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Access to Genetic Resources and Fair and Equitable Sharing of Benefits arising from their Utilization

This information package on *"Access to Genetic Resources and Fair and Equitable Sharing of Benefits arising from their Utilization* is a contribution of the Inter-Agency Technical Committee (ITC) to the Fourteenth Meeting of the Forum of Ministers of the Environment of Latin America and the Caribbean, to be held in Panama City from the 20th to the 25th November 2003.

The United Nations Environment Programme (UNEP) prepared this document. It has received inputs from the Governments of Brazil, Cuba, Honduras, Mexico, Nicaragua, Saint Lucia and Uruguay, as well as from the Economic Commission for Latin America and the Caribbean (ECLAC), the World Bank (WB) and from the United Nations Food and Agriculture Organization (FAO).

I. Background

1. To deal with the theme of biodiversity, it must be understood that all life on Earth forms part of a larger interdependent system that it interacts with and depends on other non-living components of the planet such as the atmosphere, oceans, freshwater, rocks and land. Biological diversity or "biodiversity" is the variety of life in all forms, levels and combinations. It represents the variability within and among all ecosystems, species and genetic material. Biodiversity is, then, an attribute of life, in contrast with "biological resources", which are the tangible biotic components of ecosystems. The essence of the concept is reflected in the interrelationship of genes, species and ecosystems. Biodiversity forms the chain of life of which we are an integral part and on which we are completely dependent.

2. The term biodiversity covers various interrelated aspects. Biodiversity is generally understood in terms of a wide variety of plants, animals and microorganisms. However, biodiversity also includes genetic differences within each species; in plant varieties and animal breeds, for example. Chromosomes, genes and DNA – the building blocks of life – determine the unique characteristics of each individual and each species. Another aspect of biodiversity is the variety of ecosystems such as deserts, forests, wetlands, mountains, lakes, rivers and agricultural landscapes. In each ecosystem, the living creatures, including human beings, form a community in which they interact with each other and with the air, water and land that surround them.

3. The number of species, including insects and microorganisms, is estimated at approximately 12 million. This diversity in species has emerged through genetic mutations and expansion towards new niches over the past 4.5 billion years. More complex organisms and speciation only occurred towards the end of this period. These events are still under study, but it seems they have generated the degree and extent of present-day biodiversity. It is thought that further speciation will not occur in present times and that biodiversity has reached its maximum level. Thus, biodiversity should be considered a non-renewable resource whose potential cannot be replaced and will never be reproduced by modern technology.

4. Biodiversity is therefore valuable not only for its variety *per se*, but also because it is the result of a 4-billion-year evolutionary process. Consequently, biodiversity has entered into a state of fine-tuning in relation to physical conditions and its ability to adapt to changing circumstances. It acts as a buffer against future dangers in the life-supporting ecosystems.

5. The theme of access to genetic resources and the equitable distribution of benefits consist of a variety of complex problems related to governmental policies in several senses, but also to domestic and global markets. As a source of foods, industrial products, medicines and other goods, on the one hand, and as an essential base of the evolutionary process of life on the planet, on the other, genetic resources and products arising from biological diversity have, in general, gained enormous importance, both economically and ecologically. Additionally, the specific weight that biotechnology now has on the economies of the industrial countries makes it a decisive factor for the development of agriculture and the pharmaceutical industry, as well as the expansion of the immense markets associated with these sectors.

6. The region of Latin America and the Caribbean is distinguished by its outstanding wealth in terms of biodiversity, since it contains 40 per cent of the earth's biodiversity, including 8 of the 25 land ecosystems recognized as having the earth's greatest

biological wealth. Jointly, they have more than 46,000 plant vascular species, 1,597 amphibian species, 1,208 reptile species, 1,267 bird species and 575 de mammal species. More than half of the member countries of the Group of Like-Minded Megadiverse Countries, which include 70 per cent of the planet's biological diversity and 45 per cent of its cultural diversity, are in Latin America (8 of 15 countries).

7. Unfortunately, this region is also distinguished by the dangerous and rapid disappearance of endemic species, which is affecting all levels of the region's general economic, social and political development process. That is why there is now an indispensable need for the preparation and implementation of initiatives to promote sustainable development and biodiversity conservation through improved biodiversity practices and uses.

A. The Convention on Biological Diversity

8. At the United Nations Conference on Environment and Development (UNCED, 1992 Rio Summit), as a major breakthrough, a global Convention on Biological Diversity (CBD) was concluded. This Treaty was the outcome of lengthy negotiations, initiated by the Governing Council of UNEP in 1989.

9. The Preamble starts by recognizing the intrinsic value of biological diversity together with its ecological, genetic, social economic, scientific, educational, cultural, recreational and aesthetic value. It further refers to the special needs of developing countries for new and additional financial resources and for appropriate access to relevant technologies, which are perceived as essential to address biodiversity loss. The Preamble further describes biodiversity and its conservation as a common concern of humankind (for the first time in a global treaty). It also refers to the precautionary and the inter-generational equity principles.

10. Art 1 of the Convention sets out three main goals:

a) The conservation of biological diversity;

b) Sustainable use of the components of biodiversity; and

c) Sharing the benefits arising from the commercial and other utilization of genetic resources in a fair and equitable way

11. The CBD is based on the principle of national sovereignty over genetic resources. The sovereign rights of States over their natural resources are recognized and mentioned in the Preamble and the text (articles 3 and 15.1). Article 15.1 states that: *"Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation".*

12. In accordance with the CBD, the authority to regulate access to genetic resources arises from the sovereign rights of States. The principle of national sovereignty over genetic resources is not up for discussion. But the fact that the exercise of these rights comes up against special difficulties is another matter (particularly in relation to the possible non-exclusivity of sovereign rights and the difficulty of controlling access to genetic resources).

13. It should also be noted that the CBD sets certain legal limits on sovereignty rights. In fact, emphasis is placed on national sovereignty is offset by recognition that the conservation of biological diversity is a common concern of humankind (Preamble) and by the obligation of each Contracting Party to endeavour "…to create conditions to facilitate access to genetic resources…by other Contracting Parties…and not to impose restrictions that run counter to the objectives of this Convention" (article 15.2).

14. The CBD adds that "Access, where granted, shall be on mutually agreed terms…" (article 15.4). This is linked to the concepts of prior informed consent (article 15.5) and the sharing of benefits (article 15.7).

15. In accordance with article 15.7 of the CBD, the Contracting Parties shall take legislative, administrative or policy measures for "sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms".

16. Furthermore, the Convention on Biological Diversity encourages the Contracting Parties to equitably share, the benefits arising from the utilization of knowledge, innovations and traditional practices (article 8j).

17. Sustainable use is defined in Art 2 of the Convention as

> *"…using the components of biodiversity in a way and at a rate that does not lead to the long-term decline of biological diversity, thereby maintaining its potential to meet the needs and aspirations of present and future generations."*

18. The third objective of the CBD, namely the fair and equitable sharing of benefits deriving from the use of genetic resources is of particular importance to developing countries. They hold most of the world's biological diversity but feel that, in general, they do not obtain a fair share of the benefits derived from the use of their resources for the development of products such a high-yielding crop varieties, pharmaceuticals and cosmetics. Such a system could reduce the incentive for the world's biologically richer but economically poorer countries to conserve and sustainable use their resources for the ultimate benefit of mankind.

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

19. The fifth Conference of the Parties of the CDB established an Ad Hoc Open-ended Working Group on Access and Benefit-sharing to develop guidelines and other approaches. The Bonn Guidelines, prepared by this Group, were adopted by the sixth Conference of the Parties in 2002.

20. The Bonn Guidelines indicate detailed procedures to facilitate access to genetic resources on the basis of the country of origin's 'prior informed consent' and on 'mutually agreed terms'. The guidelines provide guidance to Parties in the development of benefit sharing regimes while promoting capacity building, transfer of technology and the provision of financial resources.

21. Although compliance with the guidelines is voluntary, they provide the first widely accepted criteria for national licensing of access to genetic resources and influence legislation in many countries. The Bonn Guidelines provide guidance to national governments, stakeholders and collectors/users of genetic resources on terms that might be included in access agreements.

B. World Summit on Sustainable Development (WSSD)

22. This World Summit represents the international community's progress in protecting genetic resources. The Johannesburg Plan of Implementation, paragraph 42, indicates that implementing the Convention on Biological Diversity (CBD) is the key tool for the conservation and sustainable use of biological diversity and the fair and equitable sharing of benefits arising from genetic resources. The Plan states that biodiversity plays an important and critical role in crucial issues such as poverty eradication and

sustainable development in general, and that one of its goals is to achieve a significant reduction in the current rates of biodiversity loss by the year 2010.

23. The Johannesburg Plan of Implementation also refers to the need to conclude satisfactorily the processes under way in various intergovernmental entities that adopt decisions on these issues.[1] This goes hand in hand with the need to develop synergies and create mutual backing, while promoting constructive discussions and debate on the relationships between the CBD obligations and the obligations of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization, as called for in the Doha Ministerial Declaration.

24. Among the activities mentioned in the Johannesburg Plan of Implementation, paragraph 42, include the negotiation, in the framework of the CBD and taking into account the Bonn Guidelines, of an international system to promote and protect the fair and equitable sharing of benefits arising out of the utilization of genetic resources.

C. Latin American and Caribbean Initiative for Sustainable Development (ILAC)

25. The ILAC was approved at the World Summit on Sustainable Development (WSSD) in 2002 and incorporated into paragraph 67 of the Johannesburg Plan of Implementation. It was developed in response to the need to give a practical sense to the WSSD in the Latin American and Caribbean region by reflecting the region's unique traits, vision and goals, to address the environmental problems and to assist in identifying priorities in achieving sustainable development. Through the ILAC, key guiding goals and indicative purposes for sustainable development in the region were established, explicitly including access to genetic resources and the fair and equitable sharing of benefits arising from them, in a manner compatible with the CBD.

II. Problems Related to the Theme of Access to Genetic Resources and the Fair and Equitable Sharing of Benefits

26. Important legal and political factors directly or indirectly related to the issue of access and equitable distribution of benefits complicate discussions and pose enormous risks to the regulatory processes in which several countries are now immersed. Intellectual property rights on new plant varieties and products resulting from biotechnology; the legal status of resources in *ex situ* conditions and legal systems of access applicable to such resources; the knowledge, innovations and practices of local communities and indigenous peoples associated with biological diversity; and the developing countries' demand for technology transfer are some of the most representative unresolved issues that pose theoretical and practical problems and have important implications for the viability of the access and benefit distribution systems being developed.

27. The absence of clear and well-defined legal systems of mutual benefit to biodiversity owners and receivers means that the bioprospecting used to facilitate the selection and extraction of genetic and biochemical resources that could result in commercial products may easily lead to biopiracy.

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(1) WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore; and the Open-ended Special Group on Article 8j) and related provisions of the CBD regarding traditional knowledge.

28. The lack of protection of indigenous people's traditional knowledge seriously endangers the survival of the communities themselves, since the appropriation of their knowledge and traditional practices deprives them of all rights over such knowledge.

29. The greatest risk, however, lies in the uncontrolled exploitation of biodiversity by pharmaceutical, food and cosmetic industries that act unsustainably, endangering biodiversity in the Latin American and Caribbean region. Expansion of the agricultural frontier over forests is a pivotal issue in the dangerous loss and degradation of genetic resources in the region, just as the over-exploitation, depletion and destruction of forestry resources, particularly in the Amazon basin, pose a serious threat to biological diversity.

30. There are 834 million hectares of tropical forests and 130 million hectares of other types of forests in the region, and they cover 48 per cent of the total land surface. (FAO, 2001). Argentina, Bolivia, Brazil, Colombia, Mexico, Peru and Venezuela contain 56 per cent of regional total, covering more than 160 million m^3 of timber; that is, one third of the world total. Unfortunately, the region also holds the record in deforestation rates, since the annual average is 0.48 per cent (which varies from 1.2 per cent in Mesoamerica to 0.4 per cent in South America; in the Caribbean, there is a net gain of 0.3 per cent). A total of 5.8 million hectares of natural forest cover were lost each year between 1990 and 1995. Of the 418 million hectares of natural forests lost throughout the world in the past 30 years, 190 million hectares were lost in Latin America (FAO, 2001). The total forest area of the region decreased by 46.7 million hectares between 1990 and 2000.

31. Similarly, losses of marine biological resources are an essential factor to be taken into account in planning better environmental management. Most of the Latin American and Caribbean economies still depend on the growth of the export sector and the net income of foreign capital, apart from their consequences on the environment. These types of policies characteristically fail to incorporate environmental costs.

A. Loss of biodiversity

32. The extinction of species and their habitats and the destruction of ecosystems not only constitute an ecological tragedy, but also have profound implications for social and economic development. Estimates indicate that at least 40 per cent of the world economy and 80 per cent of people's needs in the developing countries are linked to biological resources. It should be understood that not only for local communities, whose livelihoods and cultural survival depend largely on goods and services provided by forests and other ecosystems, but for all humanity, the problem is not limited to the conservation of certain species, but rather to the conservation of the entire ecosystem.

33. The loss of life diversity, among other factors, gives rise to reduced diversity of species and genes (extinction of species and loss of genetic material); changes in ecosystems (alterations in trophic chains, land degradation, altered water flows from basins, increased sedimentation, effects on the climate) and changes in the global system (less carbon sequestration and increased carbon dioxide in the atmosphere and changes in temperature/rainfall models in the case of deforestation). Biodiversity loss also reduces the possibilities of medical discoveries, sustainable economic development and adaptive responses to challenges such as climate change.

