COP 6 Decision

The Hague, 7 - 19 April 2002

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Access and benefit-sharing as related to genetic resources

A. Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization

The Conference of the Parties

- Takes note of the report of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing⁽⁵⁸⁾;
- Takes note also of the work done by the group convened by the Executive Secretary to develop elements of a draft decision on the use of terms in paragraph 6 of the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefit Arising out of their Utilization;
- Decides to adopt the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefit Arising out of their Utilization as annexed to the present decision;
- Invites Parties and Governments to use the Guidelines when developing and drafting legislative, administrative or policy measures on access and benefit-sharing, and contracts and other arrangements under mutually agreed terms for access and benefit-sharing;
- Invites Parties and relevant organizations to provide financial and technical assistance to support developing countries, in particular least developed countries, small islands developing states, as well as countries with economies in transition, in implementing the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefit Arising out of their Utilization;
- Recognizes that the Guidelines are a useful first step of an evolutionary process in the implementation of relevant provisions of the Convention related to access to genetic resources and benefit-sharing;
- Decides to keep under review the implementation of the guidelines and consider the need for their further refinement on the basis of, *inter alia*, relevant work under the Convention, including work on Article 8(j) and related provisions;
- Decides to reconvene the Ad Hoc Open-ended Working Group on Access and Benefit-sharing to advise the Conference of the Parties on:
 - Use of terms, definitions and/or glossary, as appropriate; Other approaches as set out in decision VI/24 B; Measures, including consideration of their feasibility, practicality

and costs, to support compliance with prior informed consent of the Contracting Party providing such resources and mutually agreed terms on which access was granted in Contracting Parties with users of genetic resources under their jurisdiction;

Its consideration of any available reports or progress reports arising from the present decision;

Needs for capacity-building identified by countries to implement the Guidelines.

The Working Group will submit its report to the Conference of the Parties at its seventh meeting;

Requests the Executive Secretary to invite Parties, Governments and relevant international organizations to submit information on the issues referred to in paragraphs 8 (a), (b), (c) and (e) above, and to make this information available to the Open-ended Working Group on Access and Benefit-sharing and through the clearing-house mechanism;

Requests the Ad Hoc Open-Ended Working Group on Article 8(j) and Related Provisions to consider the Guidelines as relevant to its ongoing work.

Annex

BONN GUIDELINES ON ACCESS TO GENETIC RESOURCES AND FAIR AND EQUITABLE SHARING OF THE BENEFITS ARISING OUT OF THEIR UTILIZATION

I. GENERAL PROVISIONS

A. Key features

These Guidelines may serve as inputs when developing and drafting legislative, administrative or policy measures on access and benefit-sharing with particular reference to provisions under Articles 8(j), 10 (c), 15, 16 and 19; and contracts and other arrangements under mutually agreed terms for access and benefit-sharing.

Nothing in these Guidelines shall be construed as changing the rights and obligations of Parties under the Convention on Biological Diversity.

Nothing in these Guidelines is intended to substitute for relevant national legislation.

Nothing in these Guidelines should be interpreted to affect the sovereign rights of States over their natural resources;

Nothing in these Guidelines, including the use of terms such as "provider", "user", and "stakeholder", should be interpreted to assign any rights over genetic resources beyond those provided in accordance with the Convention;

Nothing in these Guidelines should be interpreted as affecting the rights and obligations relating to genetic resources arising out of the mutually agreed terms under which the resources were obtained from the country of origin.

The present Guidelines are voluntary and were prepared with a view to ensuring their:

Voluntary nature: they are intended to guide both users and providers of genetic resources on a voluntary basis;

Ease of use: to maximize their utility and to accommodate a range of applications, the Guidelines are simple;

Practicality: the elements contained in the guidelines are practical and are aimed at reducing transaction costs;

Acceptability: the Guidelines are intended to gain the support of users and providers;

Complementarity: the Guidelines and other international instruments are mutually supportive;

Evolutionary approach: the Guidelines are intended to be reviewed and accordingly revised and improved as experience is gained in access and benefit-sharing;

Flexibility: to be useful across a range of sectors, users and national circumstances and jurisdictions, guidelines should be flexible;

Transparency: they are intended to promote transparency in the negotiation and implementation of access and benefit-sharing arrangements.

B. Use of terms

The terms as defined in Article 2 of the Convention shall apply to these Guidelines. These 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. **C. Scope**

All genetic resources and associated traditional knowledge, innovations and practices covered by the Convention on Biological Diversity and benefits arising from the commercial and other utilization of such resources should be covered by the guidelines, with the exclusion of human genetic resources. **D. Relationship with relevant** international regimes

The guidelines should be applied in a manner that is coherent and mutually supportive of the work of relevant international agreements and institutions. The guidelines are without prejudice to the access and benefit-sharing provisions of the FAO International Treaty for Plant Genetic Resources for Food and Agriculture. Furthermore, the work of the World Intellectual Property Organization (WIPO) on issues of relevance to access and benefit-sharing should be taken into account. The application of the guidelines should also take into account existing regional legislation and agreements on access and benefit-sharing. **E. Objectives**The objectives of the Guidelines are the following:

