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MEASURES TO PROMOTE AND ADVANCE THE DISTRIBUTION OF BENEFITS FROM BIOTECHNOLOGY IN ACCORDANCE WITH ARTICLE 19

Note by the Executive Secretary

I. EXECUTIVE SUMMARY

1. In its decisions II/18 and III/22, on the medium-term programme of work of the Conference of the Parties for 1996-1997, the Conference of the Parties decided to consider the issue of benefit-sharing at its fourth meeting. The present note has been proposed to assist in these discussions and deals with "measures to promote and advance the distribution of benefits from biotechnology in accordance with Article 19", item 16.1 of the provisional agenda of the meeting.

2. This is the first time that the Conference of the Parties will address benefit-sharing, the third objective of the Convention, under a separate agenda item. Although the issue of technology transfer has been dealt with in each of the past meetings, it was addressed only in the context of Articles 16 and 18. The present note focuses on the distribution of benefits from biotechnology in accordance with Article 19, paragraphs 1 and 2. In this connection, a clear distinction must be made between subject-matter covered by the present note and the rest of Article 19, paragraphs 3 and 4 of which deal with the safe transfer, handling and use of living modified organisms (LMOs) and are linked to Article 8(g). These provisions establish appropriate procedures by which countries would receive the information necessary to take a decision on the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effects the conservation and sustainable use of biological diversity. A protocol on biosafety is currently under negotiation in the Open-ended Ad Hoc

* UNEP/CBD/COP/4/1.

Working Group on Biosafety of the Convention on Biological Diversity. 1/ Regulations on biosafety are relevant for policy and law regarding benefit-sharing from biotechnology in so far as benefit-sharing might comprise sharing of living modified organisms. In such a case, biosafety regulations apply as they would apply to every other handling, transfer and use of GMOs. As a general rule, every benefit-sharing arrangement from biotechnology has to respect and apply nationally and/or internationally agreed regulations that are in force for the parties to the arrangement, whether they be in the public or private sector.

3. Under item 16.2 of the provisional agenda at its fourth meeting, the Conference of the Parties will consider “means to address the fair and equitable sharing of benefits arising out of genetic resources”. In accordance with decision III/5, paragraph 7, a note to assist consideration of this item (UNEP/CBD/COP/4/22) has been prepared in a collaborative manner by the Secretariats of the Convention and the Global Environment Facility, and focuses on options for assistance to developing countries. Item 16.3 of the provisional agenda deals with the “compilation of views of the Parties on possible options for developing national legislative, administrative or policy measures, as appropriate, to implement Article 15”. A note by the Executive Secretary (UNEP/CBD/COP/4/23) reviews further progress in implementation of Article 15 and suggests guidelines for formulating access legislation. All three papers should be read together since they address the same issue from different angles (access and benefit-sharing regarding genetic resources). As the Conference of the Parties adopted various decisions at its third meeting requesting case-studies, the Executive Secretary has called for case studies on benefit-sharing and developed an indicative outline which has been distributed through the clearing-house mechanism. A synthesis report of the case studies received is contained in document UNEP/CBD/COP/4/Inf.7. The case-studies themselves will be made available though the clearing-house mechanism.

II. BIOTECHNOLOGY AND BENEFIT-SHARING

4. One of the three objects of the Convention on Biological Diversity, as set out in its Article 1 is the "fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding". The present note deals with sharing of benefits from biotechnology in accordance with Article 19, paragraphs 1 and 2. Since the scope of the provisions is defined as "biotechnologies based upon genetic resources provided by Contracting Parties", there are strong interlinkages between these provisions and those of Article 15, on access to genetic resources. In fact, these paragraphs parallel paragraphs 6 and 7 of Article 15, the relationships being highlighted in table 1 on page 3 below.

1/ A report on progress in that work may be found in document UNEP/CBD/COP/4/9. The reports of the second, third and fourth meetings of the Working Group (UNEP/CBD/BSWG/2/6, UNEP/CBD/BSWG/3/6 and UNEP/CBD/BSWG/4/4) will also be available at the fourth meeting of the Conference of the Parties.

Table 1

A comparison between Article 19, paragraphs 1 and 2 and Article 15, paragraphs 6 and 7

Article. 15.6 (sequence changed)	**Article 19.1 (wording)**
* Each Contracting Party1	* Each Contracting Party
* shall endeavour	* shall take legislative, administrative or policy measures, as appropriate,
* to develop and carry out scientific research based on genetic resources provided by... with the full participation of	* to provide for the effective participation in **biotechnological** research activities
* by other Contracting Parties,	* by those Contracting Parties, **especially developing countries,** which provide the genetic resources for such research,
* and where feasible in such Contracting Parties.	* and where feasible in such Contracting Parties.

