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FAIR AND EQUITABLE SHARING OF BENEFITS ARISING FROM THE USE OF GENETIC RESOURCES

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EXECUTIVE SUMMARY

This paper provides a basis for preliminary discussions on benefit-sharing: an agenda item for the fourth meeting of the Conference of the Parties in 1997. Its aim is to identify possible areas of work for the COP on the fair and equitable sharing of benefits.

The requirement for the fair and equitable sharing of benefits arising from the utilization of genetic resources is one of the three objectives of the Convention. It is triggered by the need for prior informed consent for access to genetic resources (Art 15) and for the approval of the holders of the knowledge, innovations and practices of indigenous and local communities (Art. 8(j)). These articles are linked to the provisions on access to and transfer of technology (Art.16),) exchange of information (Art.17), technical and scientific cooperation (Art. 18), the handling of biotechnology and distribution of its benefits (Art.19) and financial resources and mechanism (Art.s 20 & 21). The Convention can be interpreted broadly as an instrument to promote the equitable exchange, on mutually agreed terms, of access to genetic resources and associated knowledge for finance, technology and participation in research.

What constitutes a ´benefit´ that can be shared is limited only by the imagination and ingenuity of the partners involved. Monetary benefits include collection fees, royalties and research grants. Non-monetary benefits include benefits-in-kind, such as research on host-country diseases, conservation projects and licenses for products; technology transfer of hardware, software and know-how; training in various disciplines of science, information management, legal, administrative and management matters; joint research through participation in product development and joint ventures; institutional capacity building through developing partnerships and supporting groups such as communities, universities, botanic gardens, and small businesses; and the creation of employment opportunities. Benefits arise not only when a successful commercial or other products results, but from the initial moment of access.

To be 'fair and equitable', benefit-sharing should reflect the efforts of national authorities and of stakeholders such as communities, institutions and companies in making the genetic resource available (through conserving, allowing access to, providing information on, and collecting it) and using it (conducting research and development, etc.) Appropriate arrangements generally entail a basket of different benefits, tailored to the specific circumstances. What is ´fair and equitable´ is a matter to be decided by national authorities and mutual agreement between the parties to specific arrangements.

Since there has been little examination of benefit-sharing to date, case studies are needed on commercial and non-commercial arrangements, between different stakeholders, for example, access to genetic resources or associated knowledge for taxonomic study, or for the development of pharmaceuticals, phytomedicines, biotechnologies, agricultural or other products. Detailed dialogue is needed within countries - including all relevant stakeholders - to identify and create benefit-sharing mechanisms. A strategic approach is needed to clarify national benefit-sharing priorities and integrate them into national biodiversity strategies. The various roles that the State can play in negotiating benefit-sharing, and the scope for standardising benefit-sharing requirements could also be usefully explored.

In the light of the provisional agenda for COP4, Parties may wish to consider focusing on case studies on the sharing of benefits (1) arising from biotechnology and (2) between stakeholders working in situ and ex situ ; on (3) creating mechanisms for the sharing of benefits through technical and scientific cooperation; and (4) integrating benefit-sharing considerations into national biodiversity strategies. See Table 1, pages 15 & 16 for more detail.

FAIR AND EQUITABLE SHARING OF BENEFITS ARISING FROM THE USE OF GENETIC RESOURCES

Introduction

At its meeting in 1997, the Conference of the Parties (COP) to the Convention on Biological Diversity (Convention, or CBD) will be considering matters related to benefit-sharing. According to Decision II/18, Item 7.4.1 of the medium-term programme of work of the COP concerns 'measures to promote and advance the distribution of benefits from biotechnology in accordance with Article 19' , and item 7.4.2 will be considered in the light of the outcome of discussions on ways to promote and facilitate access to and transfer and development of technology, as envisaged by Articles 16 and 18 of the Convention (Item 6.7.1.).

This concept paper is intended to assist the COP to identify possible areas of work for the COP on benefit-sharing. Its first aim is to elicit feedback from readers, to assist the Secretariat to prepare papers on benefit-sharing for SBSTTA 3 and COP4. The second is to raise issues that will encourage Parties, between COP3 and COP4, to explore national views and experiences on benefit-sharing. This would facilitate progress on benefit-sharing at the national level and help Parties to bring information and ideas to COP4.

In Section 1, the paper considers why benefits should be shared fairly and equitably, what is a 'benefit', with whom and by what mechanisms benefits should be shared, what is 'fair and equitable' and how benefit-sharing can be encouraged. Section 2 identifies work that is needed, in the light of current experience in benefit-sharing, and Section 3 recommends priority areas of work for the COP, the SBSTTA, the Executive Secretary and for Parties.

Section 1

1.1 Why share benefits?

The 'fair and equitable sharing of the benefits arising out of the utilization of genetic resources' is one of three objectives of the CBD (Art. 1). None of the words 'fair', 'equitable', 'share' or 'benefit' is defined in the CBD, although each is used several times[1] . 'Benefit-sharing' is, however, mentioned in the context of the provisions on the knowledge, innovations and practices of indigenous and local communities (Art. 8(j)), and on access to genetic resources (Art 15). These, in turn, are explicitly linked to the provisions on access to and transfer of technology (Art.16), the handling of biotechnology and distribution of its benefits (Art. 19), financial resources (Art.20) and the financial mechanism (Art.21). Other articles, such as Art. 17 on the exchange of information, and Art. 18 on technical and scientific cooperation provide the means to share benefits. The result is that the Convention provides a number of indications of how to accomplish benefit-sharing throughout its web of Articles (see Box 1 below). It can be broadly interpreted as an instrument to promote the equitable exchange of access to genetic resources and associated knowledge for finance, technology and participation in research.

