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ACCESS TO GENETIC RESOURCES AND BENEFIT-SHARING: LEGISLATION, ADMINISTRATIVE AND POLICY INFORMATION

Report by the Secretariat

Contents

I. INTRODUCTION

A. Point 5.4.1 and structure of Secretariat report

1. At its first meeting, the Conference of the Parties to the Convention on Biological Diversity adopted a medium-term programme of work which included as point 5.4.1 for 1995 the compilation of existing legislation, administrative and policy information on access to genetic resources and the equitable sharing of benefits from their use.[1] The Secretariat has prepared the present report to assist the Parties to the Convention on Biological Diversity in considering this point and item 6.6.1 of the proposed agenda for the third meeting of the Conference of the Parties in 1996, which calls upon Parties to "compile [their] views ... on possible options for developing national legislative, administrative or policy measures, as appropriate, to implement Article 15." Parties will therefore need to develop these views prior to the third meeting of the Conference of the Parties. The development of views in an area where there is relatively little experience will be facilitated by compiling the key issues that have arisen from the experience compiled under point 5.4.1 of the medium-term programme of work of the Conference of the Parties 1995-1997.

2. The present report first provides background on the Convention's provisions relating to genetic resources. Second, it compiles information on illustrative examples of legislative, administrative or policy measures on access to and benefit-sharing of genetic resources[2], as well as specific arrangements created since the adoption of the Convention. Based on the compilation of information, the present report also outlines key issues that the Parties might need to address in preparing for item 6.6.1 and in considering the implementation of Article 15.[3]

B. Background on the Convention's provisions on genetic resources

Historical and Structural Context

3. The Convention's objective is three-fold and comprises the conservation of biological diversity, the sustainable use of its components and the equitable sharing of the benefits from the use of genetic resources. As part of the process of achieving these goals, the Convention establishes a new international framework for access to genetic resources and the sharing of benefits from their use. At the same time, it requires Parties to take numerous steps for conservation and sustainable use of biological diversity. It also establishes an international structure within which Parties can cooperate on implementation and elaboration of the Convention's requirements.

4. The provisions of the Convention on genetic resources represent the international community's effort to define principles for the use of genetic resources from all sources, including plants, animals,

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[1] See *report of the First Meeting of the Conference of the Parties to the Convention on Biological Diversity, decision I/9, Medium-term programme of work of the Conference of the Parties*, UNEP/CBD/COP/1/17, annex II (1995).

[2] The Conference of the Parties may wish to note that examples are illustrative and are taken from information available to the Secretariat as at 1 October 1995.

[3] *Ibid.*

fungi and microorganisms.[4] This broad scope is consistent with recent developments in technology, which are demonstrating that a growing range of biological materials containing genetic resources have significant value for applications such as pharmaceuticals, biotechnological processes, mining, fisheries and forestry.

5. Prior to negotiation of the Convention, most discussions had focused on a specific category of genetic resources, namely plant genetic resources (PGRs) used in agriculture.[5] Negotiations under the auspices of the Food and Agriculture Organization of the United Nations (FAO) produced a non-binding International Undertaking on Plant Genetic Resources, which reflected the then widely accepted understanding that plant genetic resources were "a heritage of mankind and consequently should be available without restriction."[6]

6. The "common heritage" doctrine was not unanimously accepted during the negotiations in particular as protection of intellectual property rights (IPRs), such as plant breeders' rights (PBRs) over "elite" crop varieties, was expanding while no corresponding formal mechanism was in place for recognizing the rights of countries and farming communities providing genetic resources to share in the benefits derived from their use in developing elite varieties. Although the Undertaking was modified in an attempt to address these concerns, debate continued. The Convention on Biological Diversity represents the international community's effort to redefine the principles governing access and benefit-sharing, starting from the principle that Parties have sovereign rights over their genetic resources, rather than from the "common heritage" principle.

7. With respect to PGRs for food and agriculture, the 110 States that have adhered to the International Undertaking are now renegotiating it under the auspices of FAO, in order to bring it into harmony with the Convention. One rationale is that PGRs for food and agriculture have distinctive features that may warrant embodiment of specific rules for access and benefit-sharing in a protocol.[7] In addition, the FAO process seeks to resolve two other key questions left. The first is the handling of existing *ex-situ* collections of genetic resources not obtained in accordance with the Convention. The second is implementation of the principle of farmers' rights, which is articulated in the Undertaking as "rights arising from the past, present and future contributions of farmers in conserving, improving and making available plant genetic resources particularly those in the centres of origin/diversity"[8] states that

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[4] Article 2 of the Convention defines genetic resources broadly to include all "genetic material of actual or potential value." "Genetic material" in turn is defined broadly as "any material of plant, animal, microbial or other origin containing functional units of heredity."

[5] Plant genetic resources are defined in the International Undertaking on Plant Genetic Resources as "the reproductive or vegetative propagating material" of cultivated varieties of plants, whether newly developed or "primitive," as well as related wild and weed species, and "elite and current breeders' lines." Resolution 8/83 and annex, article 2, 22nd session of the FAO Conference, Rome, November 1983, document C83/REP (1983).

[6] *Ibid.* article 1: 110 States have adhered to the FAO Undertaking. *See* UNEP, *Ownership of, and Access to,* Ex Situ *Genetic Resources: Farmers' Rights and Rights of Similar Groups: Progress Report on Resolution 3 of the Nairobi Final Act,* Annex at paragraph 11.

[7] See FAO Commission on Plant Genetic Resources, *Revision of the International Undertaking: Analysis of Some technical, Economic and Legal Aspects for Consideration in Stage II,* CPGR-Ex1/94/5 Supp. (1994).

[8] Resolution 5/89, 25th session of the FAO Conference, Rome, November 1989.

farmers have a right to participate fully in the benefits derived from the improved use of PGRs through plant breeding and other scientific methods.

Relevant Provisions

8. The core of the Convention's new framework for genetic resources is found in Article 15, supplemented by provisions of Articles 16 and 19. In addition, activities subject to the genetic resources provisions must be consistent with other Convention provisions that are applicable, such as Articles 10 (b) and 8 (j).

9. Article 15.1 of the Convention affirms that each Party has the authority to control access to its genetic resources and that such access is "subject to national legislation." The right to control access is not, however, absolute. Instead, Article 15.2 obligates Parties to "endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention."

10. The Convention also establishes several other key principles. Access "shall be on mutually agreed terms," it shall be "subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party," and it shall be encouraged only if the Party seeking access will put the genetic resources to "environmentally sound uses" (See Article 15.2, 15.4, 15.5).

11. The Convention recognizes that access to genetic resources can lead to significant benefits. Thus, it requires each Party to take measures "with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources ... on mutually agreed terms" (See Article 15.7). Similarly, Article 19.2 requires 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 on mutually agreed terms."

12. Furthermore, a Party receiving genetic resources from another Party "shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties" (see Article 15.6; see also Article 19.1). Finally, each Party shall take measures with the aim that Parties, in particular developing country Parties that provide genetic resources, "are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms" (see Article 16.3).

13. Many activities relating to equitable benefit-sharing will also be subject to the Convention's obligations concerning conservation and sustainable use. For example, the collection of samples of genetic resources *in-situ* (i.e. in their natural habitats or in the surroundings where they developed their distinctive properties) could have impacts on biological diversity, especially in cases of large-scale commercial harvesting of a species containing useful genetic resources. Parties will have to manage such activities consistently with Article 10 (b), which requires Parties to take measures, "as far as possible and as appropriate," to avoid or minimize harm to biological diversity from the use of biological resources.[9]

[9] Article 2 of the Convention defines biological resources as including genetic resources.

14. Another example is found in Article 8 (j), which calls for protection of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles and relevant for conservation and sustainable use, as well as promotion of broader application (with community involvement and approval) and encouragement of equitable sharing of benefits with the community. Traditional knowledge and community innovations can be valuable sources of information on actual and potential uses of genetic resources. Thus, arrangements for access to genetic resources may need to provide for community approval of the use of traditional knowledge.

II. COMPILATION OF EXAMPLES OF LEGAL EXPERIENCE

A. National experience in implementing the Convention

15. In response to a request by the Intergovernmental Committee for the Convention on Biological Diversity[10], the Interim Secretariat sent a letter to Governments requesting information on legislative, administrative or policy measures, if any, taken to regulate access to genetic resources under the Convention. Thirty-nine Governments responded. The general trend of the responses indicated that Governments were at the initial stages of considering how to proceed under Article 15. Many noted existing legislation which regulated or controlled access to resources, but with different purposes than those envisaged under the Convention. Many Governments are in the process of reviewing their legislation, in particular their wildlife and forest laws, fisheries and related laws, quarantine regulations, trade-related regulations, plant variety protection laws and research clearance requirements to see if they possess the potential to be modified or supplemented to address the concerns of the Convention.

16. Since the initial request, other recent developments have been brought to the Secretariat's attention. Most noteworthy, perhaps, is Philippines Executive Order 247, which came into effect in May 1995 and is the first new regime adopted to regulate access to and exchange of genetic resources. It is significant that the Executive Order is a product of a consultative process involving discussions with a wide range of stakeholders, including representatives of local communities, NGOs, politicians, environmental lawyers, agricultural research institutions and various Ministries. It is premised on a constitutional provision - Section I, Article XII -- which provides that fauna and flora are the property of the State and the State has control over their disposition, development and use. The Philippines Executive Order contains a wide range of provisions for regulating access to and exchange of genetic resources. The Philippines is currently in the process of formulating regulations to implement the Executive Order.

17. Another recent development is the initiative of the Andean Pact countries[11] to prepare common legislation and policy measures to regulate access to genetic resources. The Andean Pact draft legislation for a common access regime and the Philippines Executive Order share many features in common including, *inter alia*:

(a) a definition of the resources covered which is broader than genetic resources[12];

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[10] UNEP/CBD/COP/1/3/, paragraph 43 (d).