Article 15.7 (sequence changed)	**Article 19.2 (wording)**
* Each Contracting Party	* Each Contracting Party
* shall take …, as appropriate	* shall take
* legislative, administrative or policy measures	*all practicable measures
* and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21	
* with the aim of sharing in a fair and equitable way	* to promote and advance priority access on a fair and equitable basis by Contracting Parties, **especially developing countries**,
* the results of research and development	*to the results
* and the benefits arising from the commercial or other utilization of genetic resources with the Contracting Party providing such resources	* and benefits arising **from biotechnologies** based upon genetic resources provided by those Contracting Parties.
* Such sharing shall be on mutually agreed terms.	* Such access shall be on mutually agreed terms.

5. The most outstanding differences between these two Articles are the emphasis in Article 19, paragraphs 1 and 2 on the role of developing countries as beneficiaries if they are the providers of genetic resources, and the particular focus on biotechnology in those paragraphs. Apart from this, differences are of a minor character. Whereas Article 15, paragraph 6, asks for full participation, Article 19, paragraph 1 requires effective participation. Article 15, paragraph 7, requires legal, administrative or policy measures, while Article 19, paragraph 2, calls for practicable measures. Measures which are not practicable should not be considered as means to implement the Convention, and measures as a generic term refer to legal and administrative, as well as to policy, measures. Full participation may be more encompassing than effective participation. However, the reason for research participation is transfer of technology and skills. Effective participation is therefore sufficient for the purpose of the Convention. In light of the similar structure of these articles, the demarcation between the first two paragraphs and the last two paragraphs of Article 19 becomes evident.

6. As the concept of benefit-sharing is based on access to genetic resources, other paragraphs of Article 15 are also relevant, in particular paragraphs 4 (access on mutually agreed terms) and 5 (access and prior informed consent). In this context, the third aspect of Article 8(j), which encourages the equitable sharing of the benefits arising from the utilization of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for conservation and sustainable use of biological diversity, is also relevant.

7. These articles are explicitly linked to the provisions of the Convention on access to and transfer of technology (Article 16), financial resources (Article 20) and the financial mechanism (Article 21). In addition, Article 17 on the exchange of information and Article 18 on technical and scientific cooperation contains related obligations.

8. Several decisions at the third meeting addressed the issue of benefit-sharing. Decision III/15, on access to genetic resources, called for information on policy measures and guidelines for activities covered by Article 15, and, in particular, on access and benefit-sharing. Decision III/17, on intellectual property rights, encouraged case studies on the impacts of intellectual property rights on the attainment of the objectives of the Convention, including, inter alia, facilitating technology transfer and arrangements by which interested parties may determine access to and equitable benefit-sharing of genetic resources or of local and indigenous knowledge, innovations and practices. In accordance with decision III/14 on implementation of Article 8(j), an inter-sessional Workshop on Traditional Knowledge and Biological Diversity took place in November 1997. For that purpose a background note (UNEP/CBD/TKBD/1/2) addressing, inter alia, the linkages between Article 8 (j) and related issues, such as technology transfer, access to genetic resources, intellectual property rights, alternative systems of protection, incentives and Articles 6, 7 and the remainder of Article 8, was prepared.

9. By paragraph 1 of decision III/9, on implementation of Articles 6 and 8, the Conference of the Parties urged Parties to include in their national plans or strategies and legislation, measures for, inter alia, the equitable sharing of benefits arising out of the use of genetic resources. Paragraph 1 of decision III/11, on agricultural biological diversity, stated that promoting

the fair and equitable sharing of benefits arising out of the utilization of genetic resources was one of the objectives of establishing a multi-year programme. In addition, in its decision III/4 on the clearing-house mechanism, the Conference of the Parties recommended that one important role of the clearing-house mechanism at the national level was to provide relevant information linkages, in order to promote the fair and equitable sharing of benefits. These decisions suggest that the issue of benefit-sharing will be considered in the context of national strategies and work programmes under various relevant items of the agenda of the fourth meeting of the Conference of the Parties.

10. With regard to plant genetic resources for food and agriculture, the Conference of the Parties has noted that the International Undertaking on Plant Genetic Resources is currently being reviewed in the Commission on Plant Genetic Resources for Food and Agriculture of the Food and Agriculture Organization of the United Nations (FAO). In its decision III/15, paragraph 7, the Conference of the Parties expressed the wish to see a rapid conclusion to the negotiation for the adaptation of the International Undertaking on Plant Genetic Resources in harmony with the Convention.

III. BIOTECHNOLOGY AND ITS APPLICATIONS

11. Biotechnology is defined in Article 2 of the CBD as “any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use”. In order to appreciate the benefits that can be derived from biotechnology, the extent and the potential of its applications are considered in this section.