[1] benefit: (10 times) Preamble (3 times); 1; 8(j); 15(7); 16(4); 19 (title); 19(2); 20(2)
sharing: (9 times) Preamble; 1; 8(j); 15(7)(twice); 20(2); 21(2) (NB last two are 'burden-sharing')
benefit-sharing (together): (4-5* times) Preamble; 1; 8(j); 15(7); 19(2)* (*'access' to benefits)
fair: (4 times) 1; 15(7); 16(2); 19(2)
equitable: (5 times) Preamble; 1; 8(j); 15(7); 19(2)

Box 1: 'Benefit-sharing' in the CBD

• desirability of sharing equitably benefits arising from the use of traditional knowledge, innovations and practices relevant to the conservation of biological diversity and the sustainable use of its components	Preamble
• the objectives of this Convention are ... the fair and equitable sharing of the benefits arising out of the utilization of genetic resources	Art.1
• respect, preserve and maintain the knowledge, innovations and practices of indigenous and local communities ... promote their wider application with their holders' approval and involvement ... and encourage the equitable sharing of the benefits arising from their utilization	Art. 8.j
• full participation of provider in scientific research based on genetic resources provided	Art.15.6
• measures with the aim of sharing fairly and equitably the results of research and development	Art.15.7
• ... and benefits arising from the commercial or other utilization of genetic resources	Art.15.7
• access to and transfer of technology using genetic resources to countries providing them	Art.16.3
• effective participation by providers in biotechnological research on the genetic resources	Art.19.1
• priority access to the results & benefits from biotechnologies based on genetic resources provided	Art 19.2

The lack of definitions and of explicit benefit-sharing requirements, and the use of language that softens any obligations[2], leave considerable discretion for Parties as to the circumstances in which, the extent to which, and how, they will share benefits. Secondly, the obligations are between Contracting Parties, when it is 'stakeholders' such as universities, companies and local and indigenous communities, rather than governments, who are mainly involved in and affected by relevant activities. Furthermore, benefit-sharing is complex and succeeds only when tailored to the specificity of each case, so that too prescriptive an approach is impossible. The result is that, in seeking how to implement the provisions on benefit-sharing in the Convention, Parties should be guided less by any 'obligations' introduced by the Convention than by the rationale for benefit-sharing: equity, and the conservation and sustainable use of biodiversity.

1.2 What are the benefits of utilizing genetic resources, and when are they shared?

Among the direct benefits[3] of using genetic resources are the creation of information, products and technologies. These can be used directly to meet peoples' needs, but can also be applied to create other, indirect 'benefits'. For example, knowledge gained by participation in research on genetic resources can be used to add value to genetic resources in a country of origin, creating employment, and promoting trade and sustainable development. Products and technologies can be traded or licensed for money or for other goods or services. The wealth of opportunities that arise from using genetic resources creates another form of benefit: the incentive to conserve them and to use them sustainably.

Exhaustive definition of potential benefits would be impossible. Parties have approached the issue pragmatically, specifying particular benefits that must be shared in access legislation and material transfer agreements between institutions and communities. The major categories of benefit that customarily arise are listed in paragraph 68 of UNEP/CBD/COP/3/20 on access to genetic resources. Some examples of the kinds of benefit exchanged for access to genetic resources and associated knowledge are listed in Box 2, below. The list is by no means exhaustive, and the dividing line between some categories, such as technology transfer through the exchange of know-how, and others, such as training and capacity-building, is blurred.

[2] See, for example, 'subject to its national legislation' (Art. 8(j)), 'as appropriate' and 'with the aim of sharing . . .' (Art.15(7)).

[3] The 1995 edition of the Oxford English Reference Dictionary defines 'benefit' as a 'favourable or helpful factor or circumstance; advantage; profit'.

Box 2: Benefits[a]

Monetary benefits

- fees : collecting fee (small down-payment for permit); fee per sample; milestone payments;
- research budget: to conduct agreed work: up-front or in instalments;
- royalties, stake in equity or share in profit of company developing product from genetic resources;
- salary: for collection services; for work at R&D and production facilities; to pay a stipend to shaman and apprentice not to seek other work; ➲ how to apply funds? see, 'trust funds' Box 3

Non-monetary benefits

Benefits in-kind (for institutions, communities and the 'national good'):

- medical assistance: e.g. medical kits, traditional medicinal handbooks in local language; medical and dental visits for remote communities; distribution of drugs at cost or free;
- building a laboratory to manufacture local remedies; setting up an integrated health care clinic;
- focus research on host-country concerns, e.g. tropical or other orphan diseases
- food: a cow (to feed community where research team based), and other food supplies;
- transport: building an airstrip; purchasing vehicles; financing travel to meetings, conferences;
- licenses for the manufacture and sale of commercial products within the country;
- collections: creation of national collections of genetic resources by duplicate specimens;
- integration of conservation goals into projects; dedication of monetary and other benefits to conservation;
  ➲ how to decide on appropriate benefits in kind? see, ***'what is fair and equitable'***

Information:

- information on biodiversity, such as distribution, habitat; taxonomic identification; country floras
- research results: results of screens; uses to which the provider's genetic resources and knowledge have been put; clinical data on standardisation of traditional medicine used locally;
- scientific and technical literature, translated as appropriate; educational materials

Technology transfer: hardware, software and know-how

- field, laboratory and office equipment for collection and research: lights, nets, mobile fridges, cameras, GPS, vehicles etc.; milling machines, freeze-driers, chemicals, containers, automated screens, HPLCs, etc.; inventory equipment: plant presses; mounting boxes, cabinets, solvents, computers; software (compound and collection databases, collection management tools, GIS);
- know-how: how to set up and operate screens; how to use and adapt equipment, software, etc.

Training:

- science: collecting techniques & preparation of specimens; systematics; biochemistry, molecular and microbiology, ecology, ethnobotany; micropropagation, plant breeding;
- resource management: *in situ* & *ex situ* conservation techniques; protected area management, environmental & social impact assessment, etc.;
- information management: biodiversity inventories; logging material transfers and use of ethnobotanical information, for example, on herbarium specimens; developing GIS systems, etc.;
- legal, administrative and management training: administration of conservation and sustainable use of biodiversity, how to use intellectual property rights, negotiate agreements, plan benefit-sharing, manage participatory processes, etc.;
  ➲ how to train? see, 'training, capacity building and joint research' under ***mechanisms***

Joint research and development:

- collaboration in training and research programmes, participation in product development (e.g. develop and run screens); joint ventures; travel to conferences; co-authorship of publications;

Institutional capacity building:

- develop partnerships: benefit-sharing channels, e.g. identify collaborators, institutional channels for sharing benefits, building networks of research institutions, etc.;
- institutional development: community groups; university departments; botanic gardens; small businesses; national focal points for access;

Local income generation & employment:

- employment of local guides, parataxonomists, collectors; of scientists involved in R&D; manufacturing and/or plantation facilities established for long-term supply and production in country of origin.