[11] The Andean Pact countries include Bolivia, Columbia, Ecuador, Peru and Venezuela.

[12] The Philippines Executive Order covers all biological resources including samples containing biochemicals as well as genetic resources, while the Andean Pact draft covers genetic resources, derivatives and synthesized products.

(b) access is dependent on prior informed consent (PIC) granted from a national authority;[13]

(c) the provision for consent and involvement of indigenous and local communities;[14]

(d) the promotion of research and development and transfer of technology;[15]

(e) the obligation to deposit samples;[16] and

(f) the requirement for participation of nationals of the providing country in the access process.[17]

18. Several countries have established the basis from which access can be regulated. For example, the National Environment Management Act, 1994 (Law No. 13/94) of Gambia empowers the competent national authority to prohibit or restrict any trade or traffic in any component of biological diversity (article 32.g). Its article 15 deals directly with access to genetic resources and states:

> "The genetic resources of The Gambia shall constitute an essential part of the natural wealth of resources of the people of The Gambia.
>
> "The Council may make regulations and prescribe guidelines regarding access to the genetic resources of The Gambia, including:
>
> "(a) measures regulating the export of germplasm;
>
> (b) measures for sharing of benefits derived from germplasm originating from The Gambia; and
>
> (c) fees to be paid for access to germplasm".

In Cameroon, law 94/01 of 20 January 1994 sets out rules for an integrated management, conservation and sustainable utilization of forests, fauna and fisheries. It provides that genetic resources in Cameroon belong to the State. Nobody is allowed to exploit them for scientific, commercial or cultural purposes without authorization. The financial or economic benefits resulting from their utilization are subject to a royalty to be paid to the State, at a rate and upon modalities of payment to be determined by the Minister of Finances, on the basis of proposals by the competent Ministers (article 12). From the information received by the Secretariat, it is unclear whether these countries have promulgated implementing regulations.

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[13] The Philippines Executive Order establishes an interagency committee to grant prior informed consent.

[14] Philippines Executive Order, Section 2.

[15] *Ibid*, Preamble, Section 1, Section 5 (h)(i)(e).

[16] *Ibid*, Section 5 (b).

[17] *Ibid*, Section 5 (h)(i).

19. In a new field, the sharing of experience and information can be particularly useful. The Conference of the Parties may therefore wish to consider how the clearing-house mechanism (CHM) might be used to facilitate the exchange of information on the development and implementation of national access regimes.

B. International experience with access and benefit-sharing (ABS) arrangements

20. The Convention's provisions calling for access to genetic resources "on mutually agreed terms" strongly suggest that negotiated agreements will be a primary vehicle for obtaining access to genetic resources and for sharing the resulting benefits, including technologies. A number of companies, NGOs and Governments are exploring arrangements for access to genetic resources based on "mutually agreed terms," aimed at ensuring a more equitable sharing of benefits than was typical in the past. Annex II to the present report provides a compilation of basic information on illustrative examples of access and benefit sharing (ABS) arrangements and policies for the collection of organisms containing genetic material for use in industrial research and development.

Context of agreements

21. An ABS arrangement consists of the relationships among participants in an ABS arrangement, as well as the formal legal agreement that records their understanding. In addition, the legal and institutional context for the arrangement is also important. The agreements themselves are typically complex, because of the variety of future uses of the resource and the need to anticipate various possible benefits. They are also likely to involve long-term commitments or obligations, and they may involve extensive sharing of valuable information and joint research or other activities. Because access seekers may need additional samples as research progresses, they will value long-term relationships. Providers, too, will seek to monitor access seekers' use of resources over the long term, to ensure that they receive a share of the benefits. Negotiation and performance of such complex, long-term, interactive agreements are most likely to succeed where those involved have a strong sense of trust, mutual understanding and partnership.

22. Another important contextual factor is that there may be major differences in bargaining power between the actors in such agreements. Guidelines or technical assistance may be necessary to ensure that all parties interested in negotiations have access to adequate information and expertise. In general, agreements will effectively accomplish the Convention's objectives only if all sides have access to adequate information and technical expertise, as reflected in the requirement for PIC contained in Article 15 (see subsection C below).

23. ABS arrangements concerning certain resources need not be encompassed within a single agreement. Several agreements may pertain to the same resources. For example, two or more Parties could negotiate a general agreement that established standards for all agreements on use of defined categories of resources. Their nationals or government agencies might then negotiate agreements regarding specific resources within the broad category with foreign nationals, government agencies or intergovernmental organizations.

24. In addition, a single ABS arrangement could involve several different legal agreements covering the same resources. For instance, Parties could implement the Article 8 (j) provision for encouraging benefit-sharing with local and indigenous communities in use of traditional knowledge by requiring negotiation of agreements with those communities. These agreements could, however, be different from the agreements by which a commercial firm obtained access, although some of the same actors would be involved in both agreements so that they are interrelated. Thus, the providing country's national

herbarium might negotiate ABS agreements with indigenous and local communities to collect plants using traditional knowledge and sharing the resulting benefits. The herbarium might negotiate another ABS agreement with foreign research institutions or corporations. This approach can simplify negotiations because it reduces the need to bring all the actors together, while still achieving the Convention's goals. One drawback, however, is that separate negotiations may lead to inconsistent agreements. Another drawback is that one participant, such as a commercial firm, may have no legal obligation to ensure benefit-sharing with another participant, such as a local community.

Sustainable use

25. As noted in section I above, collection of genetic resources may have impacts on biological diversity. Existing incentives for actors within contractual agreements will not necessarily ensure that performance of agreements will comply with the Convention's requirements and accomplish its objectives. For example, actors may not have immediate incentives to harvest sustainably - and there may even be pressure to overharvest. Thus, Parties may need establish guidelines for ABS arrangements to minimize harm to biological diversity (Article 10 (b)). Section 1 of the Philippines Executive Order states that it is the policy of the State to regulate the prospecting of biological and genetic resources so that these resources are protected and conserved.[18] Some ABS arrangements - especially those involving large-scale harvesting - may also pose a significant threat to biological diversity such that they should be subject to environmental impact assessment, pursuant to Article 14.

Analogies to ABS arrangements: natural resource and technology licensing agreements

26. Agreements for access to genetic resources providing for the sharing of future commercial benefits are a relatively new initiative. Thus, in evaluating options, it could be useful to review experience with analogous transactions. For instance, contracts involving other resources such as oil, minerals and timber may be relevant, particularly for competitive bidding models where Parties open to the public the access to genetic resources on public lands.[19] In addition, technology licensing agreements may be relevant for negotiating payment of royalties on sales of products based on genetic resources.

Business contract terms

27. Many ABS agreements are in effect a kind of international commercial transaction. In designing such agreements, it is important to have access to general expertise relating to international transactions such as arbitration, selection of applicable laws, taxation and other business contract issues.

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[18] In addition, Section 5 (a) of the Philippines Executive Order states: "There shall be a limit on samples that the commercial/academic collector may obtain and export ..."

[19] Parties should, however, be aware of significant differences between transactions involving such commodities and genetic resources transactions. For example, ABS agreements will tend to provide for the exchange of resources, services, information and money over a longer period of time than is characteristic of many other resource extraction agreements. Providers of samples may commit to provide additional deliveries and information if requested, and users may commit to provide royalties on sales of products developed years after the original sample was provided.

Pharmaceutical research

28. The arrangements and policies in Annex II of the present report emphasize use of resources in the pharmaceutical sector, in which ABS practices appear to be evolving most rapidly. Other types of resources and other types of uses, such as PGRs for food and agriculture, may raise different issues. The descriptions provided are necessarily based on incomplete information, because participants in most ABS arrangements have kept some information about their arrangements confidential.[20]

C. International experience with Prior Informed Consent (PIC)

29. As noted above, PIC is likely to be a central procedural device to enable Parties to achieve the specific provisions of Article 15. Significant international experience has been gained in PIC procedures through other international instruments including: the 1989 Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal; the UNEP London Guidelines for the Exchange of Information on Chemicals in International Trade, Amended 1989; the FAO International Code of Conduct on the Distribution and Use of Pesticides, 1990; the IAEA Code of Practice on the International Transboundary Movement of Radioactive Waste, 1990; the FAO International Code of Conduct for Plant Germplasm Collecting and Transfer, adopted 1993; and the FAO Code of Ethics on the International Trade in Chemicals, 1994.

30. It is important to bear in mind that, apart from the FAO Plant Germplasm Collecting Code, PIC procedures in the other international instruments serve very different purposes from the PIC procedure in the Convention on Biological Diversity. Salient differences arise from the fact that disposal of hazardous waste or use of toxic chemicals can constitute a serious threat to human health and the environment. Genetic resources, on the other hand, are not intrinsically dangerous, provide countless benefits and are considered extremely valuable. Furthermore, whilst instruments dealing with hazardous wastes and chemicals are concerned with limiting imports, the Convention on Biological Diversity's PIC procedure is intended to regulate export of genetic resources in the context of Parties facilitating access to genetic resources. Still, these international instruments share common ground with the Convention on Biological Diversity. All the instruments provide for PIC where the potentially consenting country is faced with a decision on whether or on what terms to permit movements across frontiers, and that decision affects national interest.

