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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. Introduction

1. The Conference of the Parties decided at its second meeting, in the consideration of the medium-term programme of work for 1996-1997, that the issue of benefit-sharing would be considered at its fourth meeting (decision II/18). At its third meeting, the Conference of the Parties recalled this decision in decision III/22, which reconsidered the medium-term programme of work. The present paper addresses "measures to promote and advance the distribution of benefits from biotechnology in accordance with Article 19," which is included as item 16.1 in the draft provisional agenda of the fourth meeting of the Conference of the Parties.

2. This is the first time that the Conference of the Parties will address the third objective of the Convention, "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." Although the issue of technology transfer has been dealt with in each of the past meetings of the Conference of the Parties, it was addressed only in the context of Articles 16 and 18. In this paper, benefits from biotechnology in accordance with Article 19, paragraphs 1 and 2, will be addressed. A clear distinction must be made between the coverage of this paper and the rest of Article 19, paragraphs 3 and 4. Paragraphs 3 and 4 deal with the safe transfer, handling and use of

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genetically modified organisms (GMOs) and therefore they are linked to Article 8(g). These provisions provide a framework for regulating biosafety. A protocol on biosafety is currently being negotiated by the ad hoc Working Group on Biosafety of the CBD (see document UNEP/CBD/COP/4/9). Regulations on biosafety are relevant for policy and law regarding benefit sharing from biotechnology in so far as benefit sharing might comprise sharing genetically 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 which are in force for the parties to the arrangement, public or private sector likewise.

3. Two other sub-items under agenda item 16 are: 16.2 "means to address the fair and equitable sharing of benefits arising out of genetic resources" and 16.3 "compilation of views of the Parties on possible options for developing national legislative, administrative or policy measures, as appropriate, to implement Article 15 (Access to Genetic Resources)". In accordance with decision III/5 (7), a collaborative effort has been put into the preparation of a background document for sub-item 16.2, focusing on options for assistance to developing countries (UNEP/CBD/COP/4/22). Sub-item 16.3 addresses access to genetic resources as contained in Article 15, focusing on the developing of access legislation. This issue has been considered at the second and the third meetings of the Conference of the Parties. The background document, UNEP/CBD/COP/4/23, reviews further progress in implementation of Article 15 and lays out guidelines for formulating access legislation. In addition, basic concepts regarding benefit-sharing as addressed in the CBD are contained in an information document that was made available at the third meeting of the Conference of the Parties (UNEP/CBD/COP/3/Inf.53).

II. Biotechnology and benefit-sharing as contained in the CBD

4. Article 1 sets out the "fair and equitable sharing of the benefits arising out of the utilization of genetic resources" as one of the three objectives of the CBD. Our concern here is sharing of benefits from biotechnology in accordance with Article 19, paragraphs 1 and 2. These paragraphs stipulate that Contracting Parties should take legislative, administrative or policy measures for the effective participation in biotechnological research activities by those Contracting Parties which provide the genetic resources, and to promote and advance priority access on a fair and equitable basis by them to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Since the scope of the provisions is defined as "biotechnologies based upon genetic resources provided by Contracting Parties," there is a strong interlinkages between these provisions and article 15. In fact, these paragraphs parallel paragraphs 6 and 7 of Article 15 on access to genetic resources. These relationships are highlighted in the following table.

Table 1.

A comparison between Article 19.1 and 2 and Article 15.6 and 7

Article. 15.6 (changed sequence)	Article 19.1 (wording)
* Each Contracting Party	* 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 <u>full participation</u> of	* to provide for the <u>effective participation</u> 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 (systematic)	Article 19.2 (wording)
* Each Contracting Party	* Each Contracting Party
* shall take ..., as appropriate	* shall take
* <u>legislative, administrative or policy measures</u>	* <u>all practicable measures</u>
* and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21	* to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries,
* with the aim of sharing in a fair and equitable way	* to the results
* the results of research and development	* and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties.
* and the benefits arising from the commercial or other utilization of genetic resources with the Contracting Party providing such resources	* Such access shall be on mutually agreed terms.
* Such access shall be on mutually agreed terms.	

5. The most outstanding difference between these two Articles is that the emphasis in Article 19.1 and 19.2 lays on the part of developing countries as beneficiaries if they are the providers of genetic resources, and on the particular focus on biotechnology by Article 19.1

and 19.2. Apart from that, differences are of minor character. Whereas Article 15.6 asks for full participation, Article 19.1 requires effective participation. Article 15.7 requires legal, administrative or policy measures, while Article 19.2 calls for practicable measures. Measures which are not practical should not be considered anyway in order to truly implement the Convention and measures as a generic term refer to legal and administrative as well as to policy measures. Full participation might be more encompassing than effective participation. However, the reason for research participation is technology and capacity transfer. Effective participation is therefore sufficient for the purpose of the Convention. In discovering the similar structure of those articles, the demarcation between the first two paragraphs and the latter two paragraphs of Article 19 becomes evident.

6. As the benefit-sharing concept 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 provides for encouragement of 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, in turn, explicitly linked to the provisions 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 provide for some of the means to share benefits.

8. In addition to decision III/22 on the medium-term programme of work for 1996-1997, several decisions on related issues at the third meeting of the Conference of the Parties also 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 (IPR), encouraged case studies on the impacts of IPR on the achievement of the Convention's objectives, including, inter alia, in facilitating technology transfer and in 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. Furthermore, based on decision III/14 on implementation of Article 8 (j), an intersessional workshop on traditional knowledge and biological diversity took place in November 1997 and a background paper containing, inter alia, the consideration of the linkages between Article 8 (j) and related issues, such as technology transfer, access to genetic resources, IPR, alternative systems of protection, incentives and Articles 6, 7 and the remainder of Article 8, was prepared (UNEP/CBD/TKBD/1/2). All these decisions of the third meeting of the Conference of the Parties together provide considerable amount of information that is relevant to the consideration of benefit-sharing. Case studies on benefit-sharing arrangements called for by these related decisions are compiled in

UNEP/CBD/COP/4/Inf.xx and their synthesis is contained in UNEP/CBD/COP/4/Inf.xx.

9. Besides these considerations of related issues, as a general measure, decision III/9 on implementation of Articles 6 and 8 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. Decision III/11 on agricultural biological diversity spelled out that promoting the fair and equitable sharing of benefits arising out of the utilization of genetic resources was one of the objectives for establishing a multi-year programme. In addition, in decision III/4 on the clearing-house mechanism (CHM), Parties recommended that one important role of the CHM at the national level was to provide relevant information linkages, in order to facilitate the fair and equitable sharing of benefits. These decisions imply that the aspect of benefit-sharing will be integrated into national strategies and work programmes in a number of occasions by the fourth meeting of the Conference of the Parties.

III. Biotechnology and its applications

10. 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.

11. Biotechnology is an old practice of mankind. Man started using living organisms, as yeast cells, to produce bread and beer from grain around 8,000 years ago and basically the same biotechnological fermentation processes are still in use. However, it is only 25 years ago that biotechnology entered a new era, characterizing a major technological revolution, when the first successful transfer of a gene from one organism to another unrelated species was achieved. 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 improvement of microorganisms, crops, livestock, trees, etc. 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 us the potential to invent the sustainable systems of the future, that should be accompanied by a new paradigm for industry.

12. Agenda 21 recognised that, although biotechnology cannot provide solutions to all the fundamental issues of environment and development, it can contribute substantively to sustainable development by improvements in food production, feed supply, renewable raw materials, health care and protection of the environment. Biotechnology is of

special importance for the wise management of biological resources as it can greatly influence the economic basis for many management decisions relating to a more effective utilization of these resources, thus contributing to sustainable development. For example, developing pathogen-resistant crop varieties is the ideal sustainable alternative for the use of toxic pesticides in crop protection and genetic engineering has proven to be the best approach to confer pathogen-resistance to plants¹.

13. A major feature of biotechnology applied 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 dramatically improve the yields. In addition, the introduction of delayed ripening genes increases the shelf-life of the products, as in the case of the Calgene tomato, which was the first commercially available genetically engineered food, approved in 1994. However, the molecular basis of many agronomically relevant traits is often complex, owing to the number of genes involved (Quantitative Trait Loci). In such cases, rather than genetic engineering, the application of DNA molecular techniques such as marker-assisted selection to conventional breeding programmes 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 technologies 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 alone².

14. Although agri-biotechnology holds enormous economic promise, at present it does not compare to the applications of biotechnology to the sectors of pharmaceuticals and public health. In the USA, revenues from biotechnology-based pharmaceuticals were \$8.6 billion, whereas revenues from agri-biotechnology were estimated at \$ 0.304 billion in 1996³. DNA technology offers endless possibilities towards 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 70's, several human hormone genes were genetic engineered into the bacterium *Escherichia coli* and the recombinant bacteria were 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 the pathogen in earlier infection stages, 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. Concerning vaccines against several pathogenic organisms, genetic engineering provided striking results, by allowing the construction of sub-unit vaccines, which present tremendous improvements in efficacy and safety. In the near future, even the necessity of

¹ P. C. Ronald, "Making rice disease-resistant", Scientific American, 276:100-105, 1997.

² B. A. Barlow and G. T. Tzotzos, Ch. 10 Biotechnology, Global Biodiversity Assessment, UNEP, 1995.

³ C. James, "Global status of transgenic crops in 1997", ISAAA Briefs, No.5-1997.

manufacturing the subunit antigens will be overcome, thanks to the recent development of DNA vaccines. DNA vaccines consist of the gene coding for the subunit antigen, which can be injected directly to the patient, who will by himself produce the antigen needed for eliciting the immune response. There are great expectations regarding different kinds of gene therapy in the forthcoming decade.

15. In addition to giving a new dimension to Biotechnology, the modern molecular biology techniques provide powerful new tools for the assessment of biological diversity. These techniques allow us to analyze the diversity of the primary structure of DNA, the genetic material itself. Our present ability to isolate, clone and characterize specific DNA sequences from the vast array that exists in nature provides unique opportunities for biological diversity assessment. Our knowledge about biological diversity is mainly derived from biological collections, which may be either in-situ (conserving species in their normal habitats) or ex-situ. The expansion of the knowledge base through applications of molecular techniques to biological collections will not only enhance our understanding of the biological diversity of a given region of the world, but also 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 amplification 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 explored by biotechnology.

16. 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, like, for instance, the production of biofertilizers, antibiotics, and ethanol. Besides 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. Farm animals, used as bioreactors, are able to produce large amounts of the "foreign" protein encoded by the transgene. Such novel means of obtaining biopharmaceuticals is presently a significant area of development and exploitation. 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 proved to be successful in producing biodegradable bacterial polymers⁴. This was accomplished in the model plant *Arabidopsis thaliana* and the optimization of such a process for commercial utilization has not yet

⁴ Y. Poirier, C. Nawrath and C. Somerville, "Production of polyhydroxyalcanoates, a family of biodegradable plastics and elastomers, in bacteria and plants", Bio/Technology, 13:142-150, 1995.

been achieved. Biodegradable polymers can substitute 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 material using sucrose from sugar cane as the substrate.