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

To provide Parties and stakeholders with a transparent framework to facilitate access to genetic resources and ensure fair and equitable sharing of benefits;

To provide guidance to Parties in the development of access and

- benefit-sharing regimes;
- To inform the practices and approaches of stakeholders (users and providers) in access and benefit-sharing arrangements;
- To provide capacity-building to guarantee the effective negotiation and implementation of access and benefit-sharing arrangements, especially to developing countries, in particular least developed countries and small island developing States among them;
- To promote awareness on implementation of relevant provisions of the Convention on Biological Diversity;
- To promote the adequate and effective transfer of appropriate technology to providing Parties, especially developing countries, in particular least developed countries and small island developing States among them, stakeholders and indigenous and local communities;
- To promote the provision of necessary financial resources to providing countries that are developing countries, in particular least developed countries and small island developing States among them, or countries with economies in transition with a view to contributing to the achievement of the objectives mentioned above;
- To strengthen the clearing-house mechanism as a mechanism for cooperation among Parties in access and benefit-sharing;
- To contribute to the development by Parties of mechanisms and access and benefit-sharing regimes that recognize the protection of traditional knowledge, innovations and practices of indigenous and local communities, in accordance with domestic laws and relevant international instruments;
- To contribute to poverty alleviation and be supportive to the realization of human food security, health and cultural integrity, especially in developing countries, in particular least developed countries and small island developing States among them;
- Taxonomic research, as specified in the Global Taxonomy
 Initiative, should not be prevented, and providers should
 facilitate acquisition of material for systematic use and users
 should make available all information associated with the
 specimens thus obtained.
- The Guidelines are intended to assist Parties in developing an overall access and benefit-sharing strategy, which may be part of their national biodiversity strategy and action plan, and in identifying the steps involved in the process of obtaining access to genetic resources and sharing benefits. **II. ROLES AND**

RESPONSIBILITIES IN ACCESS AND BENEFIT-SHARING PURSUANT TO ARTICLE 15 OF THE CONVENTION ON BIOLOGICAL DIVERSITY A. National focal point

Each Party should designate one national focal point for access and benefit-sharing and make such information available through the clearing-house mechanism. The national focal point should inform applicants for access to genetic resources on procedures for acquiring prior informed consent and mutually agreed terms,

including benefit-sharing, and on competent national authorities, relevant indigenous and local communities and relevant stakeholders, through the clearing-house mechanism. **B.**

Competent national authority(ies)

Competent national authorities, where they are established, may, in accordance with applicable national legislative, administrative or policy measures, be responsible for granting access and be responsible for advising on:

The negotiating process;

Requirements for obtaining prior informed consent and entering into mutually agreed terms;

Monitoring and evaluation of access and benefit-sharing agreements;

Implementation/enforcement of access and benefit-sharing agreements;

Processing of applications and approval of agreements;

The conservation and sustainable use of the genetic resources accessed;

Mechanisms for the effective participation of different stakeholders, as appropriate for the different steps in the process of access and benefit-sharing, in particular, indigenous and local communities;

Mechanisms for the effective participation of indigenous and local communities while promoting the objective of having decisions and processes available in a language understandable to relevant indigenous and local communities.

The competent national authority(ies) that have the legal power to grant prior informed consent may delegate this power to other entities, as appropriate. **C. Responsibilities**

Recognizing that Parties and stakeholders may be both users and providers, the following balanced list of roles and responsibilities provides key elements to be acted upon:

Contracting Parties which are countries of origin of genetic resources, or other Parties which have acquired the genetic resources in accordance with the Convention, should:

Be encouraged to review their policy, administrative and legislative measures to ensure they are fully complying with Article 15 of the Convention;

Be encouraged to report on access applications through the clearing-house mechanism and other reporting channels of the Convention;

Seek to ensure that the commercialization and any other use of genetic resources should not prevent traditional use of genetic resources;

Ensure that they fulfil their roles and responsibilities in a clear, objective and transparent manner;

Ensure that all stakeholders take into consideration the environmental consequences of the access activities;

Establish mechanisms to ensure that their decisions are made available to relevant indigenous and local

- communities and relevant stakeholders, particularly indigenous and local communities;
- Support measures, as appropriate, to enhance indigenous and local communities' capacity to represent their interests fully at negotiations;
- In the implementation of mutually agreed terms, users should:

 Seek informed consent prior to access to genetic resources,
 in conformity with Article 15, paragraph 5, of the
 Convention:
 - Respect customs, traditions, values and customary practices of indigenous and local communities,
 - Respond to requests for information from indigenous and local communities;
 - Only use genetic resources for purposes consistent with the terms and conditions under which they were acquired;
 - Ensure that uses of genetic resources for purposes other than those for which they were acquired, only take place after new prior informed consent and mutually agreed terms are given;
 - Maintain all relevant data regarding the genetic resources, especially documentary evidence of the prior informed consent and information concerning the origin and the use of genetic resources and the benefits arising from such use;
 - As much as possible endeavour to carry out their use of the genetic resources in, and with the participation of, the providing country;
 - When supplying genetic resources to third parties, honour any terms and conditions regarding the acquired material. They should provide this third party with relevant data on their acquisition, including prior informed consent and conditions of use and record and maintain data on their supply to third parties. Special terms and conditions should be established under mutually agreed terms to facilitate taxonomic research for non-commercial purposes;
 - Ensure the fair and equitable sharing of benefits, including technology transfer to providing countries, pursuant to Article 16 of the Convention arising from the commercialization or other use of genetic resources, in conformity with the mutually agreed terms they established with the indigenous and local communities or stakeholders involved;