31. A number of important institutional, procedural and other elements emerge from the implementation of PIC in the international hazardous waste and chemical context. These might be considered the common "core" elements of PIC and thus of potential relevance to implementing PIC in the context of the Convention on Biological Diversity. Establishing the core elements requires:

(a) determining the scope of application of the PIC procedure;

(b) designating a national authority in charge of managing the PIC procedure;

(c) establishing an international database on national measures plus procedural information on authorities to be contacted, etc.;

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[20] This confidentiality is typical of private sector agreements containing information that could be used by competitors, or by potential parties to similar agreements in future negotiations. See Francesca Grifo and David Downes, "Agreements for Pharmaceutical Research on Biodiversity: a Checklist of Issues and Basic Principles," in Steven Brush and Doreen Stabinsky, eds., *Valuing Local Knowledge: Indigenous Peoples and Intellectual Property Rights* (forthcoming 1995).

(d) defining minimum standards of information required; and

(e) providing for monitoring and enforcement.

Annex III contains an examination of the provisions of the above-noted international instruments under each of these core elements.

D. International experience: statements of principles, guidelines, codes of conduct[21]

1. FAO instruments

32. A number of instruments which are relevant to the issues of access to genetic resources and the equitable sharing of benefits have been adopted by the FAO Conference. These instruments contain internationally reconized principles and recommendations to States, but are not legally binding.

(a) The International Undertaking on Plant Genetic Resources

33. The International Undertaking on Plant Genetic Resources was established in 1983 following FAO Conference resolution 9/83.[22] It is a non-binding agreement, the objective of which is to assure that PGRs, especially species of present or future economic and social importance, are explored, collected, conserved, used and made available for plant breeding and other scientific purposes. The Undertaking was introduced largely as a reaction to the perceived imbalance in terms of access to "raw germplasm" (which tended to be freely available) on the one hand, and to "improved germplasm" (which was subject to proprietary restrictions) on the other. In the Undertaking, the concept of access without restriction applies to "the plant genetic resources... of all species of economic or social interest", regardless of whether they had been developed by nature or by human intervention of farmers or developers. Three interpretative resolutions have subsequently been adopted. The first provided an agreed interpretation which recognized that PBRs were not necessarily inconsistent with the Undertaking.[23] Simultaneously, another resolution was adopted which recognized Farmers' Rights[24]. The third resolution, noted above, reaffirmed the sovereign rights of nations over their genetic resources and agreed that Farmers' Rights should be implemented through an international fund.[25] Despite the attempts of the interpretive resolutions to resolve the issues, it was agreed in 1991 that "conditions of access to plant genetic resources need further clarification."[26]

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[21] The relevance of the United Nations Convention on the Law of the Sea (UNCLOS) is discussed in section III, A, 3.

[22] See document 83/REP, 22nd session of the FAO Conference, Rome, November 1983.

[23] Resolution 4/89, 25th session of the FAO Conference, Rome, November 1989.

[24] See paragraph 6 above.

[25] Resolution 3/91, 26th session of the FAO Conference, Rome, November 1991.

[26] *Ibid*, Preamble.

34. Resolution 7/93 of the 27th session of the FAO Conference initiated a process of revision of the Undertaking to harmonize it with the Convention on Biological Diversity.[27]

(b) International Code of Conduct for Plant Germplasm Collecting and Transfer

35. The International Code of Conduct for Plant Germplasm Collecting and Transfer was adopted by the FAO Conference at its 27th session in November 1993. The Code deals with the ethics and responsibilities related to mission planning and approval, management of germplasm collection work, and the transfer, conservation and use of germplasm. It provides guidance for national collecting missions and may serve as a reference document to help individual countries establish their own laws or regulations for germplasm collection, conservation, exchange and use.

36. Article 3.2 of the Code recognizes that nations have sovereign rights over plant genetic resources. The Code substitutes the controversial concept of "common heritage of mankind" and uses the Convention's language of the "common concern of humankind". It specifically provides, that "... access to plant genetic resources should not be unduly restricted".

37. The Code contains provisions which aim at ensuring transparency. Article 6.1 provides:

> "governments should designate the authority competent for issuing permits. This authority should inform proposed collectors, sponsors and the other agencies of the government's rules and regulations in this matter, of the approval process to be followed and of follow-up action to be taken".

38. It should be noted, finally, that a substantial part of the Code (particularly Chapter III) aims at the implementation of the principle of prior informed consent by means of a system for the issuance of permits to collectors (article 6.1). Governments should designate the authority competent for issuing permits (article 6.2), and prospective collectors and sponsors should address an application including several commitments and data (article 7).

39. The Code also addresses benefit-sharing. For example, prospective collectors and sponsors should indicate, "where possible, the sort of benefit the host country may expect to derive from the collection of germplasm" (article 7 (c)) and, "if the country so desires, plans for cooperation with national scholars, scientists, students, non-governmental organizations and others who may assist or benefit from participation in the field mission or its follow-up activities" (article 7 (e)). In addition, the permit-issuing authority should expeditiously "state any special arrangement or restriction placed on the distribution or use of the germplasm or improved materials derived from it" (article 8 (e)), and define any financial obligation to be met by the applicant, including possible national participation in the collecting team and other services to be provided (article 8 (g)).

(c) Networks of collections

40. During the fifth session of the Commission on Plant Genetic Resources, in April 1993, the International Agricultural Research Centres (IARCs) of the Consultative Group on International Agriculture Research (CGIAR) offered to put *ex-situ* active and base collections stored in their gene

[27] The negotiations are carried out by the Commission on Plant Genetic Resources. More than 140 countries are members of the Commission.

banks under the auspices of FAO.[28] The Commission welcomed the offer and requested FAO to initiate negotiations on this matter with the IARCs.[29] In 1994, twelve identical agreements between FAO and the CGIAR centres were signed.[30] The agreements contain provisions related to both access and the sharing of benefits. The scope of the agreements is limited to germplasm collections held by the centres and designated for the purposes of the agreements. These accessions are now officially under the auspices of FAO and held by the centres in trusteeship for the international community.[31]

41. The agreements, in their articles 9 and 10, set the conditions for access to germplasm as follows:

"The Centre undertakes to make samples of the designated germplasm and related information available directly to users, or through FAO, for the purpose of scientific research, plant breeding or genetic resource conservation without restriction" (article 9).

"Where samples of the designated germplasm and/or related information are transferred to any other person or institution, the Centre shall ensure that such other person or institution, and any further entity receiving samples of the designated germplasm from such person or institution, are bound by the conditions set out in Article 3 (b), in case of samples duplicated for safety purposes, to the provisions of Article 5 (a)"[32] (article 10).

42. It is important to note that, in accordance with article 9 as quoted above, access is to be provided "without restriction" for the purposes specified in the same article.

43. In order to implement article 9 of the agreements, the Centers are considering requesting the

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[28] CPGR 93/5, Progress Report on the Global System for the conservation and sustainable utilization of plant genetic resources.

[29] CPGR 93/REP, Commission on Plant Genetic Resources, fifth session.

[30] CPGR-Ex1/94/Inf.5 and Add.1.

[31] The concept of "trusteeship" was introduced in order to clarify the legal status of collections held by the centres, with respect to which considerable uncertainty had prevailed.

Article 3 of the agreements provides that:

"(a) The Centre shall hold the designated germplasm in trust for the benefit of the international community, in particular the developing countries in accordance with the International Undertaking on Plant Genetic Resources and the terms and conditions set out in this Agreement.

(b) The Centre shall not claim legal ownership over the designated germplasm, nor shall it seek any intellectual property rights over that germplasm or related information".

[32] Article 5 (a) refers to the application by the Centres of international accepted standards to manage the designated germplasm.

parties receiving materials to sign a "Standard Order Form", by which the recipient agrees:

(a) Not to claim ownership over the designated germplasm received, or to seek intellectual property rights over that germplasm or related information;

(b) To ensure that any subsequent person or institution to whom he or she makes samples of the germplasm available, is bound by the same provisions.[33]

2. International intellectual property rights regimes

44. Intellectual property rights (IPR) systems were designed to meet two fundamental and interrelated objectives: (i) to act as an incentive for investment; and (ii) to facilitate technology transfer and access. These systems were not designed to address the concerns of the Convention on Biological Diversity for conservation, sustainable use and equitable benefit-sharing. Parties must, therefore, consider how to implement the Convention on Biological Diversity and the IPR agreements to which they are party, so they fulfill their obligations under each.

45. While their orientation and perspectives differ, the international IPR instruments have relevance to the Convention on Biological Diversity and, in particular, to the components of access regimes relating to information exchange and technology transfer. Of particular relevance are the International Convention for the Protection of New Varieties of Plants (the UPOV Convention) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) approved as an annex to the Marrakesh Agreement establishing the World Trade Organization. States adhering to the UPOV Convention undertake to create a system of granting PBRs within their domestic laws, but in accordance with the UPOV Convention. The TRIPs agreement sets certain minimum standards for intellectual property rights. It also provides for differentiated sui generis systems for PBRs and exemption of plants and animals from patenting.

46. While analysis of these agreements is beyond the scope of the present report,[34] it is important to note that international IPR regimes are likely to apply to the development and diffusion of technologies which make use of genetic resources (including "improved" plant varieties) but they do not require a sharing of benefits with the providers of the genetic resources. The provisions of these agreements must, therefore, be implemented side-by-side with the Convention on Biological Diversity. As Parties to the Convention on Biological Diversity consider arrangements for access to genetic resources, they will also need to consider the role of IPRs either over information obtained under the agreement or over products developed using the genetic resources provided under the agreement.[35] In addition, if the Conference of the Parties chooses to elaborate international guidelines, it will need to take into account international instruments on IPR, in particular the UPOV Convention and the TRIPs agreement.

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[33] See CPGR-6/95/12, Add.1.

[34] See, Intellectual property rights and transfer of technologies which make use of genetic resources (UNEP/CBD/COP/2/17).