[a] This is list is by no means exhaustive, but rather indicative of some benefits that have been shared.

Source: K. ten Kate, Royal Botanic Gardens, Kew

The absence of a clear definition of benefits opens up a wealth of possibilities. The benefits that can be shared are limited only by the imagination and ingenuity of the partners involved.

A popular misconception assumes that 'benefits' are purely monetary. In those cases where the use of genetic resources is commercial, any royalties arise between ten and twenty years - and sometimes many more - after the original access to genetic resources. Since the probabilities of an individual sample succeeding to the market are very small (perhaps 1 in a million: see Fig. 1 and ten Kate, 1995), only a tiny proportion of individual access transactions would give rise to such benefits. However, as Fig. 1 shows, many other valuable benefits - both monetary and non-monetary - can arise from the initial moment of access through the following years, whether or not any commercial product results.

1.3 Benefit-sharing profiles

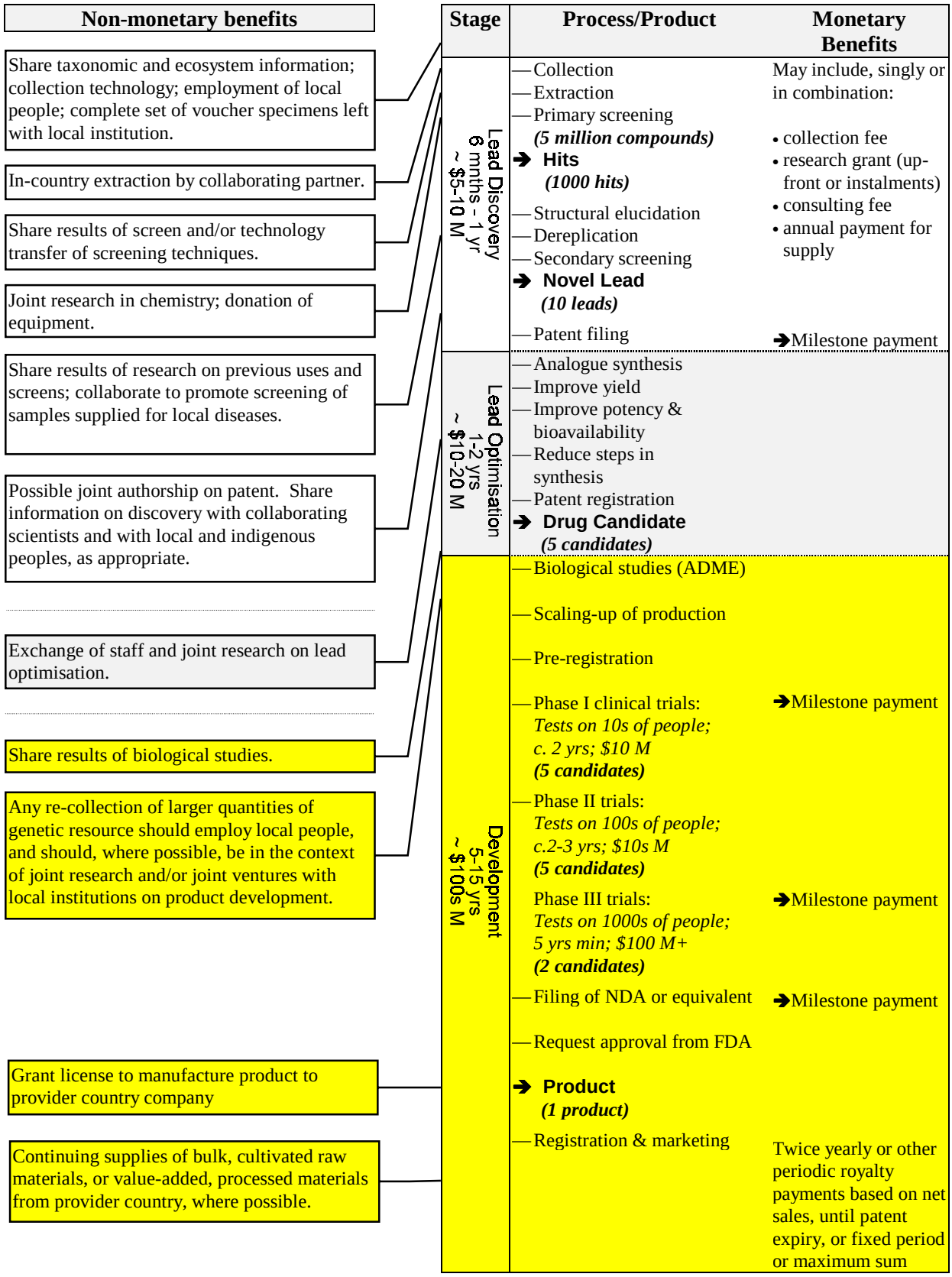
Fig. 1 is a schematic illustration of the 'benefit-sharing profile' of the development of a new drug by a major pharmaceutical company. It displays the length, expense and probabilities of success at different stages in the development of a pharmaceutical, and shows the range of monetary and non-monetary benefits that arise throughout the process. The process itself may last for thirty or more years, and certain benefits will arise and should be shared irrespective of whether a product finally succeeds on the market.

The research and development strategies and budgets even of comparable companies differ considerably. Smaller pharmaceutical and biotechnology companies would have different benefit-sharing profiles. Within a certain economic sector, benefit-sharing profiles may be variations on a theme, but will likely be different in kind for other uses, for example in sectors such as biotechnology, agriculture and horticulture.

