



CONVENTION ON BIOLOGICAL DIVERSITY

Distr.
GENERAL

UNEP/CBD/WG-ABS/1/3
11 August 2001

ORIGINAL: ENGLISH

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

First meeting

Bonn, 22-26 October 2001

Items 3 and 4 of the provisional agenda*

DEVELOPMENT OF DRAFT INTERNATIONAL GUIDELINES ON ACCESS AND BENEFIT-SHARING

OTHER APPROACHES, INCLUDING THE DEVELOPMENT OF AN ACTION PLAN FOR CAPACITY-BUILDING

*Elements for consideration in the development of guidelines and other approaches
for access to genetic resources and benefit-sharing*

Note by the Executive-Secretary

I. INTRODUCTION

1. In paragraph 11 of decision V/26 A, on access and benefit-sharing arrangements, the Conference of Parties decided to establish an Ad Hoc Open-ended Working Group, with the mandate to develop guidelines and other approaches for submission to the Conference of the Parties and to assist Parties and stakeholders in addressing the following elements as relevant to access to genetic resources and benefit-sharing, *inter alia*:

- (a) Terms for prior informed consent and mutually agreed terms;
- (b) Roles, responsibilities and participation of stakeholders;
- (c) Relevant aspects relating to *in situ* and *ex situ* conservation and sustainable use;
- (d) Mechanisms for benefit-sharing, for example through technology transfer and joint research and development; and
- (e) Means to ensure the respect, preservation and maintenance of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity, taking into account, *inter alia*, work by the World Intellectual Property Organization on intellectual property rights issues.

2. In the same paragraph, the Conference of the Parties further decided that:

“The above-mentioned elements should, in particular, serve as inputs when developing and drafting:

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

“(a) Legislative, administrative or policy measures on access and benefit-sharing; and

“(b) Contracts or other arrangements under mutually agreed terms for access and benefit-sharing.”

3. The Conference of the Parties also decided that the Working Group would be comprised of representatives, including experts, nominated by Governments and regional economic integration organizations. It is open to the participation of indigenous and local communities, non-governmental organizations, industry and scientific and academic institutions, as well as intergovernmental organizations.

4. The Conference of the Parties also decided that the work of the Working Group should take into account the reports of the Panel of Experts on Access and Benefit-sharing and other relevant information. In paragraph 96 of the Report of its second meeting, the Panel of Experts 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”.

5. The results of the deliberations of the Working Group are to be submitted for consideration by the Conference of the Parties at its sixth meeting, in April 2002, in The Hague.

6. The Executive Secretary prepared the present note in order to assist the Working Group in its consideration of the substantive items of its provisional agenda (UNEP/CBD/WG-ABS/1/1). Section II of the document provides elements that could be included in draft guidelines taking into account the reports of the two meetings of the Panel of Experts on Access and Benefit-sharing, which met in October 1999 and in March 2001. Section III reviews other approaches, including the need for guidance, capacity building and information, which could complement guidelines and form a package of measures to assist Parties and stakeholders in the implementation of access and benefit-sharing arrangements. Elements reviewed in section III could provide a basis for the development of an action plan for capacity building in the area of access and benefit-sharing as suggested by the Panel of Experts and consistent with paragraph 14 of decision V/26 A.

II. ELEMENTS OF DRAFT INTERNATIONAL GUIDELINES ON ACCESS AND BENEFIT-SHARING

7. This section provides the background and key features of guidelines as suggested by the Panel of Experts. Elements that could form the basis of draft guidelines are reviewed in section C below, which follows the structure suggested by the Panel of Experts and is based on the recommendations of the Panel of Experts and submissions by Parties. In addition, existing guidelines and codes of conduct related to access and benefit-sharing and developed for specific types of resources (e.g. Principles on Access to Genetic Resources and Benefit-sharing for Participating Institutions (botanic gardens and herbaria), ^{1/} the Micro-Organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC), Code of Conduct for Collecting and Transfer of Germplasm of the Food and Agriculture Organization of the United Nations), the draft guidelines on access to genetic resources submitted by the Government of Switzerland and the African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders prepared by the Organization of African Unity (OAU), and the Regulation of Access to Biological Resources (OAU Model Legislation)) have also been taken into account in the

^{1/} Latorre Garcia, F., Williams, C., ten Kate, K. & Cheyne, 2001 (based on contributions from 36 individuals from 28 botanic gardens and herbaria from 21 countries). *Results of the Pilot Project for Botanic Gardens: Principles on Access to Genetic Resources and Benefit-sharing, Common Policy Guidelines to assist with their implementation and Explanatory Text*. Royal Botanic Gardens, Kew.

preparation of this section. Finally, a draft structure for the development of guidelines is included in annex I below.