Providers should:

- Only supply genetic resources and/or traditional knowledge when they are entitled to do so;
- Strive to avoid imposition of arbitrary restrictions on access to genetic resources.

Contracting Parties with users of genetic resources under their

jurisdiction should take appropriate legal, administrative, or policy measures, as appropriate, to support compliance with prior informed consent of the Contracting Party providing such resources and mutually agreed terms on which access was granted. These countries could consider, *inter alia*, the following measures:

- Mechanisms to provide information to potential users on their obligations regarding access to genetic resources;
- Measures to encourage the disclosure of the country of origin of the genetic resources and of the origin of traditional knowledge, innovations and practices of indigenous and local communities in applications for intellectual property rights;
- Measures aimed at preventing the use of genetic resources obtained without the prior informed consent of the Contracting Party providing such resources;
- Cooperation between Contracting Parties to address alleged infringements of access and benefit-sharing agreements;
- Voluntary certification schemes for institutions abiding by rules on access and benefit-sharing;
- Measures discouraging unfair trade practices;
- Other measures that encourage users to comply with provisions under subparagraph ?16 (b) above.

III. PARTICIPATION OF STAKEHOLDERS

- Involvement of relevant 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.
- Relevant stakeholders should be consulted and their views taken into consideration in each step of the process, including:
 - When determining access, negotiating and implementing mutually agreed terms, and in the sharing of benefits;
 - In the development of a national strategy, policies or regimes on access and benefit-sharing.
- To facilitate the involvement of relevant stakeholders, including indigenous and local communities, appropriate consultative arrangements, such as national consultative committees, comprising relevant stakeholder representatives, should be made.
- The involvement of relevant stakeholders should be promoted by:

 Providing information, especially regarding scientific and legal
 advice, in order for them to be able to participate effectively;
 - 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.

- The stakeholders involved in access to genetic resources and benefitsharing may wish to seek the support of a mediator or facilitator when negotiating mutually agreed terms. IV. STEPS IN THE ACCESS AND BENEFIT-SHARING PROCESS A. Overall strategy
- Access and benefit-sharing systems should be based on an overall access and benefit-sharing strategy at the country or regional level. This access and benefit-sharing strategy should aim at the conservation and sustainable use of biological diversity, and may be part of a national biodiversity strategy and action plan and promote the equitable sharing of benefits. **B. Identification of steps**
- 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 commercialization and other uses, including benefit-sharing. **C. Prior informed consent**
- As provided for in Article 15 of the Convention on Biological Diversity, which recognizes the sovereign rights of States over their natural resources, each Contracting Party to the Convention shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and fair and equitable sharing of benefits arising from such uses. In accordance with Article 15, paragraph 5, of the Convention on Biological Diversity, access to genetic resources shall be subject to prior informed consent of the contracting Party providing such resources, unless otherwise determined by that Party.
- Against this background, the Guidelines are intended to assist Parties in the establishment of a system of prior informed consent, in accordance with Article 15, paragraph 5, of the Convention. 1.

Basic principles of a prior informed consent system

The basic principles of a prior informed consent system should include: Legal certainty and clarity;

Access to genetic resources should be facilitated at minimum cost;

Restrictions on access to genetic resources should be transparent, based on legal grounds, and not run counter to the objectives of the Convention;

Consent of the relevant competent national authority(ies) in the provider country. The consent of relevant stakeholders, such as indigenous and local communities, as appropriate to the circumstances and subject to domestic law, should also be obtained.

2. Elements of a prior informed consent system

Elements of a prior informed consent system may include:

Competent authority(ies) granting or providing for evidence of prior informed consent;

Timing and deadlines;

Specification of use;

Procedures for obtaining prior informed consent;

Mechanism for consultation of relevant stakeholders;

Process.