[35] *Ibid*

3. The International Labour Organization (ILO) Convention number 169 concerning Indigenous and Tribal Peoples in Independent Countries

47. The ILO Convention is a legally-binding instrument. As at 1 October 1995, the Convention had eight Parties. Of relevance to access to genetic resources and benefit-sharing is Article 15.2 of the ILO Convention, which provides the basis for sharing benefits "wherever possible." It states that "The peoples concerned [with undertakings or programs for the exploration or exploitation of resources pertaining to their lands] shall wherever possible participate in the benefits of such activities..."

III. SIGNIFICANT ISSUES ARISING IN EXPERIENCE TO DATE WITH IMPLEMENTATION

48. This section identifies major issues, based on the preceding review of experience. Where appropriate, the paper also notes possible options for the Parties to consider in building on this experience in future implementation.

A. The definition of genetic resources: implications for implementation

49. Article 2 of the Convention defines genetic resources broadly to include all "genetic material of actual or potential value." "Genetic material", in turn, is defined broadly as "any material of plant, animal, microbial or other origin containing functional units of heredity." So defined, the concept of genetic resources covers a broader range of materials than did the concept "plant genetic resources" that was the focus of earlier international discussions.[36] This reflects the fact that a growing range of genetic resources - including genetic materials from animals, plants and micro-organisms - are proving valuable for a range of technological and scientific applications.

50. The present section reviews four issues that relate to the definition of genetic resources. These concern biochemicals, plant genetic resources (PGRs), marine resources, and human genetic resources. Biochemicals are valuable resources found in diverse species; it is not yet clear whether they always come within the Convention's definition of genetic resources, although they owe their existence to genetic resources and are associated with them. PGRs, with their distinct origins and mode of use, raise special policy issues and are currently the subject of discussions within the FAO, which is overseeing the renegotiation of the International Undertaking on Plant Genetic Resources to bring it in harmony with the Convention. Marine resources are an important but not always well-known part of many Parties' stock of genetic resources, and raise unique legal issues, especially when found outside national jurisdiction. Finally, human genetic resources raise particularly difficult ethical and political issues.

1. "Biochemicals": natural sources of pharmaceuticals and other products

51. Chemicals found in diverse species of living things, sometimes termed "biochemicals," are closely associated with and analogous to genetic resources. It is not, however, clear whether they are identical to genetic resources. The value of biochemicals is analogous to the Convention's understanding of the value of genetic resources in that a natural biochemical, like genetic resources, contains information within its structure that human technologies can adapt or reproduce for human use. The collection and use of biochemicals involves the use of samples of organisms that contain genetic material. In some cases, these samples themselves are transferred from the country of origin to the

[36] See footnote 5 above.

recipient country. In other cases, extracts from the organisms are transferred. These extracts contain biochemicals, but may or may not contain genetic material. Recognizing the value of biochemicals, a number of industries are expanding efforts to collect and analyse specimens of plants, animals, fungi and micro-organisms from natural ecosystems, in search of naturally occurring chemicals that may be the sources of new products such as pharmaceuticals, paints, dyes, pesticides, food additives and flavourants.

52. Given the importance of these resources, it may be appropriate to study the relationship between biochemicals and genetic resources in preparation for discussion at future meetings. Some Parties may choose to specify that ABS rules for genetic resources apply to biochemicals as well. This approach follows logically from the affirmation in Article 15.1 of the principle that States have sovereign rights over their natural resources, including, as stated in Article 3,[37] the "sovereign right to exploit their own resources pursuant to their own environmental policies."

53. As used in current technologies, biochemicals found in a specific organism generally lead to development of a specific product, such as a pharmaceutical. This is in contrast to the typical use of PGRs in agriculture in which PGRs from one variety may be used in many different products, and many different varieties are used in a single product. Separate ABS arrangements providing for sharing of benefits from specific collecting programs may be relatively efficient and effective for biochemicals, but may not be practicable for other types of resources such as PGRs (see below).

2. Plant genetic resources: existing *ex-situ* genetic resources and *in-situ* resources

54. PGRs are an important type of genetic resources covered by the Convention. The use of PGRs in the development of new crop varieties is essential for maintaining agricultural productivity world-wide. Agriculture in every country - whether developed or developing - depends on inputs of PGRs from other countries. Thus, it is important to ensure the continued exchange of PGRs among Parties. The Convention recognizes these facts and also affirms the need for a more equitable sharing of the benefits of these resources. At least two major issues arise with PGRs:

(a) Should some or all PGRs be governed by distinct mechanisms or structures for benefit-sharing, given their distinct characteristics?

(b) How should pre-existing *ex-situ* PGRs (which are not covered by Article 15) be treated?

Distinct Characteristics of PGRs

55. The complex way in which PGRs are used has practical implications for implementing ABS provisions for PGRs. New crop varieties result from interbreeding of many different older varieties, landraces and wild relatives. A new variety may result from the interbreeding of dozens of crop varieties. The varieties used may include traditional crop varieties or "landraces," wild relatives of crops and commercial varieties. These varieties may come from many different countries and from different communities within a country. In addition, a sample may be transferred repeatedly from the collector to a series of others for use in research.

[37] This right is balanced with "the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction," also contained in Article 3.

56. In light of this complexity, the costs of forming numerous bilateral agreements and monitoring their performance would likely be very high, while the share of benefits allocated to a specific sample of genetic resources would be low. Such disproportionate "transaction costs" could impede the exchange that is beneficial for all, while failing to return significant financial benefits to countries of origin. However, some observers have complained that the regime that recognizes the need and benefit of continued exchange is already under stress because of the expanding scope and use of IPRs - in particular utility patents on plant varieties - which, they argue, discourages researchers from exchanging resources freely. In this context, contracts requiring compensation for providers of PGRs might be seen as a necessary counterbalance to IPRs over commercially developed crop varieties.[38]

57. Parties may wish to study the various options for handling PGRs under the Convention's ABS principles, including the possibility of multilateral, regional or bilateral aproaches.

Existing *ex-situ PGRs.*

58. Many PGRs of value for agriculture are held *ex-situ*, outside the country of origin. Regions of origin of PGRs - including traditional crop varieties and wild relatives of crops - are concentrated primarily in a number of developing countries. Existing *ex-situ* collections of crop varieties and wild relatives total an estimated 4.2 million accessions, including over 2 million samples of cereals.[39] Many of the samples in these collections are held outside the country of origin and many samples originally taken from territories in developing countries are held in industrialized countries.

59. Article 15.3 of the Convention defines "genetic resources being provided by a Contracting Party" to mean "only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention." As a result, Articles 15, 16 and 19 do not govern access to the vast collections of genetic resources obtained before the Convention entered into force.

60. Various multilateral and bilateral approaches have been proposed for ABS for *ex-situ* PGRs. *Ex-situ* PGRs raise additional issues that *in-situ* PGRs do not. For example, identification of the country of origin of many accessions already in *ex-situ* collections appears impracticable using current technologies for "fingerprinting" genes.[40]

3. Marine genetic and biochemical resources

61. Marine genetic and biochemical resources are notable for three reasons. First, while important and growing, relatively little is known about the value of these marine resources. Parties may wish to take special steps - such as research, legal measures and education - to ensure they are covered by ABS rules.

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[38] The TRIPs Agreement requires all WTO members to adopt a *sui generis* system for PBRs (*sui generis* means self-generated, i.e. it can be defined differently by each country). It does not, however, require them to recognize utility patents on plants.

[39] See FAO progress report, CBD/IC/3, para. 5.

[40] See FAO CPGR, Appendix 2. The costs of widespread use would be prohibitive and, in most cases, existing techniques could identify at most the region from which a sample came, without pinpointing the country of origin.

62. Second, Article 22 of the Convention provides that the Convention shall be implemented consistent with the rights and obligations of States under the law of the sea. Thus, the Convention's rules for genetic resources within national jurisdiction must be integrated with implementation of the law of the sea, within marine areas inside national jurisdiction, including exclusive economic zones. Parties may wish to ask the expert panel on coastal and marine biodiversity recommended by Subsidiary Body on Scientific, Technical and Technological Advise (SBSTTA) [41] to explore productive ways of linking implementation of the Convention with the law of the sea, as embodied in the United Nations Convention on the Law of the Sea (UNCLOS).[42]

63. Third, some of the most valuable genetic resources today are found on the deep seabed, in the form of organisms such as thermophilic bacteria. A number of these resources are situated outside national jurisdiction and therefore outside the scope of the Convention on Biological Diversity's access rules. Considering the Convention on Biological Diversity's coverage of the subject of conservation and use of genetic resources, and its growing experience in this area, the Parties may wish to request the expert panel on coastal and marine biological diversity to study the question of how to address the use of genetic resources outside national jurisdiction in light of relevant international law.

4. Human genetic resources

64. Medical researchers are increasingly interested in the diversity of the human gene pool as a source of valuable scientific and medical information. The genetic material found in human beings is "genetic material" as defined under the Convention, in that it is material of animal origin containing functional units of heredity. The collection and analysis of samples of human genetic material from many different ethnic groups around the world could provide insight into the evolution of the human species as well as the nature of human susceptibility and resistance to diseases.[43] This value for humanity indicates that these samples constitute genetic resources - genetic material "of actual or potential value" - again fitting a definition under the Convention. Yet from the history of its negotiation, it is clear that the Convention was not formulated with human genetic resources in mind.

65. The collection and use of human genetic resources raises difficult ethical and political issues. For example, the direct, physical interest of affected individuals in their own genetic resources argues strongly for extensive consultations with affected citizens. Given all the serious concerns surrounding this issue, the Conference of the Parties may wish to study the question of human genetic resources and the Convention on Biological Diversity to determine how it may be approached by the Conference of the Parties.

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[41] See, Report of the first meeting of the Subsidiary Body on Scientific, Technical and Technological Advice, UNEP/CBD/COP/2/5, recommendation I/8.