17. Another biotechnology application which has great relevance for environment conservation consists in the systematic utilization of nitrogen-fixing bacteria in symbiosis with major crops. This practice can reduce or even eliminate the need of nitrogen fertilizers in agriculture, thus avoiding serious negative environmental impacts. Besides representing a major problem in groundwater pollution, the use of nitrogen fertilizers contributes to atmospheric pollution through liberation of toxic compounds and also because fossil fuels must be burned in order to produce these fertilizers. Recent findings on endophytic nitrogen-fixing bacteria open interesting possibilities of widening the applications of these organisms to several important crops, like sugar cane and other gramineous plants⁵.

18. 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, which can substitute for petroleum-derivatives like gasoline and diesel. 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 CO₂ 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 were obtained⁶. Furthermore, new plants are being discovered or rediscovered, like 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.

19. Besides its benefits for environmental conservation, biotechnology is of 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 few 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

⁵ J. Dobereiner, "Recent changes in concepts of plant-bacteria interactions: Endophytic N₂ fixing bacteria", *Ciencia e Cultura*, 44:310-313, 1992.

⁶ A. C. G. Schenberg, E. J. Vicente and S. Astolfi-Filho, "Expression of heterologous amylases in the yeast *Saccharomyces cerevisiae*", *Ciencia e Cultura*, 45:181-191, 1993.

possible to consider constructing the desired protein by genetic and protein engineering⁷.

20. A straightforward approach for the screening of exquisite 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 the microorganisms in the environment depended mainly on studies of pure cultures in the laboratory. However, studies of several types of environments estimate that more than 99% of the organisms seen microscopically cannot be cultivated by routine techniques⁸. 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 ecosystem⁹.

21. 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 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 PCR-based method targeted at randomly cloned unique segments of the organism's chromosome¹⁰.

22. The various applications of biotechnology discussed in this section offer potentials for economic benefits. The active role of the private sector is considered to be involved in research and development of such technologies and their application. Their role will be further considered in section V.

IV The mechanisms for sharing benefits

22. An exhaustive definition of potential benefits would be impossible. Parties have approached the issue pragmatically, specifying

⁷ D. B. Janssen and J. P. Schanstra, "Engineering proteins for environmental applications", *Current Opinion in Biotechnology*, 5:253-259, 1994.

⁸ R. I. Amann, W. Ludwig and K. H. Schleifer, *Microbiology Review*, 59:143, 1995.

⁹ N. R. Pace, "A molecular view of microbial diversity and the biosphere", *Science*, 276:734-740, 1997.

¹⁰ B. A. Barlow and G. T. Tzozos, op. cit., 1995.

particular benefits that must be shared in access legislation and material transfer agreements between institutions and communities. Major categories of benefits that customarily arise in such cases are listed in paragraph 68 of the Executive Secretary's note on access to genetic resources (UNEP/CBD/COP/3/20), submitted to the third meeting of the Conference of the Parties. This paragraph is reproduced below.

23. "Examples of benefits specified in national measures, in particular Article 8 of the Andean pact Common System on Access (AP) and Section 8 of the Philippines Implementing Regulations (P), include:

- (a) the participation of nationals in research activities, as in Article 15(6) (AP 17.a; P 8.1.12);
- (b) the sharing of research result, including all discoveries, as in Article 19(2) (AP 17.d. 17.h; P 8.1.9);
- (c) a complete set of all voucher specimens left in national institutions (P 8.1.2; AP 17.g);
- (d) support for research into the conservation and sustainable use of biological diversity (AP 17.b)
- (e) strengthening mechanisms for technology transfer, including biotechnology, as in Article 16 (AP 17.c, 9);
- (f) strengthening institutional capacity in the areas of genetic resources and their derivatives (AP 17.e);
- (g) strengthening the capacities of indigenous peoples and local communities with regard to the intangible components associated with genetic resources and their derivatives (AP 17.f);
- (h) access by national to all national specimens deposited in international ex-situ collections (P 8.1.4);
- (i) the receipt by Providers, without payment of a royalty, of all technologies developed from research on endemic species (P 8.1.13);
- (j) fees, royalties and financial benefits (P 8.1.14, 8.2.2.); and
- (k) the donation to national institutions of equipment used as part of research (P 8.1.3.)."

24. The appropriate mechanisms for sharing benefits depend upon the nature of the benefits themselves. 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. The lack of preparedness to receive or allocate benefits is a frequent obstacle to the fair and equitable sharing of benefits. Assessing existing mechanisms and creating new ones are among the most important steps necessary to promote benefit-sharing.

25. In Table 2, an attempt is made to illustrate benefit-sharing arrangements, according to types, stakeholders and benefits involved.

26. As clearly shown in Table 2, benefits include much more than monetary benefits, ranging from technology transfer and training to research facilities. It is a widespread misconception that 'benefits' are purely monetary. Even in those cases where the use of genetic resources is commercial and involve monetary returns, as in the case of pharmaceutical products, any royalties arise between ten and twenty year after the original access to the genetic resources used. 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 benefits¹¹.

27. The allocation of benefits is linked to the identification of beneficiaries, as well as the basis for sharing and quantifying the benefits. The desired result is one which fairly reflects the efforts contributed by the different stakeholders in making the genetic resource available, for example through conserving, allowing access to, providing information, collecting, and conducting research on it. National authorities may provide a framework for benefit-sharing arrangement in their access legislation. It is by the negotiation among stakeholders to a specific arrangement that mutually agreed terms for access-and-benefit-sharing arrangements (ABA) will be arrived. Potential stakeholders and mechanisms of benefit-sharing are summarized in Table 2. Material transfer agreements frequently clarify the share of royalties between the various parties, however, they only address the exchange of genetic materials and no consideration is given towards benefits that accompany them. When many stakeholders are involved, 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 'multi-stakeholder' committee may be helpful to define the application of benefits for the 'national good'¹².

¹¹ For more detailed description, see "Fair and equitable sharing of benefits arising from the use of genetic resources" (UNEP/CBD/COP/Inf.53).

¹² See, for example, S. Laird and R. Wynberg, "Biodiversity prospecting in South Africa: towards the development of equitable partnerships," a discussion paper, 1996.

Table 2

Benefit-sharing arrangements

Type	Stakeholders		Mechanisms	Benefits	
	recipients of genetic resources	providers of genetic resources		recipients of genetic resources	providers of genetic resources
Non-commercial					
<ul style="list-style-type: none"> • Collection • Joint research 	<ul style="list-style-type: none"> • public ex-situ conservation facilities (botanical gardens, CG centers, zoos, etc.) • national parks • scientific institutions • public and not-for-profit research institutions • universities etc. 	<ul style="list-style-type: none"> • public and not-for profit ex-situ conservation facilities (botanical gardens, CG centers, zoos; etc.) • 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. 	<ul style="list-style-type: none"> - collection permits - material transfer agreements - research agreements 	<ul style="list-style-type: none"> - biological samples - results of research - knowledge related to samples 	<ul style="list-style-type: none"> - 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					
<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • private companies, including multinational companies • brokers • individuals • research institutions, such as universities 	<ul style="list-style-type: none"> • public ex-situ conservation facilities (botanical gardens, CG centers, 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. 	<ul style="list-style-type: none"> - collection permits - material transfer agreements - domestic and foreign direct investments to establish companies and research facilities - co-operatives - partnerships 	<ul style="list-style-type: none"> - 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 - IPR 	<ul style="list-style-type: none"> - collection fees, that reflect value of genetic resources, - 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 - IPR

28. 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 (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. The availability of technology through the technological development also affects such economic value. Third, markets often fail to integrate environmental and social costs into economic considerations. Until 'externalities' such as the costs of conservation are adequately addressed, benefits will generally not reflect the full value of genetic resources. 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.

V. The role of the private sector

29. As pointed out in section III above, a wide range of biotechnologies is being applied in agriculture and manufacturing industries. From Table 2, it is observed that the private sector is the key player in benefit-sharing arrangements which lie in the commercial domain. In the 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 used¹³.

A. Perspective of the resource providers

30. 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, an often forgotten factor is that within a process of product development, there are many stages and a wide range of biotechnologies is involved, some being less capital-intensive. Therefore the provider does not necessarily supply just raw materials, but they can attempt to add values to them, for example by providing extracts, as in the case of InBio (see a case study presented below). The distinction of industrialized countries as users and developing countries as providers of genetic resources is not always true, either. There are many cases where the genetic resources are provided within a country. From the perspective of resource providing countries, it can be easily understood that the higher the value-added of the materials they provide, the higher their bargaining position would be, accompanied by higher returns. Therefore, in considering the role of private sector in the benefit-sharing arrangement, there is a scope for considering the development and promotion of the biotechnology industry within resource providing countries.

¹³ UNIDO, Environmentally Sound Management of Biotechnology: the Task Manager's report on chapter 16 of Agenda 21, March 1995.

31. As Table 2 shows, there can be a variety of arrangements that involve commercial transactions. It starts from a simple provision of raw materials. Firms can add values by providing known characteristics based on screening or on ecological or anthropological research. Value could also be added by providing such services as high assurances of re-supply and taxonomic sophistication. As the costs of biochemical screening and processes of genetic manipulation become lower and technologies more accessible, more opportunities for resource providers to add values to their resources will appear. Furthermore, resource providers can start to provide extracts rather than raw materials. Extraction and screening close to the source of the genetic material can increase the probability of discovering valuable chemicals which would otherwise decay rapidly after the collection of the material.¹⁴ In case of low-technology products, as in the case of phytomedicine, the resource providers can even attempt to produce the final products.

32. A typical scenario that depicts industrialized countries as users and developing countries as providers of genetic resources presented earlier 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 microelectronics. In addition, biotechnology is rather knowledge-intensive than capital-intensive. Moreover, there are accomplished scientists in the developing countries, exemplified by such cases as the development of diagnostic kits for tropical diseases in Africa.¹⁵ Therefore, there is an ample opportunity for developing countries to develop their own biotechnology industry, especially by targeting at knowledge-intensive sector. The Venezuelan company Polar is a good example of collaboration between private and public institutions. Polar which is one of the largest industrial conglomerates in Latin America, distinguishes itself from other Latin American companies by actively stimulating collaborations with the academic sector. This is an important feature since it is common that firms in developing countries are poorly informed on technological matters and prefer to buy imported technology, instead of making better use of national scientific capabilities of universities and other research institutions. Since 1986, Polar initiated a process of capacity-building in biotechnology, investing more than \$10 million. It formed an industry-academic network of laboratories with the Simon Bolivar University, the Central University of Venezuela and the Venezuelan Institute of Scientific Research, with the purpose of creating a biotechnological potential applicable to agriculture and industry, especially the beer industry. Presently, Polar has 3 patents pending at the US Patent Office regarding improvement of beer shelf-life, which resulted from the network's first project, started in 1990. New projects are underway, on pollution control, molecular genetics of yeast and barley and the transformation of residuals of beer fermentation into nutritious foods for humans. In the field of agri-biotechnology, Polar is working on transgenic rice and maize, looking for virus-resistance. In the healthcare area, Polar has developed diagnostic kits for human papilloma virus, for hepatitis B virus

¹⁴ Walter V. Reid, op. cit.