Competent authority(ies) granting prior informed consent

- Prior informed consent for access to in situ genetic resources shall be obtained from the Contracting Party providing such resources, through its competent national authority(ies), unless otherwise determined by that Party.
- In accordance with national legislation, 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.
- National procedures should facilitate the involvement of all relevant stakeholders from the community to the government level, aiming at simplicity and clarity.
- Respecting established legal rights of indigenous and local communities associated with the genetic resources being accessed or where traditional knowledge associated with these genetic resources is being accessed, the prior informed consent of indigenous and local communities and the approval and involvement of the holders of traditional knowledge, innovations and practices should be obtained, in accordance with their traditional practices, national access policies and subject to domestic laws.
- For *ex situ* collections, prior informed consent should be obtained from the competent national authority(ies) and/or the body governing the *ex situ* collection concerned as appropriate. **Timing and deadlines**
- 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**
- 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 change of use including transfer to third parties 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. Specific needs of taxonomic and systematic research as specified by the Global Taxonomy Initiative should be taken into consideration.
- Prior informed consent is linked to the requirement of mutually agreed terms. **Procedures for obtaining prior informed consent**
- 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 indicative and should be adapted to national circumstances:

Legal entity and affiliation of the applicant and/or collector and contact person when the applicant is an institution;

Type and quantity of genetic resources to which access is sought; Starting date and duration of the activity;

Geographical prospecting area;

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;

Accurate information regarding intended use (e.g.: taxonomy, collection, research, commercialization);

Identification of where the research and development will take place;

Information on how the research and development is to be carried out;

Identification of local bodies for collaboration in research and development;

Possible third party involvement;

Purpose of the collection, research and expected results; Kinds/types of benefits that could come from obtaining access to the resource, including benefits from derivatives and products arising from the commercial and other utilization of the genetic resource;

Indication of benefit-sharing arrangements; Budget;

Treatment of confidential information.

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

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

The competent authority could grant access by issuing a permit or licence or following other appropriate procedures. A national registration system could be used to record the issuance of all permits or licences, on the basis of duly completed application forms.

The procedures for obtaining an access permit/licence should be transparent and accessible by any interested party. **D. Mutually agreed terms**

In accordance 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 and stakeholders in the development of mutually agreed terms to ensure the fair and equitable sharing of benefits. 1. Basic

requirements for mutually agreed terms

The following principles or basic requirements could be considered for the development of mutually agreed terms:

Legal certainty and clarity;

Minimization of transaction costs, by, for example:

Establishing and promoting awareness of the Government's and relevant stakeholders' requirements for prior informed consent and contractual arrangements;

Ensuring awareness of existing mechanisms for applying for access, entering into arrangements and ensuring the sharing of benefits;

Developing framework agreements, under which repeat access under expedited arrangements can be made;

Developing standardized material transfer agreements and benefit-sharing arrangements for similar resources and similar uses (see appendix I for suggested elements of such an agreement);

Inclusion of provisions on user and provider obligations;
Development of different contractual arrangements for different resources and for different uses and development of model agreements;

Different uses may include, *inter alia*, taxonomy, collection, research, commercialization;

Mutually agreed terms should be negotiated efficiently and within a reasonable period of time;

Mutually agreed terms should be set out in a written agreement.

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:

Regulating the use of resources in order to take into account ethical concerns of the particular Parties and stakeholders, in particular indigenous and local communities concerned;

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

Provision for the use of intellectual property rights include joint research, obligation to implement rights on inventions obtained and to provide licences by common consent;

The possibility of joint ownership of intellectual property rights according to the degree of contribution.

2. Indicative list of typical mutually agreed terms

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

Type and quantity of genetic resources, and the geographical/ecological area of activity;

Any limitations on the possible use of the material;

Recognition of the sovereign rights of the country of origin;

Capacity-building in various areas to be identified in the agreement;

A clause on whether the terms of the agreement in certain circumstances (e.g. change of use) can be renegotiated;

Whether the genetic resources can be transferred to third parties and conditions to be imposed in such cases, e.g. whether or not to pass genetic resources to third parties without ensuring that the third parties enter into similar agreements except for taxonomic and systematic research that is not related to commercialization;

Whether the knowledge, innovations and practices of indigenous

and local communities have been respected, preserved and maintained, and whether the customary use of biological resources in accordance with traditional practices has been protected and encouraged;

Treatment of confidential information;

Provisions regarding the sharing of benefits arising from the commercial and other utilization of genetic resources and their derivatives and products .

3. Benefit-sharing

- Mutually agreed terms could cover the conditions, obligations, procedures, 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**
- Examples of monetary and non-monetary benefits are provided in appendix II to these Guidelines. **Timing of benefits**
- Near-term, medium-term and long-term benefits should be considered, including up-front payments, milestone payments and royalties. The time-frame of benefit-sharing should be definitely stipulated. Furthermore, the balance among near-term, medium-term and long-term benefit should be considered on a case-by-case basis.

Distribution of benefits

- 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 indigenous and local communities. Benefits should be directed in such a way as to promote conservation and sustainable use of biological diversity. **Mechanisms for benefit-sharing**
- Mechanisms for benefit-sharing may vary 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.
- 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. **V. OTHER**

PROVISIONS A. Incentives

- The following incentive measures exemplify measures which could be used in the implementation of the guidelines:
 - 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;
 - 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:

The use of valuation methods should be considered as a tool to

inform users and providers involved in access and benefitsharing;

The creation and use of markets should be considered as a way of efficiently achieving conservation and sustainable use of biological diversity.

B. Accountability in implementing access and benefit-sharing arrangements

Parties should endeavour to establish mechanisms to promote accountability by all stakeholders involved in access and benefit-sharing arrangements.