It is worth noting that the language in the Convention, and increasingly of national legislation, requires prior informed consent and benefit-sharing for both academic and commercial purposes. In cases where genetic resources are used for scientific, non-commercial purposes only, for example in the case of access for taxonomic research by a herbarium, the benefit-sharing profile will comprise more of non-monetary aspects: predominantly exchange of information and training, and to some extent, technology transfer. Benefits arise in the commercial field whether or not a product reaches the market. Similarly, the benefits of academic research go well beyond the broad benefits to scholarship of additions to specialist literature once research is completed.

Benefits arise from the planning stage of research, since activities can be directed to meeting the sustainable development needs of countries, institutions and communities. For instance, taxonomy can focus on economically or culturally important local plants, or those endangered by overuse. Propagation and cultivation skills can be transferred, promoting conservation of wild genetic resources, and joint research on national resources can support the work of local researchers and enable them to focus on national priorities. Much conservation-related research can support practical conservation measures *in situ* and *ex situ*. Both pure and applied research can promote sustainable uses of biodiversity and the development of sustainable livelihoods. Research can attract financial support from research councils and other donors, and part of these sums should support activities by local counterparts.

As other Conventions such as CITES have found, drawing a distinction between commerical and non-commercial use is difficult. Provided there is an obligation to share all kinds of benefit as they arise, and to seek prior informed consent for any uses not initially agreed to, this need not be a barrier. The Philippines Executive Order and Implementing Regulations distinguishes between Academic and Commercial Research Agreements, but sets out basic benefit-sharing requirements for both. If access to resources or knowledge is initially for academic purposes, but subsequently used for commercial purposes, the benefit-sharing profile will alter correspondingly.



Source: K. ten Kate, Royal Botanic Gardens, Kew.

Figure 1: Benefit-sharing profile for development of a new drug by a major pharmaceutical company.

1.4 What gives rise to a benefit-sharing obligation and with whom should benefits be shared?

According to the Convention, access to genetic resources requires the prior informed consent of the Contracting Party providing the resources (Article 15(5)[4]). Application of the knowledge, innovations and practices of indigenous and local communities should be with the approval and involvement of the holders of such knowledge (Art. 8 (j)). Some national measures introduce benefit-sharing obligations not only for access to genetic resources, but also for associated knowledge. For example, the Andean Pact Common System on Access to Genetic Resources (Comisión del Acuerdo Cartagena: 1996) defines access[5] to include an 'intangible component', which means 'any knowledge, innovation or individual or collective practice of actual or potential value associated with the genetic resource, its derivatives or the biological resource containing them, whether or not it is protected by intellectual property systems'.

Although the CBD refers to securing prior informed consent from Contracting Parties, national access measures, such as those in the Philippines and Andean Pact and proposed in Brazil, require the agreement of stakeholders such as local communities, indigenous cultural communities and peoples, protected area management boards, and owners, holders and administrators of land (see UNEP/CBD/COP/3/20). This provides an opportunity for such groups to consent to access only on condition of benefit-sharing. In some national measures, benefit-sharing with such groups is explicitly required. For example, the Philippines legislation stipulates that "benefit-sharing arrangements must ensure that benefits and results received must accrue to the benefit of the Local Communities/Indigenous Peoples/Protected Areas concerned".

1.5 What is 'fair and equitable'?

1.5.1 Who decides?

What is fair and equitable[6] will depend upon the arbiter, as there is no single right answer. The authority of national governments to determine access (Art. 15(1)), their requirement for prior informed consent and the variety of roles they play in negotiating benefit-sharing, as defined in access legislation. The use of the phrase 'mutually agreed terms' in various[7] articles of the Convention allows the specific parties to access and benefit-sharing transactions to reach agreement on the basis of what they consider fair and equitable, and of meeting each others' needs. A purported breach of access legislation or of a material transfer agreement containing benefit-sharing provisions might, in the future, be dealt with under the dispute settlement provisions of the Convention (Article 27), or tried by judge or jury, in which case adjudication might be on the basis of some 'objective' view of what a 'reasonable' person would view as fair, or the view of a number of ordinary citizens. Finally, another benchmark in determining what is equitable is the kind of exchange and consideration commonly found in the market-place, which will depend on the demand for access to genetic resources.

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[4] "Unless otherwise determined" might suggest, on the one hand, that if access measures are not in place, PIC is not required or, on the other, that access remains restricted and PIC is required until a Party legally determines otherwise. See UNEP/CBD/COP/3/20.

[5] '"Access" means the acquisition and use of genetic resources conserved in ex-situ and in-situ conditions and of their derivatives or, as applicable, intangible components, for purposes of research, biological prospecting, conservation, industrial application or commercial use, among others.'

[6] The 1995 edition of the Oxford English Reference Dictionary defines 'fair' as 'just, unbiased, equitable' and 'equitable' as 'fair, just'.

[7] 15(4); 16(3); 19(2) and as 'mutual agreement' in 18(5).

1.5.2 How to quantify?

What is fair and equitable also depends on what is understood by 'sharing'[8], and the basis for it. The CBD does not mention the concept of 'compensation'. However, agreements seem to suggest that a fair and equitable sharing of benefits goes beyond simple remuneration of the costs of the exchange of genetic resources and knowledge. Fairness and equity will also be a feature of the overall package of benefits. Thus paying members of a community for their labour collecting specimens is required by fairness and equity, but does not in itself amount to a fair and equitable sharing of benefits unless accompanied by other features such as exchange of information, technology transfer, etc.

A further challenge is how to quantify the value of access to genetic resources and the various 'benefits' exchanged. This is complicated for a number of reasons. First, quantification entails refining methodologies for assessing the economic value of biodiversity (see, for example, UNEP/CBD/SBSTTA/2/13). Second, it involves quantifying the share of the market price contributed by the 'raw' biological resources themselves, by stakeholders providing access to them and knowledge concerning them, and the value added through the formal research and development process. Third, markets often fail to integrate environmental and social costs into economic decisions. Until 'externalities' such as the costs of conservation enter into cost calculations, benefits will generally not reflect the full value of genetic resources, in particular the services of communities conserving them. This stresses the importance of further work on complementary issues such as full cost pricing, access legislation and other policy interventions that can promote fairness and equity in the sharing of benefits.