¹⁵ Calestous Juma, "Policy options for scientific and technological capacity-building," in Walter V. Reid et al., *Biodiversity Prospecting: using genetic resources for sustainable development*, World Resources Institute, U.S.A., 1993.

and another for *Trypanosoma cruzi*, that can be used to diagnose Chagas' disease found in the Andean communities¹⁶.

33. In the area of biotechnology, there is a scope for promoting small enterprises. In general, small firms have competitive advantage in innovative activity 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 for the market place.¹⁷ A recent study documents an increasing exploitation by large European-based multinationals in chemicals and pharmaceuticals of the scientific knowledge and skill of the United States, generated in small dedicated biotechnology firms or the satellite laboratories of the European firms.¹⁸ 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 in section VII.

B. Perspective of resource recipients

34. It is evident that access-and-benefit-sharing arrangements are two-way arrangements. From the perspective of the resource recipients, whether they are established large corporations from industrialized countries or biotechnology companies in the developing countries, their interest rests in continued and secure access to genetic resources. In recognizing the role played by the resource providers, in particular indigenous and local communities, in maintaining biological diversity and their knowledge, innovation and practices on conservation and sustainable use, the resource recipients should come forward to contribute in capacity-building and technology transfer to the resource 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. With the implementation of the CBD, it is expected that many countries will formulate measures or modify the existing measures to regulate access to genetic resources. The public in both recipient and provider countries will become more and more aware of the value of biological diversity and thus, the cost of obtaining genetic resources will start to reflect such values. In this emerging condition, it can be recognized that voluntarily initiated access-and-benefit-sharing arrangements arrived in mutually agreed terms even in the absence of specific legislation can produce more beneficial results for both parties. Recipient companies are, therefore, urged to

¹⁶ A. Pirela, "Polar: Collaboration between public and private institutions", Biotechnology and Development Monitor, 32:10-12, 1997.

¹⁷ R. Ferguson and Chi-Ning Liu, "Promoting technology-based small enterprise," a background document submitted to the United Nations Panel on Opportunities and Participation, 1995.

¹⁸ Margaret Sharp, "The Science of Nations: European Multinationals and American Biotechnology," STEEP Discussion Paper No. 28, Science Policy Research Unit, University of Sussex, February 1996.

actively participate in access-and-benefit-sharing arrangements with their potential providers.

VI. Existing bioprospecting arrangements: lessons learnt

35. Although in most of the countries access legislation is still under development (see also UNEP/CBD/COP/4/23 on measures and guidelines to implement Article 15) the private sector already responds at least in an initial way to the requirements of the Convention. Before the entry into force of the Convention (29 December 1993), companies bioprospected¹⁹ without any sharing of benefits apart from paying the nominal fees for the work carried out (e.g. collecting plants). In order to meet the moral pressure to comply with the Convention although no legal rules are yet in place, or because of the increased bargaining power of the provider country owing to higher awareness, some companies have started to formulate agreements for bioprospecting arrangements which include benefit sharing. Two of the notable examples of such agreements are described below. Further information can be obtained from UNEP/CBD/COP/4/ Inf. XX and UNEP/CBD/COP/4/Inf. XX.

A. Merck & Co. Inc. - INBio

36. One of the oldest and maybe most known access and benefit sharing (ABS) arrangements is the one between Merck & Co. Inc., U.S.A. and the Instituto Nacional de Biodiversidad (InBio), Costa Rica.

37. InBio, who prospects in Costa Rican national parks, also assesses, identifies and monitors Costa Rica's biological diversity and is establishing a National Biodiversity Inventory. It has contacts with many different private sector partners, but the case with Merck is described here because it has set a precedent.

38. InBio provides about 10,000 extracts of plants over a two-year period of time. InBio carries out the collection, screening and extraction of the plants, providing them to Merck with a code for preventing Merck from identification. During this period, Merck provided about \$1 million in cash, \$150,000 in laboratory equipment and training of four Costa Rican researchers at Merck's laboratory. Furthermore, Merck will pay an (unreleased) royalty to InBio only on marketed products arising from a compound of InBio extracts. InBio will share any royalty equally with the National Park System and is already sharing 10 per cent of up-front payment with the National Park System, which was \$100,000 in the case of Merck.

39. The contract has been heavily criticized for being too favourable for the users. However, it is worth noting that it represents the first case where an institution in a provider country supplies value-added genetic resources and where, at the same time, the flow of benefits back to conservation and sustainable use of biological diversity is ensured.

B. Diversa Corporation - Yellowstone National Park

¹⁹ Bioprospecting is the search for genetic resources for use in biotechnology.

40. Another type of biological diversity prospecting, and one which is going to become increasingly important, is based on direct cloning of enzymatic activities from microbial (and other) sources. Diversa Corporation, based in San Diego, California, specializes in enzyme research, geared towards discovery, modification and commercialization of new protein-based biocatalysts and enzyme additives for chemical, pharmaceutical, food and industrial users. These enzymes can replace chemical catalysts used in the production process, reducing costs and environmental impacts. In order to be marketable, however, enzymes have to possess specific characteristics, in particular, to be able to be used in extremes of temperature or pH or in organic solvents in industrial processing. By using its microbial genomics expertise and developing suitable technologies, Diversa Corporation has become a world leader in this field. Since its establishment in 1994, Diversa Corporation has discovered over 340 novel, robust enzymes.

41. Yellowstone National Park represents one of the most diverse geothermal environments in the world, containing more than 80 per cent of the geysers and 60 per cent of terrestrial geothermal features of the Earth. The microorganisms living in the Park's thermal sites are of particular interest for their properties of being able to survive in such harsh environment, yet it was revealed that less than one per cent of these micro-organisms had been discovered before the Park and Diversa Corporation reached an agreement.

42. The agreement between the Yellowstone National Park and Diversa Corporation was signed on 17 August 1997 and it was the first of its kind for the Yellowstone National Park. Under the terms of the five-year agreement, the Yellowstone National Park will provide Diversa Corporation with non-exclusive access to certain areas within the Park and the ability to commercialize products that result from its research, in exchange for the latter providing a package of economic, scientific and technical benefits that will include: an annual financial contribution to the Park creditable against future royalties; royalties based on revenues generated by enzymes identified in its research and commercialized for valuable applications; and scientific training and equipment to assist the Park in development of research programmes directed toward cataloguing and understanding microbial diversity. All royalties and payments will be paid directly to Yellowstone National Park.²⁰

43. This example illustrates the case of an agreement between a public authority and a private firm within one country. The country does not have an access legislation and, in fact, is not yet a Contracting Party to the Convention. The Park had granted research permits to private firms since the 1960s, but the agreement with Diversa Corporation marked the first time the arrangement of sharing benefits from such a research was specified. This was possible because both the Park and the company became aware of the value of the microorganisms existing in the Park, both economically and scientifically.

44. Diversa also engages in cross-border agreements. One of such examples is just being finalized. An agreement has been reached in principle (and is awaiting final signing) between Diversa, the Institute of Biotechnology (IBT, UNAM) and the Mexican National Commission on Biodiversity (CONABIO) for:

²⁰ Diversa Corporation, "Diversa/Yellowstone biodiversity agreement question and answer document," a briefing note, 1997.

(a) joint microbial (molecular) bioprospecting expeditions and enzymatic cloning/screening; (b) support of laboratory at IBT to further their work in the area of protein folding motif identification (structural biology in silico) and protein engineering (in particular the concept of 'catalytic migration'); (c) making scientists at IBT consultants to Diversa; (d) Diversa's support to the establishment of a "Center for Biomolecular Diversity" at the IBT; and (e) joint work between CONABIO and Diversa in the creation of novel, proprietary biological diversity database relating ecology, biology, genetics, metabolism and chemistry²¹.

VII. Measures to promote and advance the distribution of benefits from biotechnology in accordance with Article 19

45. Articles 15.7 and 16.3 ask for legal, administrative and policy measures, Article 19.2 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.

46. Legal measures, including executive orders, include changes in existing law or the development of new legislation with regard to creating provision on access to genetic resources. This includes the creation or designation of appropriate authorities to implement the access legislation. The development of legislation on access and benefit sharing is further elaborated in document UNEP/CBD/COP/4/23. Access legislation should ensure fair and equitable access-and-benefit-sharing arrangements. What is important for a successful access regime is not only sound legislation but much more the process by which it is set up. The involvement of all stakeholders in this process is crucial.

47. Other legal measures include changes in intellectual property right law, such as patent law and plant breeders rights, to ensure the implementation of access and benefit sharing legislation and arrangements. The protection of indigenous and local knowledge, innovations and practices through a sui generis systems is one way of ensuring benefit sharing for those 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, Spain from 24-28 November 1997, include various proposals for the elaboration of a sui generis system under the CBD (see the report of the workshop, UNEP/CBD/TKBD/1/3). Some models or initial proposals are discussed in the note by the Executive secretary on traditional knowledge and biological diversity (UNEP/CBD/TKBD/1/2). Other proposals strive for an in-depth analysis of existing intellectual property right and their applicability to indigenous and local knowledge. Further study in both approaches - development of a new system and applicability of existing intellectual property right - might be necessary in order to analyze the best way of implementation.

48. In order to enhance meaningful technology transfer, developing countries need to build a broadly based capacity, which encompasses human, scientific, technological, organizational, institutional and resource capabilities. With

²¹ H. Bialy (editor at large, Nature Biotechnology), personal communication.

respect to biotechnology, which is essentially interdisciplinary, 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.²² In addition, the emphasis should not only rest on the high end of the education system but also on the intermediate levels in order to serve for skilled technical and clerical workers. Furthermore, legal provision can 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.

49. As regards to the funding, the requirements range from those 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. GEF, as the financial mechanism of the Convention, has various means to address the needs of the developing countries to implement the Convention. The secretariats of the GEF and the Convention have addressed this issue in a separate note, in accordance with decision III/5 (UNEP/CBD/COP/4/22). 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. Measures to encourage foreign direct investment include management of stable macro-economic conditions, maintaining political stability and providing incentives, including tax and tariff reductions.

50. In order to promote small enterprises specialized in biotechnology, additional specific measures may be considered. It is essential that these entrepreneurs have access to capital. A mature capital market is a preferable mechanism to facilitate such investments. An important role of a government is to build a stable capital market. Governments can also provide funds through such mechanisms as development banks and other targeted funds and loans. Other measures include tax breaks and provisions 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.

51. The important role of intellectual property rights has been pointed out. As for the high-technology oriented small firms, establishment of or availability of a secure intellectual property right system represents an effective incentive.

52. The need for educated labour force has also been pointed out. There is also a need for a specific measure to bring academic research communities and entrepreneurial communities closer together. One possible measure is the establishment of technology research parks, which target relatively high-level technology, including biotechnology. Such a park can include large and small enterprises, and can be located in conjunction with a local university. Care

²² C. Juma, *op.cit.*, 1993.