12. Biotechnology is an old practice of mankind and started around 8,000 years ago. It includes mass selection for plant breeding and the use of microorganisms to make, among other things, bread and beer from grain, Fundamentally the same biotechnological fermentation processes are still in use. Modern biotechnology covers a wide range of new and relatively new technologies, from tissue culture, somatic cell fusion, embryo transfer, and novel bioprocessing techniques to genetic engineering. Countries can have different needs in respect of the kinds of technology that are relevant to them.

13. In the last 25 years, biotechnology has entered a new era, constituting a major technological revolution, following the first successful transfer of a gene from one organism to another unrelated species. Genetic engineering and other related techniques that followed have greatly broadened the scope of biotechnology. Genetic engineering opens a new spectrum of possibilities, because it breaks the recombination barriers between different, phylogenetically unrelated organisms, making available the entire gene pool for the modification of any living organism. Modern biotechnology has multiple applications, in sectors as diverse as industry, health care, agriculture, energy, ore leaching, and environmental protection and remediation. Because of this broad spectrum of applications for human benefit, modern biotechnology offers the potential to invent sustainable systems of the future, to be accompanied by a new paradigm for industry.

14. However, the release of any living modified organism into the environment should always be subject to careful risk assessment. Regulations on the safe transfer, handling and use of living modified organisms are currently under

negotiation, towards the adoption of a protocol on biosafety under the Convention as noted in section II above.

15. A major application of biotechnology to agriculture is to improve production quantitatively as well as qualitatively (e.g. increasing crop nutritional value). The introduction of genes conferring disease resistance and stress tolerance to crops can greatly improve yields. However, the molecular basis of many agronomically relevant traits is often complex, owing to the number of genes involved. In such cases, the application of DNA molecular techniques such as marker-assisted selection to conventional breeding programmes, rather than genetic engineering can considerably speed up the results, since the selection can be performed before having to wait for the final product of gene action. This approach is particularly important in the case of forestry, given the long life-cycles of trees. The combination of modern biotechnology and the conventional techniques of breeding and screening for genetic improvement can speed up processes and often achieve targets that would be unattainable with the use of conventional approaches alone.

16. DNA technology offers endless possibilities for the design and production of new drugs, vaccines and diagnostic tools, and the pharmaceutical industry was the first to take advantage of modern biotechnology. Since the 1970s, several human hormone genes have been genetic engineered into the bacterium Escherichia coli and the recombinant bacteria turned into living factories of human somatostatin, insulin, growth hormone, etc. In addition, the development of molecular DNA markers has generated several diagnostic kits, which can detect pathogens in earlier stages of infection, on the basis of the presence of its genetic material. DNA marker diagnostics are of much higher level of sensitivity, and the creation of DNA primers that detect specific pathogens is far more rapid and economical than immunological approaches. For vaccines against several pathogenic organisms, genetic engineering has provided striking results, by allowing the construction of sub-unit vaccines, which present significant improvements in efficacy and safety. In the near future, even the need to manufacture the sub-unit antigens will be removed, thanks to the recent development of DNA vaccines. DNA vaccines consist of the gene coding for the sub-unit antigen, which can be injected directly into the patient, who will individually produce the antigen needed to elicit the immune response. There are great expectations in respect of different types of gene therapy over the forthcoming decade.

17. In addition to giving a new dimension to biotechnology, modern molecular-biology techniques provide powerful new tools for the assessment of biological diversity. These techniques allow analysis of the diversity of the primary structure of DNA, the genetic material itself. Expansion of the knowledge base through applications of molecular techniques to biological materials will not only enhance our understanding of the biological diversity of a given region of the world, but will foster practical approaches to its conservation. A recent development in data collection for ex situ collections is the storage of the DNA of the organism instead of the living cell. DNA extraction and subsequent enlargement from non-living samples, e.g. already extinct organisms, is also feasible. Of course, the ability to assess biological diversity at the molecular level, through techniques such as DNA sequence analysis and genomic markers, expands the reservoir of genetic resources that can be utilized by biotechnology.

18. Microorganisms play an important role in biotechnology, since they can easily be engineered to be used as factories delivering a variety of products, or targeted to a variety of end-uses. They can be harnessed for environmental remediation and also for various industrial processes. Many species of bacteria, yeast and filamentous fungi also present intrinsic value for biotechnological processes, such as, for instance, the production of biofertilizers, antibiotics, and ethanol. In addition to microorganisms, plants and mammals can also be used for the production of a wide variety of useful compounds. With the development of transgenic animals, the mammary gland of farm animals has proven to constitute an alternative biotechnological route to microbial fermentations for the production of pharmaceutical compounds. Such novel means of obtaining biopharmaceuticals is presently a significant area of development and exploration. On the other hand, plants can also be utilized as factories for the synthesis of different substances. For example, transgenic plants carrying the relevant bacterial genes have proved to be successful in producing biodegradable bacterial polymers. This has been accomplished in the mustard weed Arabidopsis thaliana and the optimization of such a process for commercial utilization has not yet been achieved. Biodegradable polymers can be used as substitutes for petrochemical-derived plastic materials, which are harmful for the environment, and are therefore of great relevance for environmental protection. In Brazil, genetically engineered bacteria are being used for the industrial production of such biodegradable plastic materials, using sucrose from sugar cane as the substrate.