A. Background

8. At its second meeting, the Panel of Experts recognized that a package of complementary measures and approaches could assist in addressing the needs of Parties and stakeholders in the implementation of access and benefit-sharing arrangements. International guidelines should be seen as part of this package. As a voluntary instrument, these guidelines are intended to be relevant to policy but not prescriptive.

B. Key features

9. As suggested by the Panel of Experts, key features of the proposed guidelines could include:

(a) *Voluntary nature*: the guidelines should 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;

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

C. Elements of guidelines

1. General provisions

(a) Use of terms

10. Article 2 of the Convention defines a number of key terms. In order to promote common understanding of these terms, the Panel of Experts recommended that drafters of access legislative, policy and/or administrative measures adopt those terms as they are defined in the Convention. Terms most relevant to access and benefit-sharing include: biological diversity, biological resources, biotechnology, country of origin of genetic resources, country providing genetic resources, *ex situ* conservation, *in situ* conservation, genetic material, genetic resources, and *in situ* conditions.

11. In addition the following terms could be included and defined in the guidelines²: access to genetic resources, benefit-sharing, commercialisation, derivatives, provider, user, stakeholder, *ex situ* collection.

(b) Scope of guidelines

12. The scope of the proposed guidelines could be determined by reference to the following elements:

(a) Categories of genetic resources (e.g. plant, animal, microbial);

(b) Geographical area (aquatic or terrestrial);

(c) Legal status (public or private land);

(d) Genetic resources *in situ/ex situ* collections;

^{2/} The Swiss draft guidelines on access to genetic resources and benefit-sharing, the Common Policy Guidelines for Botanical Gardens and the OAU Model Legislation contain definitions of these terms.

(e) Treatment of derivatives;

(f) Treatment and use of knowledge, innovations and practices of indigenous and local communities.

13. In accordance with decision II/11, paragraph 2, human genetic resources are not covered by the guidelines.

14. Parties may choose to apply these guidelines, as they deem appropriate, to guide them with access and benefit-sharing arrangements of both post and pre-CBD genetic material.

(c) *Objectives*

15. The Panel of Experts suggested that the objectives of the guidelines could include:

(a) To provide a non-discriminatory framework to facilitate access to genetic resources and ensure fair and equitable sharing of benefits;

(b) To provide guidance to Parties in the development of access and benefit-sharing regimes;

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

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

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

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

16. 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.

(d) *Relationship with other provisions and objectives of the Convention on Biological Diversity*

17. The guidelines should be implemented in harmony with the Convention on Biological Diversity, particularly its Articles 8(j), 10(c), 15, 16 and 19.

18. In decision V/9, the COP urged Parties to undertake priority activities to further the Global Taxonomy Initiative. The proposed guidelines on ABS should, therefore, take into account the needs of taxonomic research, as set out in the Global Taxonomy Initiative.

(e) *Relationship with other international legal regimes*

19. The guidelines should be applied in a manner that is not inconsistent with the framework provided by the FAO International Undertaking on Plant Genetic Resources for Food and Agriculture, the WTO Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPs) and work carried out in WIPO on issues of relevance to access and benefit-sharing.

20. The International Undertaking provides for a multilateral system of access and benefit-sharing for a number of crops and forages. Annex II to the present note provides a brief summary of the latest developments with regard to the International Undertaking.

2. *Roles and responsibilities of users and providers*

(a) *National focal point*

21. As suggested by the Panel of Experts, the focal point in each country should inform applicants for access to genetic resources (both domestic and foreign) on procedures for acquiring prior informed consent and mutually agreed terms, and identification of competent national authorities and relevant stakeholders. The national focal point is also the focal point for the Convention on Biological Diversity.