34. Some causes of the loss in biodiversity are:

a) Habitat loss or modification (indiscriminate extraction and exploitation of resources, opening of forests through energy production and highway construction programmes, usually accompanied by "modernization" policies and the granting of concessions that fail to take into account biodiversity; expansion of the agricultural frontier; and development of single-crop farming, which is a serious threat to biodiversity, particularly in forest ecosystems).

b) Reduction in productive ecosystems, weakening of their capability to face natural disasters (indiscriminate resource extraction and exploitation).

c) Loss of the cultural identity and lifestyle of local communities and indigenous peoples whose life is deeply rooted in the environment (for food and shelter, as well as spiritual beliefs).

d) Genetic modifications, characteristics of uniformity in plant varieties (in many cases, this is a requisite for protection eligibility as varieties in some intellectual property systems) and the introduction of exogenous species.

35. The world is becoming increasingly concerned about the disappearance of forms of life on Earth. Being able to address the problem requires dealing with its causes appropriately and taking the necessary measures at the legislative, institutional and policy levels to adopt appropriate biodiversity frameworks, including questions of access to genetic resources and equitable distribution of the benefits arising from their utilization. Adverse consequences resulting from the lack of these frameworks are necessarily reflected in the loss and deterioration of biodiversity.

36. Putting an end to the current models of biodiversity loss will require genuine political will in both the developing world and the developed world. To a great extent, current conservation activities are still limited to firefighting. Only in recent years, has there been an attempt to think beyond the immediate causes of loss in this field and to consider the fundamental causes of such loss. Participation of the local population as stakeholders is an important sep forward. Conservation, both in the field and at the political level, will require additional financial and political capital resources.

B. Intellectual Property Rights (IPR) and Recognition of "Formal" and "Informal" Innovation

37. The world's existing mechanisms for intellectual property rights (IPR) were reasonably designed, in principle, to comply with formally well-established and sound economic structures. Here, technological development focuses principally on the economic exploitation of knowledge. Consequently, research is conducted and financed when concrete financial earnings are expected.

38. In accordance with intellectual property law, innovative knowledge must fulfil various factors to receive legal protection. Innovative processes are inevitably institutionalized by the requirements of the legal framework. Innovation may possibly become a "formal" procedure, recognized if it fulfils specific parameters and legal requirements. Thus, research and development in the developed countries falls within what is known as "formal innovation", which is appropriate for modern and market societies.

39. Particularly with regard to the biotechnology domain in the framework of international trade relations and the introduction of a standard international system for intellectual property rights (IPR), the world community has encountered complex issues that have so far been ignored. The growing importance of biodiversity and genetic

information in the food, pharmaceutical and cosmetic industries has resulted in a struggle to protect innovative knowledge associated with biological material. Industry has been accused of "biopiracy" practices involving not only indigenous genetic resources, but also the traditional knowledge associated with them.

40. Indigenous peoples and local farmers have had a longstanding and significant relationship of interdependence with the land and the environment where they live. These lands and environments are vital to their survival, since they provide them with food and medicinal products. The development of these products is the result of interaction between these people and their environment.

41. Diverse plant varieties have been produced over generations to resist specific pests or diseases. The curative properties of many plants have been discovered and developed over the years to cure specific diseases in the community. Any improvement in the knowledge and biodiversity has been part of community efforts and for the community's well-being. Indigenous farmers and local communities never considered it necessary to protect their knowledge. This type of innovation, unrecognized in legal structures, is known as "informal innovation".

42. However, a large part of indigenous and traditional knowledge is important to the world food supply and to the development of diverse pharmaceutical and cosmetic products, which draws the attention of industries. Unsurprisingly, these industries have taken advantage of the lack of protection to exploit indigenous and traditional knowledge and biodiversity and, in most cases, without remuneration for the communities involved. Under national laws for domestic or foreign industries, many countries with formal intellectual property systems have already obtained intellectual property protection for knowledge and products based substantially on "informal innovation".

43. For local communities and indigenous peoples, the greatest risk of limiting the recognition of intellectual property rights to those known and established in international agreements is that, in the future, they will buy the products of these companies at high prices or that farmers will pay royalties for using products which they originally developed and have improved, used and protected for centuries.

44. Consequently, the cultural and intellectual contribution of traditional indigenous knowledge is in danger of being wiped out and lost forever. The implications for global biodiversity, food security and environment in general are unpredictable in detail, but may entail great harm.

45. A major concern is that acquiring and defending IPR protection in the context of the established system requires access to information, good legal counsel and financial resources. The legal significance of protection, as it now exists, may frequently lie beyond the reach of indigenous peoples and local farmers.

III. Framework and Perspectives for the Protection of Traditional Knowledge

A. Expansion of State freedom for designing systems to protect traditional knowledge

46. Two multilateral agreements now generally form the legal framework for the protection of traditional knowledge: the Convention on Biological Diversity and the International Treaty on Plant Genetic Resources, which has not yet entered into force. Both agreements grant the member States broad powers to regulate traditional knowledge protection measures and define pertinent policies. Furthermore, the language

used is very general, ambiguous and subject to great leeway in interpretation ("in so far as possible", "as applicable", "shall promote", "shall advocate", etc.).

47. In recent years, both the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) have held talks on issues related to the protection of traditional knowledge by intellectual property rights. The discussions in both forums have gained a new impetus that can be capitalized by the Member States interested in the protection of traditional knowledge. On the one hand, the WIPO has established the Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore; on the other, the recent Ministerial Declaration of Doha has introduced traditional knowledge into the sphere of future WTO trade negotiations.

48. In the regional sphere, Decisions 391 (Common System on Access to Genetic Resources) and 486 (Common System on Industrial Property) of the Andean Community include principles contained in the CBD, basically in reference to access contracts. They also provide defensive protection of traditional knowledge; that is, they are aimed at preventing wrongful appropriation of knowledge without the authorization of its holders. Decision 391, however, leaves the door open for the Andean Community to adopt a decision to more specifically protect knowledge, innovations and traditional practices of indigenous, Afro-American and local communities, taking into account their characteristics through, for example, the development of a *sui generis* protection system.

B. Freedom to use protection instruments

49. In considering instruments to be used to protect traditional knowledge, the CBD, the International Treaty on Plant Genetic Resources and the instruments of the Andean Community all fail to make reference to intellectual property instruments or instruments of other types. Since there are no specific indications in the framework of the WTO or the WIPO, the Member States are completely free to decide on the best instrument, based on the protection objectives they have defined.

50. However, in the discussions held in most of these forums, there seems to be an understanding that intellectual property rights play a direct role in the protection of traditional knowledge. The wrongful use or appropriation of traditional knowledge through intellectual property systems makes it necessary not to ignore discussion on the defensive protection of traditional knowledge in relation to intellectual property mechanisms and especially patents.

51. The possibility of establishing national and international registries or databases of traditional knowledge has also been proposed, and there are opposing opinions regarding the proposals.

52. Some people believe that the intellectual property instruments could be effective mechanisms for granting rights that would allow the sharing of benefits arising from the use of traditional knowledge. But international property rights, as they were conceived of and as they exist at the present time, are not appropriate instruments for the protection of traditional knowledge. Characteristics such as the entitlement of only one person to hold the right, the order of priority in claiming the rights, the necessary non-dissemination of the relevant knowledge prior to the granting of the right, etc. place the mechanisms of intellectual property rights outside the reality in which traditional knowledge is immersed.

C. Definition of protection principles

53. Even when none of the legal instruments analysed specifies what principles should be taken into account for the protection of traditional knowledge, some principles can be drawn from these instruments and from an analysis of the discussions carried out in various international forums:

a) Prior informed consent, as well as mutual agreed conditions for access authorization (CBD and the International Treaty on Plant Genetic Resources);

b) Decisions 391 and 486 of the Andean Community include revelation of the technical knowledge origin in the presentation of the access contract. This principle has also been recognized in CBD working and expert groups;

c) These Andean Community decisions explicitly express the right of the local communities and indigenous peoples to decide on the manner in which their knowledge is used;

d) According to article 8(j) of the CBD, the States shall promote the application of traditional knowledge. This calls for capacity building to enable local communities and indigenous peoples to make use of the systems to protect their knowledge.

e) The Group of Like-Minded Megadiverse Countries discusses the possibility of including proof of the legal origin of genetic resources as a requisite for granting rights related to them.

D. Effectiveness of the benefit-sharing systems

54. The International Treaty on Plant Genetic Resources, as well as the CBD and the Andean Community decisions analysed, call for the fair and equitable sharing of benefits obtained from the use of traditional knowledge.

55. The Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising Out of Their Utilization can serve the States as a base for developing legislation and policies to promote fair and equitable sharing of benefits.

56. In view of the economic importance of this aspect of protecting traditional knowledge, ways to make the sharing effective should be sought. And the need to determine which mechanisms to use (information exchange, access to technology, *in situ* training, the conducting of research in the genetic resource's country of origin, etc.) must not be forgotten.

E. The need to coordinate the efforts carried out in each of the different forums

57. The previously mentioned organizations are not the only entities responsible for coordinating work so as to prevent the duplication of efforts in the search for a system to protect traditional knowledge. The countries interested in obtaining this protection are the main parties that can and should coordinate the distinct efforts undertaken through their actions in the different forums. The following possible relationships serve as examples:

a) The discussions now being carried out in the CBD on revealing the origin of knowledge, as well as the work being conducted in the WIPO to develop intellectual property systems, can help provide a better understanding for future work reviewing the Agreement on Trade-Related Aspects of Intellectual

Property Rights (TRIPS), advocated by the WTO Doha Ministerial Declaration (See Annex);

b) Possible development of common regulations and policies on the protection of traditional knowledge in the sphere of sub-regional integration organizations in the Latin American and Caribbean region could also be useful in advocating the inclusion of new principles in the WIPO, WTO and FAO; and

c) Assessment and follow-up of the benefit-sharing mechanism of the International Treaty on Plant Genetic Resources may provide guidance for possible modifications in the instruments of international forums.

IV. Options for action

58. Access to genetic resources and the fair and equitable sharing of benefits arising from their utilization is a theme that presents numerous thorny problems, which makes integrated and coordinated activities indispensable at the national, sub-regional and region levels in Latin America and the Caribbean.

59. Factors unique to each country, such as the legal and institutional framework, as well as the framework for international cooperation, are of vital importance, since through them it is possible to help improve conditions for access to genetic resources and the fair and equitable sharing of benefits arising from their utilization, so as to protect the environment and humankind, while, at the same time, respecting the sovereignty of States over their natural resources.

60. Having appropriate legal tools, as well as specific institutional structures and arrangements in this field, is indispensable. Furthermore, the possibility of harmonizing genetic resource access and benefit-sharing systems is an option that warrants serious consideration in a region such as Latin America and the Caribbean, where there are many factors in common, including biodiversity, ethnic groups, traditional knowledge, legal systems and even language in each of its two sub-regions (Latin America and the Caribbean), in addition to sub-regional integration agreements that have given rise to organizations that carry out activities of a sub-regional scope.

61. One -or several- harmonized systems in this field would allow standard treatment in the region, which would give us equal power for negotiating with companies of the pharmaceutical, food and cosmetic industry that wish to explore and exploit our biodiversity and would free us from being concerned about the existence of differing systems in countries that share the same biodiversity. It would prevent cases in which one country that shares genetic resources with another allows indiscriminate access to such resources and cancels out any regulation that countries may have diligently established in relation to the access to their genetic resources also found in other countries with more permissive regulations. Shared legal frameworks among the nations in the region can make measures to protect genetic resources more efficient, reverse environmental deterioration and mitigate poverty.

62. Such systems would also enable the countries of the region to negotiate with greater weight and firmness at international forums, and achieve greater success in protecting the vast biodiversity in our region.

63. These measures could be carried out by compiling existing national and sub-regional legislation in order to determine the need for amendments to such legislation or for the preparation of new regulatory frameworks based on a related examination of lessons

learned. Sub-regional or regional workshops should also be held to allow the exchange of experience on how such regulatory frameworks have been working.

64. Latin American and Caribbean positions on becoming parties to international environmental conventions should also be defined. These positions and consequent decisions must necessarily be followed by concrete commitments. If several countries of the region jointly decide to become parties to a multilateral environmental agreement after having considered the benefits that it entails, it will certainly improve the possibilities of its success in the region as a whole.

65. To attain that objective, provisions can be made to facilitate consultations aimed at adopting common regional positions on genetic resource access and benefit-sharing negotiations in related international forums (i.e. CBD, WTO/TRIPS, WIPO, FAO).

66. In particular, it should be noted that one of the most important challenges in Latin America and the Caribbean lies in full compliance with and enforcement of environmental regulations when they exist and are appropriate. If they are incipient, a previous and priority step is to examine the legislation in force in order to adapt or adopt the necessary legislative instruments at the national level. The challenge facing us in the present decade is to advocate the enforcement of legal regulations on environment as appropriate tools to meet the demands for modern environmental management at high rates of efficiency on the basis of the objectives and goals in the environmental policies of the countries of the region and in the context of their own realities and priorities. Although several countries in the region already have appropriate institutional, public policies and legislation for environment and the protection of natural resources, many of these countries lack sufficient resources and appropriate institutional capacity to amply achieve the objectives of their legal mandates.

67. It will be necessary to continue providing support through studies on genetic resource access and benefit-sharing, together with studies on the conservation and sustainable use of biodiversity and the development of pertinent legislative expertise.

68. Environmental awareness-building and training are also key activities that should not be left out of related follow-up plans. These activities should benefit not only the executive branch, through the respective ministries, councils or commissions entrusted with implementing the law, but also the legislative branch, since the parliaments are where the agreements are ratified and the laws take shape, and the judicial branch, since the courts are responsible for enforcing the legal regulations.