[42] The United Nations Convention on the Law of the Sea establishes the law of the sea for its 75 Parties, and most of it, including provisions on zones of national control, is accepted as international customary law of the sea.

[43] See Anna Maria Gillis, "Getting a Picture of Human Diversity: Population geneticists and anthropologists plan to use variation in human genes to get a sense of Homo sapiens History," *BioScience* 44:8 (1994);
Mary Claire-King, *Celebrating Identity and Diversity: The Human Genome Diversity Project* (testimony to the U.S. Senate Committee on Governmental Affairs, April 26, 1993).

B. Various uses of genetic resources

66. Parties implementing the Convention's ABS provisions may wish to take into account the range of uses of genetic resources, as well as the evolution of technologies for using them. While it is not always easy to distinguish between scientific and commercial research, there may be reasons to do so. The Philippines Executive Order distinguishes betwen academic research and commercial research agreements. Perhaps recognizing the difficulty in distinguishing between scientific and commercial research, the Executive Order requires all research agreements with private persons and corporations, including all agreements with foreign or international entities, to conform to the minimum requirements of commercial research agreements. Only duly recognized Philippine universities and academic institutions, domestic governmental entities and intergovernmental entities may apply for an academic research agreement.[44] Changing technologies have implications for this distinction, as well as for questions of monitoring and enforcement.

67. Access to genetic resources, traditional knowledge and related biological resources for scientific purposes - such as ecological, taxonomic or anthopological research - sometimes has little direct potential for commercial benefits. At the same time, the research may have substantial non-commercial benefits for the host country. In such cases, access fees, complex contracts and extensive regulatory procedures could interfere with international scientific cooperation by imposing transaction costs that are disproportionately large in comparison to the economic value of the transaction or the economic resources of the researchers involved. However, international scientific cooperation is also required under the Convention, (see Article 18) and implementation of the access provisions should be consistent with that obligation to promote accomplishment of the Convention's objectives. Thus, while Parties may wish to develop standards for scientific access providing for reduced or zero fees, they may also wish to impose requirements ensuring that scientists share information and conduct joint research where possible.[45]

68. In addition, Parties may wish to ensure that standards take into account the possibility that scientific researchers might later make genetic resources available for commercial development to third parties.[46] In fact, this possibility is likely to increase in the future. As biotechnological techniques become more advanced and efficient, it will become increasingly feasible to analyse samples of organisms in museums, herbariums and other existing collections for commercial applications. Given the rapid evolution of technologies, it will be increasingly difficult to draw a clear line between scientific and commercial activities. It will also be increasingly likely that scientific research could become the basis for later commercial development. For example, some experts predict that advances in technology will soon make it possible rapidly and cheaply to screen existing samples of biota in museums, for possible uses in a variety of sectors. Technological development may also lead to new techniques for monitoring the transfer and use of genetic resources, thus supporting enforcement of ABS requirements.

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[44] See the Philippines Executive Order, section 3.

[45] For example, see the Philippines Executive Order, section 5 (h).

[46] Moreover, it is likely that research, especially biotechnology research itself, will become less and less clearly defined as either academic or commercial.

C. Valuation of genetic resources

69. Genetic resources confer tremendous benefits on humanity as sources of essential medicines, crop varieties and many other products. However, the value of any given unit of genetic resources is difficult to measure. Pharmaceutical development is one example. While some genetic resources may become the source of highly valuable commercial products, the probability is low that any given sample, randomly collected from an ecosystem, will be the source of a new product. An estimated one out of every 10,000 chemicals extracted from natural sources produces a "lead" to a pharmaceutical product.[47] Valuation of specific PGRs for food and agriculture is also difficult, because genetic resources from a particular crop variety or wild relative, if used in developing a new variety, are likely to be combined with genetic resources from many other varieties. For these and other reasons, the valuation of genetic resources poses complex problems which the Parties may wish to study further.

D. Cooperation among Parties on implementation

70. The Convention's provisions on access and benefit-sharing (ABS) among Parties clearly have an international dimension. As such, their implementation constitutes a "matter of mutual interest" on which Parties shall cooperate as far as possible, and as appropriate, under Article 5. The Convention establishes a set of institutions through which the Parties may cooperate in implementation, including the Conference of the Parties, the SBSTTA, the clearing-house mechanism (CHM) on scientific and technical cooperation and the Secretariat.

71. To date, the Parties have undertaken cooperative work on these issues by placing items 5.4.1 and 6.6.1 in the medium-term work programme. In addition, both Governments and the non-governmental sector of many Parties have convened in informal conferences and workshops to discuss implementation of the Convention and other genetic resources issues.

72. Further cooperative action could offer significant benefits. By way of illustration, Parties might cooperate in the elaboration of guidelines or model legislation. This could help Parties, in particular developing countries, by pooling limited technical resources to deal with the complex law and policy issues involved. Agreed guidelines could also help the providing countries to withstand pressure to grant access on disadvantageous terms in order to compete against other potential providers of genetic resources. Access seekers may also benefit if access requirements are more or less consistent among Parties. Scientists, for example, will often favour standardization that simplifies the bureaucratic procedures involved in international research. On the other hand, development of such guidelines must be flexible enough to ensure that the Convention's principles can be applied effectively in the broad variety of circumstances that exists among the Parties. In addition, the process should be structured to ensure that all Parties have a full chance to participate, as well as the other relevant groups identified in the Convention, non-governmental organizations, scientific and technical experts, local and indigenous communities and the private sector.

73. Parties could also coordinate at the regional level. The countries of the Andean Pact, for instance, have been exploring the development of standards for Pact members' implementation of the ABS provisions (see section II, A, above). For some purposes, regional coordination might be more efficient and effective than global cooperation, as it would involve fewer Parties, with closer geographic (and in many cases cultural and political) links. It has been suggested that Parties could form regional

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[47] See Walter V. Reid, et al., "A New Lease on Life," Using Genetic Resources for Sustainable Development, WRI, May 1993, in *Biodiversity Prospecting*, at 1, 7.

"gene cooperatives" that would negotiate ABS agreements on behalf of member Parties. In regional cooperatives, Parties could share expertise and experience, share the risk that particular genetic resources may not produce valuable products and achieve greater "economies of scale" by pooling investment in advanced scientific and technological capacity.[48] Such regional cooperation could also help countries that share endemic species share the benefits from their use as well.[49]

E. Types of benefits that may be shared under ABS arrangements

74. ABS arrangements to date have provided for a range of types of benefits, including both monetary and non-monetary benefits. Capacity- building, an important benefit that can result from ABS arrangements, is discussed separately in section III, J, below.

1. Monetary benefits

75. An ABS arrangement may provide for initial "up-front" payments, payments for samples collected, payment of royalties contingent on future development of commercially valuable products, or some combination. Initial payments are important because they can create immediate incentives for conservation and respond to the often urgent needs of developing countries and local communities. Payments for samples provided offer continuing benefits that encourage conservation and sustainable development and, if the collectors are local people, offer employment and training. Decisions about the types of benefits depend in part on the allocation of risk among the parties to the agreement. Partly because these arrangements are innovative and diverse, and partly because key terms are kept confidential, it is difficult to ascertain a market rate or "equitable share" for royalties or samples. In the past, available information indicates that payments for samples have typically ranged from US $50 to US $250 per kilogram, sometimes going as high as US $1,500 for specific items.[50] Extracts from collected organisms may be priced at US $200 or more for a 25-gram sample.

76. The terms of innovative collecting agreements can, however, expand and enhance the overall package of services and information provided with samples, thus justifying higher prices.[51] Traditional knowledge, for example, adds significant value to the package. Thus, some of the International Cooperation Biodiversity Group (ICBG) agreements provide for additional payments where the research and development process benefits from traditional knowledge. The market is not well-established for royalties for shares of benefits from future discoveries based on samples, whether collected randomly or using traditional knowledge. However, standard industry practice in related fields may offer helpful

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[48] See Walter V. Reid, "Gene Co-ops and the Biotrade: Translating Genetic Resources Rights Into Sustainable Development," *Journal of Ethnopharmacology* (in press); see also Sarah Laird & A.B. Cunningham, The Case of Ancistrocladus korupensis, paper prepared for the Rainforest Alliance's Natural Resources and Rights Program, (1994) at 22.

[49] See Laird & Cunningham, note 48 above at 21.

[50] See Laird, "Contracts for Biodiversity Prospecting," note 47 above.

[51] *Ibid.*

analogies; shares of revenues from products allocated to suppliers range from 1 per cent to 15 per cent.[52]

2. Technology transfer, cooperative research, sharing research results

77. As the Convention recognizes, in providing for shared research and access to technology, non-monetary benefits are a critical element of benefit-sharing. Thus, ABS can and do provide for: "(1) screening for therapeutic potential, particularly when the focus is on therapeutics for developing country diseases which are normally ignored by developed country pharmaceutical firms, and sharing of results with in-country institutions or communities; (2) providing training in relevant areas such as pharmacology, biochemistry or taxonomy; and (3) equipment purchases and donations and other infrastructure development."[53]

3. Intellectual Property Rights (IPRs), citation and acknowledgment

78. Technology transfer carried out under the Convention shall be consistent with the adequate and effective protection of IPRs, but the Parties shall cooperate to ensure that such rights are supportive of and do not run counter to the Convention's objectives.[54] These provisions do not provide a clear guide as to how IPRs should be addressed in access agreements, which may serve as mechanisms for achieving technology transfer under the Convention. In general, however, participants in ABS agreements will wish to address the question of IPRs, either over information obtained under the agreement (such as traditional knowledge or preliminary results of analysis of samples) or over products developed using resources provided under the agreement.