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(b) *Competent national authority*

22. It was also proposed that 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.

23. The competent national authority could have the legal power to grant prior informed consent or delegate this power to other agencies in certain cases. The same entity may serve as both the national focal point and the competent national authority.

(c) *User responsibility*

24. The Panel was of the view that users should be able to demonstrate that they satisfy any requirements for obtaining 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 also be maintained.

(d) *Provider responsibility*

25. 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.

3. *Participation of stakeholders* ^{3/}

26. The involvement of stakeholders is essential to ensure the adequate development and implementation of access and benefit-sharing arrangements. However, due to the diversity of stakeholders and their diverging interests, their appropriate involvement can only be determined on a case-by-case basis.

27. Relevant stakeholders should be consulted and their views taken into consideration in each step of the process, including: in the development of a national strategy, policies or regimes on access and benefit-sharing; when determining access; when negotiating and implementing mutually agreed terms; and in the sharing of benefits.

(a) *Establishment of a national consultative committee*

28. To facilitate the involvement of stakeholders, (e.g. in the development of the national strategy on access and benefit-sharing or in prior informed consent procedures), a committee formed of a broad range of stakeholder representatives could be formed and provisions for its consultation should be made at different steps of the ABS process.^{4/}

^{3/} Based on paras. 87-89 of the report of the second meeting of the Panel of Experts on Access and Benefit-sharing (UNEP/CBD/WG-ABS/1/2 and Corr.1).

^{4/} The Crucible II Group, Seeding Solutions, Volume 2, *Options for National Laws Governing Access to and Control Over Genetic Resources*, Draft, p. 32, provides suggestions for public consultations of stakeholders.

(b) *Promotion of stakeholder involvement*

29. The involvement of stakeholders should be promoted by:

(a) Providing information, especially regarding scientific and legal advice, in order for them to be able to participate effectively;

(b) Providing support for capacity building, in order for them to be actively engaged in various stages of access and benefit-sharing arrangements, such as in the development and implementation of mutually agreed terms and contractual arrangements.

4. *Steps in the access and benefit-sharing process*

(a) *Overall strategy*

30. Access and benefit-sharing systems, whether national or regional, should be based on an overall access and benefit-sharing strategy at the country or regional level. This access and benefit-sharing strategy should take into account the conservation and sustainable use of biological diversity and aim for the equitable sharing of benefits.

(b) *Identification of steps*

31. The steps involved in the process of obtaining access to genetic resources and sharing of benefits may include activities prior to access, research and development conducted on the genetic resources, as well as their commercialisation and other uses, including benefit-sharing.

(c) *Prior informed consent*

32. As set out in Article 15 of the Convention on Biological Diversity, recognizing the sovereign rights of States over their natural resources, each Contracting Party to the Convention is to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties.

33. Against this background, the guidelines should assist in the establishment of a system of prior informed consent by Contracting Parties when acting as providers of genetic resources, in accordance with Article 15, paragraph 5.

(i) *Basic principles of a prior informed consent system*

34. The basic principles of a prior informed consent system include:

(a) There should be legal certainty and clarity;

(b) Access to genetic resources should be facilitated;

(c) Restrictions on access to genetic resources should be non-discriminatory and should be based on legal grounds and on objective criteria in order to conserve biological diversity;

(d) Consent of the competent national authority in the provider country including relevant stakeholders, such as indigenous and local communities, as appropriate, should be ensured.

(ii) *Elements of a prior informed consent system*

35. Elements of a prior informed consent system may include:

(a) Competent authority(ies) granting prior informed consent;

(b) Timing and deadlines;

(c) Specification of use;

(d) Conditions for obtaining prior informed consent;

(e) Mechanism for consultation of relevant stakeholders (under section 3 above on participation of stakeholders);

(f) Process.

Competent authority(ies) granting prior informed consent

36. *From in situ conditions.* Prior informed consent for genetic resources obtained from *in situ* conditions could be obtained from the Government of the country of origin and other identified stakeholders.

37. Prior informed consent may be required from different levels of Government. Requirements for obtaining prior informed consent (national/provincial/local) in the provider country should therefore be specified.