69. Initiatives such as those jointly advocated in the international community by the members of the Group of Like-Minded Megadiverse Countries on issues such as the access to genetic resources and the sharing of benefits arising from their utilization, also need to be supported and strengthened.

70. The region's efforts in the specific matter of genetic resource access and benefit-sharing should also be aimed at conducting an analysis of alternatives for an international system to promote and protect the fair and equitable sharing of benefits arising from the utilization of genetic resources, as established in the Johannesburg Plan of Implementation (Paragraph 42 o).

71. It is also important for the region to explore the possibilities of becoming part of projects to build capacities in the field of genetic resource access and benefit-sharing. The Group of Like-minded Megadiverse Countries already has a UNEP/GEF proposal, which requires the endorsement of the beneficiary countries in order to initiate the preparatory stage of a project for the entire Group or concrete sub-regional projects.

72. A large part of the activities suggested above form part of the UNEP Initiative on access to genetic resources and equitable sharing of benefits arising from their utilization. Other activities included in the initiative refer to the promotion and recognition of traditional knowledge under any "type" of "formal" system of "intellectual property rights"; the harmonization of agreements related to biological diversity – and other environmental agreements - with pertinent sub-regional, regional and world trade agreements, including the WTO Agreement on Trade-Related Plant Genetic Resources (TRIPS), which also makes it necessary to carry out capacity building and strengthening programmes in this field.

73. There is also an expected need for coordinating activities with the Capacity 2015 Programme to support local capacity-building to protect and develop the traditional knowledge of local communities and indigenous peoples for fair and equitable sharing in the benefits arising from the use of genetic resources.

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Annexes

Annex I
Inventory

I. International Agreements in this field

A. Convention on Biological Diversity (CBD)

1. There are now 187 States parties to the Convention on Biological Diversity, 33 of which are Latin American and Caribbean.

2. The Convention provides for three types of access:

a) access to genetic resources;

b) access to pertinent technology, including biotechnology; and

c) access by the State providing the genetic resources to the benefits arising from the utilization of the genetic material in the development of biotechnology.

3. Article 15 recognizes that the authority to determine access to genetic resources rests with the national governments and is subject to national legislation, and it establishes that each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources and not to impose restrictions that run counter to the objectives of the Convention. Where access is granted, it shall be on mutually agreed terms (Article 15.4)[2] and subject to prior informed consent of the Contracting Party providing such resources (Article 15.5).

4. It should be noted that the Convention provisions apply equally to the flow of genetic resources in both directions. The definitions of genetic resources or genetic material (Article 2) do not in any way exclude from the scope of the Convention material modified genetically or through biotechnological procedures, which means the issue is closely linked to access and technology transfer.

5. Each Contracting Party, recognizing that technology includes biotechnology and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention, undertakes to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment (Article 16.1)[3]. The Parties have the obligation to take legislative, administrative or policy measures, as appropriate, with the aim that the Contracting Parties, in particular those that are developing countries, which provide genetic resources, are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights (Article 16.3).

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[2] Article 15.4 states: “Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article”.

[3] The CBD recognizes that *"in the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights "* (Article 16.2).

6. The CBD provisions go even further by establishing the obligation of the Contracting Parties to take legislative, administrative or policy measures, as appropriate, with the aim that the private sector facilitates access to joint development and transfer of technology for the benefit of governmental institutions and the private sector of developing countries. (Article 16.4).

7. Access to the results and benefits arising from the biotechnologies based on genetic resources provided by Contracting Parties and, in particular, the developing countries, shall be promoted and advanced on a fair and equitable basis at the bilateral level on mutually agreed terms (Article 19.2). The Contracting Parties have the obligation to take legislative, administrative or policy measures to share 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. (Article 15.7).

8. As regards the issue of indigenous peoples and local communities, the Preamble of the Convention recognizes the close and traditional dependence of many indigenous and local communities on biological resources. Article 8 (j) provides that each Party:

> *…shall respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.*

9. In order to address the implementation of this Article, an Ad Hoc Working Group was established by the fourth Conference of the Parties (COP 4). Considering the Working Group's report the COP 6 adopted recommendations of cultural, environmental and social impact assessment regarding projects likely to have an impact on indigenous people's land or waters in 2002. The COP has further taken decisions on the participation of indigenous and local communities in the operations of the Convention. These include the encouragement of Parties to include representatives of indigenous communities in their delegations, also in the Ad Hoc Working Group on Access and Benefit-Sharing.

10. Article 10 (c) further requires States to protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements.

11. With respect to the issue of living modified organisms and biosafety, Article 19 of the Convention establishes the obligation of the Parties to take the necessary measures to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties. It is also necessary for the Parties to take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. It is clearly indicated that such access shall be on mutually agreed terms.

12. Finally, the Convention envisages that the Parties would evaluate the need and modalities for the adoption of a protocol that sets out appropriate procedures like an advance informed agreement in the field of safe transfer, handling and use of any living modified organisms (LMOs) resulting from modern biotechnology that may have adverse

effects for conservation and sustainable use of biodiversity. Such a Biosafety Protocol was adopted in 2000.

a) Ad hoc Open-ended Working Group on Article 8(j)

13. Both at its third session in November 1996 (COP-3) and at its fourth session in May 1998 (COP-4), the Conference of the Parties considered aspects of intellectual property related to traditional knowledge under the basic guidance of Article 8 (j). In April 1998, COP-4 established an Ad Hoc Open-ended Working Group on Article 8 (j) to form a work programme to implement Article 8 (j) and relative provisions, as well as to assist the member countries in developing regulations and other forms of protection for the themes included in Article 8 (j).

14. The work programme is aimed at implementing each of the elements contained in Article 8 (j). The Working Group has also been entrusted with preparing a certain number of guideline proposals to help the Parties develop appropriate legislation or policies that will be in harmony with the provisions in Article 8 (j) of the Convention and will make them workable.

15. The report of the first meeting of the Working Group (Seville, March 2001), presented at COP-5, recognized the importance of a sui generis system for the protection of traditional knowledge and invited the Parties to develop legislation for the protection of traditional knowledge, incorporating the recommendations of the Panel of Experts on Access and Benefit-Sharing.

16. For the second meeting (Montreal, February 2002), the CBD Secretariat prepared a document on an assessment of the effectiveness of current sub-national, national and international instruments, particularly instruments on intellectual property rights, that may have impacts on the protection of the knowledge, innovations and practices of indigenous and local communities. The purpose of the assessment was to determine the synergies among these instruments and the objectives of Article 8 (j). The assessment may also contribute to the preparation of guidelines to provide the Parties and governments with assistance in preparing legislation or other instruments, including the possibility of a *sui generis* system, and the definitions of important terms and concepts related to Article 8 (j) and related provisions. Among the main conclusions of the assessment, it was found that the present systems to protect intellectual property could be used to protect traditional knowledge, although there are traditional knowledge components for which *sui generis* protection could be necessary. The role that two principles established in the CBD play in protecting traditional knowledge in the contractual sphere is also recognized (prior informed consent and mutually agreed terms to ensure benefit-sharing).

17. During discussion of the Secretariat document, the Working Group approved a text containing recommendations for the sixth Conference of the Parties. Some of the Working Group's main recommendations to the Conference of the Parties appear below:

a) To promote having the Parties, in their requests for intellectual property rights, disclose the origin of traditional knowledge and take into account the requirements of prior informed consent and mutually agreed clauses.

b) To request the Parties to protect traditional knowledge through a combination of approaches, including the various protection instruments that can be appropriately applied to traditional knowledge.

c) To urge the Parties to examine the viability of establishing their respective national and community registries or databases of traditional knowledge, taking into consideration common law and practices and in compliance with national laws.

b) Panel of Experts on Access and Benefit-Sharing

18. The Panel of Experts on Access and Benefit-Sharing was established by COP-4 to reach a common understanding of the basic concepts and to explore all options for access and benefit-sharing under agreed terms, including the guiding principles, guidelines and codes of good practices for agreements on access and benefit-sharing.

19. When Article 8 (j) of the CBD promotes the preservation, conservation and maintenance of traditional knowledge, it also refers to the sharing of benefits arising from their use. Consequently, this working group has also included issues linked to the protection of traditional knowledge on its agenda.

20. During its first meeting, held in Costa Rica in October 1999, the experts dealt with different options for access and benefit-sharing and reached conclusions on prior informed consent, mutually agreed terms, information needs and capacity building, which they presented to the COP-5.

21. The COP-5 decided to convene the Panel of Experts on Access and Benefit-Sharing once again for it to carry out work on issues that could not be addressed during the first meeting and to report its conclusions to the Ad Hoc Working Group on Access to Genetic Resources and Benefit-Sharing. The meeting, held in Montreal from 19 to 22 March 2001, adopted conclusions with regard to:

a) the experience of users and providers in relation to access to genetic resources and benefit-sharing, including, under this item, experience regarding intellectual property rights, traditional knowledge and access and benefit-sharing;

b) the determination of approaches related to the participation of direct stakeholders in the access to genetic resources and benefit-sharing; and

c) the study of supplementary options to deal with access and benefit-sharing in the framework of the CBD.

c) Ad hoc Open-ended Working Group on Access and Benefit-Sharing

22. The Working Group met for the first time in Bonn from 22 to 26 October 2001. It was established by the COP-5 with the mandate to prepare guidelines and other criteria to be presented to the Conference of the Parties to assist the Parties and stakeholders in the development of terms for prior informed consent, mechanisms for benefit-sharing and mechanisms to ensure respect for and the preservation and maintenance of traditional knowledge, taking into account the results of the two meetings of the Panel of Experts on Access and Benefit-Sharing.

23. This Working Group has included the protection of traditional knowledge on its agenda, since benefit-sharing is of great importance to indigenous and local communities and Article 8 (j) promotes the fair and equitable sharing of the benefits arising from the utilization of such knowledge. In recent years, this knowledge has been used by modern industry to develop new products and techniques with neither the participation nor consent of the knowledge holders, who, furthermore, have received none of the benefits obtained.

24. The Working Group prepared the proposal of the Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising Out of Their Utilization. The document on the role of intellectual property rights in the implementation of agreements on access and benefit-sharing, prepared by the Secretariat was also reviewed by the Working Group. As a result of the examination, the Working Group drew up some recommendations, which it presented to the COP-6 for the future work of the Member States. Of special importance to the protection of traditional knowledge is the recommendation that the COP ask the Parties to the Convention and the Governments to promote the disclosure of traditional knowledge in applications for intellectual property rights when an invention involves genetic resources or uses them in its preparation. This disclosure could help to track compliance with the prior informed consent and mutually agreed terms in accordance with which the access to such resources was granted.

B. The Cartagena Protocol on Biosafety

25. In January 2000, in Montreal, the CBD Conference of the Parties adopted the Cartagena Protocol on Biosafety and established an ad hoc open-ended Intergovernmental Committee for the Cartagena Protocol (ICCP), entrusted with organizing the first meeting of the Parties to the Protocol. The IPPC has held three working sessions and other Inter-Sessional meetings to discuss specific issues such as compliance with the Protocol, information exchange, and the handling, transfer, packaging and identification of living modified organisms (LMOs).

26. This Protocol is the only binding international agreement that regulates the transboundary movements of LMOs, provides a regulatory framework and creates surrounding conditions for the application of biotechnology in a way favourable to the environment. To date, of the 63 countries parties to the Protocol, 14 are in the Latin American and Caribbean region.

27. The purpose of the Protocol on Biosafety is to help guarantee an appropriate level of protection in the sphere of the safe transfer, handling and utilization of the living modified organisms that result from modern biotechnology and may have adverse effects on the conservation and sustainable use of biological diversity, also taking into account the risks to human health and focusing specifically on transboundary movements.

28. The above objective considers the rapid expansion of modern biotechnology and growing public concern regarding its possible adverse effects on biological diversity, and it also takes into account the risks to human health. Modern biotechnology has great possibilities of contributing to human well-being, if it is developed and used with appropriate safety measures for the environment and human health.

29. The Protocol recognizes the crucial importance to humankind of centres of origin and centres of genetic diversity. In this sense, the limited capabilities of many countries, particularly developing countries, to cope with the nature and scale of known and potential risks associated with living modified organisms was taken into account. In this scenario, it was recognized that trade and environment agreements should be mutually supportive with a view to achieving sustainable development. Thus, it was established in the Preamble that the Protocol should not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements, and at the same time, that the above recital was not intended to subordinate this Protocol to other international agreements.

30. There is a widespread need in the countries of Latin America and the Caribbean to generate greater institutional capacity and an appropriate legal framework at the

national level in each State in order to deal precisely with the content in the Cartagena Protocol, which includes decisive attempts to control the release of genetically modified organisms (GMOs) into the environment and, thereby, to prevent major environmental damage.

31. Some countries already have advanced systems to determine the risks to wild species posed by the release of GMOs, including basic biological information on cultivated, wild and GMO species. The analyses take into account the known spatial distribution of wild and cultivated species, their potential distribution and associated biological and ecological information, which determine whether the wild species may be affected by genetic flow and the formation of hybrids with GMOs. However, this subject area requires specific financial support for scientific research, not only to update the flora and fauna inventories in each nation, but also to install information technology systems to enable observation of distribution potential and possible harm to the environment in real time.

C. Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

32. Within the GATT framework several international negotiation rounds have aimed at harmonizing and facilitating global trade. The TRIPS Agreement is one of the results of the Uruguay Round.

33. The objective of the agreement is set out in Article 7 which states that the protection of intellectual property rights should aim at promoting technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge, in a manner conducive to social and economic welfare; it should also aim at a balance of rights and obligations.