To promote accountability, Parties may consider establishing requirements regarding:

Reporting; and

Disclosure of information.

The individual collector or institution on whose behalf the collector is operating should, where appropriate, be responsible and accountable for the compliance of the collector. **C. National monitoring and reporting**

Depending on the terms of access and benefit-sharing, national monitoring may include:

Whether the use of genetic resources is in compliance with the terms of access and benefit-sharing;

Research and development process;

Applications for intellectual property rights relating to the material supplied.

The involvement of relevant stakeholders, in particular, indigenous and local communities, in the various stages of development and implementation of access and benefit-sharing arrangements can play an important role in facilitating the monitoring of compliance.

D. Means for verification

Voluntary verification mechanisms could be developed at the national level to ensure compliance with the access and benefit-sharing provisions of the Convention on Biological Diversity and national legal instruments of the country of origin providing the genetic resources.

A system of voluntary certification could serve as a means to verify the transparency of the process of access and benefit-sharing. Such a system could certify that the access and benefit-sharing provisions of the Convention on Biological Diversity have been complied with.

E. Settlement of disputes

As most obligations arising under mutually agreed arrangements will be between providers and users, disputes arising in these arrangements should be solved in accordance with the relevant contractual arrangements on access and benefit-sharing and the applicable law and practices.

In cases where the access and benefit-sharing agreements consistent with the Convention on Biological Diversity and national legal instruments of the country of origin of genetic resources have not been complied with, the use of sanctions could be considered, such

as penalty fees set out in contractual agreements. **F. Remedies**Parties may take appropriate effective and proportionate measures for violations of national legislative, administrative or policy measures implementing the access and benefit-sharing provisions of the Convention on Biological Diversity, including requirements related to prior informed consent and mutually agreed terms.

Appendix I

SUGGESTED ELEMENTS FOR MATERIAL TRANSFER AGREEMENTS

Material transfer agreements may contain wording on the following elements:

A. Introductory provisions

Preambular reference to the Convention on Biological Diversity Legal status of the provider and user of genetic resources Mandate and/or general objectives of provider and, where appropriate, user of genetic resources

B. Access and benefit-sharing provisions

Description of genetic resources covered by the material transfer agreements, including accompanying information

Permitted uses, bearing in mind the potential uses, of the genetic resources, their products or derivatives under the material transfer agreement (e.g. research, breeding, commercialization)

Statement that any change of use would require new prior informed consent and material transfer agreement

Whether intellectual property rights may be sought and if so under what conditions

Terms of benefit-sharing arrangements, including commitment to share monetary and non-monetary benefits

No warranties guaranteed by provider on identity and/or quality of the provided material

Whether the genetic resources and/or accompanying information may be transferred to third parties and if so conditions that should apply Definitions

Duty to minimize environmental impacts of collecting activities

C. Legal provisions

Obligation to comply with the material transfer agreement Duration of agreement

Notice to terminate the agreement

Fact that the obligations in certain clauses survive the termination of the agreement

Independent enforceability of individual clauses in the agreement Events limiting the liability of either party (such as act of God, fire, flood, etc.)

Dispute settlement arrangements

Assignment or transfer of rights

Assignment, transfer or exclusion of the right to claim any property rights, including intellectual property rights, over the genetic resources received through the material transfer agreement

Choice of law

Confidentiality clause

Guarantee

Appendix II

MONETARY AND NON- MONETARY BENEFITS

1. Monetary benefits may include, but not be limited to:

Access fees/fee per sample collected or otherwise acquired;

Up-front payments;

Milestone payments;

Payment of royalties;

Licence fees in case of commercialization;

Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;

Salaries and preferential terms where mutually agreed;

Research funding;

Joint ventures;

Joint ownership of relevant intellectual property rights.

2. Non-monetary benefits may include, but not be limited to:

Sharing of research and development results;

Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the provider country;

Participation in product development;

Collaboration, cooperation and contribution in education and training; Admittance to *ex situ* facilities of genetic resources and to databases;

Transfer to the provider of the genetic resources 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;

Strengthening capacities for technology transfer to user developing country Parties and to Parties that are countries with economies in transition and technology development in the country of origin that provides genetic resources. Also to facilitate abilities of indigenous

and local communities to conserve and sustainably use their genetic resources;

Institutional capacity-building;

Human and material resources to strengthen the capacities for the administration and enforcement of access regulations;

Training related to genetic resources with the full participation of providing Parties, and where possible, in such Parties;

Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies:

Contributions to the local economy;

Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in provider countries;

Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities;

Food and livelihood security benefits;

Social recognition;

Joint ownership of relevant intellectual property rights.