38. National procedures should facilitate the involvement of all relevant stakeholders from the community to the government level, aiming at simplicity and clarity. (see section 3 above on the participation of stakeholders).

39. Relevant stakeholders should include indigenous and local communities when the genetic resources concerned are found on land occupied by them or who are the holders of related traditional knowledge. The prior informed consent of such communities should be obtained in accordance with their customary laws.

40. *From ex situ collections.* For *ex situ* collections, the PIC should be obtained from the body governing the *ex situ* collection concerned, and such other consents as that body indicates are required.

41. If the provider country is not the country of origin, in accordance with Article 15 consent should be granted by the provider country, subject to any existing agreement between the country of origin and the provider country regarding the genetic resources being acquired.

Timing and deadlines

42. Prior informed consent is to be sought adequately in advance to be meaningful both for those seeking and for those granting access. Decisions on applications for access to genetic resources should also be taken within a reasonable period of time.

Specification of use

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

44. Prior informed consent is linked to the requirement of mutually agreed terms. Depending on the terms for access and use, prior informed consent may or may not be granted.

Conditions for obtaining prior informed consent

45. An application for access could require the following information to be provided, in order for the competent authority to determine whether or not access to a genetic resource should be granted. This list is merely indicative and should be adapted to national circumstances:

- (a) Legal entity and affiliation of the applicant and/or collector;
- (b) Type and quantity of genetic resources to which access is sought;
- (c) Starting date and duration of the activity;

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- (d) Geographical prospecting area;
- (e) Evaluation of how the access activity may impact on conservation and sustainable use of biodiversity, to determine the relative costs and benefits of granting access;
- (f) Accurate information regarding intended use (collection, research, commercialization);
- (g) Identification of where the research and development will take place;
- (h) Information on how the research and development is to be carried out;
- (i) Identification of local bodies for collaboration in research and development;
- (j) Possible third party involvement;
- (k) Purpose of the collection, research and expected results;
- (l) Kinds/types of benefits that could come from obtaining access to the resource;
- (m) Indication of benefit-sharing arrangements;
- (n) Budget;
- (o) Treatment of confidential information.

46. It should be noted that permission to access genetic resources does not necessarily imply permission to use associated knowledge and vice versa.

Process 5/

47. Applications for access to genetic resources through prior informed consent and decisions by the competent authority, to grant access to genetic resources or not, shall be documented in written form.

48. The competent authority could grant access by issuing a permit or license. A national registration system could be used to record the issuance of all permits or licenses, on the basis of duly completed application forms.

49. The procedures for obtaining an access permit/license should be transparent and accessible by any interested party.

(d) Mutually agreed terms

50. In conformity with Article 15, paragraph 7, of the Convention on Biological Diversity, each Contracting Party shall “take legislative, administrative or policy measures, as appropriate (...) with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms”. Thus, guidelines should assist Parties in the development of mutually agreed terms to ensure the fair and equitable sharing of benefits.

(i) Basic requirements for mutually agreed terms

51. The following principles or basic requirements should guide the development of mutually agreed terms:

- (a) Legal certainty and clarity;
- (b) Minimization of transaction costs, by, for example:
 - (i) Establishing and promoting awareness of Government’s requirements for prior informed consent and contractual arrangements;

^{5/} These elements are based on the Swiss draft guidelines, the OAU Model Legislation, the Common Policy Guidelines for Participating Botanical Gardens.

- (ii) Ensuring awareness of existing mechanisms for applying for access, entering into arrangements and sharing benefits;
- (iii) Developing framework agreements, under which repeat access under expedited arrangements can be made;
- (iv) Developing standardized material transfer agreements;
- (e) Inclusion of provisions on user and provider obligations;
- (f) Development of different contractual arrangements for different resources and for different uses;
- (g) Different uses may include: collection, research, commercialization;
- (h) Mutually agreed terms should be negotiated efficiently and within a reasonable period of time;
- (i) Mutually agreed terms should be set out in a written agreement.