79. Patents - the exclusive right to apply an invention commercially for a limited time period - are the type of IPRs most likely to be relevant. Access seekers are likely to seek patent protection over products developed using genetic resources, in order to maximize the return on their investment in research and development. The other type of IPRs most likely to be relevant are trade secrets, discussed in section III, I, below. Existing ABS arrangements tend to provide that the participants will recognize IPRs as conventionally defined. For example, they provide that inventions shall be patented by the inventors; if there is a sole inventor, the patent will belong to that inventor; if the parties invent a new product jointly, they will hold the patent jointly.

80. It is unlikely that patents or other IPRs, as conventionally defined, will provide significant protection to traditional knowledge, innovations and practices, because they themselves are unlikely to constitute commercially valuable inventions. Rather, they tend to serve as sources of insight regarding natural compounds or processes for refining or modifying them; commercially valuable inventions result from further research and development that builds on traditional knowledge, innovations and practices. Consistent with this, ABS arrangements could require access seekers to obtain communities' informed consent and negotiate an agreement for sharing benefits before using knowledge. Further

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[52] *Ibid*. at 111 (citing Harvard Business School Case Study, A Case on the Merck/INBio Joint Venture (1992)).

[53] See Grifo & Downes, note 20 above.

[54] See Article 16.2, 16.4. IPR issues relevant to access and benefit-sharing are discussed in detail in the background paper for item 5.4.2. of the annex to decision I/9 of the Conference of the Parties.

discussion of sharing of benefits with local and indigenous communities is found in section III, K, below, discussing the relevant provisions of Article 8 (j).

F. Types of participants in ABS arrangements

81. Efforts to forge ABS arrangements so far indicate that there can be many different types of actors involved in an ABS arrangement. In-country institutions may include private sector firms, universities, conservation groups, government agencies and local and indigenous communities. Foreign institutions may include universities, government agencies, research institutes, companies and conservation groups. Most agreements are not simply bilateral, although they may involve participants from only two countries; rather, they involve a number of different types of players.

82. This diversity of actors is consistent with the terms of the Convention, which acknowledge that a range of actors may be involved in access and benefit-sharing, including local and indigenous communities, holders of traditional knowledge, scientific and academic institutions and the private sector, (See Articles 8 (j), 11, 10 (e), 12, 15.7, 16.4, 18.1, 18.5). The Convention's requirements of mutually agreed terms (MATs) and PIC may be interpreted to apply to all of these players: not only to a Contracting Party Government but also to its nationals. Thus, a Party will need to enforce the requirement of PIC and MATs for foreign firms and academic researchers, as well as foreign government agencies.

Role of national Government

83. The language of the Convention as well as practical experience suggest that a Party's national Government may play a variety of roles in ABS arrangements. It may develop and enforce standards for agreements. In the case of a Party providing access, it may designate an agency to serve as the gatekeeper for determining PIC. It may also be a participant in an agreement, either as access seeker or access provider. In addition, it may be a provider of seed grants to encourage new ventures. The Government could also provide technical or legal assistance to potential parties to such agreements.

Treatment of non-parties and their nationals

84. Parties to the Convention must endeavour to create conditions to facilitate access for other Parties to the Convention, and shall endeavour to avoid restrictions on access that are counter to the Convention's objectives. There is no obligation with respect to non-Parties. Administratively, a Party might find it simplest to impose conditions on access that are identical for Parties and non-Parties. On the other hand, a Party might decide to restrict access for non-Parties, on the ground that its obligation to take steps to facilitate access is part of the interwoven web of reciprocal obligations created by the Convention, and it owes no obligation to a non-Party that has not subscribed to the Convention's overall framework.[55]

G. Prior informed consent (PIC)

85. The review of international guidelines (see section, II, C, above and Annex II) relating to PIC suggests that Parties may wish to consider the following elements in implementing the Convention's PIC requirement for providing and receiving Parties.

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[55] Such an interpretation might, however, be challenged as inconsistent with General Agreement on Tariffs and Trade (GATT)/WTO obligations.

Implementation by providing Parties - elements to consider

86. (a) Designation of a single government authority: the Party providing genetic resources may wish to appoint a single authority to grant or deny PIC. This can speed the process of obtaining needed information, evaluating and deciding on access requests and negotiating ABS agreements. The authority could be a committee drawn from relevant agencies and interest groups.[56]

(b) Definition of minimum information required for a PIC decision. For example, Parties might wish to define the information that an access seeker must provide to demonstrate an intent to devote the genetic resources to "environmentally sound uses", within the terms of Article 15.2.[57]

(c) Procedures for participation of local and indigenous communities, including prior approval of use of traditional knowledge, innovations or practices, as provided for under Article 8 (j).

Implementation by receiving Parties - elements to consider

87. Parties receiving genetic resources may also wish to take steps on implementation at the national level. While receiving Parties do not have specific obligations under Article 15, the Article's language - providing that access "shall be on mutually agreed terms" and "shall be subject to prior informed consent" - indicates that the general obligation to ensure that access is in accordance with these requirements is not limited to providing Parties alone. Measures by receiving Parties to ensure PIC could also be useful ways of implementing Article 15.7 and 16.3. The following measures by receiving Parties could enhance implementation:

(a) A requirement that imported genetic resources have export permits evidencing PIC from the providing Party;[58]

(b) A requirement that importers, within national jurisdiction, maintain records of imported genetic resources, showing origin, date of receipt and other information;[59]

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[56] In Cameroon, the Government designated an inter-agency committee to negotiate an ABS agreement for the *Ancistrocladus* vine. Similarly, the Philippines Executive Order provides that a committee of representatives from relevant government agencies and non-governmental groups shall review and approve all proposed ABS arrangements.

[57] See UNEP London Guidelines for the Exchange of Information on Chemicals in International Trade, article VI.

[58] See Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, article VI; UNEP London Guidelines, article 7.3 (forbidding export of a chemical unless importing country evidences PIC by responding to notification of intent to export).

[59] An analogy is found in the UNESCO Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property, adopted 14 November 1970. In order to discourage illegal removal of cultural property from Parties, Article 10 requires each Party to require domestic antique dealers to maintain registers of items of cultural property in stock and to impose penal or administrative sanctions for violations of this requirement.

(c) Designation of a governmental authority to administer the regulation of imports of genetic resources from other Parties.

Providing and receiving Parties

88. Both providing and receiving Parties could also provide for administrative or judicial penalties for violations of the requirements for access seekers.[60]

International measures

89. As discussed in annex II to the present report, PIC regimes typically include an international database or register of information about materials and transactions subject to PIC, established under the auspices of an appropriate international organization. Thus, the Parties may wish to establish an international database/register of types of genetic resources for which PIC is required, as well as a list of PIC grants/denials by Parties.

H. Possible elements of guidelines on mutually agreed terms (MATs)

90. As discussed above, guidelines on elements of MATs could prove useful in encouraging equitable benefit-sharing and helping to ensure that prior consent is indeed informed. Experience with national legislation and regulation and with ABS agreements suggests that Parties may wish to consider requiring that access seekers include one or more of the following elements in at least some categories of ABS arrangements:

(a) Providing *monetary benefits* through fees for shipments of samples and royalties on profits from future products;

(b) Providing *technology transfer or training*, or agreeing to *joint research;*

(c) *Reporting* on results of future research or development involving the genetic resources to the providing institution or Party;

(d) Agreeing on respective *intellectual property rights* over the genetic resources and technologies developed using them;[61]

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[60] Other agreements dealing with import-export controls require their Parties to enforce standards through such measures, suggesting that this mechanism could be helpful in effectively implementing the Convention. See Article VIII of the Convention on International Trade in Endangered Species of Flora and Fauna; Article 10 of the UNESCO Cultural Property Convention; Article 9, paragraph 5 of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (requiring each Party to "introduce appropriate national/domestic legislation to prevent and punish illegal traffic").

[61] Parties to the Convention have a variety of viewpoints on IPRs. Variations will likely continue, even as many countries implement the TRIPs Agreement, because some Parties will not join TRIPs, and TRIPs provides for phase-ins, differentiated *sui generis* systems for plant breeders' rights, and exemption of plants and animals from patenting. Within the bounds of the general principles established by the Convention (for instance, in Article 16.2 and 16.5), each Party may tailor its guidelines to conform with its viewpoint on IPRs and its respective treaty obligations.

(e) Agreeing to *cite or acknowledge sources* of genetic resources that contribute to research findings, including products or inventions; for example, a scientist could acknowledge the country of origin of genetic resources that are the subject of a publication in a professional journal, or an inventor could acknowledge in a patent application the country of origin of genetic resources used in the invention;

(f) Providing benefits to *local and indigenous communities* (see section K below).

91. As explained in section III, D, above, it will probably be useful to design guidelines that reflect the different types of uses to which access seekers may put genetic resources. In addition, guidelines must be flexible enough to accommodate the diversity of situations that will arise, and the rapid change in relevant technologies.

92. A prime example is the size of the royalty payment that would be due if a product is derived from the genetic resources. Because the market for these types of resources is changing rapidly, and because institutions offering genetic resources are offering a variety of combinations of resources and associated information and services, it will be impossible for Governments or international agencies to establish a uniform "fair" price for most transactions involving genetic resources. A more effective approach would be to require some provision for sharing of future benefits that may result and, at the same time, provide education and advice to negotiators in providing countries so that they can negotiate effectively.

I. Research results: tensions between public disclosure and confidentiality

93. The Convention embodies two different perspectives on the treatment of the results of research and development on genetic resources. On the one hand, it promotes open disclosure and publication of results as a way of stimulating cooperation and innovation. Article 15.6, for example, requires Parties to endeavour to develop and carry out scientific research on genetic resources "with the full participation of, and where possible in," the Party providing the resources (See also Article 15.7 and Articles 16-19).

