations. No contractual negotiations should be completed without the sanction of the appropriate ministry or governmental agencies. When the knowledge, territories and biological resources of indigenous people are involved there should be a high degree of participation of indigenous people throughout the process, including in the distribution of benefits.

89. Nevertheless, approaches that addressed the following general needs of many stakeholders across a broad range of situations would promote stakeholder involvement:

(a) More information, especially regarding scientific and legal advice, is required for stakeholders to be able to participate effectively;

(b) More support for capacity-building is needed for stakeholders engaged in various stages of access-and-benefit-sharing arrangements. Further development of information packages, skills and capacity regarding all aspects of mutually agreed terms and contractual arrangements are especially necessary for those stakeholders having special interests that must be addressed in any contracts governing access and benefits. However, many countries lack the resources to properly develop capacities and therefore need to be supported in their efforts. GEF is one important source for support. Other potential sources could include: multilateral and bilateral donors, industry, and civil society. Capacity-building should therefore be considered as a complementary option and a longer-term programme could be addressed as part of a package;

(c) A committee formed of a broad range of stakeholder representatives can provide an important mechanism for promoting stakeholder involvement where there are a number of providers; and

(d) Focal points and national competent authorities are important in reducing transaction costs for users and facilitating access for users.

Agenda item 3.3. Study of complementary options to address access and benefit-sharing in the framework of the Convention on Biological Diversity

90. The Panel agreed on the following indicative outline of elements for guidelines on access and benefit-sharing.

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A. Context

Broad arrangements for access and benefit-sharing

91. International access and benefit-sharing guidelines are one of a range of possible measures aimed at assisting Parties and others involved in access and benefit-sharing arrangements in developing legislative, administrative or policy measures, or contractual arrangements. The guidelines should be seen as part of a package of complementary measures or approaches that may be considered to address the different needs of Parties and stakeholders. This package should include and be guided by a national strategy on access and benefit-sharing. As a voluntary instrument, the guidelines are intended to be relevant to policy but not prescriptive.

92. Other complementary measures that may provide guidance and therefore assist Parties include codes of conduct, model agreements, and access guidelines developed by other organizations. The use of indicators, as referred to in the report of the first meeting of the Panel of Experts, is another complementary measure that can assist in addressing the procedural and substantive aspects of benefit-sharing. Information-exchange mechanisms can also assist Parties by making relevant existing legislative texts and policy decisions available and by providing thematic reports and analysis based on that information. Such mechanisms can also provide information on users and providers of genetic resources. Capacity-building at national and local levels is essential. It should therefore be considered as an integral part of any package for establishing and implementing access-and-benefit-sharing arrangements.

93. Guidelines will assist users and providers to establish fair and equitable access and benefit-sharing arrangements both in countries that have developed access and benefit-sharing measures and in those that have not.

94. Multilateral approaches to access and benefit-sharing may be appropriate for particular categories of genetic resources.

B. Scope and level of detail of guidelines

95. The Panel was of the view that the scope and level of detail of guidelines could include:

- (a) Use of key terms;
- (b) A broadly applicable framework which can be elaborated through other more specific documents including some addressing specific sectors. The level of detail should be as follows:
 - (i) Guidelines should be sufficiently general for a broad set of applications;
 - (ii) Additional detail should be given in annexes, for example to cover specific sectors or applications;
 - (iii) Guidelines should cover all major elements but should enable Parties and stakeholders to define specific approaches in their own context;
- (c) Type of genetic resources: all types covered by the Convention. It should, however, be noted that:
 - (i) Plant genetic resources for food and agriculture under the International Undertaking are not to be covered by the guidelines but the guidelines should be consistent with the framework provided by the International Undertaking;
 - (ii) Human genetic resources are excluded;

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(d) Content of guidelines should not infringe on the national sovereignty of countries over their genetic resources and on customary practices and usages of indigenous and local communities, taking into account work carried out in the Ad Hoc Open-Ended Working Group on Article 8(j) of the Convention on Biological Diversity;

(e) Genetic resources and associated traditional knowledge, innovations and practices;

(f) Different locational and geographical contexts, including ecosystems: terrestrial and aquatic, including marine;

(g) Genetic resources not acquired in accordance with the Convention on Biological Diversity should be treated consistent with its Article 15, paragraph 3.