34. The TRIPS Agreement encompasses, in principle, all forms of intellectual property and aims at harmonizing and strengthening standards of protection and providing for effective enforcement at both national and international levels. It addresses applicability of general GATT principles ("national treatment", the "most-favoured-nation") as well as the provisions in international agreements on IP (Part I). It establishes standards for availability, scope, use (Part II), enforcement (Part III), acquisition and maintenance (Part IV) of IPR. Furthermore, it addresses related dispute prevention and settlement mechanisms (Part V). Formal provisions are addressed in Part VI and VII of the Agreement, which cover transitional and institutional arrangements, respectively.

35. Part I of the Agreement contains general provisions and basic principles. In Article 1 the implementation framework is set out for Members. Governments commit themselves to minimum standards, for which compliance is mandatory. Governments are free to increase additional intellectual property rights (IPR) protection and to decide how such protection should be adopted in their own legal system and practice, provided such protection does not contravene the provisions of the Agreement.

36. Part II of the Agreement addresses, in its various sections, the different kinds of IPR and establishes standards for each category (i.e. copyright and related rights, trademarks, geographical indications, industrial designs, patents, layout-designs (topographies) of integrated circuits and protection of undisclosed information -trade secrets).

a) Patents - Protection of Plant Varieties

37. Section 5 of Part II deals with patents. A patent is an IPR granted to inventors. The inventor, as owner of the patent, has the right to exclude any other person from

making, using, selling or importing the invention protected by the patent, for a certain period of time in a given territory.

38. According to the provisions of the Agreement, Members are committed to make patents available for any invention, whether products or processes, in all fields of technology –this includes biotechnology- without discrimination as to the place of invention and whether products are imported or locally produced, provided the requirements of novelty, inventiveness (non-obviousness) and usefulness (capacity of industrial application) are fulfilled.

39. Members can exclude from patentability plants and animals other than micro-organisms, as well as naturally occurring breeding methods. However, Members are required to provide for the patentability of non-biological and microbiological processes such as biotechnological gene manipulation, gene transfer and so on. Members must also provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof (Article 27.3(b)). The complexity of this subject matter prevented a clear definition of the implementation terms and left unresolved differences among the contracting Parties. The main concern is that the current terminology refers to a scientific subject matter, yet remains vague in the legal delimitation of the subject matter, i.e. some of the terms used to define the patentable subject matter are, apparently, scientifically imprecise, leading to legal interpretation problems.

40. At first glance, this regulatory approach of exceptions, and exceptions to exceptions, is somewhat complicated. It reflects, however, the complexity of the issues governing intellectual property rights over living matter. To determine to what extent Members are actually obliged to introduce intellectual property rights on plants and plant varieties, the system of rules and exceptions must be carefully examined.

b) 1999 Review of the Provisions of Article 27.3(b)

41. The TRIPS Council was scheduled in 1999 to "review" Article 27.3(b) of the TRIPS Agreement. The text of the article states that “the provisions of [this] subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement”. Within the TRIPS Council, countries have largely discussed the nature of the review. On the one hand, most developed countries’ delegations consider that the review should be a review of the implementation of the article. On the other hand, most developing countries’ delegations interpret the provision as a mandate to re-open the discussion on the wording of the article, implying a revision of the text. Where that discussion will lead is not predictable.

42. If the review process turns into a revision of the vague wording of Article 27.3(b), the review negotiations will supply a unique opportunity to raise concerns and needs related to plant variety protection. The TRIPS review negotiations will furthermore supply the opportunity to develop a more pragmatic text bringing in the first experiences of implementation and interpretation in practice by the Parties.

43. The Third Ministerial Conference of the WTO took place in Seattle from 30 November to 3 December 1999 and no agreement could be reached there regarding the inclusion of various issues and among them that of IPR, in a Seattle Declaration, which could not be adopted and remained just a “Draft Declaration”.

44. The November 2001 Declaration of the Fourth WTO Ministerial Conference, held in Doha, Qatar, presents two key environmental achievements. First, it includes “the environment” as an agenda item in the new trade round. Second, the Ministers

encourage efforts to promote cooperation between the WTO and UNEP, and other international environmental and development organizations.

45. In the field of TRIPS, the Doha Declaration provides the mandate for negotiations on a range of subjects, among them the trade-related aspects of intellectual property rights, expressed in paragraphs 17 to 19. Paragraph 19 focuses on the necessity for reviewing TRIPS provisions. Two reviews have been taking place in the TRIPS Council, as required by the TRIPS Agreement: a review of Article 27.3(b) and a review of the entire TRIPS Agreement (required by Article 71.1). The Doha Declaration states that work in the TRIPS Council on these reviews or any other implementation issue should also look at the relationship between the TRIPS Agreement and the Convention on Biological Diversity; the protection of traditional knowledge and folklore; and other relevant new developments that member governments raise in the review of the TRIPS Agreement. It adds that the TRIPS Council's work on these topics is to be guided by the TRIPS Agreement's objectives (Article 7) and principles (Article 8), and must take the development dimension fully into account.

46. Regarding the examination of the relationship between the TRIPS Agreement and the Convention on Biological Diversity, it seems to be presented as a neutral exercise since the text does not identify the need for review of the TRIPS Agreement in light of the CBD. It rather mandates the analysis of the existing relationship between the two international agreements. The countries´ positions on the issue are clear, for developed countries there is no conflict between them, while for most developing countries there are several conflicting aspects between these two international agreements that need to be addressed in order to achieve the objectives and principles of the CBD.

47. As far as the "protection of traditional knowledge" is concerned, the wording seems to give more maneuvering space to developing countries. It identifies the need to protect traditional knowledge and not just to study its relationship with the TRIPS Agreement. Traditional knowledge not being covered by the TRIPS Agreement, the statement of the DOHA Declaration opens the door for discussion on the recognition of alternative systems for rewarding "informal innovation".

c) Review of the Implementation of the TRIPS Agreement

48. The TRIPS Council was called to undertake the task of reviewing the implementation of the entire TRIPS Agreement, in year 2000. According to Article 71.1 of the Agreement, the TRIPS Council shall review its implementation five years after the entry into force of the WTO Agreement, and shall "having regard to the experience gained in its implementation" review it two years after the year 2000, and at identical intervals thereafter.

49. It is to be noted that in this case the Agreement's provision explicitly states that the review is a "review of the implementation". This was not done in the case of the "review" mentioned in Article 27.3 b).

d) Alternatives and consequences for the review of Article 27.3.b)

50. Negotiations for the review of Article 27.3 b) provide an exceptional opportunity to express concerns and needs related to the protection of plant varieties. TRIPS Agreement review negotiations furthermore offer an opportunity to prepare a more pragmatic text bringing in the first experiences of the Contracting Parties in the implementation, practice and interpretation of the Agreement. The review possibilities are innumerable. However, some recommendations that constitute valuable contributions and viable alternatives should be noted:

a) *Do nothing*, while offering greater flexibility in the framework of the existing Agreement; an option supported by the United States of America and the European Union;

b) *Extend the patentability exclusions* to include all living organisms and knowledge related to their improvement, conservation and sustainable use (low-cost option); an the option preferred by the developing countries;

c) *Eliminate* the *sui generis* protection of new plant varieties;

d) *Consider the deletion* of Article 27.3 b) entirely, which would eliminate the patentability exclusions of living organisms and intellectual property associated with such organisms; an option defended by some industrialized countries because it would favour biotechnology industries, but it would also eliminate the obligation to protect plant varieties;

e) *Exclude the theme* of biodiversity from the TRIPS Agreement completely, the only way to fully ensure an equitable solution for the communities and peoples in the developing countries; an option supported by the developing countries and NGOs;

f) *Introduce amendments* to the TRIPS Agreement referring specifically to the UPOV Convention, obligating the countries to adhere to the UPOV and apply its special provisions on intellectual property rights; an option supported by the governments of the developed countries and the UPOV;

g) *Add a paragraph* to underscore the concept of "public domain" (State property), allowing the patentability exclusion of inventions based on biological diversity and associated knowledge in the public domain; a very concrete option.

51. To achieve a more equitable solution for all the Members, it is essential for all the Parties who participate in the review to have the same level of knowledge and preparation on the TRIPS Agreement and its consequences. This is the only way to guarantee fair negotiations among the countries and an equitable conclusion to them. UNEP, in its Initiative on Access and Equitable Sharing of Benefits, includes capacity-building and institutional strengthening activities in these fields.

D. International Convention for the Protection of New Varieties of Plants (UPOV Convention)

a) General remarks and legal nature

52. The International Union for the Protection of New Varieties of Plants, UPOV (Union Internationale pour la Protection des Obtentions Végétales), is an intergovernmental organization established in 1961 to coordinate the implementation, at the international level, of the Plant Breeder's Rights (PBR) established by the Convention for the Protection of New Varieties of Plants. The UPOV Convention came into existence in 1961. It was revised in 1972, 1978 and 1991. The 1961 Act of the Convention entered into force in 1968, the Additional Act of 1972 in 1977, the 1978 Act in 1981, and the 1991 Act on 24 April 1998.

53. Currently two States are members of the UPOV 1961 Act, 26 States are bound by the 1978 Act and 25 by the 1991 Act.

b) Objective

54. The UPOV Convention is aimed at ensuring that Member States acknowledge the accomplishments of new plant variety breeders and make available to them exclusive rights of exploitation if their varieties are distinct, homogeneous and stable.

c) Breeder's Exemption and Farmer's Privilege

55. From 1961 to 1991, the UPOV Convention provided for a Breeder's Exemption and, at least implicitly, a Farmer's Privilege, where both principles provide flexibility within the IP protection.

56. According to the Breeder's Exemption, authorization by the breeder is not required either for the utilization of the variety as an initial source of variation for the purpose of creating new varieties or for the subsequent exploitation of such new varieties.

57. Under the 1991 Convention, the only compulsory exceptions to the exclusive right of the breeder are:

a) acts done privately and for non-commercial purposes;

b) acts done for experimental purposes; and

c) acts done for the purpose of breeding and exploiting other varieties, provided they are not essentially derived. The Breeder's Exemption is thus not applicable to essentially derived varieties, i.e. varieties predominantly derived from another (initial) variety which retains the expression of the essential characteristics from the genotypes or combination of genotypes of the initial variety.

58. In accordance with the Farmer's Privilege, farmers are allowed to use their own harvested material of the protected varieties for subsequent sowing on their own farms.

59. The Farmer's Privilege, as it is implicitly recognized under the 1978 Act, allows a broad interpretation and thus, exercise, of the said "privilege". The 1991 Act has narrowed this "privilege" by explicitly including it in its text. According to this Act, the Farmer's Privilege is no longer the general rule but only an exception. In fact, the 1991 Act contains an optional exception that provides that it is up to national governments to decide whether to permit farmers to use the seed of a protected variety for propagation purposes on their own holdings, within reasonable limits and subject to safeguarding the legitimate interest of the breeder (Article 15.2).

d) Discovery and Double Protection

60. Under the 1978 Act, the breeder is entitled to protection whatever the origin, artificial or natural, of the initial variation from which his variety is derived, thus including the mere discovery of a new plant variety. Under the 1991 Act the simple discovery is not sufficient. The breeder must also have developed his variety in order to be entitled to the protection.

61. As far as double protection is concerned, there is an explicit prohibition in the 1978 Act. Under Article 2, a State may provide protection to plant varieties either in the form of Plant Breeder’s Rights or a patent, but once it has opted to protect a plant species by Plant Breeder’s Rights it must not subsequently protect varieties of that same species by a patent. The 1991 Act provides Parties with the possibility of simultaneous protection for the same plant variety by more than one type of intellectual property rights (i.e. they can choose both Plant Breeder’s Rights and patents).

e) Scope of protection

62. The 1978 Act limits the scope of protection to the commercial use, offering for sale and marketing of reproductive or vegetative propagating material of the variety. This means that Plant Breeder's Rights do not extend to the harvested products, while the 1991 Act extends them to the commercial use of all material of the variety. Besides the protected variety itself, the Breeder's Rights extend to varieties that are not clearly distinguishable from the protected variety; varieties whose production requires the repeated use of the protected variety; and varieties that are essentially derived from the protected variety.

63. The 1978 Act requires the authorization of the breeder of a variety for the repeated use of the plant variety only in cases of commercial production of another variety. Authorization from the breeder is required, under the 1991 Act, for production or reproduction, conditioning for the purpose of propagation, offering for sale, selling or other marketing, exporting and importing, stocking for any other purposes. These activities relate to the propagating material, the harvested material (including entire plants and parts of plants) and products made directly from harvested material of the protected variety, provided such material has been obtained through the unauthorized use of propagating material and that the breeder has had no reasonable opportunity to exercise his right in relation to the propagating material.

64. The 1978 Act requires Member States to protect a minimum of five genera or species when becoming a Party to the Convention, and to protect thereafter genera or species on a progressive basis, leading to a minimum of 24 genera or species after eight years. The 1991 Act requires existing Member States to protect all plant genera and species five years after becoming bound by the 1991 Act and requires new Member States to protect all plant genera and species ten years after they become bound by the 1991 Act.

f) Period of Protection

65. According to the 1978 Act, States have to grant Plant Breeder's Rights protection for a minimum period of 18 years for vines, forest trees, fruit trees and ornamental trees, and 15 years in the case of all other species. The duration of the Plant Breeder's Rights has been extended in the 1991 Act to 25 years and 20 years respectively.

E. Agenda 21

66. Agenda 21 is a programme of action agreed to by the United Nations Conference on Environment and Development (UNCED) or the Rio Summit in 1992. This legally non-binding instrument is a broad programme of work to be implemented from 1993 to the twenty-first century by Governments, development agencies, United Nations organizations and independent sector groups in every area where human (economic) activity affects the environment.