19. Another biotechnology application which has great relevance for environmental conservation consists of the systematic utilization of nitrogen-fixing bacteria in symbiosis with major crops. This practice can reduce or even eliminate the need for nitrogen fertilizers in agriculture, thus avoiding serious negative environmental impacts. In addition to representing a major problem in groundwater pollution, the use of nitrogen fertilizers contributes to atmospheric pollution through liberation of toxic compounds and because fossil fuels must be burned in order to produce such fertilizers. Recent findings on endophytic nitrogen-fixing bacteria open interesting possibilities for widening the applications of these organisms to several important crops, such as sugar cane and some cereals.

20. Biotechnology can also greatly contribute to the energy sector. Biomass is an alternative source of energy when used for the production of fuels such as ethanol, a possible substitute for petroleum derivatives such as gasoline. In contrast to fossil fuels, the energy from biomass is renewable and less harmful to the environment. Since atmospheric pollution brought about by the burning of fossil fuels has serious consequences for climate change, the utilization of cleaner fuels, like ethanol, which produces less carbon dioxide and does not need lead additives, is desirable. With the aim of broadening the spectrum of carbohydrates to be used as substrates for the production of ethanol, the yeast Saccharomyces cerevisiae (the main agent in alcoholic fermentations) has been genetically engineered, and recombinant strains possessing all the enzymatic activities needed for the production of ethanol from starchy materials have been obtained. Furthermore, new plants are being discovered or rediscovered, such as the African Jatropha curcas and certain tropical palm trees, which produce oils that are good substitutes for diesel. The discovery of an endophytic nitrogen-fixing bacterium in sugar cane can also significantly reduce the costs of ethanol production using sugar cane as the raw material.

21. In addition to its benefits for environmental conservation, biotechnology is of the utmost importance for environmental remediation. Microbial diversity is the key resource for the rehabilitation and remediation of degraded and contaminated ecosystems. Given that the main diversity of life is microbial, the lack of evidence of a given bio-transformation may simply mean that scientists have not looked extensively enough for the desired phenotype. It is likely that only a small percentage of the microorganisms that exist in nature have been discovered, but if nature has not produced a gene for the desired transformation, it is now possible to consider constructing the desired protein by genetic and protein engineering.

22. A straightforward approach for the screening of unknown microbial activities, which has the potential to allow full utilization of microbial diversity, consists of recovering, not the organism, but rather its genes, directly from community DNA extracted from nature, thus avoiding the need to cultivate fastidious organisms. Until recently, knowledge of microorganisms in the environment depended mainly on studies of pure cultures in the laboratory. However, estimates from studies of several types of environments indicate that more than 99 per cent of the organisms seen microscopically cannot be cultivated by routine techniques. Nowadays, owing to sequence-based taxonomic data, only a gene sequence, not a functioning cell, is required to identify the organism in terms of its phylogenetic type. The occurrence of phylogenetic types and their distribution in natural communities can be surveyed by sequencing ribosomal RNA genes obtained from DNA isolates directly from the environment. Analysis of microbial ecosystems in this way is more than a taxonomic exercise, because the sequences provide experimental tools (e.g. molecular hybridization probes) that can be used to identify, monitor and study the microbial inhabitants of natural ecosystems. As a result of this novel approach to biological diversity analysis, the opportunities for the discovery of new organisms and the development of biotechnological processes based on microbial diversity are greater than ever before. Microbial biology can now be a whole science; the organism can be studied in the ecosystem.

23. Another important application of biotechnology is in tracking the fate of a microbial strain added to the environment. This is essential in order to assess the organism's survival, growth and dispersal, and thus its effectiveness as a product, as well as in order to evaluate any unintended effects. Interest in the environmental impact of genetically modified organisms has stimulated new tracking techniques. The most sensitive method for detecting microorganisms without relying on their cultivation has been the polymerase chain reaction (PCR)-based method targeted at randomly cloned unique segments of the organism's chromosome.

24. The various applications of biotechnology discussed in this section offer the potential for economic benefits and for the conservation and sustainable use of biological diversity. The private sector will be actively involved in research and development of such technologies and their application, provided that it can be proved that the technology is ethically responsible and environmentally sound. The role of the private sector will be further considered in section V below.