1.5.3 How to allocate?

The allocation of benefits is linked to the identification of beneficiaries (1.4), as well as the basis for sharing and quantification of benefits (1.5.2). Just as with fairness and equity, there is no correct method for allocation. The desired result is one which fairly reflects the efforts contributed by the different stakeholders in making the genetic resource available (through conserving, allowing access to, providing information on, collecting, and conducting research on it.). This will be a matter to be decided by national authorities and mutual agreement between parties to specific arrangements. Material transfer agreements frequently clarify the share of royalties between the various parties, and may be an appropriate mechanism for allocating benefits when there are relatively few beneficiaries. When there are many, for example where the knowledge on which an invention is based is common throughout a country, or where conservation efforts have been a shared responsibility among farming communities for generations, it may be appropriate to share benefits nationally, as well as allocating some to local institutions and communities that have contributed. For this purpose, a 'multistakeholder' committee may be helpful to define the application of benefits for the 'national good'[9]. These are issues to which policy responses should be clarified, in consultation with all relevant stakeholders during the development of national measures to regulate access.

1.6 What are the mechanisms for sharing benefits, and how can benefit-sharing be encouraged?

The appropriate mechanisms for sharing benefits depend upon the nature of the benefits themselves. Some mechanisms are described in Box 3. The key criterion for any benefit is to be able to identify appropriate beneficiaries, and set up partnerships or find institutional channels through which the benefits can be transferred.

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[8] The 1995 edition of the Oxford English Reference Dictionary defines 'share' as ' a portion that a person receives from or gives to a common amount'; 'to use or benefit from jointly with others'.

[9] See, for example, Laird and Wynberg, 1996.

The lack of preparedness to receive or allocate benefits is a frequent obstacle to the fair and equitable sharing of benefits. There are cases where monetary benefits have arisen and there have been no routes through which to share them with local and indigenous communities, even though such arrangements were required as conditions of prior informed consent. In such cases the benefits that were agreed do not reach the beneficiaries, which is hardly fair and equitable. Assessing existing mechanisms and creating new ones are among the most important steps necessary to promote benefit-sharing.

Box 3: Mechanisms for sharing various benefits

- **Mechanisms for sharing monetary benefits**

The government authority providing prior informed consent may identify how any payments of financial benefits to it should be made. Different departments of government may need to agree upon the appropriate recipient of funds, and the purposes for which they should be applied. The basis for governance, administration and use of funds should be clarified in the consultative process leading up to access legislation.

Working out how to compensate local-level stakeholders such as indigenous and local communities poses a further challenge, since such groups often do not have representative organizations with legal standing, bank accounts or other mechanisms through which to channel monetary benefits.

The use of trust funds[10], which can be governed by committees with representation from government, indigenous and local communities and the private sector, has emerged as one mechanism to deliver monetary benefits. Such funds can be applied for agreed purposes, such as conservation programmes, sustainable development strategies, or other purposes to be determined by the community, e.g. activities such as building a health clinic; regulating access to genetic resources and knowledge; legal costs to pursue land and resource rights, etc.

Mutual agreement between providers and users on the purposes to which such funds might be applied - for example, stipulating the share returned to local communities and the share dedicated to conservation - can act as an incentive for all parties to enter into the partnership.

- **Mechanisms for sharing non-monetary benefits**

Information can be exchanged through multilateral channels such as the clearing-house mechanism and publications, or communicated between individual organizations.

Technology transfer, joint research and capacity building can take place through courses, staff exchanges, conferences, by sponsoring students or research at academic institutions or within communities (e.g. supporting the work of shamans, documenting local knowledge, or creating community genebanks etc.); and by supporting institutions such as *ex situ* collections. It can be done by individual partners, or by joint efforts through networks, for example to place students in industry. Collectors and companies will need the help of local communities and organizations to identify suitable communities and institutions to receive benefits such as equipment and training.

[10] See, for example, Report of the First Global Forum on Environmental Funds, 1994; Grifo, 1996; Laird & Wynberg, 1996.

Section 2: What further work is needed?

The challenge posed to national authorities, communities, and companies by the complexity of benefit-sharing issues is enormous. Work is needed in three major areas: assessment of the current situation of benefit-sharing; clarification of benefit-sharing obligations to match new legislative developments; and implementation.

2.1 ASSESSMENT OF BENEFIT-SHARING AND EXCHANGE OF INFORMATION

2.1.1 Assessment of benefit-sharing

There has been little analysis to examine what kinds of benefit arise in different situations in which there is access to genetic resources or use is made of indigenous peoples' knowledge. **Further work is needed to identify the current flows of benefits to and from different kinds of institution** (for example, government departments, protected areas, universities, *ex situ* collections, companies, indigenous and local communities) in the context of different uses of genetic resources and associated information.

In particular, **case studies are needed** on access and benefit-sharing for taxonomic and other 'purely scientific' purposes and for commercial development of pharmaceuticals, phytomedicines, biotechnologies, agricultural and horticultural products, cosmetics and personal care products, foods and beverages, flavours and fragrances and other products.

Such case studies should be linked to an **assessment of the demand by business and industry for access** to genetic resources. One component of such case studies could be to **compile 'benefit-sharing profiles'**, as introduced earlier in this paper.

2.1.2 Exchange of information

If there is to be progress on benefit-sharing, a considerable degree **of awareness raising and exchange of information and experience** will be needed. Policy-makers and practitioners involved in access and benefit-sharing are often unaware of the legal, economic, political and management issues surrounding it. A particular barrier to progress is the lack of understanding of the extent and limitations of demand for access to biodiversity, the costs, risks and alternative methods of product development, and thus of realistic expectations for benefit-sharing. A further barrier is the lack of understanding of the broad range of information, technologies and partnerships that can be the benefits of utilizing genetic resources.