C. Elements of guidelines

96. The Panel identified key elements to be considered in the preparation of international guidelines for access and benefit-sharing, to serve as a basis for the work of the Ad Hoc Open-Ended Working Group on Access and Benefit-sharing. The Panel also suggested that the Working Group consider other relevant information including the report of the Panel's first meeting and sections 3.1 and 3.2 of the present report of its second meeting, as well as the results of relevant regional workshops on access and benefit-sharing.

1. Objectives

97. The objectives of the guidelines could include:

(a) To facilitate access to genetic resources and ensure fair and equitable sharing of benefits;

(b) To contribute to conservation and sustainable use of biological diversity;

(c) To provide capacity-building to promote access and benefit-sharing;

(d) To promote awareness on implementation of relevant provisions of the Convention on Biological Diversity;

(e) To promote the adequate transfer of appropriate technology to indigenous and local communities..

2. Key features

98. The key features could include:

(a) *Voluntary nature*: the guidelines will be voluntary in nature, to be applied by users and providers of genetic resources;

(b) *Ease of use*: to maximize their utility and to accommodate a range of applications, the guidelines should be simple, flexible and transparent;

(c) *Practicality*: the elements contained in the guidelines should be practical to implement and be aimed at reducing transaction costs;

(d) *Acceptability*: the guidelines should gain the ready acceptance of Governments and other users and providers;

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(e) *Complementarity*: the guidelines need to be consistent with and supportive of other relevant international instruments.

3. Elements

(a) Steps in the process

99. The guidelines should assist Parties in developing an overall access and benefit-sharing strategy and identifying the steps involved in the process of obtaining access to genetic resources and sharing benefits. These steps may include activities prior to access, research and development conducted on the genetic resources, as well as their commercialization and other uses, including benefit-sharing.

100. *Prior informed consent*: the guidelines should assist in the establishment of a system of prior informed consent, including clear procedures to follow in order to obtain prior informed consent and identification of those from whom prior informed consent is required (e.g. agencies of governments and relevant stakeholders at all levels).

101. *Mutually agreed terms, including terms on benefit-sharing*: the guidelines should assist users and providers to take due account of the distinction between different uses of genetic resources and the needs of different users and providers engaged in access and benefit-sharing agreements. The guidelines could identify an illustrative checklist of typical kinds of terms that are included in mutually agreed terms.

(b) Roles and responsibilities of stakeholders

102. The guidelines should assist users and providers in identifying the roles and responsibilities of stakeholders in the process of obtaining access to genetic resources and sharing benefits.

National focal point

103. The national focal point should provide two-way information flow on procedures for acquiring prior informed consent and mutually agreed terms and identification of competent national authorities and relevant stakeholders (including beneficiaries). These functions may be undertaken by the competent national authorities.

Competent national authority(ies)

104. Competent national authorities, where they are established, will, in accordance with applicable national legislative, administrative or policy measures, be responsible for determining access applications and/or advising on:

- (a) Requirements for obtaining prior informed consent and entering into mutually agreed terms;
- (b) Monitoring, evaluation and enforcement of access and benefit-sharing agreements;
- (c) Assistance to the negotiating process;
- (d) Endorsement of agreements;
- (e) The conservation and sustainable use of the genetic resources accessed.

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User responsibility

105. Users should be able to demonstrate that they satisfy the requirements to obtain access to genetic resources and/or traditional knowledge, such as prior informed consent on mutually agreed terms. Documentation regarding the source and/or origin of materials accessed, the terms and conditions under which they were acquired, the use of genetic resources and benefits arising from that use should be maintained.