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.

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

VII. Conclusions and recommendations

53. Protecting access to biological diversity can only be accomplished by the individual parties. Therefore, efforts to put legal measures in place must be intensified. While awaiting such measures to be formulated, several mechanisms to achieve benefit-sharing arrangements can be considered. Three such cases have been illustrated in the paper. The direct and indirect economics of a "fair and equitable" benefit sharing arrangement depends on the potential value-added of the provider. Therefore, capacity-building efforts must be further enforced in the developing countries. In addition, industrial policies targeted at biotechnology industries have the potential to play a major role in promoting and advancing the distribution of benefits from biotechnology.

54. The Conference of the Parties may wish to take into consideration the following recommendations regarding measures to promote and advance benefits from biotechnology in accordance with Article 19:

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

2. to hold regional workshops to promote private sector involvement in the development and the advancement of national and international partnerships towards the implementation of the CBD;

3. to urge Governments, regional economic integration organizations and other international, regional and national competent organizations:

- a) to promote measures, policies and programmes that have been pointed out as effective to facilitate the distribution of the benefits from biotechnology, including measures aimed at the enforcement of legal provisions for the protection of access to microbial, plant and animal genetic diversity;

- b) to submit the experiences on the benefit-sharing arrangements in time for the next meeting of the Conference of the Parties, including the survey of the private-sector activities in the field of biotechnology;

- c) to urge the private sector to participate more actively in the implementation of the CBD;

4. to request the Executive Secretary:

a) to compile the information and to facilitate the exchange of information through appropriate means such as the clearing-house mechanism;

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

5. to request the GEF to support projects and activities that have been identified as contributing to the fair and equitable benefit-sharing.

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Item 16.3 of the provisional agenda

REVIEW OF NATIONAL, REGIONAL AND SECTORAL MEASURES AND GUIDELINES
FOR THE IMPLEMENTATION OF ARTICLE 15

Note by the Executive Secretary

I. INTRODUCTION

1. As stated in Article 1 of the Convention (Objectives), access to genetic resources is one of the main means to share, in a fair and equitable manner, the benefits arising out of the utilization of genetic resources. A framework for the implementation of this third objective of the Convention with regard to access to genetic resources is provided in Article 15 of the Convention. Article 15, Article 19 paragraphs 1 and 2, Article 16 paragraph 3 and Article 8 (j) are key provisions of the Convention dealing with benefit-sharing related to genetic resources.

2. The Conference of the Parties (COP) already considered Article 15 in depth at previous meetings. At its second meeting, it considered the compilation of "existing legislation, administrative and policy information on access to genetic resources and the equitable sharing of benefits derived from their use"; and "information provided by Governments as well as relevant reports from appropriate international organizations regarding policy, legislative, or administrative measures related to intellectual property rights as provided in Article 16 of the Convention and to access to and transfer of technology that makes use of genetic resources".

3. The third meeting of the Conference of the Parties considered a compilation of "views of the Parties on possible options for developing national legislative, administrative or policy measures, as appropriate, to implement Article 15".

4. At this meeting of the COP, access to genetic resources will be considered as part of one of the main items of the meeting: "16. Matters related to benefit-sharing". Under agenda item 16, the Conference of the

Parties will first consider sub-item "16.1. Measures to promote and advance the distribution of benefits from biotechnology in accordance with Article 19 ('Handling of biotechnology and Distribution of its Benefits') UNEP/CBD/COP/4/21, (see also UNEP/CBD/COP/4/Inf. xxx and UNEP/CBD/COP/4/Inf. xxx on case studies on benefit-sharing). Sub-item 16.2 deals with "Means to address the fair and equitable sharing of benefits arising out of genetic resources" (UNEP/CBD/COP/4/22). Sub-item 16.3 addresses the issue of the present Note, "Compilation of views of the Parties on possible options for developing national legislative, administrative or policy measures, as appropriate, to implement Article 15 ('Access to Genetic Resources')".

5. At its third meeting, the COP urged in decision III/15 para. 1

"Governments, regional economic integration organisations and other international, regional and national competent organizations to send to the Secretariat, five months before the fourth meeting of the Conference of the Parties, information on:

(a) National, regional, and sectoral legislative, administrative and policy measures and guidelines for activities covered by Article 15, and in particular, on access and benefit-sharing, both adopted and under development, including information on their implementation;

(b) National participatory processes for the activities covered by Article 15, and in particular, ways by which access and benefit-sharing measures and guidelines, including related institutional arrangements are developed and implemented;

(c) As appropriate, research programmes on genetic resources.

6. In paragraph 2 in decision III/15, the Executive Secretary was requested "(a) to prepare a note based on information provided in response to paragraph 1, further summarizing legislative, administrative and policy measures, including guidelines and regional and sectoral measures for the activities covered by Article 15, and in particular on access and benefit-sharing, both under development and adopted. The note should include a summary of the scope of the genetic resources included and being considered; any national and regional interpretations of key terms; the elements included in access measures and consideration of the process by which such measures are prepared and implemented, including interim measures; relevant national experiences in the development and implementation of such measures, including, as available, case studies."

7. The present Note has been prepared by the Executive Secretary in response to that request from the COP. It draws upon two previous documents which have been prepared by the Executive Secretary for the second and third meeting of the COP respectively:

(i) UNEP/CBD/COP/2/13, *Access to genetic resources and benefit-sharing: Legislation, administrative and policy information*;

(ii) UNEP/CBD/COP/3/20, *Access to genetic resources*.

8. The latter one is a response to a request by the second meeting of the COP in decision II/11 in which the Executive Secretary was requested to "[f]urther elaborate the survey of measures taken by Governments to implement Article 15, including any national

interpretations of key terms used in that article with a view to completing the survey in time for circulation at the third meeting of the Conference of the Parties".

9. The present Note assumes a familiarity with the contents and ideas of both UNEP/CBD/COP/2/13 and UNEP/CBD/COP/3/20 (additional copies of the documents are available upon request from the Secretariat or can be downloaded from the Internet as <<http://www.biodiv.org/cop2/COP2-13>> and <<http://www.biodiv.org/cop3/COP3-20>>).

10. Sub-item 16.3 is a continuation of the discussions on the implementation of Article 15 which took place at the second and third meetings of the COP. This Note is a continuation of the previous papers. As of 22 January 1998, the Secretariat had received few official communications by Governments in response to paragraph 1 of decision III/15, quoted above, although reminders were sent out to the National Focal Points on 4 February 1997 and 27 October 1997. Information has been provided by the Government of Tunisia, the Government of Turkey, the Government of Costa Rica on the work of the Central-American Commission on Environment and Development, and the Government of Germany and the European Commission on a Workshop on 'Towards Best Practices for Access to Genetic Resources', held on the 15 and 16 January 1998 in Córdoba, Spain. The report of the latter workshop, which was co-sponsored by the European Commission and the Government of Germany, has been made available by those two Parties as UNEP/CBD/COP/4/Inf. Xxx.

12. The Secretariat has received some informal communication on measures and activities (including initial discussions) related to Article 15 in: the Association of South East Asia Nations (ASEAN); the Andean Pact and its member States Bolivia, Colombia, Ecuador, Peru and Venezuela; Angola; Argentina; Australia (including two of its states); Brazil; Cameroon; Egypt; Eritrea; Ethiopia; Fiji; The Gambia; Ghana; India; Indonesia; Kenya; Laos Peoples Democratic Republic; Lesotho; Malawi; Malaysia (including Sabah and Sarawa); Mauritius; Mexico; Mozambique; Nigeria; Philippines; Seychelles; South Africa; South Korea; Sri Lanka; Tanzania; Thailand; Tunisia, United States of America; Yemen and Zimbabwe. It has also received information on access measures and benefit-sharing arrangements in response to its call for case studies on benefit-sharing (a synthesis report on which is contained in UNEP/CBD/COP/4/Inf. xxxx and the case studies itself/a selection of case studies are made available as UNEP/CBD/COP/4/Inf. xxxx and can be accessed through the Clearing-House mechanism at <<http://www.biodiv.xxxxxxx>>). The status of implementation of Article 15 varies significantly between the parties. Whereas some have already adopted comprehensive laws and administrative regulations, others are still in the process of discussing whether to adopt access legislation at all.

13. The present note draws on the information available to the Secretariat and synthesizes it to a more general statement. This shall serve two purposes: to give some orientation to those countries in a process or planning to establishing access laws, regulations and policy and to provide some preliminary standards for users seeking access in countries without any provisions on access. Users often miss legal and institutional certainty and at least for the first concern the paper might provide some initial guidance.

II. MEASURES TO IMPLEMENT ARTICLE 15

14. The Convention on Biological Diversity regulates access to genetic resources and sharing of benefits derived from its use in Articles 15, 16.3, 19.1 and 2. It is complemented by Article 8 (j) in so far as genetic resources are subject to knowledge, innovation and practices of indigenous and local communities and Article 17.2, which deals with the exchange of information including knowledge which makes use of genetic resources. All Articles require action from "each Contracting Party". Only Articles 16.3 and 19.1 and 2 ask for special consideration of developing countries in the context of technology transfer, participation in biotechnological research and the sharing of results and benefits from biotechnology. Apart from these provisions, the Convention bases its provisions on the participants in the transaction of genetic resources: providing countries, which are countries of origin or those having acquired the genetic resources in accordance with the Convention, and users of genetic resources provided by other Parties.

15. The addressees of the Convention's provision on access and benefit-sharing are users and providers of genetic resources alike; both categories are also addressed in the decisions of the Conference of the Parties. The Convention establishes a new framework for how to deal with genetic resources in terms of access and benefit-sharing. In order efficiently to implement the Convention, measures are required not only for regulating the provision of genetic resources, but also the commitments of the user. This will be the case if provider and user of the accessed genetic resource are subject to the same jurisdiction. It differs, however, if provider and user are from different countries and therefore subject to different national legal, administrative and policy systems.

15a. As measures of countries might differ considerably, there is a need for harmonisation for the interest of both the users and providers of genetic resources: i) without harmonised standards, access might be rather made more difficult than facilitated as asked for in Article 15.2; ii) legal and institutional uncertainty is a hindrance for users to seek access and, hence, share benefits; iii) access and benefit sharing measures in one country might turn out to be useless if the user remains uncontrolled in the country of provenience; iv) the same is true if provider countries with similar biodiversity have lower or no standards: users will choose the country where benefit-sharing requirements are the lowest ones. The Andean Pact has responded to that latter problem in establishing a common regime on access.

15b. As more and more access legislation is being set up, there is a need for guidelines which help the harmonization of efforts to implement the framework at the national and regional level and ensure fair and equitable sharing of benefits. Those guidelines emerge from the best practices developed by those countries which have set up legislation, including administrative regulations, other administrative and policy measures.