The compilation of **case studies on access and benefit-sharing** between **different stakeholders** for **different uses** and benefit-sharing profiles, as described above, would contribute significantly to raising the awareness of what is desirable and feasible in benefit-sharing. Such information could be summarised in a Note by the Executive Secretary to assist Parties at SBSTTA3 and COP4.

Greater **accessibility** of the following categories of **information** would also help:

- access legislation containing benefit-sharing requirements made by national authorities;
- the requirements made by institutions and communities, as expressed in institutional policies, codes of conduct for collection and material transfer agreements;
- policies of institutions seeking access to genetic resources (e.g. botanic gardens and companies).

Such information could be exchanged through the clearing-house mechanism, and, as appropriate, summarised in a Note by the Executive Secretary, as proposed above.

2.2 CLARITY IN BENEFIT-SHARING OBLIGATIONS AND PROCESSES

Clarification of four main kinds is needed: identification of beneficiaries at the local level and mechanisms for sharing benefits with them; identification of national benefit-sharing priorities; the role of government authorities in benefit-sharing; and exploration of the scope for defining and standardising benefits in national access legislation, in material transfer agreements, and in systems to exchange *ex situ* collections of resources.

2.2.1 Identification of beneficiaries and benefit-sharing mechanisms at the local level

National access legislation is increasingly introducing an obligation on the part of applicants for access to seek the prior informed consent of, and share benefits with, local stakeholders, such as indigenous and local communities, landowners, etc. If applicants are to be able to fulfil this requirement, a major initiative will be needed at the national level in each country.

Applicants wish to be confident that they have secured all relevant consents. Since they are likely not to be expert in the geography, social organization and culture of the location in which they are requesting access, **applicants will need assistance from provider country authorities, institutions and communities**, and this advice must be definitive. If companies, in particular, fear that despite time and effort invested in securing the relevant consents, the result may be the subject of disputes that could affect their rights to use the materials received after they have committed substantial time and investment in research, they will not seek partnerships in these circumstances. Indeed, the effect of such obstacles is to reduce corporate interest in natural product development altogether.

This situation calls for **detailed dialogue within countries - including representatives from local and indigenous communities - to decide how prior informed consent might work at the local level**; how the country's population will subdivide into units competent to give consent and appropriate to receive benefits. Since the class of potential beneficiaries will vary with the location of the genetic resources and associated knowledge, which themselves form a complicated pattern, since the definition and organization of communities may be nebulous and subject to change, and since political factors will inevitably intrude, this task will be extremely difficult. The scientific uncertainties and cost of implementing precise solutions call for **pragmatic solutions** with which can satisfy all major stakeholders.

Once those communities and institutions with which benefits should be shared have been identified, an **assessment is needed of the availability of mechanisms to channel benefits** of different kinds to them. This is a particularly important issue, and is taken up under 'implementation', in 2.3.1 below.

2.2.2 Clarification of national benefit-sharing priorities

The sharing of benefits will not be accomplished, or maximise the possible advantage to all stakeholders if it is conducted in an *ad hoc* manner. Rather, a **strategic approach is needed**, in which countries and the stakeholders within them identify priority 'benefits' and consider the policy and institutional measures necessary to secure them (see ten Kate, 1995). A national process that involves all relevant stakeholders is necessary. Such a process would entail an assessment of the demand for access to genetic resources, evaluation of the different markets for natural products, assessment of national resources and capacities to provide genetic resources, and identification of priority needs to guide benefit-sharing requirements.

Box 4: How to encourage benefit-sharing

Benefit-sharing will always depend upon the motivation and honesty of the parties seeking and providing access, but a number of tools can be used to encourage it:

- **Legislation** can be used to introduce basic benefit-sharing requirements, clarifying what activities trigger benefit-sharing, with whom benefits should be shared, and setting out indicative lists of the kinds of benefit that should be shared.
- **Intellectual property rights** can provide shares in royalties agreed in contracts and act as an incentive for partners to transfer technology and collaborate on research. A record of the country of origin in patents (which are publicly disclosed) could, if feasible, promote benefit-sharing by alerting provider countries of the use made of their genetic resources. However, IPRs are likely to represent a minor contribution to benefit-sharing (see 'Benefit-sharing Profiles', page 4).
- **Material transfer agreements** can set out precise benefits and their allocation between partners. These can be reviewed by governments for consistency with the broad requirements of legislation.
- **Policies** on a range of issues, from science and health to foreign direct investment, can act as incentives for sharing of benefits such as technology and joint research.
- **Strategy**: A national biodiversity strategy or a strategy at the community level can help identify benefit-sharing priorities, and mechanisms for channelling benefits.
- **Capacity building**: Potential recipients may not have the human or institutional resources to receive certain benefits, such as technology. Capacity-building programmes can help to enable them to assimilate more valuable benefits.

2.2.3 The role of the State in negotiating benefit-sharing

A spectrum of roles is possible for government involvement in the sharing of benefits. At one extreme, government can leave access to genetic resources and associated information unregulated, and play no part in the negotiation of any agreements that may arise on the sharing of benefits. At the other extreme, government can introduce legislation that sets a number of prior informed consent and benefit-sharing requirements of applicants, and involves government departments in benefit-sharing negotiations. In the middle, government can introduce access and benefit-sharing legislation, nominate a focal point or competent national authority and inter-disciplinary committee to oversee the implementation of the law. The role of government in this case is to set basic norms and thereafter oversee access agreements to ensure that they meet these, without becoming involved in negotiation of the agreements themselves.

These different approaches have a range of political, economic and management implications, which need to be thought through prior to introducing access legislation. Different approaches to this issue within the five countries of the Andean Pact led to a flexible instrument that allows the Member Countries discretion on the level of involvement of the State in access determinations. The lessons learned through this process could be very helpful to other Parties which will have to decide upon this issue as they develop access legislation.