Provider responsibility

106. Providers need to ascertain whether they are entitled to supply genetic resources, to ensure that any such supply is on terms consistent with their acquisition, and further need to document the terms and conditions under which resources were supplied.

(c) Benefit-sharing

107. The types, timing, distribution and mechanisms of benefits to be shared should be decided under mutually agreed terms. Mechanisms for conflict resolution should be defined under mutually agreed terms.

Types of benefits

108. Monetary and non-monetary benefits can be important means of promoting provider capacity for conservation and sustainable use of biodiversity. Monetary benefits include access fees, milestone payments and royalties.

Timing of benefits

109. In this context, near-term, medium-term and long-term benefits should be considered.

Distribution of benefits

110. Pursuant to mutually agreed terms established following prior informed consent, benefits should be shared fairly and equitably with all those who have been identified as having contributed to the resource management, scientific and/or commercial process. The latter may include governmental, non-governmental or academic institutions and local and indigenous communities. Benefits should be directed in such a way as to promote conservation and sustainable use of biodiversity.

Mechanisms for benefit-sharing

111. Mechanisms for sharing benefits should include full cooperation in scientific research and technology development, as well as those that derive from commercial products including trust funds, joint ventures and licences with preferential terms.

*(d) Cross-cutting elements**Capacity-building*

112. The Panel was of the view that:

(a) Capacity-building, together with technology transfer, should be the main thrust of the work on access and benefit-sharing under the Convention on Biological Diversity and should be operationalized based on an assessment of the needs of individual countries;

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(b) Awareness-building amongst the community of users and providers is a key activity to be developed within individual countries;

(c) Countries have to draw up practical action plans including monitoring and evaluation programmes to operationalize both capacity-building and awareness-building;

(d) Information exchange or networking amongst all stakeholders and between countries is one of the important milestones in implementing the guidelines.

Intellectual property rights in access and benefit-sharing

113. The relationship between intellectual property rights and the provisions of the Convention on Biological Diversity calls for multisectoral collaboration at all levels in the development of adequate regulatory frameworks or policies. The role of intellectual property rights is seen, *inter alia*, as a means to build trust and to improve implementation of the Convention on Biological Diversity, in particular of Articles 8(j), 15, 16 and, 19. Guidelines may take into consideration the following elements:

(a) Rights of the country of origin over its genetic resources and their components and parts;

(b) Adequate intellectual-property-right provisions to ensure means to safeguard stakeholder rights within access and benefit-sharing contractual arrangements;

(c) Appropriate provisions within relevant national and regional intellectual property laws and procedures to support Article 15 of the Convention on Biological Diversity, in harmony with existing international intellectual property standards;

(d) The use of intellectual property rights as well as other measures for the protection of genetic resources and associated traditional knowledge, innovations and practices, taking also into account the work of the Working Group on Article 8(j);

(e) Measures to strengthen capacity needs of holders of traditional knowledge to safeguard their rights;

(f) Measures to ensure adequate recognition and consideration of genetic resources and associated traditional knowledge, innovations and practices in existing procedures for the examination of applications for intellectual property titles;

(g) Measures to ensure traceability by introducing requirements into existing intellectual property rights procedures, such as in the filing of patent applications (e.g. specification of the country of origin or source of the genetic materials and resources), taking into account the ongoing work in WIPO.

Incentive measures

114. Taking into account the decisions of the Conference of the Parties on incentive measures, particularly decisions IV/14 and V/15, the guidelines should also address:

(a) The identification and mitigation or removal of perverse incentives that may act as obstacles for conservation and sustainable use of biological diversity through access and benefit-sharing;

(b) The use of well-designed economic and regulatory instruments directly or indirectly related to access and benefit-sharing to foster equitable and efficient allocation of benefits;

(c) Valuation methods as a tool to inform users and providers involved in access and benefit-sharing;

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(d) The creation and use of markets as a way of efficiently achieving conservation and sustainable use of biological diversity.