16. This paper includes both a section on provider-related guidelines and a section on user-related guidelines. It is up to each Contracting Party to decide which part of the guidelines might be drawn upon first. Those countries that are more a provider than a user state might wish to start setting up measures, such as legislation, for providing genetic resources. By contrast, those countries whose emphasis is more on the user side might wish to establish some regulation or at least guidance on ensuring that when their bodies and their nationals use genetic

resources from other countries, they have secured prior informed consent and reached mutually agreed terms which strive for the fair and equitable sharing of benefits.

1. Provider-related Guidelines

1.1 Preparatory process

17. As with every law and policy, access legislation is only as good as the process through which it is developed, allowing stakeholders in the field of genetic resources to articulate their concerns and have them taken into consideration, to define the objectives of access legislation, and to develop capacity through the planning process. It is through and with the help of these stakeholders that access legislation will generally be implemented later on.

18. The national or regional¹ planning process can either be built into an overall strategy on biological diversity according to Article 6 (a) or be established as a stand-alone process for access and benefit-sharing in relation to genetic resources. After the identification of the stakeholders which should be part of the process, the strategic plan should include an assessment of the natural resources related industrial, administrative, institutional, and legal *status quo*, the identification of parameters for access legislation and the implementing process.

1.1.1 Identification of stakeholders

19. Stakeholders vary from country to country. As an initial step, stakeholders in the country which should be part of the planning process should be identified. They may include:

- ministries and government agencies concerned with natural resources, agriculture including fisheries, and forestry, customs, protected areas; health, research, justice;
- the industrial sector, in particular pharmaceutical, phytomedicine, horticultural, personal care and cosmetic, flavour and fragrance, food and beverage, and other biotechnological companies;
- the scientific and academic communities, such as universities and research institutions dealing with genetic material;
- *ex-situ* conservation facilities such as botanic gardens, zoos, microbial resource centres, universities and research institutions;
- indigenous and local communities or their representative organizations;
- people's organizations
- traditional healers or their associations;
- non-governmental organisations working in the field of genetic resources.

For example, Australia, Malaysia, the Philippines and South Africa had or have set up a committee. Australia, however, only includes governmental stakeholders in its planning process.

1.1.2 Assessment of *status quo*

¹In the following, the paper describes the national process and legislation. This process applies, however, to regional processes and legislation as well, with the modifications that derive from the nature of such an exercise at the regional level.

20. As part of the process in which legislation is developed, a country should assess its own needs, opportunities, resources, and capacities. This should include a review of

- which kind of biological resources are available in the country;
- the types of commercial uses to which genetic resources might be applied;
- the kind of legislation related to biological diversity and in particular genetic resources is already in place. This includes legislation related to natural resources, such as constitutional norms on biodiversity, natural resources etc., wildlife laws, conservation legislation, sectoral laws related to fisheries, forestry and agriculture, laws on protected areas; land tenure law; intellectual property law; regulations related to research (permit requirements); phytosanitary regulations; import and export regulations related to biological resources including regulations related to CITES.
- which institutions are carrying out which functions related to genetic resources and what are their capacities.

1.2 Elements for legislation

21. Countries choose a variety of strategies to introduce access measures into their national law. Approaches include changes in existing and development of new legislation, either as stand-alone laws or as inclusions into framework sustainable development laws, nature conservation or biodiversity laws covering a broader range of issues related to biological diversity or a specific sector such as fisheries or forestry or protected areas. Those laws have been either changed accordingly or, in case of their actual setting up, included, provisions related to access genetic resources and benefit-sharing. When using sectoral or issue specific laws, only a certain set of genetic resources are covered, such as fish genetic resources or genetic resources in protected areas. This might be an advantage or disadvantage, according to the assessment described above. The other approach is to set up specific, stand-alone legislation on access to genetic resources and benefit-sharing.

New stand-alone legislation has been adopted since the third meeting of the COP by Bolivia (Decreto Supremo No. 24676 of 21 June 1997 implementing Decision 391 of the Common Regime on Access to Genetic Resources of the Andean Pact), Brazil (Bill of Law No. 306/95 on Access to Genetic Resources of 19 November 1997) and India (Bill on Access to Genetic Resources).

22. Whether a stand-alone law has been chosen, an existing sectoral law amended or access and benefit -sharing provisions built into a broader biodiversity law, a set of generic elements emerges from the analysis of the legislation adopted or under development so far..

1.2.1 Scope of application

a. Types of Genetic Resources

23. The scope of application can be distinguished first of all according to the taxonomic origin and classical kingdoms: animals, plants and micro-organisms. For example, Costa Rica's and the Philippines' regulation only apply to (wild) fauna and flora.

24. The scope can include genetic resources and derivatives. Most countries do not only regulate genetic resources (any material of plant, animal, microbial or other origin containing functional units of heredity of actual or potential value) but also derivatives from that material (like the Philippines, the Andean Pact and Brazil). This includes raw extracts, biochemicals and molecules in general, unimproved and modified ones likewise. In practice, the national legislation applies access and benefit-sharing provisions in a broader way than does the definition of genetic resources in Article 2 of the Convention (this definition does not include derivatives).

24. The scope can be determined according to human impact: The Brazilian legislation distinguishes domesticated and semi-domesticated crops; the draft Eritrean law applies to wild and domesticated genetic resources.

25. The scope can include all genetic resources and derivatives from all origin but the applicable rules may differ within the regulation

26. Genetic resources from human origin are often explicitly excluded from the scope (Andean Pact, Brazil, Eritrean draft).

b. *In-situ* and *Ex-situ* conditions

24. Provisions on access and benefit-sharing include material from both *in-situ* as well as *ex-situ* conditions (Brazil, Andean Pact, Costa Rica).

c. Local and Indigenous Knowledge, Innovations and Practices

26. The scope of the law often includes "traditional", "intangible", "indigenous" and "local" knowledge which is associated with genetic resources or its derived products. The Brazilian Bill defines traditional knowledge similar to the Andean Pact Regime as: "any knowledge, innovation, or individual or collective practice of an indigenous population or local community, having real or potential value, associated with a genetic resource or derived product, protected or not by intellectual property legislation.

1.2.2 Property Right and Ownership Clauses

27. The material which is covered by the scope of the provisions is often submitted to a special property regime, such as "public property of special use" (Brazil) or "national patrimony" (Costa Rica), being "inalienable, imprescriptible and cannot be seized" (Andean Pact).

28. This is done in order to avoid ownership of the genetic component or a potential derivative by those owning the physical natural resource as such. What was former an overall ownership can thus be divided into two parts. Genetic resources and related material are submitted to a qualified regime in relation to the ownership of the physical entity which forms the biological resource. The genetic resource is submitted to different rights for its information value which is different from the direct use value of the biological resource.

1.2.3 Definitions

29. Stand alone legislation on access and benefit-sharing contains a set of definitions of important terms for the legislation and whose content exceed the use and understanding in the normal language. These

definitions draw partly on definitions in the Convention and partly define terms in a broader sense. Defined terms include: access to genetic resources; intangible property; traditional knowledge; competent national authority; biotechnology; access contract; derivative/derived product.

1.2.4 Requirements for Prior Informed Consent (PIC)

30. Prior informed consent (PIC), required by Article 15.5, is the central procedural device enabling the provider of genetic material or related knowledge to negotiate the terms of the access and benefit-sharing agreement (the bioprospecting arrangement or, in general, the "mutually agreed terms"). It enables the providers of genetic resources or related knowledge to negotiate on a more equal basis with the users of those resources. Requirements for information to be provided by the user of the material or related knowledge set up in the legislation include:

- (a) Quantity and kind of material to which access is sought for;
- (b) Duration of the access activity
- (c) Locality or area including geographical coordinates in which access will be made.
- (d) Assessment of the impact of the access activity on conservation and sustainable use of biological diversity.
- (e) Purpose of research and expected result.

1.2.5 PIC Procedure

a. General

31. The procedure of the application is as important as the information provided by the entity (natural or legal person) regarding the material or knowledge. Most countries either designate a national authority to execute the functions related to the PIC procedure or create a national committee or commission involving various stakeholders or choose a combination of both. In the latter case, the commission might approve the decisions of the national authority regarding both policy and individual decisions (e.g. in the Brazilian Bill) or makes recommendations (e.g. in the Philippine Executive Order). Whatever kind of institutional arrangement is decided upon, the consent of those directly concerned by the accessing activity should be sought. This is stipulated in all existing access laws and regulations. For example, if the applicant seeks access to genetic resources on the territory of indigenous and local communities or to their knowledge, these communities should take part in the PIC procedure as is needed according to Article 8 (j). If the bioprospecting relates to a protected area, the authority managing that area is involved in the process.

32. Provisions regulating the involvement of stakeholders in the decision-making process should balance the rights with the interest of the applicant and the practicability of the PIC procedure in order to facilitate access. To meet those concerns, some legislation establishes time frames within which access must be denied or granted (e.g. the Andean Pact Regime and the Brazilian Bill). Countries have been criticised in not being practicable and providing disincentives for potential private sector partners of access and benefit-sharing arrangements or non-governmental organisations involved in conservation which have difficulties in doing so as access has become more difficult.

b. Use related distinctions

33. Some legislation distinguishes different kind of procedures according to whether the intended use of the material or knowledge is linked to academic research or commercial research (e.g. the Philippine Executive Order). However, the distinction between both uses is often difficult to draw. There is a continuum between accessing the information related to the resource without even collecting it and a marketed product based on that knowledge and the genetic resource. What started as a research might end up in the development of a drug or another biotechnological product. This may be true even where the original academic researcher merely published the results of the research. To prevent this situation, access for research purposes might follow an easier procedure but the agreement might stipulate that new negotiations are required in the case of potential commercialisation. The access agreement could also state that publication is only permitted with due regard to the source of the resource and knowledge and the deposit of the publication with the competent authority.

c. Nationality related distinction

34. Other legislation distinguishes between national and foreign users of genetic resources, establishing different procedural standards on PIC and requirements for the agreement (e.g. the Indian Bill). In this regard it is important to bear in mind that genetic resources are not just subject to transboundary trade but are often used and processed within the country itself.

34a. For example, the Hoechst Marion Russels Research Centre in India is an Indian Corporation and explores genetic resources collected in India. Although there is in-country value-added and commercial research carried out, no benefits are shared with those communities where the genetic resources are collected and no benefits are flowing back to conservation. Therefore, the bioprospecting does not create incentives for conservation and sustainable use.

34b. Another in-country example of bioprospecting is the biotechnological company Diversa which signed an access and benefit-sharing agreement with the authorities of the Yellowstone National Park of the US. The Park receives a package of economic, scientific and technical benefits that includes an annual financial contribution to the Park creditable against future royalties, royalties based on revenues generated by enzymes commercialized for valuable applications, and research training. As this example shows, benefit-sharing can also take place between different sectors of society within one country, thus creating incentives for conservation and sustainable use. Countries might wish to strive for in-country benefit-sharing and not differentiate between users on the basis of their origin but rather on the basis of the purpose of the use. Some legislation wisely exempts the trade of genetic resources between indigenous and local communities and small-scale farmers from its provisions, like the Andean Pact Regime.