52. The Panel of Experts emphasized that the following elements could be considered as guiding parameters in contractual agreements. These elements could also be considered as basic requirements for mutually agreed terms:

- (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.
- (ii) *Indicative list of typical mutually agreed terms*

53. The following provides an indicative list of typical mutually agreed terms:

- (a) Type and quantity of genetic resources and the geographical area of activity;
- (b) Any limitations on the possible use of the material;
- (c) Ownership of the resource;
- (d) Capacity building in various areas to be identified in the agreement;
- (e) A clause allowing renegotiation of the terms of the agreement in certain circumstances (e.g. change of use);
- (f) Whether the genetic resources can be transferred to third Parties and conditions to be imposed in such cases, e.g. not to pass genetic resources to third parties without ensuring that the third parties enter into similar agreements;
- (g) Whether the rights of indigenous and local communities have been respected as far as their knowledge, innovations and practices are concerned, and rights to the continued customary use of biological/genetic resources for which access is sought;
- (h) Time limitation;
- (i) Treatment of confidential information;
- (j) Provisions regarding the benefits to be shared.

(iii) *Benefit-sharing*

54. Mutually agreed terms will cover the types, timing, distribution and mechanisms of benefits to be shared. These will vary depending on what is regarded as fair and equitable in light of the circumstances.

Types of benefits

55. Monetary and non-monetary benefits can be important means of promoting provider capacity for the conservation and sustainable use of biodiversity.

56. Monetary benefits may include:

- (a) Access fees/fee per sample collected or otherwise acquired;
- (b) Milestone payments;
- (c) Payment of royalties;
- (d) License fees in case of commercialization;
- (e) Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;
- (f) Salaries;
- (g) Taxation;
- (h) Research funding;
- (i) Joint ventures;

57. Non-monetary benefits may include:

- (a) Sharing of research results;
- (b) Collaboration in scientific research and development programmes, particularly biotechnological research activities, where possible in the provider country;
- (c) Participation in product development;
- (d) Collaboration in education and training;
- (e) Admittance to *ex situ* facilities of genetic resources and to databases;
- (f) Transfer of knowledge and technology under fair and most favourable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity;
- (g) Strengthening capacities for technology transfer and capacities of local and indigenous people to conserve and sustainably use their genetic resources;
- (h) Institutional capacity-building;
- (i) Human and material resources to strengthen the capacities of personnel responsible for the administration and enforcement of access regulations;
- (j) Training related to genetic resources with the full participation of providing Parties, and where possible, in such Parties;
- (k) Scientific information relevant to conservation and sustainable use, including biological inventories and taxonomic studies;
- (l) Contributions to the local economy;

- (m) Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in provider countries;
- (n) Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities;
- (o) Food security benefits, consistent with the work of FAO;
- (p) Joint ownership of patents and other relevant forms of intellectual property rights.

Timing of benefits

58. Near-term, medium-term and long-term benefits should be considered, e.g. up-front payments, milestone payments and royalties.

Distribution of benefits

59. 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

60. Mechanisms for benefit-sharing may vary widely depending upon the type of benefits, the specific conditions in the country and the stakeholders involved. The benefit-sharing mechanism should be flexible as it should be determined by the partners involved in benefit-sharing and will vary on a case by case basis.

61. 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.

Mediator

62. The stakeholders involved in access to genetic resources and benefit-sharing may wish to seek the support of a mediator when negotiating mutually agreed terms.

5. *Other provisions*

(a) *Monitoring of compliance*

63. Depending on the terms of access, monitoring of compliance may include:

- (a) Whether the use of genetic resources is in compliance with the terms of access;
- (b) Research and development process;
- (c) Applications for patents relating to the material supplied.

(b) *Verification of mechanisms in user countries*

64. Verification mechanisms could be developed at the national level to ensure compliance with the provisions of the Convention on Biological Diversity dealing with access to genetic resources and benefit-sharing. The provider should have the possibility to seek assurance that the Convention has been complied with by the user before transferring the genetic resources.

65. A possible verification system could be evidence of prior informed consent and the existence of a contract providing for an equitable sharing of benefits.

(c) *Guarantees from the collector*

66. For example, the OAU Model Legislation provides that the parent institution of the collector is to take responsibility for the “good behaviour” of the collector. ^{6/}

(d) *Sanctions for breach of terms of access*

67. In cases where the provisions of the Convention on Biological Diversity have not been complied with, the use of sanctions could be considered such as the payment of special fees in funds for the conservation and sustainable use of biodiversity in developing countries.