2.2.4 Scope for standardising benefit-sharing requirements

There are several potential disadvantages associated with access regimes that do not define benefit-sharing obligations up-front. First, complete freedom to negotiate different benefit-sharing arrangements would make it difficult to set benchmarks and ensure that the result of each case is fair and equitable. Second, the time, effort and cost involved in negotiating access agreements afresh on each occasion that access is granted to a single sample is prohibitively expensive. Further, the ultimate use to which a sample is put is not known from the outset, so that it is not cost effective to predict the final details of benefit-sharing for each sample initially. However, users do not like to leave agreement of the range of benefit-sharing possibilities until late in the research and development process, for fear that it may ultimately be impossible to reach agreement, so that the considerable investments in product development are hostage to fortune and may not be retrieved. Third, for genetic resources whose use is unlikely to lead to substantial monetary benefits but which are widely exchanged, standardised benefit-sharing regimes might facilitate access, promote fair benefit-sharing, and substantially reduce transaction costs (see IPGRI, 1996).

These arguments appear to support the idea of developing a benefit-sharing regime that would set out, prior to access, the range of obligations that would arise depending on different circumstances and uses to which the genetic resources were ultimately put. Such a scheme need not be exclusive. Parties and institutions could be free to pursue other means of satisfying legal obligations and each others' requirements, but could, if they chose, opt to participate in a voluntary scheme. In this case, Parties and/or participating institutions would commit at the outset to share benefits within the ranges described for the different uses.

Potential advantages of such a scheme might include a reduced need for individual benefit-sharing negotiations, lower transaction costs, and less scope for conflict. It could be implemented by individual parties agreeing to live by the terms of an elaborate umbrella material transfer agreement, which would describe in detail the schemes for assessing benefits, depending on factors such as the level of joint discovery and research, proximity of the final product to the original genetic resource explored, use of ethnobotanical knowledge, etc.

2.3 IMPLEMENTATION ISSUES

It is difficult for decision-makers to commit to legislation, policies and agreements without knowing what will be the legal, institutional and financial feasibility and implications of implementing them. For this reason, exploration of two issues concerning implementation are important, despite the challenges arising from the fact that certain aspects of benefit-sharing are still at an early stage of development. The two priority issues for consideration are development of mechanisms for benefit-sharing, and assessment of transaction costs.

2.3.1 Creating mechanisms for sharing benefits

An important barrier to the fair and equitable sharing of benefits is the lack of mechanisms available for channelling benefits back to stakeholders at the national level. Consequently, creating such mechanisms is an important part of national and local capacity-building. There are three main aspects to the process of creating mechanisms for sharing benefits: identifying potential partners (whether communities or institutions), making information on them available so that potential partners can identify each other and cooperate, and capacity-building within communities and institutions.

The mechanism that is appropriate will depend upon the nature of the benefit, as described in Box 3. Typically, accounts should be identified to receive any monetary benefits. It may be appropriate to establish trust funds, in which case institutional issues such as governance and criteria for application will need to be clarified. To facilitate benefit-sharing with communities, it may be necessary to establish community groups and non-governmental organizations, and identify which of these are representative of particular stakeholder groups, whether they are accountable, and whether they have legal personality entitling them to enter into contractual relationships, own property and receive funds. Institutions such as university departments, *ex situ* collections and protected areas may require human and institutional capacity building if they are to received certain technologies. **Stakeholders of all kinds may require training in establishing partnerships and negotiating benefit-sharing agreements**.

At the national level, the **creation of mechanisms for benefit-sharing** should be **an important part of Parties' work on national biodiversity strategies**, closely linked to the development of access legislation. At the international level, **an exchange of experience** related to benefit-sharing mechanisms would be helpful, and could be encouraged through the work of the COP.

2.3.2 Transaction costs

The importance of considering transaction costs was alluded to in section 2.3.1 above. The CBD's general requirement to facilitate access would be thwarted, and its capacity to promote sustainable use and benefit-sharing severely curtailed, if the transaction costs involved in securing access, negotiating benefit-sharing and delivering benefits outweighed their value. Efficient, clear and cost-effective solutions that minimise transaction costs will be essential. Studies are badly needed, since there have as yet been none on the transaction costs associated with access and benefit-sharing (although IPGRI is currently estimating the transaction costs of implementing the various options for access outlined in IPGRI, 1996).

One aspect upon which such a study should focus is to examine whether benefits must be individually tailored to specific access determinations, or could be generalised to standardised services by institutions. For example, does fairness and equity require each individual access transaction to be matched to specific benefit-sharing, or can these be more general, provided they are proportionate? Do the transaction costs entailed merit identifying the precise benefits that arise from each sample explored, or could institutions agree to provide general benefits 'in consideration for', but not explicitly tied to individual access transactions?

Two illustrations may serve to bring this point to life. Shaman Pharmaceutical Inc. has set up a not-for-profit NGO, the Healing Forest Conservancy, to enable Shaman to implement its benefit-sharing obligations, as negotiated with governments and communities. In the event that Shaman develops a product derived from an ethnobotanical lead from one community, the company´s stated aim is to share the benefits that arise with all the communities that have provided it with genetic resources and knowledge. Given the small probability that any one lead will succeed, such an approach acts as a mechanism to share risk and benefits among all potential Shaman beneficiaries. The merits and acceptability of this approach could be explored.

Secondly, botanic gardens provide a host of services that are benefits to the institutions that grant them access to genetic resources. These include the provision of information, training and technology transfer, capacity building and joint research (see UNEP/CBD/COP/3/Inf.46). Would it satisfy the benefit-sharing demands of Parties and individual institutions if individual botanic gardens that generated enough such benefits were to guarantee to provide these free to collaborating institutions, in exchange for access to genetic resources, subject to additional agreement to seek the provider's prior informed consent and share monetary benefits in the event of commercialization? Such an approach might reduce the need to specify the exact benefits to flow for each sample, or batch of samples, transferred.

Section 3: Recommendations for future work

Section 2 developed a set of recommendations for further areas of work. This section will recommend priority areas of work for the COP. Before doing so, a brief consideration is needed of the two aspects of benefit-sharing that are on the agenda for COP4: 'promote and advance the distribution of benefits from biotechnology', and benefit-sharing in the context of facilitating access to and transfer and development of technology.

