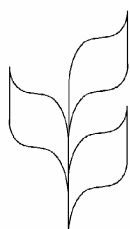




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Item 7 of the provisional agenda*

INTERNATIONAL REGIME ON ACCESS AND BENEFIT-SHARING

Proposals for an international regime on access and benefit-sharing

Note by the Executive Secretary

I. INTRODUCTION

1. The Plan of Implementation adopted by the World Summit on Sustainable Development ^{1/} calls for action to “negotiate within the framework of the Convention on Biological Diversity, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources”. ^{2/} In light of the significance of this commitment for the work of the Convention, following consultation with the Bureau, it was decided to include the issue of an international regime on access and benefit-sharing as a distinct agenda item for the Inter-sessional meeting on the Multi-Year Programme of Work of the Conference of the Parties up to 2010. The present note was prepared to assist in the deliberations on this item.

2. Section II provides a brief overview of the Convention process related to access and benefit-sharing and of the latest developments at the sixth meeting of the Conference of the Parties. Section III reviews the outcome of the World Summit on Sustainable Development as it relates to access and benefit-sharing; and section IV suggests approaches which may be followed under the Convention process for the negotiation of an international regime on access and benefit-sharing. For information purposes, an overview of existing benefit-sharing frameworks is also included as an annex.

* UNEP/CBD/MYPOW/1.

^{1/} Report of the World Summit on Sustainable Development, Johannesburg, South Africa, 26 August-4 September 2002 (A/CONF.199/20), chap. I, resolution 2, annex.

^{2/} Ibid., para. 44 (o)

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II. BACKGROUND

A. *Consideration of access and benefit-sharing issues by the Conference of the Parties*

3. As provided for in Article 1 of the Convention, “the fair and equitable sharing of the benefits arising out of the utilization of genetic resources” is one of the three main objectives of the Convention. Article 15 sets out the principles that should underpin the implementation of this objective. The access and benefit-sharing provisions of the Convention have been considered at various meetings of the Conference of the Parties. At its fourth meeting, in 1998, the Conference of the Parties established a regionally balanced Panel of Experts to address the issue of access to genetic resources and benefit-sharing. The mandate of the Panel was to develop a common understanding of basic concepts and to explore all options for access and benefit-sharing on mutually agreed terms, including guidelines, and codes of conduct on best practices for access and benefit-sharing arrangements. The Panel met in Costa Rica, in October 1999, and reported to the Conference of the Parties at its fifth meeting, in May 2000 (UNEP/CBD/COP/5/8).

4. At that meeting, the Conference of the Parties established the Ad Hoc Open-ended Working Group on Access and Benefit-sharing with the mandate to develop guidelines and other approaches for submission to the Conference of the Parties at its sixth meeting. The Conference of the Parties also reconvened the Panel of Experts to conduct further work on outstanding issues and to report to the newly established Ad Hoc Open-ended Working Group at its first meeting.

5. The Ad Hoc Open-ended Working Group held its first meeting in Bonn in October 2001 and successfully developed the draft Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising Out of Their Utilization.

6. The draft Bonn Guidelines were subsequently adopted, with amendments, by the Conference of the Parties at its sixth meeting, in The Hague, in April 2002.

B. *Bonn Guidelines on access to genetic resources and the fair and equitable sharing of benefits arising out of their utilization*

7. The main purpose of the Bonn Guidelines, as annexed to decision VI/24 A, is to assist Parties, Governments and other stakeholders in developing an overall access and benefit-sharing strategy, and in identifying the steps involved in the process of obtaining access to genetic resources and benefit-sharing. Parties, non-Party Governments and other stakeholders are invited to use the Guidelines when establishing legislative, administrative or policy measures on access and benefit-sharing and/or when negotiating contractual arrangements for access and benefit-sharing.

8. In paragraph 6 of decision VI/24 A, the Conference of the Parties recognised “that the Guidelines are a useful first step of an evolutionary process in the implementation of the relevant provisions of the Convention related to access to genetic resources and benefit-sharing”. In paragraph 7, it decided to keep the implementation of the Guidelines under review and to consider the need for their further refinement on the basis of relevant work under the Convention, including work on Article 8(j) and related provisions.

9. In addition, in paragraph 8 of the same decision, the Ad Hoc Open-ended Working Group on Access and Benefit-sharing has been reconvened and is scheduled to meet from 1 to 5 December 2003 to advise the Conference of the Parties on the following issues:

- (a) Use of terms, definitions and/or glossary, as appropriate;

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- (b) Other approaches as set out in decision VI/24 B;
- (c) 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;
- (d) Its consideration of any available reports or progress reports arising from the present decision;
- (e) Needs for capacity-building identified by countries to implement the Guidelines.