(e) *Remedies for breach of terms of access*

68. The competent national authority could be given the authority to seek compensation (e.g. damages), unilaterally withdraw consent and repossess the permit/license, ^{7/} or impound the material when the terms of access have been breached. The remedies used should be proportional to the breach of terms. It has been suggested that a breach in the terms of access could be established in a number of circumstances, such as:

(a) When there is evidence that the collector has violated any of the provisions of national access legislative, administrative or policy measures;

(b) When there is evidence that the collector has failed to comply with the agreed terms;

(c) When there is failure to meet any of the conditions of access;

(d) When a patent has been applied for or secured in contravention with mutually agreed terms.

(e) *System of certification*

69. A system of certification could serve as a means to verify implementation of the guidelines. Such a system would certify that the guidelines and the Convention on Biological Diversity have been complied with by the stakeholders involved. ^{8/}

(f) *Dispute resolution*

70. Provision for access to dispute resolution in cases where legislation or agreements have been violated should be provided for in national access legislative, administrative or policy measures and/or in contractual arrangements on access and benefit-sharing, in accordance with national or international law. Irrespective of the level at which a dispute may take place, affected indigenous and local communities should be fairly and adequately represented.

D. Cross-cutting elements

1. Means to ensure the respect, preservation and maintenance of knowledge, innovations and practices of local and indigenous communities

71. The Panel of Experts was of the view that when the knowledge, territories (where applicable) and biological resources of local and indigenous communities are involved, there should be a high degree of participation of these communities throughout the process, including in the distribution of benefits. Means to ensure the respect, preservation and maintenance of knowledge, innovations and practices of local and indigenous communities are to be taken into account throughout guidelines on ABS.

^{6/} OAU Model Legislation, Article 10.

^{7/} OAU Model Legislation, Article 14.

^{8/} A certification system is described in annex D of the Swiss draft guidelines on access to genetic resources and benefit-sharing.

2. *Intellectual property rights in access and benefit-sharing arrangements*

72. The issue of intellectual property is addressed in a separate note prepared by the Executive Secretary on the role of intellectual property rights in the implementation of access and benefit-sharing arrangements (UNEP/CBD/WG-ABS/1/4). In addressing the development of international guidelines on access and benefit-sharing, however, it is useful to refer to elements identified by the Panel of Experts.

73. The Panel was of the view that intellectual property rights could constitute a means to build trust and improve the implementation of the Convention on Biological Diversity. In this context, it was suggested that guidelines could include provisions relating to the following:

- (a) The rights of the country of origin over its genetic resources and their components and parts should be recognized;
- (b) Adequate intellectual-property-rights provisions should be considered to ensure means to safeguard stakeholder rights within access and benefit-sharing contractual arrangements;
- (c) Appropriate provisions should be included 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) Measures should be considered to strengthen the capacity needs of holders of traditional knowledge to safeguard their rights;
- (e) Measures should be considered to ensure adequate recognition and consideration of genetic resources and associated traditional knowledge, innovations and practices in existing procedures for the examination of applications of intellectual property titles;
- (f) Measures should be considered 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.

3. *Incentive measures*

74. The following elements relating to incentive measures were also identified by the Panel as potential elements for consideration in the development of guidelines:

- (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, should be considered;
- (b) The use of well-designed economic and regulatory instruments, directly or indirectly related to access and benefit-sharing, should be considered to foster equitable and efficient allocation of benefits;
- (c) The use of valuation methods should be considered as a tool to inform users and providers involved in access and benefit-sharing;
- (d) The creation and use of markets should be considered as a way of efficiently achieving conservation and sustainable use of biological diversity.

III. OTHER APPROACHES

75. The Panel of Experts recognized that guidelines should be seen as part of a package of measures or approaches that may be considered to address the different needs of Parties and stakeholders in the implementation of access and benefit-sharing arrangements. Other measures or approaches that may provide guidance to Parties include codes of conduct, model agreements and indicators. In addition,

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capacity building and information exchange mechanisms were also identified as useful complementary approaches in assisting Parties and stakeholders to implement ABS.