1.2.6 Requirements for Mutually Agreed Terms

35. "Mutually agreed terms" is the second pillar of the access and benefit-sharing regime set up by the Convention. Mutually agreed terms presuppose prior informed consent to negotiate the access and benefit-

sharing-arrangement (ABA)². Terms are mutually agreed-upon if they are reciprocally accepted. Inherent in the phrase *mutually agreed terms* is the expectation of a negotiation between the Party providing genetic resources and a potential user. Mutual agreement does not, however, imply complete liberty in what might be agreed upon. Every access and benefit-sharing-arrangement is embedded in the regime of the Convention. This implies that some key features are part of the agreement and might be required by the access legislation.

36. In order to comply with the provisions of the Conventions, stipulated conditions of mutually agreed terms - an access and benefit-sharing arrangement - might include:

- a) Kind, quantity of prospected material and location of prospection;
- b) Deposit of specimens and registered knowledge with the competent national authority of country of origin;
- c) Research participation;
- d) Benefit-sharing, e.g. immediate benefits in cash and kind exceeding normal salaries and reflecting the economic value of genetic resources; payment of royalties; flow-back of benefits into conservation and sustainable use of biological diversity;
- e) Confidentiality of information;
- g) Clause allowing renegotiation during the project;
- f) Ownership of the resource;
- h) Agreement on whether the material can be passed on to entities not being party to the mutually agreed terms;
- i) Time limitation of the agreement.
- k) Recognition of the origin of related information, for example in publications or the description of the marketed product.

37. The kind of benefit-sharing to be included in the agreement can be stipulated in the access regulation. However, the amount and scope of the benefits to be shared should be decided during the negotiations. The kind of benefits which are possible are elaborated upon in UNEP/CBD/COP/4/21 and 22.

38. Some legislation foresees a public review process. In this case the access agreement is - apart from confidential clauses - published, including in the area where the bioprospecting activities shall take place. Such a process allows for comments from the public within a certain period of time (Brazil and Andean Pact Regime).

1.2.7 Partners to the mutually agreed terms

39. It is up to the legislator to decide who should enter in the access and benefit-sharing arrangement with the potential user. Various arrangements have been used:

- (i) Agreement between the competent authority/institution responsible for the PIC procedure and the user.

² The term access and benefit-sharing arrangement (ABA) describes an agreement which is in line with the provisions of the Convention. The term "Material Transfer Agreement" is a term generally used for every exchange of genetic resources on a contractual basis, disregarding whether benefit-sharing is part of that agreement. For example, the private sector uses the term Material Transfer Agreements for all transactions of genetic material since a long time. It is therefor proposed to use the term Access and Benefit-sharing Agreement (ABA) to describe contracts and taking the provisions of the CBD into account.

(ii) Tri-partite agreement between the competent authority/institution, the user, and any other entity involved, such as the local and indigenous community or private landowner on whose land the bioprospecting is taking place, the national park authority etc.

(iii) Agreement approved by the authority/institution between the user and the entity involved, such as the local and indigenous community or private landowner, the national park authority.

(iv) Four-partite agreement between the competent authority, the user, the agency of access and the provider of traditional knowledge.

1.2.8 Monitoring and enforcement

40. To monitor agreements on access and benefit sharing is difficult. One possibility is a regular report requirement on the advances made in research and development conducted on genetic resource accessions. Some legislation foresees penalties or the cancellation of the agreement in case of violation of its provisions (Brazil, Philippines). More case studies and information on best practices on monitoring and enforcement is required.

1.3 Institutional Arrangements

41. During the process to prepare measures on access the most appropriate kind of institution or administrative structure to handle biodiversity prospecting should be identified. The responsibilities might well exceed the negotiations of access and benefit-sharing arrangements but include

- to develop and implement an efficient, simple and transparent process for bioprospecting arrangements;
- to provide legal and business expertise to providers of genetic resources, organising capacity building activities (in, e.g. drawing on GEF funding for such activities);
- to coordinate the consultative policy process surrounding bioprospecting and examine the macropolicy context in which it operates (e.g. other laws, government incentives);
- develop a strategic approach to promoting research and capacity in the country providing genetic resources in the field of biotechnology;
- to monitor the bioprospecting arrangements together or in collaboration with other stakeholders such as the patent office or research related institutions;
- to receive and disburse revenues/benefits from bioprospecting arrangements which are not dedicated to local and indigenous communities or other direct stakeholders such as the national park management.

42. The institutional arrangement for implementing access and benefit-sharing must be designed or selected according to the tasks that must be fulfilled. Types of institutional arrangements include a single national governmental institution; a research institution, an NGO or other private entity; and a national committee. In most cases where specific access legislation has been developed, countries have decided to establish a committee at the national level which includes stakeholders from all levels of society.

2. User-related Guidelines

43. Responding to the new international ethic set up by the Convention, two companies, Glaxo Wellcome and Novo Nordisk, have developed on a voluntary basis some policy for their companies regarding genetic resources. Some botanical gardens are developing policy for acquiring and distributing their material, including those which has been received before the entry into force of the Convention. Kew Botanical Gardens just issued an institutional policy in that regard. However, the Convention is in general not yet very well known in the private sector, let alone its implications understood and turned into a policy of the company.

44. Article 15.7 includes legislative, administrative, or policy measures to ensure the fair and equitable sharing of benefits. Some user countries have already taken policy measures, such as setting up programmes for joint research between institutions in the provider and user countries related to genetic resources or developing economic incentives for their nationals to negotiate access and benefit-sharing arrangements.

45. However, policy measures might not be sufficient in order to help to enforce legislation of provider countries but changes in law required. Policy measures are optional and might not reach all of the users. Legislation in the provider country might be easily by-passed by users from other countries as modern biotechnology requires less and less quantities of samples for screening and other research purposes.

45. As the discussions on user-related guidelines is still in its infancy, the following guidelines will need more development by the Contracting Parties.

2.1 Preparatory process

45. What is true for the provider country is also true for the user country: every law and regulation is as good as the process which has set it up. The user country should therefore initiate a process which analyses existing legislation and discusses practicable changes with all stakeholders in that country.

46. The user country should start with an analysis of existing laws, administration and policy measures related to genetic resources. Areas include

- Access regulations to *ex-situ* facilities;
- Import regulations related to species protection; phytosanitary regulations;
- Intellectual property rights, in particular conditions to grant patent applications, plant breeders rights, trademarks, appellations of origin;
- Food and drug administration laws and other official authorization systems;
- Natural resources law.

2.2 Legislative and administrative measures

47. Once an analysis has taken place on which part in the legal and administrative system is the most appropriate for including regulations for access and benefit-sharing, those area(s), which might vary from country to country, should be changed accordingly to ensure that the user of a genetic resource has negotiated a bioprospecting arrangement based on prior informed consent according to the law of the country of origin of the genetic resource or knowledge.

III. CONCLUSIONS AND RECOMMENDATIONS

49. The regime on access and benefit-sharing which has been set up by the Convention is still under development. Best practice is just emerging and no final conclusions can be drawn from the experience which has been gained so far. It is therefore important to review and readjust measures to implement Article 15 on a regular basis.

50. The Conference of the Parties might wish to consider to take the following decisions regarding the implementation of Article 15:

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

2. to initiate a process, for example through a technical committee of SBSTTA, through an expert group or by other means, to elaborate on the above guidelines in considering best practices and case studies on benefit sharing;

3. to urge Governments, regional economic integration organizations and other international, regional and national competent organizations

a) to send to the Secretariat information which updates information on measures and guidelines for activities covered by Article 15, including information on their implementation in time for each meeting of the Conference of the Parties.

b) to submit to the Secretariat experiences on the implementation of Article 15 and access and benefit-sharing arrangements on the national or regional level in time for each meeting of the Conference of the Parties.

c) to have included in the national report requirements the obligation to report on changes in law and policy concerning access to genetic resources and on measures regarding benefit-sharing.

4. to urge Governments to deposit legal documents such as constitutional changes, laws and executive orders with the Secretariat on the Convention Biological Diversity and in hardcopy and, if available, electronic form.

5. to request the Secretariat

a) to compile information on bioprospecting arrangements, material transfer agreements and access-and-benefit-sharing arrangements, for example through contacting the private sector, and to disseminate the information in a standardised form through the Clearing-house mechanism.

b) to request the Secretariat to disseminate information submitted according to 2 a and b and 3 through the Clearing-house mechanism.

c) to improve on the guidelines in using the information and experiences submitted by Governments and relevant bodies and to report back to the COP on a regular basis.

6. to request the GEF to give special emphasis to the following program priorities for assistance to developing country Parties:

a) stock taking activities,

b) formulation of access legislation and incentive measures, and

c) implementation of specific benefit sharing initiatives

(See also UNEP/CBD/COP/4/21, para. 58).

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ADDRESSING THE FAIR AND EQUITABLE SHARING OF THE BENEFITS ARISING
OUT OF GENETIC RESOURCES: OPTIONS FOR ASSISTANCE TO DEVELOPING COUNTRY
PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY

Note by the Executive Secretary

The attached note has been jointly prepared by the Secretariat of the CBD
and the Secretariat of the GEF in response to decision III/5, paragraph 7
of the Conference of the Parties to the Convention on Biological Diversity.

Introduction

Background and mandate of the paper

1. In paragraph 7 of Decision III/5, Additional guidance to the financial mechanism, adopted at the third meeting of the Conference of the Parties (COP) to the Convention on Biological Diversity (CBD), the COP “[r]equests the Secretariat of the Convention and the Global Environment Facility to collaborate in preparing, for consideration by the Conference of the Parties at its fourth meeting, a proposal on the means to address the fair and equitable sharing of the benefits arising out of genetic resources including assistance to developing country Parties”.
2. This paper has been prepared in response to the request of the COP, and is the result of a collaborative effort by the Secretariats of the CBD and the Global Environment Facility (GEF). The objective of the paper is to assist the Conference of the Parties in its consideration of steps that Parties may consider undertaking with a view to addressing the objective of the Convention concerning the fair and equitable sharing of the benefits arising out of genetic resources.