C. *The role of intellectual property rights in access and benefit-sharing arrangements*

10. Another important development at the sixth meeting of the Conference of the Parties relates to the role of intellectual property rights in access and benefit-sharing arrangements. In paragraphs 1 and 2 of decision VI/24 C, the Conference of the Parties invited Parties and Governments to encourage the disclosure of the country of origin of genetic resources and related traditional knowledge in application for intellectual property rights, where the subject matter of the application concerns or makes use of genetic resources or related traditional knowledge in its development.

11. However, the Conference of the Parties recognized the need for further work on this issue in collaboration with a number of relevant organizations, such as the World Intellectual Property Organization (WIPO), the World Trade Organization (WTO), the Food and Agriculture Organization of the United Nations (FAO), the United Nations Conference on Trade and Development (UNCTAD) and others. In addition, in paragraph 4 of decision VI/24 C, the World Intellectual Property Organization was invited “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*:

- (a) Genetic resources utilized in the development of the claimed inventions;
- (b) The country of origin of genetic resources utilized in the claimed inventions;
- (c) Associated traditional knowledge, innovations and practices utilized in the development of the claimed inventions;
- (d) The source of associated traditional knowledge, innovations and practices; and
- (e) Evidence of prior informed consent.”

12. The relationship between intellectual property rights and access to and transfer of technology is also of relevance. In the context of access and benefit-sharing, transfer of technology has been considered as an important benefit-sharing option. It is worth recalling that Article 16 of the Convention on access to and transfer of technology provides, in its paragraph 3, that:

“Each contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights, where necessary, through the

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provisions of Article 20 and 21 and in accordance with international law and consistent with paragraphs 4 and 5 below.”

13. Paragraph 5 of the same article also provides that:

“The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.”

D. Capacity-building for access and benefit-sharing

14. The need to build capacities at all levels, from the national to the international, for the effective implementation of the access and benefit-sharing provisions of the Convention has been recognized as essential. In decision VI/24 B, the Conference of the Parties decided to convene an Open-ended Workshop on Capacity-building for Access and Benefit-sharing in order to further develop draft elements of an Action Plan on capacity-building for access to genetic resources and benefit-sharing. The Workshop was held in Montreal, from 2 to 4 December 2002. The report of the workshop, including the draft action plan and further recommendations will be presented to the Ad Hoc Working Group on Access and Benefit-sharing for its information, and to the Conference of the Parties at its seventh meeting for further consideration.

III. OUTCOME OF THE WORLD SUMMIT ON SUSTAINABLE DEVELOPMENT RELATED TO ACCESS AND BENEFIT-SHARING

15. One of the significant outcomes of the World Summit on Sustainable Development in the area of biodiversity relates to access and benefit-sharing. In paragraph 44 (n) of the Plan of Implementation, Governments committed themselves to promoting “the wide implementation of and continued work by the Parties to the Convention on the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits arising out of their Utilization, as an input to assist the Parties when developing and drafting legislative, administrative or policy measures on access and benefit-sharing as well as contract and other arrangements under mutually agreed terms for access and benefit-sharing”.

16. In addition, as noted in paragraph 1 above, the Plan of Implementation, provides for the negotiation within the framework of the Convention on Biological Diversity, bearing in mind the Bonn Guidelines, of an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources. At its fifty seventh session, in December 2002, the General Assembly recalled “the commitment made at the World Summit on Sustainable Development to negotiate within the framework of the Convention on Biological Diversity, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources” and invited “the Conference of the Parties to take appropriate steps in this regard”.

17. The implementation of this commitment within the framework of the Convention requires that two basic questions be addressed:

- (a) The scope of such a regime; and
- (b) The nature of the “international regime”.

18. With respect to the scope of the regime, the Johannesburg Plan of Implementation specifically refers to “actions at all levels... to negotiate within the framework of the Convention on Biological Diversity ...an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources” without making specific reference to access to genetic resources. Parties to the Convention may wish to exchange views on the scope of such regime with the aim to identify the elements to be covered

19. Parties may also wish to consider the nature of the international regime in order to determine whether it will take the form of a legally or non-legally binding instrument or a combination of these and to determine as well the role of the Bonn Guidelines. When considering the nature of the regime, it may be noted that in regime theory the term “international regime” has been defined as “a set of principles, norms, rules and decision-making procedures around which actors’ expectations converge in a given area of international relations”. ^{3/} Such principles, norms, rules and procedures can be laid down in legally binding or non-legally-binding instruments. It has also been asserted that the concept implies “some minimal effectiveness which can be measured by the degree of rule-compliance”. ^{4/}