IV. THE MECHANISMS FOR SHARING BENEFITS

25. The allocation of benefits is linked to the identification of beneficiaries and of the potential benefits, and dependent upon negotiation of

an arrangement on benefit sharing. Such arrangements should reflect the efforts by the different stakeholders in making the genetic resource available, for example through its conservation, allowing access, providing information, collecting, conducting research and developing commercial applications for the material. A two party agreement might not be sufficient to reflect this. Benefit-sharing should rather be seen as an integrated process aiming at long term partnerships involving all relevant stakeholders which should benefit conservation and sustainable development. In fact, access legislation, if developed, should provide a framework for this kind of benefit sharing as access is a tool for sharing benefits and ultimately for conservation and sustainable use of biological diversity. 2/ Stakeholders negotiate access-and-benefit-sharing arrangements (ABA) and agree on "mutual terms" (cf. Article 15, paragraph 4, of the Convention). Potential stakeholders and mechanisms for benefit-sharing are summarized in table 2 below.

26. An exhaustive definition of potential benefits is not possible. Major categories of benefits that have been exemplified in existing legislation include

(a) The participation of nationals in research activities, as provided for in Article 15, paragraph 6, of the Convention;

(b) The sharing of the results of research, including all discoveries, as provided for in Article 19, paragraph 2, of the Convention;

(c) A complete set of all voucher specimens left in national institutions;

(d) Support for research into the conservation and sustainable use of biological diversity;

(e) Strengthening mechanisms for technology transfer, including biotechnology, as provided for in Article 16, paragraph 3, of the Convention;

(f) Strengthening institutional capacity in the areas of genetic resources and their derivatives;

(g) Strengthening the capacities of indigenous peoples and local communities with regard to the intangible components associated with genetic resources and their derivatives;

(h) Access by national to all national specimens deposited in international ex situ collections;

(i) The receipt by providers, without payment of a royalty, of all technologies developed from research on endemic species;

(j) Fees, royalties and financial benefits; and

(k) The donation to national institutions of equipment used in the research.

2/ See also the note by the Executive Secretary on the review of national, regional and sectoral measures and guidelines on access to genetic resources (UNEP/CBD/COP/4/23), which is also before the Conference of the Parties at its fourth meeting.

27. The appropriate mechanisms for sharing benefits depend upon the nature of the benefits themselves. It is necessary to identify appropriate beneficiaries, and set up partnerships or find institutional channels through which the benefits can be transferred. The lack of preparedness to receive or allocate benefits is a frequent obstacle to their fair and equitable sharing. Assessing existing mechanisms and creating new ones are among the most important steps necessary to promote benefit-sharing.

28. In table 2 on pages 13 and 14 below, an attempt is made to illustrate benefit-sharing arrangements, according to types, stakeholders and benefits involved. As the table shows, benefit consists of much more than monetary benefits, ranging from technology transfer and training to research facilities. It is a widespread misconception that 'benefits' are purely monetary. In cases of commercial use, e.g., in pharmaceuticals, royalties generally arise between seven and twenty years after the original access to the genetic resources in question. In addition, the probabilities of an individual sample succeeding to the market are very small. Therefore, only a small proportion of individual access transactions would give rise to such benefits.

29. A further challenge is the quantification of the value of genetic resources and the various 'benefits' involved. This is complicated for a number of reasons. First, quantification entails refining methodologies for assessing the economic value of biological diversity. 3/ Secondly, 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. The availability of technology through the technological development also affects such economic value. Thirdly, markets often fail to integrate environmental and social costs into economic considerations. Until 'externalities' such as the costs of conservation are adequately addressed, market prices will generally not reflect the full value of genetic resources. This fact highlights the importance of further work on complementary issues such as full-cost pricing, research into existing private sector practices, and markets for these materials, access legislation and other policy interventions that can promote fairness and equity in the sharing of benefits.

V. THE ROLE OF THE PRIVATE SECTOR

30. A wide range of biotechnologies is being applied in agriculture and manufacturing industries (see section III above). The private sector is the key player in benefit-sharing arrangements. In developed countries, biotechnology research and development are increasingly privatized and many biotechnological products and services have already been placed on the market and are widely used. Benefit-sharing might also include activities by the private sector in partnership with other institutions that are not based on an access to genetic resources, but on a joint interest in conservation and sustainable use. For example the seed industry through the International Association of Plant Breeders for the Protection of Plant Varieties, (FIS/ASSINEL) has expressed its willingness to participate with in-kind

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3/ See, for example, the note by the Secretariat on economic valuation of biological diversity (UNEP/CBD/SBSTTA/2/13) prepared for the second meeting of the Subsidiary Body on Scientific, Technical and Technological Advice, held in Montreal from 2 to 4 September 1996.

contributions in the implementation of the Global Plan of Action for the Conservation and Sustainable Utilization of Plant Genetic Resources for Food and Agriculture, adopted in Leipzig in 1996, in particular as regards to: regeneration of endangered ex situ accessions; evaluation and characterization of the accessions; and pre-breeding. Similar offers might be possible from all industrial sectors using genetic resources.