The concept of benefit sharing in the CBD

3. Under Article 1, the objectives of the Convention are “the conservation of biological diversity, the sustainable use of its components and 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”.
4. The Convention can be interpreted broadly as an instrument to promote the equitable exchange, on mutually agreed terms, to genetic resources and associated knowledge, innovations and practices, in return for appropriate sharing of benefits. Provisions of the Convention that assist a party in promoting the sharing of the benefits arising out of genetic resources include Art.15.5 (access and prior informed consent), Art. 15.4 (access on mutually agreed terms) and Art. 8 (j) (third aspect: sharing of benefits arising out of the use of knowledge, innovations and practices of indigenous and local communities).
5. These provisions are also 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.19.1 and 19.2) and financial resources and financial mechanism (Art.s 20 & 21).
6. The issue of benefit-sharing has also been addressed, directly or indirectly, by several decisions of the COP, including III/5, III/14, III/15, III/16, III/17, III/22. This meeting of the COP will deal with benefit sharing in Agenda item 16, “Matters related to benefit-sharing”, under three sub-items: 16.1, “Measures to promote and advance the distribution of benefits from biotechnology in accordance with Article 19 (Handling of Biotechnology and Distribution of its Benefits)”; 16.2 “Means to address the fair and equitable sharing of benefits arising out of genetic resources”; and 16.3, “Compilation of views of the Parties on possible options for developing national legislative, administrative or policy measures, as appropriate, to implement Article 15 (‘Access to Genetic Resources’)”. This paper

addresses the sub-item 16.2. Based on various resources

and associated knowledge, innovations and practices from local and indigenous communities. A synthesis of the findings in the case studies is provided in the information document UNEP/CBD/COP/4/Inf.xx. A set of some typical case studies/The case studies themselves has/have been made available in document UNEP/CBD/COP/4/Inf. xx

Assistance to developing country Parties

7. Many organizations assist developing countries in meeting the objectives of conservation, sustainable use, and benefit sharing of the Convention on Biological Diversity. These include bilateral and multilateral development agencies, foundations, non-governmental organizations.
8. The Conference of the Parties to the Convention on Biological Diversity (CBD) designated the GEF to serve as the institutional structure to operate the financial mechanism of the CBD on an interim basis (Article 39 and Decisions I/2 and II/6). The GEF is a mechanism for international cooperation for the purpose of providing new and additional grant and concessional funding to meet the agreed incremental costs of measures to achieve agreed global environmental benefits in its four focal areas, including biological diversity. Article 21 of the Convention provides that the Conference of the Parties is to determine the policy, strategy, program priorities and eligibility criteria related to the access to, and utilization of, the resources of the Financial Mechanism. To date, the Conference of the Parties has not approved specific guidance to the GEF concerning benefit sharing.
9. Benefit sharing in a broad sense is already becoming standard practice in many biodiversity-related activities. Stakeholder involvement, participation and sharing in the project's benefits are increasingly perceived as essential ingredients of technical, social and financial sustainability, and therefore indispensable conditions for a projects' success.

Scope of the paper

10. The three objectives of the Convention on Biological Diversity are closely inter-related. No biological resources will be available for sustainable use unless they are properly conserved; on the other hand, there will be few incentives for conservation and sustainable use, unless biological resources generate benefits for, *inter alia*, local stakeholders and the country of origin, which are the principal custodians of biological diversity.
11. This first, joint exploration of the issue of benefit-sharing by the CBD and GEF Secretariats takes as its mandate the language of the CBD itself. The paper will confine itself to an examination of sharing of the benefits arising out of utilization of genetic resources, and of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity, as defined in the CBD.

12. Broader context. As discussed in the rest of the paper, fair and equitable sharing of genetic resources' benefits requires undertaking legislative, administrative and capacity building measures in the countries of origin of these resources. However, there are broader dimensions of the problem, including legislation in user countries on exchanges of genetic resource, and international regimes of intellectual property rights, related to the trade of genetic material. Initiatives to be taken by non-recipient countries, as well as issues related to international negotiations (e.g. farmers rights in the negotiations on the International Undertaking on Plant Genetic Resources) fall outside the scope of this paper, and will be addressed only in the context of possible synergies with country-driven initiatives undertaken in developing country Parties to the Convention on Biological Diversity.

1. Definitions and scope

2.1 Genetic resources

13. Article 2 of the Convention defines genetic resources as “genetic material of actual or potential value” and genetic material as “any material of plant, animal, microbial, or other origin containing functional units of heredity”. The scope of the access and benefit-sharing provisions of the Convention are limited to those genetic resources provided by Contracting Parties that are countries of origin of such resources, or Parties that have acquired genetic resources in accordance with the Convention, as set out in Article 15(3) and the relevant definitions in Article 2¹.

2.2 Benefit sharing

14. The Convention mentions the sharing of benefits in several articles, but does not define ‘benefit’, ‘sharing’, or the ‘sharing of benefits’. Consequently, the meaning of benefit-sharing is open to interpretation within the letter and spirit of the Convention as a whole. Any interpretation of benefit-sharing needs to address the nature of ‘benefits’; how the obligation to share benefits arises; with whom benefits should be shared (who are the beneficiaries?); how to quantify and allocate benefits between beneficiaries; measures to promote the sharing of benefits; and the mechanisms by which benefits can be delivered to beneficiaries. These issues are reviewed below.

2.3 Benefits

15. Benefits can be either monetary or non-monetary in nature. Monetary benefits include collection fees, royalties and research grants. Non-monetary benefits can be environmental, social or economic in nature. They include benefits-in-kind, such as technology transfer of hardware, software and know-how; training, joint research, capacity- and institution building, and creation of employment opportunities. What constitutes a ‘benefit’ that can be shared is limited only by the imagination and ingenuity of the partners involved.

2.4 The trigger for benefit-sharing: prior informed consent

16. According to the Convention, access to genetic resources requires the prior informed consent of the Contracting Party providing the resources (Article 15.5), unless otherwise determined by that Party. 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)). Prior informed consent is thus the trigger for benefit-sharing.

¹ This excludes from the remit of the Convention’s provisions on access and benefit-sharing all genetic resources, such as those in *ex-situ* collections, acquired before the entry into force of the Convention in December 1993, or acquired by non-Parties.

17. Requirements to obtain prior informed consent provide an opportunity for those whose consent is sought to reach 'mutually agreed terms'² (Art.15.4) with those seeking access, and to stipulate the exact nature of the benefits to be shared. Various measures for reaching and recording such agreement on the sharing of benefits include access legislation, partnerships and contracts, which are described in section 3 below.

2.5 Beneficiaries

18. The CBD makes access conditional to prior informed consent from Contracting Parties. However, access legislation in different countries should take into account the interest of different stakeholders, including local communities, indigenous groups, protected area management boards, and owners, holders and administrators of land. In some national measures, benefit-sharing with such groups is explicitly required³.
19. Other stakeholders whose involvement or prior informed consent may be required in national measures include the departments of environment, development, science and technology, trade and industry, health education and tourism in central or state government, regional and local offices of government, protected area management boards and municipalities, *ex-situ* collections, universities and research centers, and non-governmental and inter-governmental organizations.

2.6 "Fair and equitable" benefit-sharing

20. Several sources are likely to be involved in a determination of fairness and equity. These range from national authorities that regulate access, grant prior informed consent and negotiate mutually agreed terms with applicants for access and agreements reached between parties to specific arrangements, to courts and tribunals charged with deciding disputes concerning breaches of access legislation or contracts.
21. Assessment of fairness and equity entails tackling issues of quantification and valuation of (a) the benefits that arise from using genetic resources and knowledge; (b) the contributions from different stakeholders to the creation of these benefits; (c) the benefits provided in exchange for access to, and use of, genetic resources; and (d) the allocation of benefits between different beneficiaries. 'Best practice', in terms of common market transactions, may offer a useful benchmark.
22. The allocation of benefits arising from the utilization of genetic resources should fairly reflect the efforts contributed by the different stakeholders in making genetic resources available (through conserving, allowing access to, providing information on, collecting, and conducting research on them).

² The phrase 'mutually agreed terms' appears in various articles of the Convention 15.4; 16.3; 19.22 and as 'mutual agreement' in 18. 5.

³ For example, the Philippines Executive Order No. 247 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".

23. A number of conditions can contribute to a fair and equitable sharing of benefits from genetic resources. One is a conducive policy setting, where measures such as access legislation, incentives, partnerships and contracts are encouraged, monitored and enforced. Another is adequate capacity to negotiate on the part of provider country authorities, local and indigenous communities and other stakeholders. To counteract inequality of bargaining power, such groups may need training in negotiation skills, law, and an understanding of the markets for genetic resources, the economics of product development, the risks and time frames involved, and knowledge of best practice in partnerships.

2.7 Mechanisms for sharing benefits

24. Institutional frameworks can help ensure that benefits are delivered to the appropriate beneficiaries. These include partnerships between institutions that allow technologies to be transferred between them, trust funds that can receive and distribute financial benefits, non-governmental organizations or citizen groups that enable a community to make joint decisions and enter into legally binding agreements, and networks, journals and internet facilities that enable information to be shared.

2. Measures for benefit sharing

25. According to Article 15(7) of the Convention, Contracting Parties are to “take legislative, administrative or policy measures”... “with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources”. This leaves the field open for the Parties to design measures of their choosing to facilitate benefit sharing. In practice, the measures most commonly adopted are access legislation, incentive measures, partnerships and contracts.

3.1 Access legislation

26. National measures on access to genetic resources, in forms such as laws, executive orders and regional regulations, have already been adopted in some countries such as the Philippines and countries participating to the Andean Pact. Most access legislation contains definitions of terms such as ‘genetic resources’ or ‘prior informed consent’, set out the scope of their application, and designate appropriate authorities empowered to take decisions on access applications. Access legislation provisions generally contain both procedural and substantive elements. The procedural elements typically set out the steps that must be followed by an individual or institution applying for permission to explore for genetic resources. The substantive elements often set certain conditions that an applicant must fulfill to gain access to genetic resources, such as protecting biodiversity during the access activities, and providing certain benefits in exchange for permission to collect.

27. National measures on access to date have commonly required the following ‘benefits’ to be shared in exchange for access: participation of nationals in research; sharing of research results, including discoveries; deposit of voucher specimens in national institutions and access by nationals to specimens lodged in international collections; support for research in conservation; technology transfer, such as donation of equipment and technologies derived from endemic species; capacity building of institutions and indigenous and local communities; and fees, royalties and other financial benefits.

3.2 Incentive measures

28. Incentives are inducements for companies, communities and individuals to undertake certain activities in their own interest. Incentive measures are designed to encourage stakeholders to engage in benefit sharing activities *out of their own initiative* (as opposed to complying with an external norm or law).

29. Incentive measures to promote benefit-sharing include taxes raised on the sale of goods derived from genetic resources and used to support benefit-sharing activities, tradable bioprospecting permits, and demarcation of property rights. Some incentive measures purport to promote benefit-sharing by influencing the supply of genetic resources. These include export permits, and tax and investment policies to encourage the transfer of technology and capacity building.

30. Both legislative and non-compulsory incentive measures have also been proposed in countries which are users of genetic resources. These include import requirements; procedural and/or substantive changes in intellectual property law requiring disclosure of country of origin and/or proof of prior informed consent; tax policies to encourage technology transfer and joint research; provision of financial resources (for example to trust funds); and concessional loans to support activities that facilitate the sharing of benefits.

3.3 Contracts

31. While several developing countries are now introducing access legislation, the majority of countries has not yet enacted such legislation. In the absence of access legislation, contracts between providers and users of genetic resources can introduce and clarify benefit-sharing obligations. Even in those countries where access and benefit-sharing measures are in place, these measures often require individual arrangements to be captured in a contract⁴. Material transfer agreements frequently clarify royalty sharing arrangements between the various parties, and can be a tool for allocating benefits among beneficiaries.
32. Contracts are the most common way of recording 'mutually agreed terms'. Historically, before the advent of either the Convention or access legislation covering benefit-sharing, collecting permits, memoranda of understanding between institutions exchanging genetic resources and expertise, material transfer agreements, and partnership agreements were the standard means for setting out benefit-sharing obligations.