A. Codes of conduct, guidelines, indicators and model agreements

1. Existing codes of conduct and guidelines addressing access to genetic resources and benefit-sharing

76. Numerous professional and institutional guidelines and codes of conduct relevant to access and benefit-sharing have been developed, ^{9/} such as MOSAICC, Principles on Access to Genetic Resources and Benefit-sharing for Participating Institutions (botanic gardens and herbaria) ^{10/} and the FAO Code of Conduct for Plant Collecting and Transfer of Germplasm. These texts apply to specific types or uses of genetic resources and may therefore be useful complementary approaches to international guidelines on access and benefit-sharing.

77. It should also be noted that a compilation of existing instruments, guidelines, codes and other relevant statements by indigenous and local communities and other institutions (UNEP/CBD/WG8J/2/INF/1) is available on the Secretariat website (www.biodiv.org) in the section dedicated to traditional knowledge.

2. Model agreements

78. Both the guidelines developed for microbial culture collections and those developed for botanical gardens contain model documents and/or agreements for the supply and acquisition of genetic resources.

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

3. Indicators

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

B. Capacity building

81. In paragraph 11 of its decision V/26 A, the Conference of the Parties decided that, in order to build capacity for access and benefit-sharing, the Open-ended Working Group shall consider issues of capacity building, including those needs identified in paragraphs 14 (a), (b), (c) and (d) of the same decision, by which the Conference of the Parties noted that further development of capacities regarding all aspects of access and benefit-sharing arrangements is required for all stakeholders, including local governments, academic institutions, and indigenous and local communities, and that key capacity-building needs include:

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

^{9/} See the note by the Executive Secretary prepared for the second meeting of the Panel of Experts on Access and Benefit-sharing (UNEP/CBD/EP-ABS/2/2).

^{10/} See footnote 1 above.

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

83. The Panel of Experts emphasized that capacity-building at national and local levels is essential and that it should be considered as an integral part of any package of measures to assist in the implementation of access and benefit-sharing arrangements. In this context, awareness-raising on the importance of capacity-building was deemed essential at all levels, from government to local communities.

84. Finally, the Panel suggested that 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. The progress in building capacity should also be monitored and evaluated. In addition, the Panel noted that many countries lack the resources to properly develop capacities and need to be supported in their efforts by the Global Environment Facility and other potential donors.

85. Accordingly, in considering a possible action plan for capacity-building, the Working Group may wish, in a preliminary stage, to identify the needs and priorities of Parties in the implementation of access and benefit-sharing arrangements. It may also wish to take into consideration the type of capacity required to implement access and benefit-sharing arrangements (i.e., institutional strengthening, human resource development).

C. Information exchange mechanisms

86. In paragraph 12 of decision V/26 A, the Conference of the Parties noted that information is a critical aspect of providing the necessary parity of bargaining power for stakeholders in access and benefit-sharing arrangements, and that, in this respect, there is particular need for more information regarding:

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

87. In notifications following the fifth meeting of the Conference of the Parties, the Executive Secretary invited Parties to provide information on any recent developments related to access and benefit sharing, including texts of any legislative, administrative or policy measures, as well as information regarding the issues listed in paragraph 12 of decision V/26 A. This information would enable the Secretariat to develop a database on existing legislative texts and policy decisions in this field. The Secretariat, through the clearing-house mechanism, could serve as a centre for information exchange among Parties.

88. Thematic reports on benefit-sharing submitted to the Secretariat pursuant to paragraph 8 of decision V/19, on national reporting, are being made available through the clearing-house mechanism as they are received by the Secretariat.