A. Perspective of the resource providers

31. A typically held conception of benefit-sharing arrangement resulting from the utilization of genetic resources is the sharing of royalties from a successful drug development between a large pharmaceutical company based in an industrialized country and a local authority, local company or a community in a developing country, which provides the genetic resources. However, there are many stages within a process of product development and a wide range of biotechnologies is involved, some being less capital-intensive. In order to capture higher benefits, the provider should attempt to add values to raw materials, for example by providing extracts. The higher the value-added of the materials provided, the greater the knowledge of markets, industry needs, and scientific and technological trends, the higher is the bargaining position of the provider. Therefore, in considering the role of private sector in the benefit-sharing arrangement from the perspective of resource providers, there is scope for considering the development and promotion of the biotechnology industry within these countries.

32. As table 2 shows, there can be a variety of arrangements that involve commercial transactions. Starting from a simple provision of raw material, value can be added throughout the process: through the reliability of the collector, the guarantee of re-supply, accurate taxonomic identification, local or indigenous knowledge regarding resource, extraction, primary screening, structural elucidation, replication, etc.

33. A typical scenario that depicts industrialized countries as users and developing countries as providers of genetic resources is based on the conviction that the technologies involved are advanced, costly and need highly skilled labour and that they are only available in industrialized countries. However, the entry barriers for biotechnology, for example by mastering traditional techniques, such as tissue culture, are lower than other frontier technologies, such as, for example, microelectronics. In addition, biotechnology is rather knowledge-intensive rather than capital-intensive. There is an ample opportunity for developing countries to develop their own biotechnology industry.

34. In the area of biotechnology, there is scope for promoting small enterprises. In general, small firms have a competitive advantage in innovation through their ability to identify and serve new markets earlier than large firms. Many areas of technology have become increasingly dynamic while at the same time requiring greater depth of scientific and engineering expertise. Small firms, which are inherently flexible and agile, are rapidly becoming a dominant source of innovation in the market place.

35. In addition, as a development strategy, small firms contribute in a specific way. Small firms contribute significantly to job growth, entrepreneurial growth, export growth and, most importantly, technological competitiveness. Small firms that compete in the world market also serve as

agents for technology transfer. As long as the research and development costs are relatively low, as in many biotechnologies, small firms can compete effectively. In order to promote small enterprises specialized in biotechnology, measures must be taken to address education, capital markets and intellectual property rights. These measures will be elaborated on in section VII below.

Table 2

Benefit-sharing arrangements

Type	Stakeholders		Mechanisms	Benefits	
	recipients of genetic resources	providers of genetic resources		to the recipients of genetic resources	to the providers of genetic resources
Non-commercial					
• Collection • Joint research	• public ex situ conservation facilities (botanical gardens, Consultative Group centres, zoos, etc.) • national parks • scientific institutions • public and not-for-profit research institutions • universities • etc.	• public and not-for profit ex situ conservation facilities (botanical gardens, Consultative Group centres, zoos, etc.) • Governments, national parks and other public authorities • NGOs • public and not-for-profit research institutions • universities • indigenous or local communities • private land-owners, including farmers • etc.	- collection permits - material transfer agreements - research agreements	- biological samples - results of research - knowledge related to samples	- collection fees, reflecting the value of the genetic resources - results of research - research know-how - training - equipment - technology - increased capacity

Type	Stakeholders		Mechanisms	Benefits	
	recipients of genetic resources	providers of genetic resources		recipients of genetic resources	providers of genetic resources
Commercial					
• Collection of raw materials • Intermediate services, such as: information on the resources by the indigenous and local communities on specifics of the service and the use; taxonomy; and extracts • Production of final products, such as medicines and cosmetics	• private companies, including multinational companies • brokers • individuals • research institutions, such as universities	• public ex situ conservation facilities (botanical gardens, Consultative Group centres, zoos, etc.) • national parks and other public authorities • NGOs • public research institutions • indigenous or local communities • private research institutions • private ex situ conservation facilities • private companies • individuals etc.	- collection permits - material transfer agreements - domestic and foreign direct investments to establish companies and research facilities - co-operatives - partnerships	- genetic resources - information by provider on characteristics of the resource - result of research - product development - revenue from the end product - revenue from the royalty - profits/dividends - intellectual property rights	- collection fees that reflect value of genetic resources - milestone payments - advanced payments - result of research - research know-how - product development - training - equipment - facilities - infrastructure - technology - increased capacity - share of revenue from the end products - share of revenue from the royalty - profits/dividends - intellectual property rights