B. Other approaches, including the development of an action plan for capacity-building

The Conference of the Parties,

I. CAPACITY-BUILDING

Recognizing the need to assess ongoing capacity-building activities for access and benefit-sharing, in view of elaborating an action plan for capacity-building for access and benefit-sharing,

Decides to convene an Open-ended Expert Workshop on Capacity-building for Access to Genetic Resources and Benefit-sharing. The Workshop will be open to participation by representatives, including experts, nominated by Governments and regional economic integration organizations; as well as representatives of relevant intergovernmental organizations (including donor organizations), non-governmental organizations, and indigenous and local communities. The Workshop should further develop the draft elements for an Action Plan on Capacity-building for Access and Benefit-sharing annexed to the present decision;

Requests the Executive Secretary to make appropriate arrangements for the Workshop;

Invites Parties and indigenous and local communities to provide to the Executive-Secretary information regarding capacity-building needs, priorities and existing initiatives for capacity-building for access to genetic resources and benefit-sharing;

Invites relevant intergovernmental organizations, non-governmental organizations and the private sector to provide information regarding existing initiatives and activities for capacity-building for access to genetic resources and benefit-sharing;

- Welcomes the complementary initiative of the United Nations
 Environment Programme to provide capacity-building to developing
 countries on access to genetic resources and benefit-sharing, and
 invites the United Nations Environment Programme to provide
 information to the Executive Secretary on its activities;
- Requests the Executive Secretary to prepare a report for the workshop on capacity-building, providing a compilation of needs and priorities of countries, and ongoing capacity-building activities on access and benefit-sharing, with a view to developing an action plan for capacity-building on access and benefit-sharing which responds to the needs of Parties, focuses on priority areas and also complements capacity-building efforts under way in the area of access and benefit-sharing;
- Invites the financial mechanism and other relevant intergovernmental organizations to participate in the Workshop and to support the implementation of the Action Plan on Capacity-building for Access and Benefit-sharing;
- Requests the Executive Secretary to establish a roster of experts on access to genetic resources and benefit-sharing;
- Urges Parties, other Governments and relevant bodies when nominating their experts for inclusion in the roster to consider gender balance, involvement of representatives of indigenous and local communities, and a range of relevant disciplines and expertise; **II.**OTHER APPROACHES
- Recognizes that a package of measures may be necessary to address the different needs of Parties and stakeholders in the implementation of access and benefit-sharing arrangements
- Recognizes also that other approaches could be considered to complement the Bonn Guideline, such as model contractual agreements, existing regional agreements and model laws on access to genetic resources and benefit-sharing.
- Requests the Executive Secretary to compile information on existing complementary measures and approaches, and experiences with their implementation, and to disseminate such information to Parties and relevant stakeholders through, *inter alia*, the clearinghouse mechanism of the Convention.

Annex

DRAFT ELEMENTS FOR AN ACTION PLAN FOR CAPACITY-BUILDING FOR ACCESS TO GENETIC RESOURCES AND BENEFIT-SHARING

1. Objective of the Action Plan

- The objective of the Action Plan is to facilitate and support the development and strengthening of capacities for the effective implementation of the provisions of the Convention relating to access to genetic resources and benefit-sharing at the local, national, subregional, regional and international levels.
- To achieve the objective, the Action Plan will provide a framework for identifying country and stakeholder needs, priorities, mechanisms

of implementation and sources of funding. 2. Key areas requiring capacity-building

The following key areas, which require capacity-building initiatives, should be considered in a flexible and transparent manner, based on a demand-driven approach, taking into account the different situations, needs, capabilities and stages of development of each country and should avoid duplication of efforts between various capacity-building initiatives:

Strengthening of relevant institutions;

Assessment, inventory and monitoring of biological resources, and traditional knowledge including taxonomic capacity, within the context of the Global Taxonomy Initiative;

Valuation of genetic resources and market information, including production and marketing strategies;

Inventory and case-studies of existing legislative measures and development of appropriate legislation, including sui generis systems;

Development of information systems, and information management and exchange, linked with the clearing-house mechanism of the Convention;

Development and strengthening capacities of indigenous and local communities for participation in decision making and implementation;

Public education and awareness focusing on relevant stakeholders;

Human resources development and training at all levels, including legal drafting skills for development of access to genetic resources and benefit-sharing measures;

Funding and resource management;

Contract negotiation skills for all relevant stakeholders, in particular indigenous and local communities;

Means for the protection of traditional knowledge associated with genetic resources;

Scientific and technical areas, including technology transfer relevant to access to and use of genetic resources and benefit-sharing:

Development of instruments, tools, and indicators to monitor and assess the implementation of capacity-building for access to genetic resources and benefit-sharing at all stages.

3. Processes

The following processes and measures should be undertaken:

Awareness raising for the issues at stake and identification of capacity needs at the local, national, subregional, and regional levels, taking into account, as appropriate, the work of the Global Environment Facility on national capacity self-assessment;

Integration of capacity-building for access to genetic resources and benefit-sharing within the framework of national biodiversity strategies and other related initiatives and strategies;

Prioritization at the local, national, and regional levels of the key

areas;

Sequencing of actions, including timelines for the operation of capacity-building for access to genetic resources and benefit-sharing;

Identification of existing and planned capacity-building initiatives at the local, national, subregional and regional levels, both public and private, and their coverage including by:

National sources;

Bilateral sources;

Regional sources;

Multilateral agencies;

Other international sources;

Other stakeholders, in particular indigenous and local communities;

Enhancing synergies and coordination of capacity-building initiatives;

Establishment of indicators for monitoring capacity-building implementation.