3.4 Partnerships

33. Rarely does one individual or institution possess both the authority and the technological, human, institutional and financial resources necessary to conduct all the activities involved in accessing and utilizing genetic resources. More often, a network of different institutions is involved, performing a range of functions such as collecting genetic resources or traditional knowledge, granting access on certain terms, conducting various kinds of research, and possibly developing and marketing commercial products derived from the resources. The different institutions involved in these activities may enter into partnerships, in which genetic resources, traditional knowledge or their derivatives are exchanged for other benefits.
34. The rights and responsibilities of the individuals and institutions involved in a partnership are usually clarified in a contract or partnership agreement. Complementary arrangement can take many forms including small-scale loans to finance community entrepreneurs, memoranda of understanding for cooperation between two scientific research institutes, and agreements between governments and companies specifying the terms of access to genetic resources for screening.

⁴ See, for example, the Philippines Executive Order and Implementing Regulations, and Decision 391 of the Andean Pact.

3. Facilitating benefit sharing: options for assistance to developing countries

35. Section 3 has illustrated that there is a range of measures that developing country Parties to the Convention may wish to undertake in order to promote the sharing of benefits arising out of the use of genetic resources. In discussing options for assistance to these Parties, there are two issues that have to be considered. The first one concerns broad strategic aspects. The second regards possible options for Parties to consider in seeking assistance. These two issues are discussed below.

4.1 Strategic considerations

36. Complementarity of objectives. In order to meet the Convention's fundamental objectives, assistance should be targeted to activities that promote benefit sharing, and at the same time support conservation and/or sustainable use of biological diversity.
37. Process orientation. Section 3 has highlighted a set of key activities that may promote fair and equitable benefit sharing. These include the establishment of access legislation, the identification of incentive measures, the formation of partnerships and the negotiation of contracts. A common element of all these is the importance of the "process" dimension. Processes of dialogue and consultations among domestic stakeholders are key consensus-building tools for the development of a country's approach to benefit sharing, and for determining the appropriate mix of access and incentive measures. Another important set of processes include those required for conducting negotiations and reaching agreements for partnerships and contracts, both within recipient countries and with partners outside the country.
38. Benefit sharing can be promoted by facilitating those country-driven processes. Resources employed in supporting dialogue, consultations and capacity building for benefit sharing, can help in 'leveling the playing field' for the various stakeholders, thereby contributing to fairness and equity.
39. Enabling partnerships. In several of the cases illustrated in section 3, promoting benefit sharing is tantamount to facilitating cooperation among parties interested in transactions involving the exchange of genetic resources on a sustainable basis. A dimension of the facilitative role of assistance to developing country is to help create conditions conducive to "fair and equitable" negotiations among prospective partners (as defined in section 2). Strengthening the capacity of stakeholders likely to be involved in access-related activities, through improvement of legal and technical knowledge, is an example of interventions that would help leveling the playing field.

40. Removing obstacles. In some cases, there may be opportunities for mutually advantageous exchanges of genetic resources between parties in developing and developed countries. These opportunities may go unseized if the former are at a disadvantage vis-à-vis the latter (and hence unwilling to negotiate with them), because of limited access to informational, technical or managerial resources. These limitations may effectively act as an obstacle to benefit sharing.
40. In the process of developing a strategic approach to benefit sharing, countries may realize that they in fact do face barriers to "fair and equitable" negotiations and agreement. In these cases, assistance to developing countries would catalyze financially sustainable solutions, through removing obstacles⁵ to exchanges of genetic resources which otherwise would be in the economic interest of domestic stockholders to undertake.

⁵ The GEF Operational Strategy and the GEF policy on incremental cost discuss the role of the GEF in removing the institutional, information or organizational obstacles or barriers that prevent recipient countries from selecting environmentally friendly technologies and management options out of their own initiative. GEF Operational Strategy, page 6. GEF/C.7/Inf. 5, "Incremental Cost".

4.2 Option for assistance

41. In order to ensure programmatic, long-lasting benefits, as well as efficient use of resources, developing countries Parties may want to integrate benefit sharing activities in existing or planned national biodiversity strategies or national environmental action plans. Because of the different steps that may need to be followed for that purpose, developing countries are likely to sequence their efforts. The different steps may be clustered in: a) stock taking exercises, b) development of strategies and plans for their implementation, and c) implementation of specific initiatives.
42. Assistance to developing Country Parties may be provided at each stage of this sequence, as discussed below. The order of presentation of the different activities is not mandatory; rather, it tries to encompass the various needs that developing countries may have in a logical path leading from planning to implementation of benefit sharing.

Stock-taking activities

43. Stock-taking activities may consist of assessments of the current legislative and regulatory frameworks on access to genetic resources, evaluations of strengths and weaknesses of the country's institutional and human capacity, and consensus building among the country's different stakeholders. Some stock-taking activities may be conducted with a regional focus in instances where the sharing of neighboring countries' experiences may result in the harmonization of existing or planned access legislation.
44. Stock-taking activities, which may be carried out through workshops, consultants assistance to national experts preparing reports, public consultations or others initiatives, would also help countries laying out options for further benefit sharing activities, such as access legislation, incentive measures or project level initiatives (discussed below). Consultations to be undertaken in the context of stock-taking activities may also help identify which groups among the different stakeholders (local and indigenous communities, academic and research centers, private sector, public agencies) are likely to play a major role in the development and implementation of the country's approach to benefit sharing.
45. In some cases, stock-taking may require addressing, through country-driven, targeted research, issues like:
 - identification of stakeholders, and potential partnership participants;
 - financial sustainability: revolving funds, cost-sharing and other options;
 - issues of traditional knowledge and intellectual property rights;
 - assessment of overseas markets.

Access legislation and incentive measures

46. Through stock-taking activities, some countries may identify framework arrangements for sharing of benefits arising out of genetic resources as a national priority. These may be the introduction of access legislation, modifications to the existing biodiversity strategy to include benefit sharing provisions, or the design of incentive measures that would facilitate the formation of partnerships, or the negotiations of contracts.
47. In those cases, assistance would be provided to help developing Countries undertaking activities required for the identification, design and implementation of access legislation (including the necessary regulatory system) and incentive measures. Broad principles guiding assistance would be flexibility to respond to different national situations, and adaptation to experiences gradually accumulating over time. Where appropriate, the formulation of regionally harmonized access legislation would be encouraged.

Specific initiatives

48. In parallel to processes of stock-taking and access legislation or incentive measures design, those countries that have identified benefit sharing as a national priority may be assisted in the implementation of specific project initiatives.
49. In conformity with some of the strategic considerations discussed earlier, a reasonable principle for support to specific initiatives would be to stress 'processes', *i.e.* the creation of national conditions conducive to fair and equitable sharing of benefits, arising out of genetic resources. Some key measures which are likely to contribute to these processes include: capacity building, entrepreneurial development, facilitating financial sustainability (e.g., revolving funds, cost sharing), institution building or strengthening, targeted research.
50. Capacity building. An area of particular relevance is capacity building. In some cases, there may be specialized skills which need to be developed in-country, such as for taxonomists or other scientists; these may include basic technological skills (e.g. extraction, chemical analysis, purification).
51. Entrepreneurial development. Significant capacity building efforts would be directed at 'leveling the playing field' among key stakeholders involved in the process of defining how to share benefits from genetic resources. For example, appropriate technical training would strengthen or enhance legal, administrative, and negotiation skills. These would help forge partnerships for research and commercial use purposes. Local communities who are keepers of the genetic resources or have specific knowledge on their use, may be the primary beneficiaries. Emphasis may be given to the development of entrepreneurial strategies (community based, market based) and specialized skills (financial, legal, administrative) which improve business acumen. Attention would also be paid to project design arrangements that ensure financial sustainability, such as revolving funds or cost sharing schemes.

52. Institutional capacity. Sustaining benefit sharing over time is likely to require mechanisms that ensure continuity of relevant processes. Recipient country institutions which can contribute to promoting benefit sharing over time may be both at the central level (government ministries or specialized technical agencies) and the local level (e.g., traditional healers organizations). Contributing to the formation of institutions, or to the strengthening of existing ones, may help create a framework conducive to benefit sharing, rather than supporting activities on a case by case basis.
53. Targeted research. Targeted research efforts would include market analysis, assessments of traditional knowledge systems, including innovations and practices of indigenous and local communities related to genetic resources as prerequisite for benefit sharing.

Synergies among development organizations

54. As there are many organizations that assist developing countries in fulfilling the obligations of the Convention, there may be a number of opportunities for synergies in development work that may help promoting benefit sharing.
55. For example, the Implementing Agencies (IA) of the GEF (the United Nations Development Program, the United Nations Environment Program, and the World Bank) support a host of development activities in sectors with a clear bearing onto the sustainable and equitable use of genetic resources: for example, reforms of land tenure systems, support to traditional systems of natural resource management in indigenous people communities, development of human and institutional capacity in natural resource management.
56. Where relevant GEF projects already exist, these can provide lessons and suggestions for replication of benefit sharing activities to be funded through the Implementing Agencies' regular programs. In other cases, GEF may provide seed money for capacity building and development of alliances and partnerships, which may be subsequently expanded at larger scale through the Implementing Agencies.

Broader aspects of benefit sharing

57. Apart from studies and assessments to be undertaken in the context of stock-taking activities, development of access legislation or incentive measures, and specific initiatives, a separate area for investigation concerns some of the non-country specific aspects of benefit sharing. As discussed in section 1, fully realizing benefit sharing may require addressing broader issues, like intellectual property rights, linkages between access legislation and trade agreements, legislation on genetic resources in user countries etc. In this cases, there may be opportunities for synergies between research supported by organizations entrusted with the appropriate thematic mandate (e.g. WIPO, WTO, OECD, UNCTAD) and activities implemented through direct assistance to developing country Parties.

4. Conclusions

The Conference of the Parties, in its consideration of the means to address the fair and equitable sharing of benefits arising out of genetic resources, may wish to give special emphasis to the following program priorities for assistance to developing country Parties: a) stock taking activities, b) formulation of access legislation and incentive measures, and c) implementation of specific project initiatives.

In particular, assistance to developing country Parties should help them integrate benefit sharing into national biodiversity strategies or action plans through:

- a) stock-taking activities, such as for example, assessments of the current legislative and regulatory frameworks on access to genetic resources, evaluations of strengths and weaknesses of the country's institutional and human capacity, and promotion of consensus building among the country's different stakeholders;
- b) for those developing country Parties that have identified arrangements for benefit sharing as a national priority, through:
 - the development of access legislation or incentive measures;
 - specific benefit sharing initiatives, such as capacity building, entrepreneurial development of local and indigenous communities, facilitation of financial sustainability of projects promoting the sustainable use of genetic resources, and appropriate targeted research components within biodiversity projects.