B. Perspective of resource recipients (users)

36. For the user of the genetic resources, whether a large corporation from an industrialized country or a biotechnology company in a provider country, their interest rests in continued and secure access to genetic resources. With the growth of local firms in the resource-providing countries, there are increasing cases where international companies enter into strategic alliances or partnerships with those local firms. In such cases, international firms often supply technology in return for the local firm's value-added services, for example, preliminary screening and extraction. Companies that obtain resources from indigenous and local communities, in recognizing the role played by the resource providers, especially indigenous and local communities, in maintaining biological diversity, can contribute in capacity-building and technology transfer to those providers. By increasing the capacity of the communities and making relevant technology available, the recipients will be assured of the supply of high-quality materials, including value-added products. Many countries are currently formulating measures to regulate access to genetic resources. The public in both recipient and provider countries is becoming more and more aware of the value of biological diversity and, hence, the cost of obtaining genetic resources will start to reflect such values. In this emerging situation, voluntarily initiated access- and benefit-sharing arrangements, based on mutually agreed terms even in the absence of specific legislation can produce more beneficial results for both parties. Recipient companies in both developing and developed countries can actively participate in access-and-benefit-sharing arrangements with their potential resource providers.

VI. EXISTING BIOPROSPECTING ARRANGEMENTS

37. Although in most countries, access legislation is still under development, 4/ the private sector has already begun to respond to the requirements of the Convention. Before the entry into force of the Convention, companies bioprospected without any sharing of benefits other than the payment of fees for the work carried out (e.g. collecting plants). In order to comply with the new ethic contained in the Convention, some companies have started to conclude access-and-benefit-sharing arrangements, although legal rules are not yet in place. This development might also be due to the increased bargaining power of the provider country arising from higher awareness. Such arrangements vary considerably in respect of partners and in terms of scale and include arrangements between partners from one country, developing and developed, or from different countries. A synthesis of the case studies on benefit-sharing submitted to the Secretariat is contained in document UNEP/CBD/COP/4/Inf.7. The arrangements typically include the following features: partnerships for 2 to 3 years which are renewable; cooperation with research or academic institution, such as a university in the providing country; one set of samples deposited with the institution or another body in the providing country;

4/ See the above-mentioned note by the Executive Secretary on review of national, regional and sectoral measures and guidelines for the implementation of Article 15 (UNEP/CBD/COP/4/23).

exchange of researchers; joint research; provision of hardware and laboratory equipment; up-front or milestone payment, some share of net sales/royalties if a product based on the genetic resource is marketed; information requirement on the status of the research by the recipient partner.

VII. MEASURES TO PROMOTE AND ADVANCE THE DISTRIBUTION OF BENEFITS FROM BIOTECHNOLOGY IN ACCORDANCE WITH ARTICLE 19

38. Articles 15, paragraph 7, and 16, paragraph 3, of the Convention call for legal, administrative and policy measures, and Article 19, paragraph 2, for practicable measures. Article 1 mentions appropriate access to genetic resources, appropriate transfer of relevant technologies and appropriate funding as means for benefit sharing. Policy measures include incentive measures and other economic measures such as industrial policies. These might include a review of existing legislation in order to identify how it can be used best for access-and-benefit-sharing arrangements.

39. Legal measures, including executive orders, are changes in existing law or the development of new legislation with regard to creating provision on access to genetic resources. They include the creation or designation of appropriate authorities to implement the access legislation. 5/ Access legislation should ensure fair and equitable access-and-benefit-sharing arrangements. Important for a successful access regime is both sound legislation and a broadly based process through which it is set up. The involvement of all stakeholders in this process is crucial.

40. Another measure is an in-depth analysis of how existing intellectual property rights might be used to support benefit-sharing and to protect indigenous and local knowledge. The protection of indigenous and local knowledge, innovations and practices through sui generis systems is another way of ensuring benefit-sharing for such stakeholders. The recommendations for a programme of work on the implementation of Article 8(j) put forward by the Workshop on Traditional Knowledge and Biological Diversity, held in Madrid from 24 to 28 November 1997, include various proposals for the elaboration of a sui generis system under the Convention. 6/ Some models are discussed in the note by the Executive Secretary on Traditional Knowledge and Biological Diversity (UNEP/CBD/TKBD/1/2).

41. In order to enhance meaningful technology transfer, developing countries will need to build broad-based capacity, which encompasses human, scientific, technological, organizational, institutional and resource capabilities. With respect to biotechnology, which is essentially multidisciplinary, training in a wide range of subjects is necessary, including genetics, microbiology, molecular biology, biochemistry, process engineering and economics, among others. Training in both basic bioscience and in the applied disciplines, such as biochemical engineering skills from biochemistry and microbiology, should be emphasized. In addition, the emphasis should not be placed only on the high end of the education system, but also on the intermediate levels, in order to train skilled technical and clerical workers. Furthermore, legal provision can

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5/ Ibid.