4. Means of implementation

The following mechanisms could be used for the implementation of capacity-building measures for access to genetic resources and benefit-sharing:

Development of appropriate national regulatory framework; Scientific and technical cooperation among Parties, and between Parties and relevant multilateral agencies and other organizations through, *inter alia*, the clearing-house mechanism of the Convention;

Information exchange, through the clearing-house mechanism of the Convention, the use of the internet, databases, CD-ROMs, hard copies and workshops;

Identification and dissemination of case-studies and best practices;

Regional and subregional collaborative arrangements;

Coordination between multilateral and bilateral donors and other organizations;

Development of model agreements and codes of conduct for specific uses, users and sectors;

Training workshops;

Full and effective involvement and participation of all relevant stakeholders, in particular indigenous and local communities taking into account the tasks defined within the programme of work on the implementation of Article 8(j) and related provisions of the Convention;

Funding through the Global Environment Facility and other donors;

The participation of the private sector as provider of capacitybuilding in specific areas, for example through collaborative research, transfer of technology and funding;

The Global Taxonomy Initiative;

The roster of experts on access to genetic resources and benefit-

sharing to be established under the Convention; National focal points and competent national authorities.

5. Coordination

- In view of the multiplicity of actors undertaking capacity-building initiatives for access to genetic resources and benefit-sharing, mutual information and coordination should be promoted in order to avoid duplication of effort and to identify existing gaps in coverage. Initiatives for coordination should be encouraged at all levels.
- The Conference of the Parties should encourage voluntary submissions by Parties and Governments and relevant international organizations on steps taken, including by donors, towards the implementation of capacity-building measures, to be accessible through the clearing-house mechanism of the Convention.
- Parties may consider including in their national reports information on the implementation of capacity-building measures on access to genetic resources and benefit-sharing.

C. Role of intellectual property rights in the implementation of access and benefit-sharing arrangements

The Conference of the Parties

- Invites Parties and Governments to encourage the disclosure of the country of origin of genetic resources in applications for intellectual property rights, where the subject matter of the application concerns or makes use of genetic resources in its development, as a possible contribution to tracking compliance with prior informed consent and the mutually agreed terms on which access to those resources was granted;
- Also invites Parties and Governments to encourage the disclosure of the origin of relevant traditional knowledge, innovations and practices of indigenous and local communities relevant for the conservation and sustainable use of biological diversity in applications for intellectual property rights, where the subject matter of the application concerns or makes use of such knowledge in its development;
- Requests the Executive Secretary, with the help of other international and intergovernmental organizations such as the World Intellectual Property Organization and through the Ad Hoc Open-ended Inter-Sessional Working Group on Article 8(j) and Related Provisions of the Convention, where appropriate, to undertake further information gathering and analysis with regard to:
 - Impact of intellectual property regimes on access to and use of genetic resources and scientific research;
 - Role of customary laws and practices in relation to the protection of genetic resources and traditional knowledge, innovations and practices, and their relationship with intellectual property rights;
 - Consistency and applicability of requirements for disclosure of country of origin and prior informed consent in the context of

international legal obligations;

- Efficacy of country of origin and prior informed consent disclosures in assisting the examination of intellectual property rights applications and the re-examination of intellectual property rights granted;
- Efficacy of country of origin and prior informed consent disclosures in monitoring compliance with access provisions;
- Feasibility of an internationally recognized certificate of origin system as evidence of prior informed consent and mutually agreed terms; and
- Role of oral evidence of prior art in the examination, granting and maintenance of intellectual property rights;
- Invites the World Intellectual Property Organization to prepare a technical study, and to report its findings to the Conference of the Parties at its seventh meeting, on methods consistent with obligations in treaties administered by the World Intellectual Property Organization for requiring the disclosure within patent applications of, inter alia:
 - Genetic resources utilized in the development of the claimed inventions;
 - The country of origin of genetic resources utilized in the claimed inventions;
 - Associated traditional knowledge, innovations and practices utilized in the development of the claimed inventions;
 - The source of associated traditional knowledge, innovations and practices; and
 - Evidence of prior informed consent;
- Requests the Executive Secretary to collect, compile and disseminate information on the matters specified in paragraphs 3 and 4 above, including through the clearing-house mechanism of the Convention and other appropriate means;
- Invites Parties and Governments to submit case-studies that they consider relevant to the issues specified in paragraphs 3 and 4; and Requests the Executive Secretary to gather information and prepare a report on national and regional experiences;
- Invites other relevant international organizations (such as the Food and Agriculture Organization of the United Nations, the United Nations Conference on Trade and Development, the World Intellectual Property Organization, the World Trade Organization, and the United Nations Commission on Human Rights), as well as regional organizations, Parties and Governments to contribute to the further study and analysis of the issues specified in paragraphs 3 and 4;
- Encourages the World Intellectual Property Organization to make rapid progress in the development of model intellectual property clauses which may be considered for inclusion in contractual agreements when mutually agreed terms are under negotiation;
- Recognizes the importance of the work being undertaken by the World Intellectual Property Organization on international models and encourage the World Intellectual Property Organization to also consider means by which Parties could collaborate to protect

traditional knowledge for further consideration by the Conference of the Parties;