20. Parties may also wish to provide information on the progress made and on the steps envisaged for the implementation of the Bonn Guidelines. In this context, they could also express their views on the possible synergies/complementarity between the Bonn Guidelines and existing instruments on access and benefit-sharing, such as those mentioned in the annex as well as other on-going international processes, with a view to fulfilling the objective of paragraph 44(o) of the Plan of Implementation of the World Summit. In this regard, the ongoing work of the Ad Hoc Working Group on Access and Benefit-sharing should be taken into account.

IV. IMPLEMENTATION OF PARAGRAPH 44 (o) OF THE PLAN OF IMPLEMENTATION WITHIN THE FRAMEWORK OF THE CONVENTION: RECOMMENDATIONS

21. On the basis of discussions on the nature of the international regime and the scope of such a regime, the Inter-Sessional Meeting is invited to make recommendations for consideration at the seventh meeting of the Conference of the Parties with regard to the appropriate process or steps to be undertaken to address this issue within the framework of the Convention. In addition, the meeting may wish to consider the impact of its recommendations on the work of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing.

22. It should be noted that a negotiating mandate may only be provided by the Conference of the Parties. The existing Ad Hoc Open-ended Working Group on Access and Benefit-sharing could be mandated by the Conference of the Parties to carry out the work. In this respect, the Conference of the Parties may wish to elaborate specific terms of reference for the Working Group in light of recommendations of the Inter-sessional meeting on the scope and nature of the international regime. In addition, the Conference of the Parties could also request that the Working Group finalize its work within a specified time period. The international regime would then be submitted for adoption by the Conference of the Parties and subsequently opened for signature and ratification in the case of a legally binding instrument.

^{3/} Krasner, Stephen D., (ed.) *International Regimes*, London, (1983), p.2

^{4/} Martin List and Volker Rittberger, “Regime Theory and International Environmental Management” in Hurrell, Andrew and Kingsbury, Benedict (eds), *The International Politics of the Environment*, Oxford, (1992), 85.

Annex

OVERVIEW OF BENEFIT-SHARING FRAMEWORKS

1. This note provides a brief overview of existing instruments, at the international, regional and national levels that have been developed to address access to genetic resources and the fair and equitable sharing of benefits derived from their use.^{5/} Although access to genetic resources and benefit-sharing are addressed jointly in these instruments, the following overview highlights the benefit-sharing components.

I. EXISTING LEGAL AND POLICY FRAMEWORKS

A. *International frameworks*

1. International Treaty on Plant Genetic Resources for Food and Agriculture

2. In November 2001, the Conference of the Food and Agriculture Organization of the United Nations (FAO) adopted the International Treaty on Plant Genetic Resources for Food and Agriculture. The Treaty, which is legally binding, covers all plant genetic resources relevant to food and agriculture. Its objectives are “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 centrepiece of this Treaty is a Multilateral System of Facilitated Access and Benefit-sharing that supports the work of breeders and farmers. The Multilateral System applies to more than 60 plant genera, which include 64 major crops and forages. The Treaty makes provision for benefit-sharing through information-exchange, access to and transfer of technology, capacity-building and sharing of monetary and other benefits of commercialization. It also sets out the elements of a funding strategy to mobilize funds for priority activities, plans and programmes, particularly for small farmers in developing countries. The obligation of users to share the monetary benefits derived from commercialization is part of this funding strategy.

2. Non-legally-binding instruments

3. Prior to the adoption of the Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising Out of their Utilization, professional and institutional guidelines and codes of conduct relevant to access and benefit-sharing had already been developed. These guidelines or codes of conduct generally apply to specific types or uses of genetic resources. They have been developed to facilitate access to genetic resources. It is interesting to note that these guidelines distinguish between different possible uses of genetic resources and provide a range of illustrative documents,

^{5/} Information on access and benefit-sharing frameworks is also included in the following notes by the Executive Secretary prepared for the Conference of the Parties, the Inter-Sessional Committee on the Operations of the Convention, the Panel of Experts on Access and Benefit-sharing, and the Ad Hoc Open-ended Working Group on Access and Benefit-sharing: access to genetic resources and benefit-sharing: legislation, administrative and policy information (UNEP/CBD/COP/2/13); access to genetic resources (UNEP/CBD/COP/3/20); review of national, regional, and sectoral measures and guidelines for the implementation of Article 15 (UNEP/CBD/COP/4/23); review of options for access and benefit-sharing mechanisms (UNEP/CBD/ISOC/3); options for access and benefit-sharing arrangements (UNEP/CBD/EP-ABS/2); access to genetic resources (UNEP/CBD/COP/5/21); assessment of user and provider experience, identification of approaches to involvement of stakeholders, and complementary options (UNEP/CBD/EP-ABS/2/2); elements for consideration in the development of guidelines and other approaches for access to genetic resources and benefit-sharing (UNEP/CBD/WG-ABS/1/3).