6/ See the report of the Workshop (UNEP/CBD/TKBD/1/3).

be geared to emphasize the development and utilization of local resources, including human resources, in technology transfer contracts. One such example can be seen in the requirement for local contents, whereby the percentage of locally manufactured inputs to the final products is specified.

42. As regards to funding, the requirements range from funding in the public domain, such as support for drawing up access legislation, building scientific capacity and infrastructure investment, to those in the private-sector domain to finance their investments and other necessary expenses. The Global Environment Facility, as the financial mechanism of the Convention, can assist in various ways to address the needs of the developing countries to implement the Convention. 7/ Other development agencies, both bilateral and multilateral, such as development banks, can also play a role in assisting in the promotion of benefit-sharing. Regarding plant genetic resources for food and agriculture, the negotiations to revise the International Undertaking on Plant Genetic Resources (see para. 10 above) include mechanisms to share benefits and discussions about a possible fund. As for the private sector, if it is in accordance with their national policy, Governments may consider providing subsidized funds for targeted sectors for their investment, including research and development. Foreign direct investment also provides opportunities for the private sector. Its role and the measures to promote it are discussed in the note prepared to assist consideration of item 14.4 of the provisional agenda, on additional financial resources (UNEP/CBD/COP/4/17).

43. In order to promote small enterprises specialized in biotechnology, additional specific measures may be considered. For example, access to capital is an important element for an entrepreneur to be able to start off a company. A mature and stable capital market facilitates such investments. In any case, Governments can provide funds through such mechanisms as development banks and other targeted funds and loans. Other measures might include tax breaks and the provision of seed money targeted at the biotechnology industry and its research and development activities. Governments can also ease the burdens on small firms by identifying excessive transaction costs, including market regulations, legal costs and government services.

44. In the long run, Governments should strive for an educated labour force, as biotechnology is knowledge intensive. Specific measures to bring academic research communities and entrepreneurial communities closer together is another element which might help increase technology transfer and capacity building. At the far end of such measures the establishment of technology research parks, which target relatively high-level technology, including biotechnology might be envisaged. Such a park can include large and small enterprises, and can be located in conjunction with a local university. Care must be taken that such a measure should fit the local culture and that the ultimate goal of such a plan is the promotion of indigenous technological innovation.

45. In general, more efforts should be made to raise public awareness in order for the value of genetic resources to be fully appreciated.

7/ See the note by the Executive Secretary on means to address the fair and equitable sharing of benefits (UNEP/CBD/COP/4/22), which has also been prepared for the fourth meeting of the Conference of the Parties.

VIII. RECOMMENDATIONS

46. Various efforts are necessary to implement the third objective of the Convention: legal measures should be put in place in the Contracting Parties; the provider should strive to add value to the genetic resource; capacity-building efforts must be further enforced in the developing countries; and industrial policies targeted at biotechnology industries play a major role in promoting and advancing the distribution of benefits from biotechnology.

47. The Conference of the Parties is invited to consider the following recommendations regarding measures to promote and advance benefits from biotechnology in accordance with Article 19:

The Conference of the Parties,

1. Decides to make access to genetic resources and benefit-sharing a standing item for the meeting of the Conference of the Parties;

2. Decides to hold inter-sessional workshops on the role of the private sector in promoting benefit-sharing;

3. Urges Parties and Governments:

(a) To promote measures effective to facilitate the distribution of benefits from biotechnology, including measures aimed at the enacting of legal measures for access to microbial, plant and animal genetic diversity;

(b) To provide information on experiences of benefit-sharing arrangements in time for the fifth meeting of the Conference of the Parties, including the survey of the private-sector activities in the field of biotechnology;

(c) To promote more active participation of the private sector in the implementation of the objectives of the Convention on Biological Diversity;

4. Requests the financial mechanism to give special emphasis to the following programme priorities for assistance to eligible Parties, in accordance with paragraph 59 of the note by the Executive Secretary on means to address the fair and equitable sharing of benefits (UNEP/CBD/COP/4/22):

(a) Stock-taking activities;

(b) Formulation of access legislation and incentive measures; and

(c) Implementation of specific benefit-sharing initiatives;

5. Invites all relevant organizations:

(a) To support efforts by Parties to promote measures, policies and programmes that have been identified as effective to facilitate the distribution of the benefits from biotechnology;

(b) To provide information on experiences of the benefit-sharing arrangements in time for the fifth meeting of the Conference of the Parties, including the survey of the private-sector activities in the field of biotechnology;

6. Invites the representatives of the private sector to participate more actively in the process of the implementation of the objectives of the Convention on Biological Diversity:

7. Requests the Executive Secretary:

(a) To facilitate the exchange of information through appropriate means such as the clearing-house mechanism;

(b) To prepare a background document for each Conference of the Parties on the review of implementation of measures to promote and advance benefit-sharing arrangements, based on the experiences submitted by Parties, Governments and relevant organizations.