67. Chapter 14 of Agenda 21 deals with the plant genetic resources of the world within the context of long term food security, sustainable agriculture and rural development. Chapter 15 addresses the conservation of biological diversity, and Chapter 16 the environmentally sound management of biotechnology.

68. Throughout these chapters Agenda 21 recognizes the importance of indigenous and local communities, their knowledge and culture, and the contribution they can make to protecting biodiversity, and states that they should be rewarded.

69. Agenda 21 suggests the introduction of appropriate measures for the fair and equitable sharing of benefits derived from the sustainable use of biological resources. It

states that Governments should develop measures and arrangements to implement the rights of countries of origin of genetic resources or countries providing them, as defined in the CBD, particularly developing countries, to benefit from the biotechnological development and the commercial utilization of products derived from such resources.

70. The recommendations of Agenda 21 regarding biotechnology focus on the fact that traditional methods and knowledge of indigenous people and their communities should be protected and they should share in the economic and commercial benefits arising from biotechnology. Biotechnology offers new opportunities for global partnerships between industrialized countries, rich in technological expertise, and developing countries, rich in biological resources. Technology transfer, professional training, information gathering, scientific exchanges, research and development, venture capitalization and other capacity building measures should be promoted and accelerated.

71. The role of patent protection and intellectual property rights in the transfer of environmentally sound technology should be further examined. Consideration should be given to assuring developing countries access to technologies covered by proprietary rights. Technology should be transferred on concessional and preferential terms, as mutually agreed, taking into account the need to protect intellectual property rights as well as the special needs of developing countries. Technical cooperation for capacity building, including technology transfer and know-how, should be driven by the individual needs and specific conditions of the recipients.

F. FAO International Treaty on Genetic Plant Resources for Agriculture and Food

72. The first exhaustive international agreement on genetic resources was the International Undertaking on Plant Genetic Resources for Food and Agriculture. It was adopted by the FAO Conference in 1983 as a non-binding instrument to promote international harmony in matters concerning access to plant genetic resources for food and agriculture. The Undertaking, which was adhered to by 113 countries, attempted to "safeguard the prospecting, conservation, evaluation and availability, for the improvement of plants and for scientific purposes, of plant genetic resources of economic and/or social interest, particularly for agriculture". In 1993, the FAO Conference, pursuant to the petition in Agenda 21, Chapter 14, and resolution 3 of the Final Act of the Nairobi Conference, adopted a review of the International Undertaking, so that, among other measures, it would be compatible with the CBD. This series of decisions initiated the review of the International Undertaking which, after seven years of negotiations, concluded in November 2001, with the adoption by the FAO Conference of the International Treaty on Plant Genetic Resources for Agriculture and Food. The Treaty has been negotiated by more than 150 member countries of the FAO Commission on Genetic Resources for Food and Agriculture.

73. The objectives of this legally binding Treaty are the conservation and sustainable use of plant genetic resources for food and agriculture, and the fair and equitable sharing of benefits arising from their utilization in harmony with the Convention on Biological Diversity for sustainable agriculture and food security. The Treaty, which is at the point where agriculture, environment and trade converge, is on an equal standing with other international agreements on trade and environment and is a multilateral instrument to promote cooperation and synergy among these sectors. This Treaty was established as an important instrument to safeguard the continuous availability of plant genetic resources and the sharing of benefits needed by the countries to achieve the universal objectives of food security and sustainable agriculture.

74. The Treaty, which covers all the plant genetic resources important to food and agriculture, develops a general framework for the management and exchange of these resources. The Treaty establishes a set of measures to promote an integrated approach to the prospecting, conservation and sustainable use of plant genetic resources for food and agriculture.. The Contracting Parties will, as applicable, incorporate these measures into rural and agricultural development policies and programmes. The Treaty includes a number of requirements and priorities for international cooperation and technical assistance in the field of plant genetic resources for agriculture and food. It also provides for the formulation of a financing strategy to mobilize funds for assistance activities, plans and programmes aimed, above all, at small-scale farmers in developing countries.

75. Through the Treaty, the countries agree to establish a multilateral system of access and benefit-sharing to be applied to a list of more than 64 major crops and forages that were chosen, taking into account the criteria of food security and interdependence. Resources from the System may be obtained for purposes of utilization and conservation for research, improvement and training. When a commercial product is obtained using these resources, the Treaty calls for mandatory payment of an equitable part of the resulting monetary benefits, as long as the product cannot be freely used by others for subsequently research and improvement. If others can use it, the payment is voluntary. The benefits arising from the utilization of these resources, including commercial benefits, shall be shared fairly and equitably through the following mechanisms: information exchange, access to technology and its transfer, capacity-building and the sharing of the benefits arising from the marketing.

76. The Treaty recognizes the enormous contribution that farmers and their communities have made and continue making to the conservation and development of plant genetic resources, and this recognition is the basis of the Plant Breeder's Rights. The Treaty grants the governments the responsibility of enforcing these rights through a number of possible measures that include the protection of traditional knowledge and the right to participate equitably in the sharing of benefits and in the adoption of national decisions regarding plant genetic resources.

Other international negotiations in the FAO Commission on Genetic Resources for Food and Agriculture (CGRFA)

77. The conservation and use of genetic resources for food and agriculture appeared on the international agenda long before the idea of a convention on biological diversity emerged. In fact, the FAO Conference established the Commission on Plant Genetic Resources in 1983 to deal with matters concerning plant genetic resources. In 1995 its mandate was extended to include all the components of agro-biodiversity of interest to food and agriculture. Consequently its name was changed to the Commission on Genetic Resources for Food and Agriculture (CGRFA). The main objectives of the CGRFA are to guarantee the conservation and sustainable use of genetic resources for food and agriculture, as well as the fair and equitable sharing of the benefits arising from their utilization for present and future generations. To achieve its objectives, the Commission and its intergovernmental technical working groups coordinate the preparation and supervision of the Global System on Plant Genetic Resources for Food and Agriculture and the Global Strategy on the Management of Farm Animal Genetic Resources. These frameworks include a non-binding international agreement, several codes of conduct, scientific norms, technical mechanisms and global instruments for the conservation and sustainable use of plant genetic resources, such as the Report on the State of the World's Plant Genetic Resources and the Global Plan of Action on the Conservation and Sustainable Use of Plant Genetic Resources.

78. Some elements of the Global System are relevant to international discussions in the field of access to genetic resources and equitable sharing of the benefits, such as the International Code of Conduct for Plant Germplasm Collecting and Transfer. The purpose of this non-binding instrument approved in 1993 is to promote the sound collection and sustainable utilization of plant genetic resources, to prevent genetic erosion and protect the interest both of the germplasm donors and collectors. The Code of Conduct establishes a number of general principles the governments should use in preparing their national regulations or in formulating bilateral agreements on germplasm collection. The Code makes an appeal for the active participation of local farmers and institutions in the missions of collecting and proposes that the germplasm users share the benefits arising from the use of the plant genetic resources with the host country and its farmers. Many countries have used the Code of Conduct in efforts such as providing guidance for collection or they have used parts of it for drafting laws or model laws.

79. The FAO Global Strategy for the Management of Farm Animal Genetic Resources provides a technical and operational framework for assisting the countries in the formulation of international policies for the sustainable management of these valuable resources. In this framework, the countries on the CGRFA warned that the erosion of animal genetic resources constituted a threat to world food security and asked the FAO to coordinate the preparation of a report requested by the countries on the situation of world animal genetic resources. The preparation of this report, which is expected to conclude in the year 2006, is aimed at achieving specific results, including the determination of priorities for preparing a national improved programme for the conservation and sustainable utilization of the genetic resources in the farm animal sector. These national priorities could encompass short- and long-term needs for the creation of institutions, research, the development of information systems, and the formulation of policies, legislation and regulations. Another expected output is a number of recommendations regarding international cooperation, priority spheres, levels and types of cooperation that the countries wish to put into practice, and their proposals of contributions and requirements to ensure that the appropriate strategic interventions are carried out to enable the achievement of sustainable use and conservation of animal genetic resources. In determining national priorities and recommendations for international cooperation, some countries have developed topics regarding access and equitable sharing of benefits.

80. Finally, another intergovernmental CGRFA initiative of relevance to the topics of access and benefit-sharing is the Project for a biotechnology code of conduct in relation to genetic resources for food and agriculture. At its ninth session the Commission received a document on the situation regarding the code of conduct project, based on more than 300 responses from the Member States of FAO and a large number of interested parties in a survey carried out by the Secretariat. Among the matters traditionally included in such a code were issues related to access and benefit-sharing linked to biotechnology, the use of appropriate biotechnologies and the building of public awareness. Among the new issues and concerns identified through the survey were: ethical issues linked to biotechnologies related to genetic resources for food and agriculture; appropriate regulatory frameworks; technologies to restrict genetic use s; biotechnology and increased control over the world agricultural food system; gene flow from genetically modified organisms (GMOs) and the question of responsibility; and universal declarations of FAO on the genome. The CGRFA has asked the FAO Secretariat to prepare a study to determine what still needs to be done in relation to the matters set forth in the document. When preparing the study, pertinent international organizations should be consulted when appropriate.

G. International Negotiations within the framework of the World Intellectual Property Organization (WIPO)

a) Overview of its work on genetic resources, traditional knowledge and folklore

81. Within the framework of the WTO/TRIPS negotiations, many developing country members proposed to initiate work in WIPO because of the need for a study phase before initiating the design and the negotiations of an international framework to protect traditional knowledge. For many developed countries the work in the area of traditional knowledge in the TRIPS Council should be limited to follow up WIPO discussions.

82. It is a fact that in recent years, significant questions have been raised regarding the relationship between intellectual property (IP) and genetic resources, in particular access to genetic resources and benefit-sharing; between IP and traditional knowledge (TK), whether or not associated with those resources; and between IP and traditional cultural expressions (folklore).

83. As the specialized United Nations agency responsible for the promotion of IP worldwide, WIPO has worked in the field of folklore for over thirty years, often in collaboration with the United Nations Educational, Scientific and Cultural Organization (UNESCO), and has, only more recently, considered specific IP issues related to TK and genetic resources.

84. In particular, in 1998-1999 WIPO undertook fact-finding missions to consult with a wide range of stakeholders such as Indigenous and local communities, non-governmental organizations, governmental representatives, academics, researchers and private sector representatives to determine the IP needs and expectations of holders of TK.

b) Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC)

85. In October 2000, the WIPO General Assembly agreed to establish a unique intergovernmental body for debate and dialogue concerning the interplay between IP, TK, genetic resources and folklore. These issues cut across the conventional branches of IP law, and therefore did not fit into existing WIPO bodies, i.e. (i) the Standing Committee on the Law of Patents (SCP); (ii) the Standing Committee on Copyright and Related Rights (SCCR); (iii) the Standing Committee on Trademarks, Industrial Designs and Geographical Indications (SCT); and the Standing Committee on Information Technologies (SCIT).

86. The IGC, has since met, in Geneva, five times, the fifth session took place in July 2003. In September 2003, the Committee will report any further recommendations for action on these work programs to the WIPO General Assembly.

c) Traditional Knowledge

87. The Committee's work programme considers issues such as the role of IP systems in relation to TK, and how to preserve, protect and equitably make use of TK, since this topic has recently been under increasing attention in a range of international policy discussions, on matters as diverse as food and agriculture, the environment, notably the conservation of biological diversity, health, including traditional medicines, human rights and Indigenous issues, cultural policy, and aspects of trade and economic development.

88. The IGC has also worked on both the defensive and the positive protection of TK. The defensive protection of TK consists of measures that ensure that other parties do

not obtain IP rights over pre-existing TK. The positive protection consists of the use of existing legal mechanisms to protect and promote TK. In some countries, legislation has been developed specifically to address the positive protection of TK.

89. Examples of studies carried out by the IGC on the subject include a study on the operational definitions relevant to TK; a review of existing national systems of intellectual property protection for TK; an analysis of the elements for a possible sui generis system for the protection of TK, among others.

d) Genetic Resources

90. The work of the IGC has concentrated on examining the relationship between IP and genetic resources in the areas of contractual agreements for access to genetic resources; legislative, administrative and policy measures to regulate access to genetic resources; and the protection of biotechnological inventions.

91. The Committee's focus on contractual agreements for access to genetic resources is a direct response to a widely-felt need for more information about current practices concerning the IP aspects of agreements on access to genetic resources, and the sharing of the associated benefits deriving from their utilization.

92. Another key area of recent WIPO activity relates to a recent request by Member States to CBD, to carry out a technical study on methods consistent with obligations in treaties administered by WIPO for requiring the disclosure within patent applications of, *inter alia*, genetic resources used in the development of the claimed inventions; the country of origin of genetic resources used in the claimed inventions; associated traditional knowledge, innovations and practices used in the development of the claimed inventions; the source of associated traditional knowledge, innovations and practices; and evidence of prior informed consent (PIC).