Urges the World Intellectual Property Organization to provide to the Conference of the Parties with the results of its deliberations of relevance to access to genetic resources and benefit-sharing related to traditional knowledge;

Encourages Parties to facilitate the participation of indigenous and local communities and other relevant stakeholders in the various forums, in particular the World Intellectual Property Organization, the Convention on Biological Diversity, the World Trade Organization, the United Nations Conference on Trade and Development and regional forums, as well as in the preparation of national strategies, policies, regulatory frameworks and legislation related to access to genetic resources and benefit-sharing, from a very early stage;

Requests the Executive Secretary to compile information, and to make it available through the clearing-house mechanism of the Convention and other means, on the principles, legal mechanisms and procedures for obtaining prior informed consent of indigenous and local communities under national access regimes for genetic resources, and also on assessments of the effectiveness of such mechanisms and procedures, and requests Parties to provide such information to assist the Executive Secretary.

D. Other issues relating to access and benefit-sharing

The Conference of Parties,

The relationship between the Agreement on Trade-related Aspects of Intellectual Property Rights of the World Trade Organization and the Convention on Biological Diversity

Noting that the provisions of the Agreement on Trade-related Aspects of Intellectual Property Rights of the World Trade Organization and the Convention on Biological Diversity are interrelated,

Noting also that the relationship between the Agreement on Trade-related Aspects of Intellectual Property Rights and the Convention on Biological Diversity is being examined by the Council for Trade-related Aspects of Intellectual Property Rights, in conformity with Article 19 of the Doha WTO Ministerial Declaration, adopted in November 2001,

Noting further that the Convention Secretariat has still not been granted observer status on the Council for Trade-related Aspects of Intellectual Property Rights, notwithstanding the official request of the Executive Secretary to the Director-General of the World Trade Organization in a letter dated 4 July 2000,

Requests the Executive Secretary of the Convention to renew the application for observer status on the Council for Trade-related Aspects of Intellectual Property Rights, and to report back to the Conference of Parties on his efforts;

Requests the Executive Secretary to follow discussions and developments in the Committee on Trade and Environment of the World Trade Organization and the Council for Trade-related Aspects

of Intellectual Property Rights regarding the relationship between the Agreement on Trade-related Aspects of Intellectual Property Rights and the Convention;

Cooperation with other relevant intergovernmental organizations

Acknowledges relevant work being carried out by other intergovernmental organisations, such as the World Intellectual Property Organization, the World Trade Organization, the Union for the Protection of New Varieties of Plants, the United Nations Conference on Trade and Development, and the Food and Agriculture Organization of the United Nations, on issues related to access to genetic resources and benefit-sharing;

Requests the Executive Secretary to further collaborate with the above relevant organisations to ensure mutual supportiveness and avoid duplication of work;

Recognizes the important role that the International Treaty on Plant Genetic Resources for Food and Agriculture will have, in harmony, with the Convention, for facilitated access to plant genetic resources for food and agriculture and for the fair and equitable sharing of benefits arising out of their utilization and refers to decision VI/6, on the International Treaty on Plant Genetic Resources for Food and Agriculture;

Information related to access and benefit-sharing arrangements

Recognizing that access to information is an essential instrument in the development of national capacity for dealing with access and benefit-sharing arrangements and important in enhancing the necessary bargaining power of stakeholders in access and benefit-sharing arrangements,

Noting that, since the adoption of the Convention, an increasing number of Parties have developed national/regional regimes on access and benefit-sharing and that Parties and stakeholders could learn from sharing their respective experiences relating to the development and implementation of access and benefit-sharing regimes,

Recognizing that the Secretariat of the Convention could assist in disseminating this information among Parties and stakeholders, *inter alia*, through strengthening of the clearing-house mechanism,

Requests Parties and relevant organizations, as appropriate, to make available to the Executive Secretary:

Detailed information on the measures adopted to implement access and benefit-sharing, including the text of any legislation or other measures developed to regulate access and benefit-sharing

Case-studies on the implementation of access and benefit-sharing arrangements:

Other information, such as that listed in decision V/26, paragraph 12;

Requests the Executive Secretary to compile the information received and to make it available, through, *inter alia*, the clearing-house

mechanism, including in hard copy and CD-ROM and relevant meetings under the Convention on Biological Diversity in order to facilitate access to this information by Parties and relevant stakeholders;

ex situ collections acquired prior to the entry into force of the Convention and not addressed by the Commission on Genetic Resources for Food and Agriculture

Notes with appreciation the report International Review of the *ex situ* Plant Collections of the Botanic Gardens of the World: Reviewing the Plant Genetic Resource Collections of Botanic Gardens Worldwide, prepared by Botanic Gardens Conservation International with the support of the Government of the United Kingdom and the Secretariat of the Convention on Biological Diversity.

(58) UNEP/CBD/COP/6/6.