Annex I

**DRAFT STRUCTURE FOR THE DEVELOPMENT OF GUIDELINES ON ACCESS AND
BENEFIT-SHARING**

- 1. General provisions**
 - (a) Use of key terms
 - (b) Scope of guidelines
 - (c) Objectives
 - (d) Relationship with other provisions and work programmes of the CBD
 - (e) Relationship with other international legal regimes
- 2. Roles and responsibilities of users and providers**
 - (a) National focal point
 - (b) Competent national authority
 - (c) User responsibility
 - (d) Provider responsibility
- 3. Participation of stakeholders**
 - (a) Establishment of a consultative committee
 - (b) Promotion of stakeholder involvement
- 4. Steps in the ABS process**
 - (a) Overall strategy
 - (b) Identification of steps
 - (c) Prior informed consent
 - (i) Basic principles of prior informed consent
 - (ii) Elements of a prior informed consent system
 - (d) Mutually agreed terms
 - (i) Basic requirements for mutually agreed terms
 - (ii) Illustration of typical mutually agreed terms
 - (iii) Benefit-sharing:
 - Types of benefits
 - Timing of benefits
 - Distribution of benefits
 - Mechanisms for benefit-sharing
 - Mediator
- 5. Other provisions**
 - (a) Monitoring of compliance
 - (b) Verification of mechanisms in user countries
 - (c) Guarantees from the collector
 - (d) Use of sanctions
 - (e) Use of remedies for breach of terms of access
 - (f) System of certification
 - (g) Dispute resolution

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Annex II

**THE INTERNATIONAL UNDERTAKING ON PLANT GENETIC RESOURCES FOR FOOD
AND AGRICULTURE.**

1. The Commission on Genetic Resources for Food and Agriculture completed its work to revise the International Undertaking, in harmony with the Convention on Biological Diversity. The text of the Undertaking, as prepared by the Commission, will be forwarded by the Director-General to the FAO Conference in November 2001, for finalization and adoption.
2. The objective of the Undertaking (Article 1) is to achieve the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of benefits derived from their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security. The objectives are to be attained by closely linking the International Undertaking to both FAO and the Convention on Biological Diversity. Other links to the Convention provide for: cooperation between the Global Information System and the clearing house mechanism, and for the Governing Body to cooperate with the Conference of the Parties and take note of its relevant decisions.
3. The centerpiece of the Undertaking is the “Multilateral System for Access and Benefit Sharing”: Article 11, paragraph 2, states that:

“In the exercise of their sovereign rights, the Contracting Parties agree to establish a multilateral system, which is efficient, effective, and transparent, both to facilitate access to plant genetic resources for food and agriculture, and to share, in a fair and equitable way, the benefits arising from the utilization of these resources, on a complementary and mutually reinforcing basis”
4. While the general provisions of the Undertaking apply to all PGRFA, the Multilateral System applies only to a list of crops and then only to material that is in the public domain (Article 12). The list includes most major food crops (some 35 crop genera), plus a list of forages (32 genera containing some 70 species). For such material, the Contracting Parties agree to facilitated access to plant genetic resources for food and agriculture under the Multilateral System (Article 13, para. 1). Access shall be provided solely for the purpose of utilization and conservation in research, breeding and training for food and agriculture, subject to various property rights and other conditions (Article 13, para. 3). Relevant conditions of access and benefit-sharing shall be set out in a standard material transfer agreement (Article 13, para. 4).
5. Benefits arising from the use, including commercial, of plant genetic resources for food and agriculture under the Multilateral System shall be shared fairly and equitably through the following mechanisms: the exchange of information, access to and transfer of technology, capacity-building, and the sharing of the benefits arising from commercialization (Article 14, para. 2). In the case of commercialization of a product that is a plant genetic resource for food and agriculture and that incorporates material accessed from the Multilateral System, recipients shall pay to a mechanism, an equitable share of the benefits arising from the commercialization of that product, except whenever such a product is available without restriction to others for further research and breeding, in which case the recipient who commercialises shall be encouraged to make such payment. The Governing Body shall determine the level, form and manner of the payment, in line with commercial practice (Article 14, para. 2 (d) (ii)). There shall be additional voluntary modalities for benefit sharing (Article 14, para. 6) as well as a funding strategy for the overall implementation of the Undertaking (Article 19).
6. Pending items that need to be resolved prior to adoption of the final text include:
 - (a) Whether or not *limits to the Intellectual Property Rights* that can be claimed on material received from the multilateral system extend to “parts and components”, and a related question in the definition of plant genetic resources for food and agriculture;
 - (b) *The list of crops*; and
 - (c) *The relationship of the Undertaking to existing international agreements* (ie, in particular, the WTO agreements).