93. In July 2002, WIPO issued its Member States with a questionnaire on this subject and has undertaken to provide the resulting technical study to the seventh meeting of the Conference of the Parties to the CBD in 2004.

e) Folklore

94. The IGC's work programme has focused on an on-going technical analysis of the use of existing intellectual property and sui generis approaches for the legal protection of traditional cultural expressions

95. The relationship between IP and folklore raises some specific cultural and policy issues. Accordingly, although, in practice, such expressions may overlap with the broader field of TK, this area has been given a distinct focus in WIPO's work. WIPO uses the term "traditional cultural expressions" (or "expressions of folklore") in the sense in which it is used in the UNESCO-WIPO Model Provisions for National Laws on the Protection of Expressions of Folklore Against Illicit Exploitation and other Prejudicial Actions, 1982, that is, as productions consisting of characteristic elements of the traditional artistic heritage developed and maintained by a community, or by individuals reflecting the traditional artistic expectations of such a community. The four most typical kinds of such expressions include verbal expressions (i.e. stories, poetry and languages); musical expressions (i.e. songs and music; expressions by action (dances, plays and rituals); and tangible expressions (i.e.) paintings, sculptures, pottery, woodwork, jewelry, basket weaving, textiles, carpets, musical instruments and handicrafts.

f) Database of Biodiversity-related Access and Benefit-Sharing Agreements

96. As part of the work of the IGC, WIPO is currently in the process of compiling an on-line, searchable database of biodiversity-related Access and Benefit-Sharing Agreements, with a particular emphasis on the intellectual property aspects of such agreements. The database seeks to provide information on the general approach taken in concluding relevant agreements, and to stimulate the flow of information in this important area, rather than to serve as a database of legal texts and precedents.

97. Other databases and inventories currently being developed by WIPO include Traditional Knowledge Databases and Prior Art; Non-exhaustive Inventory of Traditional Knowledge-related Databases; and Non-exhaustive Inventory of Traditional Knowledge-related Periodicals.

98. While documentation of TK and associated biological resources may be established for reasons including its preservation for future generations, it is considered by some that such documentation could undercut the interests of TK holders. Unless the right steps are taken in advance, documented TK can more readily be accessed, disseminated and used without authorization, for instance contrary to customary laws and practices. Reflecting these concerns, the IGC noted the further development of a toolkit for managing the IP implications of documentation of TK and biological resources. This should heighten awareness of the need to ensure that documentation does not lead to an unintentional loss of rights or of control over TK. According to them, the toolkit will clarify practical options for documentation that do not necessarily place the documented material in the public domain, when communities wish to retain control over it and limit access, for cultural, spiritual, legal or commercial reasons.

II. Regional Agreements in the Field

A. The Group of Like-Minded Megadiverse Countries

99. The Group of Like-Minded Megadiverse Countries was established through the Cancun Declaration, adopted on 18 February 2002, as the final output of the meeting held there at the initiative of the Mexican Government, with the participation of 14 countries, which were subsequently joined by Bolivia. The purpose of the Group is to serve as a consultation and cooperation mechanism to promote common interests and priorities related to the conservation and sustainable use of biodiversity.

100. More than half of the member countries of the Group of Like-Minded Megadiverse Countries are Latin American countries, where 70 per cent of the planet's biological diversity and 45 per cent of its cultural diversity are found.

101. In its Declaration on the Conservation and Sustainable Use of Biodiversity, adopted at the meeting held on the occasion of the World Summit in Johannesburg, the Group underscored the importance of advocating an international system to promote and effectively safeguard the fair and equitable sharing of benefits arising from the use of biological diversity and its components, as well as promoting the development of a *sui generis* system to protect traditional knowledge associated with biodiversity.

102. At its meeting on Access to Genetic Resources, Traditional Knowledge and Intellectual Property Rights, held in November, 2002, in Valle de Urubamba, in Cusco, Peru, the Group adopted a Declaration in which it recognized the crucial importance of genetic resources to the Like-Minded Megadiverse Countries, which are the countries of origin and centres of diversity of genetic resources, as well as the importance of their applications in technological, economic and socio-cultural areas. It recognized that the

mechanisms for access to genetic resources and traditional knowledge should secure the conservation and sustainable use of biological diversity for the countries of origin, with all types of benefits, including monetary benefits, technology transfer, the development of value-added products and improved economies in favour of their peoples, particularly of their local communities. In the Declaration, the Group also recognized its commitment to improve its efforts to promote negotiations, in the framework of the Convention on Biological Diversity and bearing in mind the Bonn Guidelines, towards an international system to promote and safeguard the fair and equitable sharing of benefits that arise from the utilization of genetic resources.

103. The Declaration also includes agreement on actions to, *inter alia*, strengthen or establish a mechanism for cooperation and the exchange of information among the member countries, including case studies and the development of projects in areas such as applicable legal systems in each country, property rights on genetic resources and traditional knowledge, and the promotion of cooperation and information exchange, technology transfer and capacity building among such countries, as well as the exchange of successful experiences in enforcing laws and regulations. Also included are the strengthening of national and regional processes to incorporate the elements contained in the Cusco Declaration into policies and regulations, particularly with regard to genetic resources, traditional knowledge and intellectual property rights.

104. The Group held an Experts Meeting on Institutional Building in Kuala Lumpur, Malaysia, on 21–23 July, 2003. At this meeting the Group agreed to request the Chair of the meeting to table for the consideration and adoption at the next Ministerial Meeting of the Group, to be held in Kuala Lumpur in February 2004, in conjunction with CBD COP-7, the following:

a) The draft Rules of Procedure for the Group of Like-Minded Megadiverse Countries on the organization, meetings and activities of the Group.

b) The Draft Action Plan for the Group of Like-Minded Megadiverse Countries on the priorities, work programme and modalities for consultation and cooperation on biodiversity conservation and sustainable utilization of biological resources.

c) The establishment of a Trust Fund for the Group of Like-Minded Megadiverse Countries as a matter of urgency, in accordance with the principles set out in the Cancun Declaration, in order to finance its activities, develop its capacities as well as promote cooperation on agreed projects for common benefit related to the conservation and sustainable use of biological diversity.

105. Consultations were held on the UNDP Project Proposal to Create a Megadiverse Cooperation Fund (MCF) and the UNEP Proposed Project on Capacity Building on Access to Genetic Resources and Fair and Equitable Sharing of Benefits. The latter is a GEF mid size project for up to one million dollars (on grant basis) on Capacity Building for Access and Benefit Sharing. It encompasses support for further continued work on the Bonn Guidelines including the identification and elaboration of elements for possible inclusion in an international regime on ABS. The meeting agreed to request the Technical Secretariat, with UNEP's support, to further consult the proposal and produce a new version incorporating comments from the member countries. The revised proposal would be considered by the Group at its next meeting in December 2003.

106. The Experts favoured the idea of the Megadiverse Initiative on Biodiversity and Development that was presented by the Technical Secretary. They requested a concrete proposal to be considered at their next meeting. The consultative initiative would be

useful for undertaking research, information sharing, analysis of best practices, as well as for preparing documents and policy recommendations for consideration of the Group.

107. The deliberations of the Kuala Lumpur Meeting were outlined in the declaration known as the Kuala Lumpur Communiqué on Institutional Building that will also be tabled for consideration and endorsement at the next Ministerial Meeting of the Group.

B. Common Regime of the Andean Community on Access to Genetic Resources

108. At the sub-regional level, the States of the Andean Community (Bolivia, Colombia, Ecuador, Peru and Venezuela) have adopted "supranational legislation". In accordance with the Cartagena Agreement, the "Decisions" adopted by the Commission of the Andean Community are directly applicable in the five countries without needing to be ratified. However, the member States need to adopt national regulations, as required, to implement and enforce the Decisions (the structure and establishment of the competent national authority, the definition of procedural aspects and sanctions, etc.).

109. The Andean Community has undertaken several important initiatives related to the establishment of common regimes to harmonize national environmental policies that have an influence on global management and the conservation of regional biological diversity. In 1993, It adopted Decision 345 to establish a common regime for the protection of plant breeder's rights.

110. Decision 391 provides a minimum set of rules for each Member State to implement. More detailed national legislation can be implemented provided it does not fall below the standard set by the Decision. The primary political and economical justification for the common regime was the need to prevent unnecessary conflicting interests among member States over generally shared, easily accessible genetic resources found widely throughout their territories.

111. The Decision applies to:

a) genetic resources of which member States are countries of origin;

b) derivates (derived products include molecules, combinations or mixtures of natural molecules including raw extracts of living or dead organisms (Article 1), i.e. bio-chemicals); and

c) associated "intangible components" – any knowledge associated with the genetic resources or derivates sought.

d) It also applies to the genetic resources of migratory species which by natural circumstances are found within and taken from the areas of jurisdiction of a member State.

112. The common regime does not apply to human genetic resources and their by-products[(4)]; or to the exchange of genetic resources, their by-products, the biological resources containing them or their associated intangible components among indigenous, African-American or local communities for their own use, based on customary practices.

113. Decision 391 defines "access" broadly. It includes obtaining and using genetic resources conserved ex-situ or in-situ, by-products or, where applicable, "intangible components" for research, bio-prospecting, conservation, industrial application or

[(4)] This could be interpreted in the sense that the common regime therefore leaves open the possibility that human genetic resources are still accessible without prior informed consent of or benefit-sharing with the State or the people targeted.

commercial use (Article 1). Intangible components are all individual or collective knowledge, innovations and practices associated with a particular genetic resource or its derived products, whether or not protected by intellectual property rights.

114 The scope of the Andean Community Decision is broad. It applies to all genetic resources for which a member State is a "country of origin" (Article 6). The country of origin is the country which possesses genetic resources in in-situ conditions, including those taken from in-situ sources and found ex-situ (Article 1). Emphasizing the country of origin leaves open the possibility that both wild and domesticated or cultivated species fall within the scope of the Decision, whether or not they are publicly, communally or privately owned.

115. The Decision confirms the precautionary principle by enabling member States to adopt measures necessary to avoid genetic erosion. It also confirms the principle of sovereignty over genetic resources and their derivatives of countries where they are found (Article 5). In this sense genetic resources are either the patrimony of the Nation or property of the State (Article 6) depending on national legislation. It also confirms that biological resources which contain genetic resources or derivates can be subject to the private or collective property rights of individuals or indigenous and local communities. The Common Regime is interesting in this sense because it makes a distinction between the legal status of genetic resources and the biological resources that contain them. Biological resources which contain the genetic materials sought can be subject to private or collective property rights but genetic resources are deemed "inalienable, cannot be seized and have no deadlines, without prejudice to property regimes applicable to the biological resources which contain them, the land on which they are found, or the associated intangible component" (Article 6).

116. As far as conservation and sustainable use of genetic resources and their derivatives are concerned, Decision 391 establishes that they will be regulated by each member State according to the principles and provisions of the Convention on Biological Diversity and the Decision itself.

117. By adopting the Andean Pact Decision 391, member states "recognise and value the rights and the power of decision of indigenous, Afro American and local communities over their traditional knowledge, innovations and practices associated with genetic resources and derivate products thereof" (Article 7). This is to be accomplished through national legislation complementing the Decision.

118. The Common Regime is based upon a common procedure before the relevant national authority, whose steps include:

a) the submission, admission, publication and approval of an access request by the legal or natural person seeking access;

b) the signature of an access contract with the competent authority of the member State in which genetic resources are sought;

c) the adoption and publication of the relevant Resolution; and

d) the registration of the activities related to access in question (Article 16).

119. The access requests and contracts should include conditions such as the participation of nationals from the sub-region in the relevant genetic resources and derivatives research activities; the support to research activities to be carried out within the jurisdiction of the country of origin or any other country of the sub-region, which contribute to the conservation and sustainable use of biological diversity; the strengthening of knowledge and technology –including biotechnology- transfer mechanisms; the provision of information on the background, state of the art or any

other information that can contribute to a better knowledge of the genetic resource; the strengthening and development of the national and sub-regional institutional capacity associated with the relevant genetic resources and their derivatives; the strengthening and development of the capacities of the indigenous, Afro American and local communities as relate to the associated intangible component of the relevant genetic resources and their derivatives; the compulsory deposit of duplicates of all collected materials in the institutions designated by the relevant national competent authority; the obligation to inform the national competent authority about the results of the undertaken research; the terms under which the acceded genetic material can be transferred to third parties.

120. It is important to note that the Common Regime only applies to traditional knowledge where it is associated with the genetic resources sought. Application is indirect and there is no explicit provision referring to prior informed consent. Where genetic resources have an associated "intangible component" an access contract with the state must incorporate an annex which has terms for fair and equitable benefit-sharing (Article 35). Failure to perform annex obligations causes the termination of the contract.

121. Any person undertaking "access activities" without the required authorisation is subject to sanctions according to national legislation (Article 46). Non-authorised transactions involving derivates, synthesised products or associated knowledge are also ground for actions. Administrative sanctions such as fines, confiscations and barring the transgressor from applying for future access are possible in accordance with the national legislation of each Member State (Article 47).

122. Under Decision 391, the competent national authority of each Member State is to maintain a national inventory of genetic resources and derivate products (Article 50(n)). Explicit provisions on monitoring genetic resources for conservation purposes are not provided, but the competent national authority is to supervise and monitor the conditions of the access contract (Article 50(g)) and the conservation status of biological resources which contain genetic resources (Article 50(l)).

123. Decision 486 (2000) establishes a common regime on industrial property which grants respect for the biological and genetic heritage, as well as the traditional knowledge of its indigenous, Afro-American and local communities. This decision makes a connection between the CBD and intellectual property objectives by setting down criteria regarding the biological and genetic heritage, as well as the traditional knowledge of communities. It also recovers the postulates of the 1969 International Labour Organisation agreement related to the power of indigenous peoples to adopt decisions on their resources.

124. In July 2002, The Andean Council of Foreign Ministers, through Decision 523, approved the Regional Biodiversity Strategy for the Countries of the Andean Tropics to contribute to the generation of viable alternatives for sustainable regional development based on the sub-region's natural resources and consensus on joint positions at various international negotiation forums.