including model documents and/or agreements for the supply and acquisition of genetic resources, including the sharing of benefits derived from their use. Examples of these include the following:

(a) *Micro-Organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC)*. ^{6/} MOSAICC is a voluntary code of conduct. Its development was initiated by the Belgian Coordinated Collections of Micro-organisms (BCCM) in 1997, with the support of the Directorate General XII for Science, Research and Development of the European Commission, and involved twelve partners from various sectors in both developed and developing countries. Its purpose is to facilitate access to microbial genetic resources in conformity with the Convention on Biological Diversity and other applicable national and international law, and to help partners to make appropriate arrangements when transferring microbial genetic resources. MOSAICC covers the terms of access to microbial genetic resources, which include the terms of agreement on benefit-sharing, access to and transfer of technology, scientific and technical cooperation as well as technology transfer;

(b) *Principles and Common Policy Guidelines on Access to Genetic Resources and Benefit-sharing for Participating Institutions (botanic gardens and herbaria)*. This project involved 28 botanic gardens and herbaria from 21 countries in the development of a common approach on access and benefit-sharing and includes: Principles on Access to Genetic Resources and Benefit-sharing for Participating Institutions; Common Policy Guidelines; and an explanatory text. ^{7/} The Principles include benefit-sharing and also promote the sharing of benefits arising from the use of genetic resources acquired prior to the entry into force of the Convention, in the same manner as for those acquired thereafter. The Common Policy Guidelines provide a list of possible benefit-sharing options, including: transfer of technology, training, joint research, institutional development and other non-monetary or monetary benefits, in case of commercialization;

(c) *International Code of Conduct for Plant Germplasm Collecting and Transfer*. The International Code of Conduct adopted by the FAO Conference in 1993 is another voluntary instrument. It provides a framework for Governments in developing national regulations or formulating bilateral agreements for the collection of germplasm. Among other elements, it sets out minimum responsibilities of collectors, sponsors, curators and users of collected germplasm, in the collection and transfer of germplasm.

4. In addition to these guidelines or codes of conduct developed by institutions working on specific types of genetic resources, institutional policies have also been adopted by certain private companies and research institutions. For example, in the private sector, certain pharmaceutical and biotechnology companies such as Novo Nordisk and GlaxoSmithKline have developed corporate policies to deal with access to genetic resources and benefit-sharing. A number of botanical gardens and research institutes have also developed bioprospecting policies that address benefit-sharing options.

B. Regional frameworks

5. At the regional level, four instruments have been developed. In decision 391, the Andean Pact countries adopted, in July 1996, a legally binding framework for access to genetic resources and benefit-sharing. Guidance has also been provided at the regional level in Africa, Central America and by the

^{6/} Further information is available at: www.belspo.be/bccm/mosaicc

^{7/} 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.

Association of South-East Asian Nations (ASEAN) in the development of access and benefit-sharing regimes.

6. *African Model Law.* The African Model Law for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources (2000) was developed by the Organization of African Unity (OAU). Benefit-sharing is recognized by the African Model Law as a right of local communities (part IV, article 22). The State must guarantee that a specific percentage (minimum 50 per cent) of any financial benefits returns to the local community. The same applies for the farming communities and is addressed in the section dealing with Farmers' Rights. The Model Law covers both monetary and non-monetary benefits. A Community Gene Fund is to be established in view of reinvesting monetary benefits arising from the use of genetic resources into the community (part VII, article 66). The Model Law also recognizes the importance of non-monetary benefits for the development of capacities, through participation in research and development, repatriation of information on biological resources accessed and access to technologies used to study and develop the biological resource. The section on enabling provisions (part VIII) contains provisions on sanctions and penalties and an appeal process.

7. *Andean Pact decision 391 on the Common Regime on Access to Genetic Resources.* One of the objectives of decision 391 is to "create the conditions for fair and equitable sharing of the benefits accruing from such access" (article 2(a)). Article 35 of the decision provides that:

"When access is requested to genetic resources or their derivatives with an intangible component, the access contract shall include, as an integral part of the same, an annex providing for the fair and equitable distribution of the benefits arising from the use of the said component....Failure to comply with the terms of the annex shall be grounds for termination and annulment of the access contract."