94. On the other hand, the Convention also acknowledges the interest in private control of some types of information. Article 16.2 provides that transfer of and access to technology under Article 16 "shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights." Patents, which the Convention notes are one type of IPRs, provide for public disclosure of information sufficient to reproduce the invention, but give the patent holder the exclusive right to control commercial use of the invention for a limited period. In contrast, trade secrets, which are classified as IPRs under the TRIPs Agreement, give the holder the right to prevent the acquisition and use of information, where the information has commercial value because it is secret, and the holder has taken reasonable steps to keep it confidential.[62]

95. In fact, confidentiality requirements seem to be characteristic of ABS agreements. Corporations funding commercial research will often seek to keep research results secret until they can obtain patent protection over the resulting invention. Their concern is that if research results are disclosed before they are patentable, competitors may use the information to develop a competing product and patent the same or a similar invention. Where a participant in an ABS arrangement insists on including confidentiality of research results in a legal contract, the research results may constitute trade secrets as

[62] See TRIPs Agreement, Article 39.

defined by the TRIPs Agreement. Even provisions of an ABS agreement themselves - such as the clause requiring payment of a certain percentage of profits from future products -may be considered confidential by some participants, for competitive reasons.

96. If trade secrets come within the definition of IPRs under the Convention on Biological Diversity as well, then this language suggests that Parties may reasonably require enforcement of provisions in ABS agreements that require participants to keep research results confidential for a certain period of time. However, Article 16.5 also provides that Parties must cooperate to ensure that IPRs "are supportive of and do not run counter to [the Convention's] objectives." This suggests that Parties might discuss whether to require disclosure of certain types of research results in some circumstances, for example after a certain number of years have passed. The general language of the Convention would seem to give Parties the opportunity to experiment with different techniques for balancing the Convention's provisions on publication and confidentiality.

J. Building capacity to use genetic resources

97. A repeated theme in the experience so far with ABS arrangements has been the need to build up capacity in developing countries to make use of their genetic resources. Many developing country Parties are eager to build up the expertise of institutions involved in negotiating ABS agreements, to strengthen expertise in a range of scientific and technological fields, and to enhance capacity to acquire, manage, modify and develop technologies. A number of commentators argue that building Parties' capacity to add value to their own resources will be the most effective way of sharing benefits equitably in the long run.

98. This theme reflects many of the Convention's provisions relating to genetic resources. The Article 15 provisions on PIC in essence set the stage for the negotiation of mutually agreed terms. Notification of the providing Party's Government of a request for access will trigger a PIC procedure under which the access seeker must provide additional information regarding the material and possible future uses of it. That step, in turn, leads to negotiation of mutually agreed terms for access.[63] Thus, the terms of access granted under Article 15 will be an important mechanism for achieving technology access and transfer for providing Parties (Article 16), providing Parties' participation in biotechnology research (Article 19.1), and sharing benefits of biotechnology that makes use of genetic resources provided by Parties (Article 19.2). In this way, Parties can seek to enhance investment in their own capacity to use their own resources.

K. Local and indigenous communities

99. Under Article 8 (j), "as far as possible and as appropriate" and "subject to national legislation," Parties shall take three types of action: (a) "respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for conservation and sustainable use"; (b) "promote [the] wider application" of indigenous and local communities' knowledge, innovations and practices that are relevant to sustainable use, while ensuring the communities' approval for this use; and (c) encourage the equitable sharing of benefits with those communities.

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[63] Note that national legislation could establish minimum standards for some elements of mutually agreed terms, although experience suggests that regulation should permit significant flexibility in the design of individual transactions. The Parties could also cooperate on international guidelines.

100. Traditional knowledge can be highly valuable in identifying sources of new products derived from genetic resources, including pharmaceuticals and crop varieties.[64] For example, when researchers investigate plants for medically active compounds based on traditional uses, the proportion of active leads is well above the number found using taxonomic relationships or random collection.[65] In addition, many genetic resources found in traditional crop varieties may result in part from innovations of indigenous or local communities embodying traditional lifestyles.[66]

101. Given these connections between genetic resources and local and indigenous knowledge and innovations, Parties might consider implementing Article 8 (j) in conjunction with Article 15. For example, PIC procedures might also provide that access seekers must obtain the informed consent of local and indigenous communities. As noted in section II, A, above, at least one Party has already taken this approach in domestic implementation.[67] Parties could also mandate that access seekers negotiate with local and indigenous communities to provide a share of the benefits, monetary or otherwise. In this case urgent consideration would need to be given to ways and means of equipping these communities with the necessary legal and negotiating skills.

102. In another example, Parties might require that those who obtain access to genetic resources must acknowledge any use of indigenous and local communities' knowledge embodying traditional lifestyles, through citation in publications or patent applications. Citation or public acknowledgment of contributions of providing countries or communities to research or product development is also a way of demonstrating "respect" for those contributions, which is also required under Article 8 (j). A number of indigenous groups and leaders have emphasized that one of their main goals is to ensure such fair attribution and credit for their contributions.

103. An example of implementation of Article 8 (j) in an ABS arrangement is found in the National Cancer Institute's Letter of Collection (summarized in annex II). The letter provides that, if "knowledge of the medicinal use of any plants by the local population or traditional healers ... guide[s] the collection of plants," then such information will be kept confidential until the National Cancer Institute and involved source country institutions agree on publication, and "the permission of the traditional healer will be sought before publication of their information, and proper acknowledgement will be made of their contribution." Most of the other ABS arrangements and policies reviewed in annex I to this report make some provision for sharing of benefits with indigenous communities.

104. By obtaining prior approval and sharing benefits, Parties can create incentives for local and indigenous communities to assist in the process of developing genetic resources sustainably. This will also create incentives for these communities to continue their work of conserving genetic resources and

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[64] See UNEP Intergovernmental Committee on the Convention on Biological Diversity, second session, *Farmers' Rights and Rights of Similar Groups: The rights of indigenous and local communities embodying traditional lifestyles: experience and potential for implementation of Article 8(j) of the Convention on Biological Diversity: Note by the Interim Secretariat*, UNEP/CBD/IC/2/14, Annex, (1994) [hereinafter *Note on Local and Indigenous Communities*].

[65] See Geoffrey Cordell, "The Discovery of plant anticancer agents," *Chemistry and Industry*, 1 November 1993 (citing R. W. Spjut and R.E. Perdue, *Cancer Treatment Reports* 60:979-85 (1976).

[66] See David Downes, "Global Trade, Local Economies and the Biodiversity Convention," in William J. Snape, ed., *Biodiversity and the Law: Challenges and Opportunities* (forthcoming 1995).

[67] See Philippines Executive Order, preamble, section 5 (e).

to continue to maintain the knowledge, innovations and practices by which they conserve and sustainably use those resources. It also responds to the need to reward equitably these communities' investment in conservation; in this sense, Article 8 (j) is analogous to the concept of Farmers' Rights articulated in the FAO Undertaking on Plant Genetic Resources.

IV. CONCLUSIONS AND RECOMMENDATIONS

105. The entry into force of the Convention on Biological Diversity ushered in a new era with regard to access to genetic resources. Article 15 contains the broad framework within which access to genetic resources is to take place. In brief, access must be on mutually agreed terms (see Article 15.2 and 15.4). It must be by prior informed consent (unless otherwise determined by the providing Party) (see Article 15.5). It must be for environmentally sound uses. Receiving Parties must share resulting benefits equitably (see Articles 15.7 and 19.2). They must also take steps to help providing Parties to participate in research on their genetic resources, and obtain access to resulting technology (see Articles 16.3 and 19.1). Experience is new and is still growing in giving practical meaning to this framework in the context of the Convention's three-fold objective.

106. As noted in the introduction to the present report, agenda item 6.6.1 of the medium-term programme of work for the third meeting of the Conference of the Parties calls upon Parties to compile their views on possible options for developing national legislative, administrative or policy measures to implement Article 15. The Conference of the Parties may wish to request an analysis of the advantages and disadvantages of possible options for developing such measures. For example, as noted in paragraph 73 above, the Andean Pact countries are developing a regional approach to establishing guidelines for national access regimes. It was also suggested (see paragraph 74) that minimum standards for PIC may be desirable provided they contain appropriate flexibility for individual transactions. The same could be said for guidelines or minimum requirements for MATs. An analysis of the benefits of different approaches and the level at which each approach might most effectively be undertaken might help the Conference of the Parties in deciding how to develop measures to implement Article 15.

107. Developing and implementing access regimes is a complex process. It involves diverse stakeholders and requires a supportive policy, legal and institutional setting. Designing an appropriate regime requires the identification of needs and priorities and the understanding of viable options. The design phase itself implies a certain level of knowledge and expertise. Related to paragraph 102 above, the Conference of the Parties may wish to consider how developing country Parties can best be assisted in: (a) formulating effective national measures to implement Article 15; (b) building capacity to use and add value to genetic resources; (c) strengthening research and development capacity and creating a policy environment that supports technological innovation; and (d) gaining expertise in negotiating ABS agreements, including expertise in international business transactions. The Conference of the Parties may wish to consider, in particular, how the clearing-house mechanism might be used to facilitate joint ventures/research which assist Parties in acquiring the necessary knowledge, skills and expertise.

108. As noted in the introduction to the present report, the survey of measures taken by Governments was not comprehensive. The Conference of the Parties may wish to consider requesting the Secretariat to collect and organize all extant national legislation. In addition, consideration should be given as to how the clearing-house mechanism might incorporate and maintain this information.

109. The present report and its annex II have examined the texts of international instruments containing PIC procedures. The Conference of the Parties may wish to consider an analysis of actual experience in implementing the PIC procedure to see what lessons might be drawn of relevance to the

Convention on Biological Diversity. In addition, as noted in section II, C, and in annex II, PIC procedures typically provide for an international database containing policies, regulations and other measures as well as procedural information regarding what authorities to contact and how. The Conference of the Parties may wish to consider how this information can be incorporated and disseminated through the clearing-house mechanism.