C. Central American Protocol on Access to Genetic and Biochemical Resources and to the Associated Traditional Knowledge

125. The Protocol has as its objective the regulation of access to genetic and biochemical resources and to the associated knowledge, innovations and practices, existent in any of the States Parties; with the intention to, inter alia, ensure the conditions for a fair and equitable sharing of the benefits derived from access to such resources; ensure the conservation of biological diversity and the sustainable use of its

components, as a mechanism to keep and improve the quality of life of their populations; ensure capacity building and development at the local, national and regional levels on the use of such resources and the traditional associated knowledge; establish an appropriate system of access to such resources, based on prior informed consent and mutually agreed terms; strengthening the negotiating capacity of States parties in relation to access and benefit sharing; recognize, compensate and protect local communities for their knowledge, innovations and practices for the conservation and sustainable use of biological diversity.

126. Access to genetic and biochemical resources is defined as "the authorization" conferred by the national competent authority to obtain samples of the elements of wild, native and domesticated biological diversity, in existence both in in situ and ex situ conditions, and to the traditional knowledge associated with such elements. The ultimate goal should be for research, conservation, bio-prospecting or commercial use. It is important to note that this definition closely follows that in the Costa Rican Law analysed above. Traditional knowledge is defined as any individual or collective knowledge, innovation or practice of real or potential value, associated with biological resources, whether or not it is protected by intellectual property systems. This definition is interesting, since it broadly refers to knowledge, innovation and practices associated with biological resources in general and not to genetic resources specifically. The notion of "real or potential" is an important addition, but the idea of "traditional knowledge" protected or not protected by intellectual property systems makes no sense because the characteristics of intellectual property protection do not permit the protection of "traditional" or "informal" innovations.

127. Human genetic resources and their derivatives are excluded from the scope of this sub-regional agreement. The exchange of genetic resources and their derivatives that is undertaken among local communities according to their traditional practices, is also excluded.

128. The agreement includes an Article on recognition and compensation for traditional knowledge according to which member States should recognize and protect, through their competent national authority, when applicable, knowledge, innovations and practices of local communities, useful for the conservation, management and sustainable use of the biodiversity components. Such authorities should therefore protect the faculty of these communities to decide over their knowledge, innovations and practices (Article 7).

129. Explicit reference is made to the precautionary principle, which should be taken into account by the States parties to the Agreement, in the access procedures (Article 9).

130. Access to genetic and bio-chemical resources is subject to the prior informed consent of the natural and legal persons "holders of rights". The Agreement is not clear as to the rights whose holders are entitled to PIC. The relevant State should ratify such PIC (Article 13).

131 Among the requirements for the submission of an access application one finds the following: presentation and approval of the relevant environmental impact assessment; the mechanisms proposed for the distribution of benefits, including technology transfer and any other modality of sharing of benefits with the relevant sector of the State; the existence of a national research counterpart; an indication of the economic, social, cultural, scientific and spiritual benefits that will derive for the State and the involved sectors; a description of knowledge, innovations and practices of local communities, when applicable; the identification of the provider of genetic or biochemical resources and the associated knowledge and the terms of prior informed consent obtained from

them as well as of the agreed sharing of benefits terms (Article 16). The way the knowledge, innovations and practices of local communities is to be "described" is certainly not clear since this should previously require a system of recognition of such traditional knowledge under an intellectual rights regime.

132. Total or partial restrictions of access may be imposed in case of adverse effect over human health, species and ecosystems or over essential elements of the autonomy or cultural identity of local communities.

133. National competent authorities are called to issue "certificates of origin" establishing the legal access to the relevant resource and knowledge. This authority should also keep a registry of applications and of access contracts.

134. An interesting and newly inserted provision in this type of legislation is the one dealing with the consideration of the interests of other States parties. In case during the negotiation of the terms of an access contract it should be noted that another State party is also a provider of the resource in question, the national competent authority should require its opinion. This opinion should be taken into consideration in the final decision.

135. A very peculiar provision of the Agreement under analysis is the one that establishes that States parties should take care that "intellectual property rights, in particular patents, contribute to the objectives of conservation, sustainable use and fair and equitable sharing of benefits derived from the use of the relevant resources and knowledge, as contained in the Agreement, the Convention on Biological Diversity and the Convention for the Conservation of Biodiversity and the Protection of Priority Wild Areas in Central America". The essence itself of intellectual property rights (IPR), in particular patents, is that of rewarding the person whose "creation" or "invention" is new, useful and subject to industrial application, by entitling this person to the exclusive right of exploitation of such invention and the economic reward that this right confers. IPR are not "public interest" rights. They are, on the contrary, private, exclusive rights of market economies.

136. Intellectual property rights are accredited to persons over the creation of their minds. IPR give the creator an exclusive right over the use of her/his creation for a certain period of time and within a certain territory. IPR have in fact been created as a means of protection and reward for inventiveness. Patents have been created to stimulate innovation and technology. The only social purpose of patents is that of providing protection for the results of investment in the development of new technology, thus giving the incentive and means to finance research and development activities. As a consequence, IPR allow gene "technology" to be rewarded, but there is still no equivalent legal system whereby the indigenous-related knowledge be rewarded.

137. IPR as they exist nowadays do not protect "informal" "traditional" "communal" knowledge and innovation. Current IPR mechanisms seem to be inherently unsuitable for the equitable and fair sharing of benefits. The contributions are in fact often made by entire communities and therefore cannot be attributed to distinct groups or even individuals; a gene, critical to the success of a new variety has origin in different areas, it is therefore not possible to establish the IPR requirement of "priority" in recognition and reward.

138. The Central American Agreement establishes that knowledge, innovations and practices of local communities cannot be used without the prior informed consent of the person who has "the right to confer it". Again, this provision seems extremely vague and difficult to implement and enforce.

139. The Agreement also introduces the obligation of States parties to create a consultation participatory process and provides some elements to be considered in such establishment, including the identification of requirements and procedures to recognize a sui generis right.

140. The Agreement approved and adopted by the Ministers of Environment of the Member States of the Central American Commission on Environment and Development (CCAD) (i.e. Belize, El Salvador, Guatemala, Honduras, Nicaragua and Panama) will enter into force on the date of the deposit of its fourth ratification instrument.

III. National Legislation on Access to Genetic Resources in the Countries of Latin America and the Caribbean

141. Worldwide there has been a significant amount of planning and legislative activity at the regional and national levels dealing with access to genetic resources since the Convention on Biological Diversity entered into force in 1994. However, despite the fact that in many States it is the national Constitution which is generally the source of law specifying the legal status of biological resources within a country, it appears that genetic resources are not yet referenced specifically in national Constitutions. This is the case also in the Latin America and the Caribbean region. In the LAC region only Argentina, Brazil, Costa Rica, Peru and Mexico have enacted national legislation on the subject.

142. A comparative analysis of existing and draft legislation on access to genetic resources indicates that access provisions are being incorporated into five groups of legislation [(5)].

a) The **first group** comprises general environmental framework laws. These tend only to be enabling in nature. As enabling laws, they all merely charge a competent national authority to examine the issue in order to provide more specific guidelines or regulations sometime in the future. There are no examples in the LAC region.

b) The **second group** includes framework sustainable development, nature conservation or biodiversity laws. These include laws in Costa Rica (Wildlife Conservation Law (1992) and Biodiversity Law (1998)), Mexico (Environmental Act (1996)) and Peru (Law for the Conservation and Sustainable Use of Biodiversity (1997). Generally, the access provisions in this group tend to be more detailed than the ones described in the first group. In all cases they clearly establish the mutually agreed terms (MAT) and prior informed consent (PIC) principles.

143. The Costa Rican Biodiversity Law (Law No.7788) includes among its objectives the integration of conservation and sustainable use of the biodiversity elements into the development of socio-cultural, economic and environmental policies; the promotion of the active participation of all social sectors in the conservation and ecologically sustainable use of biodiversity, in order to attain economic, social and cultural sustainability; the regulation of access to genetic resources and thus to make it possible an equitable sharing of the social, environmental and economic benefits derived from

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[(5)] Glowka Lyle. A Guide to Designing Legal Frameworks to determine Access to Genetic Resources. IUCN Environmental Law Centre, 1998. The exercise of placing LAC legislation under these groups follows Glowka's identification of the relevant groups.

the utilization of such genetic resources, with special attention to the local communities and indigenous peoples.

144. Law 7788 defines "access to biochemical and genetic elements" as the activity undertaken in order to obtain samples of wild or domesticated biodiversity, in ex situ or in situ conditions as well as the procurement of the associated knowledge. The ultimate goal of access should be basic research, bio-prospecting or economic utilization (Article 7).

145. According to this law, any research programme or bio-prospecting activity to be carried out in the national territory, involving biodiversity genetic or biochemical material, requires an access "permit" (Article 69).

146. The Law includes a series of criteria necessary to enforce it (Article 11). Among these criteria the following are found: the preventive criterion, the precautionary criterion or *in dubio pro natura*, and the environmental public interest criterion.

147. According to the Law, it is the Biodiversity Management Commission who proposes the biodiversity genetic and biochemical elements access policies, both in situ and ex situ, and perform the role of a compulsory consultation body in the processes of request of protection of "intellectual rights". The provisions approved by the Commission on this issue constitute the general regulations of access to genetic and biochemical elements as well as for the protection of biodiversity "intellectual rights".

148. In order to be able to submit an access application it is necessary to have obtained the prior informed consent of the representatives of the place where access will materialize; the ratification of such PIC by the Technical Office of the Commission; the terms under which technology transfer and equitable sharing of benefits will take place; as well as the type of protection required by the representatives of the place where access will materialize; and the definition of the way in which such activities will contribute to the conservation of species and ecosystems.

149. An interesting provision is that of Article 66: Right to cultural objection, according to which the local and indigenous communities are enabled to oppose to access to "their" resources and the associated knowledge on the basis of cultural, spiritual, social, economic or other reasons.

150. It is the Technical Office of the Commission who issues the access permits. It should organize and keep updated a registry of access rights to genetic and biochemical elements. Such permits should clearly state the certificate of origin, the possibility –or prohibition- to extract or export samples or, where applicable, the duplication and deposit of such samples; the periodical reports; the necessary monitoring and control; the ownership and publicity of results; as well as any other condition that according to the applicable scientific and technical rules are necessary in the view of the Technical Office of the Commission. This Office should also establish the obligation of the interested party to deposit in the account of the national System of Conservation Areas up to the 10% of his/her research budget and up to the 50% of the royalties that will be collected, as well as any other benefit or technology transfer agreement that is part of the PIC.

151. The Costa Rican Wildlife Conservation Law (Law No. 7317) applies to genetic resources of wild flora and fauna (Article 3). Although this Law does not extend to domesticated or cultivated species, the Law still applies to wild fauna and flora which are located ex-situ. Since they remain state owned or national patrimony, access to them requires authorisation from the State. Genetic resources can be removed from Costa Rican national parks only with prior authorisation (Article 43).

152. The activities regulated by this Law are related to the ultimate purposes or objectives of physical access to genetic resources. Article 50 of the Law makes a distinction between commercial and non-commercial activities. It sets out different requirements for each. This access legal instrument applies to nationals and non-nationals. However, nationals may be entitled to special treatment, i.e. this includes being subject to lower licensing fees or being authorised access for longer periods than to non-nationals (Article 39).

153. Export controls are used by Costa Rica under this Law in order to ensure that prior informed consent requirements have been fulfilled. The 1992 Wildlife Law requires written permission to export wildlife from the Wildlife Office of the Ministry of Natural Resources, Energy and Mines (Article 44).

154. The Mexican Environmental Act: General Law for Ecological Balance and Environment Protection, as revised in 1996, includes a new Article that states that the exploitation of wild flora and fauna species and other biological resources to be used in biotechnology requires the prior authorization of the Ministry of Environment as well as the prior explicit consent of the owner of the estate where the biological resource is found. Such owner has the right to an equitable sharing of the benefits that derive therefrom (Article 87 BIS). Article 87 establishes that the sustainable use of endemic species shall be authorized in conformity with the standards to be adopted by the Ministry of Environment. The exploitation of wild flora and fauna species requires also the explicit consent of the owner of the state in which they are found. When the ultimate goal of such exploitation is scientific research, the authorization should be subject to the standards to be adopted by the Ministry of Environment and there should be a guarantee that the results of such research will be made public.

155. Article 79 establishes that for the preservation and sustainable use of wild flora and fauna, criteria such as the following should be applied: The promotion and development of research on wild flora and fauna and the relevant genetic materials, with the objective to know their scientific, environmental, economic and strategic value for Mexico; Traditional Biological Knowledge and the participation of indigenous communities and peoples in the elaboration of biodiversity programmes for the areas inhabited by them; The combat against the illegal appropriation of such species; etc.

156. Article 82 determines the application of the Law to the possession, management, re-population, propagation, importation, exportation and development of wild flora and fauna as well as genetic material.

157. The Peruvian Law for the Conservation and Sustainable Use of Biodiversity (Law 26839) dedicates Title VIII to genetic resources and establishes that the rights conferred over biological resources do not confer any right over the genetic resources therein contained.

158. The Law establishes that the State is a party and therefore participates in the genetic resources access procedures. The law states that partial or total access limitations might be established by the competent authority in the following cases: Endemic, rare or endangered species, sub-species, varieties or breeds; vulnerability or fragility conditions in the structure or functioning of ecosystems that could worsen by access activities; adverse effects of the access activities over human health or over essential elements of the cultural identity of peoples; undesirable environmental impacts of the access activities over species and ecosystems; danger of genetic erosion; biosafety regulations; genetic resources or geographical areas considered strategic.