Supplementary contracts to the access contract address the benefit-sharing counterpart (heading VI). The decision provides that, *inter alia*, the annulment of the access contract causes the annulment of the supplementary contract. Infractions and penalties are addressed under heading VIII.

8. *Central American Agreement on Access to Genetic Resources and Bio-chemicals and related Traditional Knowledge.* This Agreement was developed by the Central American States and will enter into force when the fourth instrument of ratification is deposited. With respect to benefit-sharing, article 16 (i) of the Agreement provides in that an indication of economic, social, cultural, scientific and spiritual benefits for the State and interested sectors is one of the requirements which must be met in order to obtain access to the genetic resources. In addition, article 19 stipulates that access contracts must include provisions relating to the sharing of benefits, including capacity-building, the percentage of benefits to be shared and the sharing of research results. Article 19 also provides that conditions for access must include terms of technology transfer and a fair and equitable share of benefits for the State, including local communities, the scientific community and private sector, in each case;

9. *ASEAN Framework Agreement.* The draft ASEAN Framework Agreement on Access to Biological and Genetic Resources addresses "fair and equitable sharing of benefits" in article 11 which provides for a minimum set of requirements to be included in benefit-sharing arrangements. The Framework Agreement is also to contain an annex that will illustrate options and guidelines for appropriate benefit-sharing arrangements. Article 12 also provides for the establishment of a Common Fund for biodiversity conservation, which would be based on a share of the benefits derived from the commercialization of resources and the fees imposed by States for access to their resources.

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C. National regimes

10. At the national level, countries have adopted a diversity of approaches to address access and benefit-sharing. Policy measures, including national legislation, have been adopted or are in the process of being developed in over 50 countries. The following typology has been suggested for the classification of legislative frameworks.^{8/} By way of illustration, reference is made to countries which have taken measures to address access and benefit-sharing:

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

(b) Access provisions in nature conservation or biodiversity laws: Costa Rica (1998), Australia (1999), India (2000);

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

(d) Specific access and benefit-sharing laws: Philippines (1995), Bolivia (1997), Bangladesh (1998, draft), Peru (1999, draft), Brazil (interim measure, 2001).

11. These instruments generally provide for the establishment of a competent national authority to deal with access and benefit-sharing, a prior informed consent procedure and requirements for benefit-sharing through mutually agreed terms. The benefit-sharing components of certain of these instruments, include the following:

(a) Benefit-sharing is addressed by the Indian Biological Diversity Bill 2000, under chapter V, which provides that the determination of equitable benefit-sharing is the responsibility of the National Biodiversity Authority (NBA). The NBA is to determine the type of benefit-sharing to be given effect, the Bill lists a number of benefit-sharing options;

(b) In Bolivia, chapter VI, article 40, of the Supreme Decree No. 24676 (1997), implementing decision 391 on the Common Regime for Access to Genetic Resources (see para. 7 above), provides under that the Bolivian State will participate in the fair and equitable sharing of the benefits that derive from access to genetic resources and that these benefits will be distributed for conservation, sustainable use and development of genetic resources in the national territory. Possible benefit-sharing options are listed under article 41 and include: transfer of technologies and knowledge and the development of technical and scientific capacities of national institutions.

12. It is difficult to draw any conclusions from these national approaches because of the small amount of experience acquired with their implementation. Concerns have been expressed by stakeholders, such as the private sector and the research community, that procedures established in a number of these instruments are too cumbersome and would create a disincentive to accessing genetic resources.

II. CONTRACTUAL ARRANGEMENTS ADDRESSING BENEFIT-SHARING

13. Contractual arrangements have been the most widely used instrument to control access to genetic resources and benefit-sharing. They have included a broad range of benefits, both monetary and non-

^{8/} Lyle Glowka, *A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources*, IUCN Environmental Law Centre, 1998, p. 23.

monetary. Experience to date has demonstrated differences between the types of benefits shared in contractual arrangements when the users are commercial companies compared to when they are public institutions. In the latter case, there is a greater emphasis on non-monetary benefits. Mechanisms through which these benefits are shared have been established on a case-by-case basis.

14. Benefit-sharing arrangements brought to the attention of the Secretariat through case-studies (available at www.biodiv.org) are mostly negotiated on the basis of prior informed consent and are mutually agreed. Provisions for sharing of monetary and non-monetary benefits include sharing of royalties, joint research and more.