3.1 Agenda items 7.4.1: biotechnology and 7.4.2: technology

Article 2 of the Convention defines "biotechnology" as 'any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use'. Although 'technology' itself is not defined, the breadth of this definition means that a large subset of activities that give rise to benefit-sharing will involve biotechnology, so that agenda item 7.4.1 does not immediately provide a focused agenda on benefit-sharing. The same can be said of agenda item 7.4.2 on access to and transfer and development of technology. First, technology transfer itself comprises a very broad range of benefits, including access to and transfer and development of hardware, software and know-how. Second, all benefits are interlinked, and fair and equitable benefit-sharing partnerships cannot be seen in light of a single benefit, for example technology transfer, but rather of a package involving other monetary and non-monetary benefits such as royalties, information, etc. Finally, agenda item 7.4.2 will be considered 'in the light of the outcome of' agenda item 6.7.1, so that it is difficult to plan this agenda item in advance.

Despite these difficulties, the focus on biotechnology and technology transfer provided by Agenda item 7.4 can help to prioritise work on benefit-sharing. Recommendation II/3 (a) of SBSTTA suggests that technology transfer should not be dealt with as a stand-alone issue, but rather in the context of the thematic approaches found in the Medium Term Programme of Work (MTPW): an 'integrated' approach. The thematic approaches that appear for 1997 in the COP's MTPW are: 7.2: models and mechanisms for linkages between *in situ* and *ex situ* conservation; 7.5: technical and scientific cooperation; and 7.6: inland water ecosystems.

3.2 Conclusions

Table 1 sets out the major recommendations of this paper and which bodies are targeted to implement them. In the light of the paragraphs above, the Parties may wish to consider focusing on the following areas:

- COP4/MTPW 7.4.1 (**benefit-sharing/biotechnology**): benefit-sharing profiles related to benefits from biotechnology (see 1(a)(i) in Table 2);

- COP4/MTPW 7.5 and SBSTTA3 agenda item 4.4 (***in situ*/*ex situ* linkages**): benefit-sharing profiles entailing partnerships between stakeholders working *in situ* and *ex situ* (see 1(a)(ii) in Table 2);

- COP4/MTPW 7.5 and SBSTTA3 agenda item 4.3 (**technical and scientific cooperation**): creating mechanisms for benefit-sharing (see 3 (a) in Table 2);

- integrating benefit-sharing considerations into **national biodiversity strategies** and national reports (see 1(a); 2 (a), (b), (c) in Table 2).

Table 1: Recommendations for future work

RECOMMENDATIONS	ACTIONS
1. Assessment of benefit-sharing and the exchange of information (a) *Assessment of benefit-sharing* (i) prepare case on the use of genetic resources and the knowledge, innovations and practices of indigenous and local communities in developing: pharmaceuticals, phytomedicines, biotechnologies, agricultural and horticultural products, cosmetics and personal care products, foods and beverages, flavours and fragrances, etc. (ii) assess the flows of benefits between different stakeholders: government departments, protected areas, universities, *ex situ* collections, companies, indigenous and local communities.	• During discussion of Agenda item 11.1 (Art. 8(j)) and 12.1 (Art. 15), raise priorities for work on benefit-sharing. • Submit case studies of benefit-sharing to Secretariat. • Conduct review/assessment of benefit-sharing as part of national biodiversity strategies (Art. 6 (a)) and integrate with other sectors (Art. 6 (b)).
(b) *Exchange of information* raise awareness of the factors affecting access and benefit-sharing	• During discussion of Agenda item 5 (clearing-house mechanism - ´CHM`), define role for the CHM in exchanging information on access and benefit-sharing • Exchange national experience, through clearing-house mechanism, networks of NGOs, meetings of professional societies, etc. • Identify and provide information on Art 15 and national measures at other for a, e.g. meetings of botanic gardens, academic research councils, trade associations, etc. • Disseminate case studies, as above, through CHM or other means.
2. Clarification of benefit-sharing obligations and processes (a) *Identification of beneficiaries at the local level and Benefit-sharing mechanisms*	• Initiate or continue dialogue in-country, between different stakeholders to work out national systems for identifying those whose prior informed consent is needed, with whom benefits should be shared, and available mechanisms for doing so. • Ensure clarification of benefit-sharing obligations and processes is part of the national biodiversity strategy process, closely linked to development of access legislation. • Submit case studies on national and local processes to develop and implement measures on access and benefit-sharing, and how these can be integrated into national biodiversity strategies.

(b) *Clarification of national benefit-sharing priorities as part of the process of preparing a national biodiversity strategy*	• Recommend inclusion of a strategic 'access and benefit-sharing' assessment into national strategies and inclusion of the results into national reports. • Conduct an assessment of the demand for access and markets for natural products, and also of national resources and capacities to provide genetic resources and priority needs to guide benefit-sharing requirements.
(c) *Assessment of the legal, policy and management implications of the different approaches to the role of the State in negotiating benefit-sharing.*	• Explore the various options and bring experiences from countries which have, or are, developing measures on access and benefit-sharing to COP4.
(d) *Standardisation of benefit-sharing regimes:* assessment of the feasibility of developing a benefit-sharing regime that would set out, prior to access, the range of benefit-sharing obligations that would arise depending on different circumstances and uses to which the genetic resources were ultimately put.	• Representative groups of interested individuals and institutions - including companies, representatives from local and indigenous communities, managers of *ex situ* collections and government competent national authorities - to explore the possibilities and bring experiences to COP4.
3. Implementation (a) *Creation of mechanisms for benefit-sharing* identify potential partners (whether communities or institutions), make information on them available so that potential partners can identify each other and cooperate, and build capacity within communities and institutions. (b) *Assessment of transaction costs associated with different approaches to access and benefit-sharing.*	• Identify potential partner communities and institutions for benefit-sharing or create mechanisms as appropriate, through networks and capacity-building. • Conduct research on costs of current and proposed regimes on access and benefit. Compile reports, submit information to the Secretariat and bring experiences to COP4. • Exchange resulting information.

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