159. Another title of the Law deals with native and peasant communities. This Title recognizes the importance and value of knowledge, innovations and practices of these

communities for the conservation and sustainable use of biodiversity. The necessity to protect this knowledge and establish mechanisms for promoting its use with the informed consent of such communities is therefore recognized. The equitable and fair sharing of the benefits derived from its use should be guaranteed.

160. The knowledge, innovations and practices of peasant and native communities, associated with biological diversity, constitute cultural patrimony of such communities. They have therefore rights over them and faculty to decide with respect to their utilization (Article 24).

161. The **third group** of the analysis consists of dedicated or stand-alone national laws or decrees. The Brazilian Provisional Measure No.2186-16, of 23 August 2001 and its regulation: Presidential Decree No.3945, of 28 September 2001 are examples of this group.

162. Brazilian Provisional Measure No.2186-16 applies to:

a) access to the components of the genetic patrimony in existence in the national territory, in the continental platform and in the exclusive economic zone carried out with scientific research, technology development and bio-prospecting purposes;

b) access to traditional knowledge associated with such genetic patrimony, relevant to biological diversity conservation, the integrity of the Brazilian genetic patrimony and the use of its components;

c) the fair and equitable sharing of the benefits derived from the use of such genetic patrimony and traditional associated knowledge; and

d) access to technology and technology transfer for the conservation and use of biodiversity. It is not applicable to the exchange of the genetic patrimony components and traditional associated knowledge that takes place among local and indigenous communities for their own benefit and performed on the basis of customary practice.

163. The Brazilian Provisional Measure protects traditional knowledge of local and indigenous communities, associated with the national genetic patrimony, against illicit use and exploitation, other dangerous activities and activities not authorized by the Council for the Management of the Genetic Patrimony, established by this Provisional Measure within the Ministry of Environment. The State recognizes the right of such communities to decide on the use of their traditional knowledge associated with the national genetic patrimony.

164. The Brazilian Provisional measures guarantee to local and indigenous communities that generate, develop and conserve traditional knowledge associated with the national genetic patrimony:

a) the indication of origin of access to such traditional knowledge in every publication, use, exploitation and information activity;

b) the prohibition to third non-authorized parties to use, undertake research or exploitation relating to associated traditional knowledge, spread, transmit or retransmit data or information that form part or constitute the associated traditional knowledge;

c) perceive benefits for the economic exploitation by third parties, directly or indirectly, of the associated traditional knowledge.

165. For the purposes of the Provisional Measure under analysis, any community, even if only one member of such community holds such knowledge, shall be the holder of the rights over any traditional knowledge associated with the national genetic patrimony.

166. Access to the components of the national genetic patrimony existent in in situ conditions in the national territory, in the continental platform and the exclusive economic zone, and to the associated traditional knowledge should be authorized by the relevant national authority.

167. In the case of commercial use perspective, access to the components of the national genetic patrimony, in in situ conditions, and to the associated traditional knowledge, shall take place only after the signature of the respective contract for the use of the national genetic patrimony and the relevant benefit sharing. It is the President of the Council for the Management of the Genetic Patrimony who is authorized to sign such contracts, on behalf of the Union.

168. Authorization of access should take into account the prior informed consent of the involved indigenous community –when access occurs in indigenous lands; of the competent body –when access occurs in protected areas; of the private rights holder –when access occurs in private property; of the National Defence Council –when access occurs in areas of national security; of the maritime authority –when access occurs in Brazilian jurisdictional waters, the continental platform or the exclusive economic zone.

169. *Ex situ* conservation of components of the national genetic patrimony should be carried out in the national territory. It can exceptionally be undertaken abroad, with the consent of the Council for the Management of the Genetic Patrimony.

170. Chapter VI of the Provisional Measure contains new and interesting provisions regarding technology transfer. Article 21 states that the institution beneficiary with the component of the national genetic patrimony or associated traditional knowledge should facilitate access to technology and technology transfer for the conservation and use of such patrimony or traditional knowledge to the national institution responsible for access.

171. Access to technology and technology transfer between a national institution of research and development, public or private, and an institution abroad can be undertaken through scientific research and technological development, training of human resources, information exchange, consolidation of scientific research and technological development infrastructure, or economic exploitation of the process and product derived from the use of the component of the national genetic patrimony.

172. Chapter VII deals with benefit sharing and establishes that the benefits arising from the economic exploitation of the product or process developed on the basis of the accessed component of the national genetic patrimony or associated traditional knowledge should be fairly and equitably distributed between the institution that obtained access and the relevant national institution. This could take the form of sharing of profits, payment of royalties, access to and transfer of technologies, free licensing of products and processes, and human resources training.

173. Finally, a vanguard provision of the Brazilian Provisional Measure under analysis establishes that the grant of industrial property rights by the competent bodies, over a process or product obtained on the basis of a sample of a component of the national genetic patrimony, is conditioned to a strict observance of the Provisional Measure. It is an obligation of the industrial property rights applicant to inform about the origin of such genetic material and associated traditional knowledge.

174. The **fourth group** is characterized by the modification of existing laws or regulations. No example of this group could be identified on the Latin American level this far.

175. The **fifth group** includes actions taken at the regional level. The existing examples are Decision 391 of the Andean Community: Common Regime on Access to Genetic Resources, and the Central American Protocol on Access to Genetic and Biochemical Resources and to the Associated Traditional Knowledge, described above.

176. As a conclusion it is possible to ascertain that the approaches taken to date with existing or draft access legislation concentrate only on excluding potential users from physically accessing genetic resources located within the jurisdiction of a country without a permit or license. This is sometimes supplemented with measures to control genetic resource exports.

177. The establishment –with a concrete application- of intellectual property rights over wild or "unimproved" domesticated/cultivated genetic resources has not yet been manifested and it is unlikely unless technical problems related to describing genetic resources and accurately identifying rights holders are overcome.

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Annex II: Ongoing and planned activities of the various agencies in the field of access and benefit sharing

United Nations
Environment Programme

1. The UNEP Initiative on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization, which includes a strong capacity-building component, is a means of helping the countries to fulfill the objectives of the Convention on Biological Diversity. An essential component of this initiative lies in its capacity to bring together different actors (governments, indigenous peoples, local communities, environment professionals, the private sector and civil society), so that all of them can benefit from the rich exchange of experiences that can take place.

2. The goal of the UNEP Initiative on Access and Benefit-Sharing is to achieve the Rio and Johannesburg objectives by assisting the countries in capacity building, including the preparation or adaptation of the respective environmental legislation and necessary institutional arrangements of the countries parties to the CBD; as well as in the development and implementation of benefit-sharing mechanisms based on agreements between the holders of knowledge, innovations and traditional practices and those who use them, and through the appropriate participation of local communities and indigenous peoples in the respective decision-making processes.

3. Another objective of the UNEP Initiative is the negotiation of an international system to promote and protect the fair and equitable sharing of benefits arising from the utilization of genetic resources, as called for in paragraph 42 (o) of the Johannesburg Plan of Implementation. These efforts will be carried out in collaboration with other United Nations agencies working towards the achievement of the Millennium Development Goals and the goals of the World Summit on Sustainable Development.

4. In close coordination and collaboration with other United Nations agencies and programmes, as well as regional and sub-regional organizations, NGOs, the scientific community, financial institutions and corporate sectors, UNEP supports and advises the governments on addressing the principal needs indicated above, through the following groups of activities:

a) management and information assessment and tools;

b) preparation of the framework for national policies and options;

c) national institutional capacity-building and the promotion of activities to generate awareness;

d) design and implementation of regional and sub-regional cooperation activities;

e) specialized training courses; and

f) support for global and regional meetings, as well as sub-regional and national seminars and workshops in the field of integrated management of land ecological systems.

5. UNEP promotes the establishment of biological corridors in the region, and is now supporting and providing advisory services for projects such as the Mesoamerican Biological Corridor and initiatives for the establishment of an Andean Biological Corridor (Gran Ruta Inca), the Cocos Island – Galapagos Marine Corridor and the Gulf of Fonseca in Central America.

6. Joint work with FAO and IUCN is now being carried out to restructure and reactivate the Latin American Network of National Parks and Other Protected Areas, Wild Fauna and Flora. Through this network, efforts will seek to channel support and training to the Focal Points of the Protected Areas and strengthen their institutional capacity.

7. In coordination with the World Conservation Monitoring Centre (WCMC), work is being carried out on an initiative for the harmonization of reporting for biodiversity-related international treaties (CBD, CITES, CMS, Ramsar, Natural Heritage and the SPAW Protocol). This initiative forms part of a broader effort to strengthen synergies among international environmental conventions.

8. Since 1995, the Environmental Law Programme (ELP) has been supporting the design of environmental policies and the development of environmental law and its enforcement in the countries of the region. The ELP advocates the integration of sustainable development principles in national policies through the promotion of national environmental legislation, national capacity-building for the implementation of multilateral environmental agreements and policy instruments that take into account environmental problems.

9. UNEP is the implementing agency of the GEF Project on the Development of National Frameworks for Biosafety, whose execution began in 2002. This three-year project was designed to help more than 100 countries develop their national frameworks for biosafety and thereby enable them to comply with the Cartagena Protocol on Biosafety. Most of the countries in the region are beneficiaries of this project and are working hard to achieve results.

10. UNEP is in charge of follow-up on the development and implementation of the UNEP/GEF projects for capacity-building in access and benefit-sharing, presented to the 15 countries of the Group of Like-Minded Megadiverse Countries. The project objectives are to provide these countries, as Parties to the Convention on Biological Diversity, with assistance and capacity-building in the design and implementation of national frameworks on access and benefit-sharing, in accordance with the Bonn Guidelines, as well as to identify and disseminate good practices and lessons learned in these countries located in various regions of the world.

11. A similar project is being developed by the countries of the Andean Community to assist them in the implementation of a common regime on access to genetic resources and equitable sharing of the benefits arising from their utilization, as well as in the implementation of their regional strategy on biodiversity.

The World Bank (WB)

12. In the area of genetic resources, the World Bank is the implementing agency of the project GEF-MSP Y03 "Capacity Building in Biosafety", which is being executed in Colombia.

13. Project GEF 6L "Building the Inter-American Biodiversity Information Network (IABIN)" is also in preparation.

United Nations Food and Agriculture Organisation

14. Since the adoption of the International Treaty on Plant Genetic Resources for Food and Agriculture, there have been numerous appeals calling for its ratification and consequent entry into force as soon as possible, particularly in the Declaration of the World Summit on Food; five years later, in the Ministerial Declaration of the sixth meeting of the Conference of the Parties to the Convention on Biological Diversity, held in The Hague; and in the Johannesburg Plan of Implementation adopted at the World Summit on Sustainable Development.

15. The Treaty shall enter into force 90 days after 40 governments have ratified it. The governments that have ratified it shall constitute its governing body. In accordance with the text of the Treaty, the governing body, at its first meeting, shall adopt decisions on important issues such as the amount, procedure and form of monetary payments related to marketing, mechanisms to promote fulfillment of the Treaty and the financing strategy. Thus, the countries of Latin America and the Caribbean may find it very important to be among the first to ratify the Treaty, so as to ensure that their national interests are taken into account at the first meeting of the governing body. In mid September of this year, 2003, 32 countries had ratified the Treaty, and it will probably enter into force in early 2004.

16. In October 2002, the Intergovernmental Commission on Genetic Resources for Food and Agriculture (CGRFA), in its capacity as the Interim Committee of the International Treaty, initiated discussions to facilitate the adoption of decisions by the governing body of the Treaty. The Interim Committee of the Treaty decided to establish two Working Groups of intergovernmental experts to discuss various issues, such as the project on procedures to promote fulfillment of the Treaty and the terms of the Agreement on the transfer of standardized material. These meetings are expected to be held in the spring of 2004, as the necessary funds are received.

17. At the Tenth Ordinary Meeting of the CGRFA, to be held in November 2004, negotiations on some of the instruments that this Intergovernmental Commission has been developing in recent years will continue.

18. The main ECLAC activities in the area of genetic resources is related to the challenges and opportunity of biotechnology and particularly to the use of transgenics in Latin America from a broad perspective that ranges from environmental themes to issues involving business competitiveness and a joint project with the Andean Development Corporation (ADC), which is now under way.

19. The above-mentioned project consists of a study on biotechnology capacity to make use of biodiversity in the countries of the Andean Community. The need to conduct this study emerged from studies that have identified the sustainable use and development of biodiversity markets as a priority objective. The principal lines for attaining this objective have been established, and are: 1) the direct use of species and ecosystems that produce environmental services and 2) the use and processing of genetic resources and biotechnology. This project falls mainly within the second line. The project objective is to identify and analyse the biotechnological and institutional capacity of the Andean countries to use and process genetic resources. The results of the study should provide the ADC and ECLAC with a database to identify opportunities for activities to support the countries in formulating biotechnology development policies.

20. The study will have two basic components: a study on research and development capacity in areas related to the use and processing of genetic resources and biotechnology; and policy recommendations to support selected countries and regional and sub-regional analysis, promotion and development institutions.

21. Some publications in the areas of biodiversity and biosafety are: (i) Technological evaluation of biotechnology capability in Amazon institutions (in press), September 2003; (ii) *Fatores de competitividade e barreiras ao crescimento no pólo de biotecnología de Belo Horizonte*, July 2002; (iii) *Organismos genéticamente modificados: su impacto socioecononómico en la agricultura de los paises de la Comunidad Andina, Mercosur y Chile*, April 2002; and (iv) Las nuevas fronteras tecnológicas; promesas, desafíos y amenazas de los transgénicos.

22. A book on transgenics in the agriculture of Latin America and the Caribbean is also being prepared and deals with the topic extensively, from aspects such as production, trade and competitiveness to issues involving intellectual property and biosafety.

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