110. As noted in section I, A, the genetic resources provisions of the Convention on Biological Diversity apply to genetic resources within the national jurisdiction of Parties. Article 22 of the Convention provides that it shall be implemented consistent with the rights and obligations of States under the law of the sea. The United Nations Convention on the Law of the Sea (UNCLOS) establishes the law of the sea for its 75 parties, and most of it is accepted as international customary law of the sea. UNCLOS establishes detailed provisions requiring coastal States to consent to marine scientific research within their exclusive economic zones under normal circumstances, excluding research with direct significance for exploitation of exploration of resources. Review of a 1989 survey[68] of national legislation and regulations regarding marine scientific research shows that none referred directly to genetic resources. An analysis of the survey indicates: (a) the synergistic effect the 1982 UNCLOS could have on the implementation of Article 15 of the Convention on Biological Diversity; (b) that many coastal States may already have in place legislation that is adaptable for ensuring the sharing of benefits derived from the scientific or commercial use of genetic resources taken from their internal waters, territorial sea, continental shelf, fishing zone or exclusive economic zone; and (c) that with proper internal harmonization, marine scientific research legislation and similar legislation for terrestrial scientific research could serve as the basis for a coastal State's comprehensive treatment of genetic resources and the benefits derived from their use.

111. The genetic resource provisions of the Convention on Biological Diversity do not apply to genetic resources in areas outside national jurisdiction, such as the high seas and the deep seabed. Genetic resources in these areas may, however, have major value for humanity. UNCLOS did not anticipate this value and it is unclear whether or how the common heritage principle applies to the living resources of the deep-sea bed. The Conference of the Parties may therefore wish to request the expert panel recommended by the SBSTTA[69] to undertake an in-depth analysis of the relationship between the Convention on Biological Diversity and UNCLOS looking, in particular, at (a) how to address the use of genetic resources outside national jurisdiction, (b) how UNCLOS and the Convention on Biological Diversity could be mutually reinforcing with regard to access to marine genetic resources under national jurisdiction.

112. Finally, there are two issues which might benefit from further study either by the SBSTTA or the Secretariat in preparation for future discussions on the development of access regimes. One is looking at the relationship between biochemicals and genetic resources and how the former might be handled in access regimes. The second issue is how human genetic resources relate to the Convention on Biological Diversity and options for action by the Conference of the Parties to clarify the situation.

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[68] United Nations Office for Ocean Affairs and the Law of the Sea, *National Legislation, Regulations and Supplementary Documents on Marine Scientific Research in Areas Under National Jurisdiction* U.N. Sales No. E.89.V.9 (1989). The document compiles legislation from 103 of 140 coastal States, self-governing associated States and Territories, at 3.

[69] See, paragraph 62 above.

ANNEX I

Examples of Access and Benefit-Sharing Arrangements

	NCI/Smokebush	INBio/Merck
Description of Arrangement	Prior to adoption of the Biodiversity Convention, the United States National Cancer Institute obtained a sample of the smokebush, genus *Conospermun*, from the state of Western Australia in Australia.* NCI's analysis of the plant revealed conocurvone, a compound with potential for AIDS treatment, and NCI applied for a United States patent. NCI published an offer to license the rights to develop the patented compound; an Australian pharmaceutical company, AMRAD Corporation, applied for and received preliminary approval, but was unable to agree with NCI on licensing terms. The Western Australia Department of Conservationa and Land Management (CALM) is now negotiating with NCI on terms for access to additional smokebush samples. **Australia ratified the Convention on 18 June 1993.*	In 1991, the Instituto Nacional de Biodiversidad (a government-chartered NGO in Costa Rica*) signed a two-year agreement with Merck & Co. Inc. (a multinational corporation based in the United States*) to collect organisms and supply extracts; the participants renewed the agreement for another two years in 1994. **Costa Rica ratified the Convention on 26 August 1994. The United States signed the Convention on 4 June 1993, but has not ratified it.*
Participants and Their Roles	***National Cancer Institute*** • Screening • Product development • Patent holder on chemical derived from the smokebush plant ***Western Australia Department of Conservation & Land Management (CALM)*** • Dealt with AMRAD to allow research on the use of conocurvone and other conservation activities. Since AMRAD has withdrawn, a consortium of CALM scientists will work with NCI on collection of smokebush samples for use in developing conocurvone.	***Instituto Nacional de Biodiversidad (INBio)*** • Collection of plant specimens • Extraction ***Merck & Co., Inc.*** • Screening • Post-screening product development
Resources from Providing Country	• Smokebush samples	• Extracts of plants collected from rainforests in Costa Rican national parks
Benefits to Providing Country	• In negotiation	• Initial advance payment to INBio, $1,135,000 includes: • Contribution to Costa Rica's National Park Fund, $100,000 • Training, $120,000 • Extracting fee paid to University of Costa Rica, $80,000 • Lab equipment, $135,000 • Salaries, $100,000 • Contribution to biodiversity inventory, $60,000 • Supplies & expenses, $120,000 • Equipment for biodiversity inventory, $285,000 • Administration, $135,000 • Royalty payments to INBio to be paid on any future derived products (percentage not disclosed)
Intended Uses of Resources	• Pharmaceuticals	• Pharmaceuticals
Sources	(11), (12), (13)	(8), (10)

Examples of Access and Benefit-Sharing Arrangements

		ICBG in Suriname*
Description of Arrangement		The International Cooperative Biodiversity Group (ICBG)[1] collaborative agreement between Suriname and United States institutions and NGOs seeks sources of new pharmaceuticals from Suriname rainforest plants, using both random collecting and collecting based on traditional knowledge. [1]For details of the ICBG program see explanatory note 1 below. **Suriname signed the Convention on 13 June 1992, but has not ratified it.*
Participants and Their Roles		***United States National Institute of Health (NIH), National Science Foundation (NSF), and Agency for International Development (USAID)*** • These government agencies plan to provide $2.7 million in funding over 5 years ***Conservation International and CI-Suriname*** • Collection & documentation of specimens • Documentation of traditional knowledge ***Missouri Botanical Gardens*** • Collection of specimens ***National Herbarium of Suriname*** • Collection of specimens ***Bedrijf Geneesmiddelen Vorziening Suriname*** • Extraction and in-country screening ***Bristol-Myers Squibb Pharmaceutical Research Institute*** • Further screening, chemical analysis and product development ***Virginia Polytechnic Institute and State University*** • Further screening, chemical analysis
Resources from Providing Country		• Chemical extracts from collected organisms • Traditional knowledge and uses
Benefits to Providing Country		• Initial payment of US$50,000 • BMS will pay royalties equal to an undisclosed percentage of sales of derived products • A newly-established Forest People's Fund with a board including local leaders will receive 50% of royalties from future sales • 50% of royalties to be distributed among Surinamese collaborating institutions and government agencies • Contract provides that local healers who help invent new products share patent rights • Creation of Shaman's Apprentice Programs • BMS provides some training and equipment
Intended Uses of Resources		• Pharmaceuticals
Sources		(1), (3), (5), (14), (16)

Examples of Access and Benefit-Sharing Arrangements

	ICBG[1] in Cameroon/Nigeria[*]	**ICBG[1] in Argentina/Chile**/Mexico
Description of Arrangement	This arrangement pursues ethnobotancial and ethnomedical investigation of rainforest plants in the Oban hills in Nigeria and the Kourup forest of Cameroon as sources of treatment for parasitic diseases such as malaria. [*]*Nigeria ratified the Biodiversity Convention on 29 August 1994; Cameroon ratifed on 19 October 1994.*	The collaborative study between United States universities and firms and institutions in Argentina, Chile and Mexico is surveying plants from dryland ecosystems for their potential pharmacological uses. [*]*Chile ratified the Convention on 9 September 1994; Argentina on 22 November 1994; Mexico on 11 March 1995.*
Participants and Their Roles	***United States NIH, NSF, USAID*** • These government agencies plan to provide $2.2 million in funding over 5 years ***Smithsonian Institution*** • Inventorying • Constructing a permanent forest plot for studying forest dynamics ***Bioresources Development and Conservation Programme (international NGO)*** • Inventorying • Extracting • Training ***University of Yaounde (Cameroon)*** • Extracting ***University of Nigeria*** • Extracting ***Shaman Pharmaceuticals*** • Product development ***Bristol-Myers Squibb Pharmaceutical Research Institute (BMS)*** • Product development ***Walter Reed Army Institute of Research (WRAIR)*** • Screening and product development	***United States NIH, NSF, USAID*** • These government agencies plan to provide $2.7 million over 5 years ***University of Arizona*** • Extraction, screening ***Purdue University*** • Bio-assay guided fractionalization, *screening* ***American Cyanamid Company*** • Screening and product development ***Louisiana State University*** • Screening ***Catholic University of Chile*** • Biodiversity inventory and collection National University of Patagonia (Argentina) • Biodiversity inventory and collection ***Institute of Biological Resources (Argentina)*** • Biodiversity inventory and collection
Resources from Providing Country	• Extracts from rainforest plants • Traditional knowledge • Preliminary bioassay	• Chemical extracts from dryland plants • Knowledge of local non-indigenous traditional healers
Benefits to Providing Country	• Training in forest management • BMS will pay royalties equal to an undisclosed percentage of sales of derived products • Assistance in community development projects • 20% of royalties on patented products will be distributed to contributing inventors, if any, in some countries • 50% of royalty income will be distributed to Bioresources Development and Conservation Program • 30% of IPR royalties will be donated to WRAIR Tropical Disease Drug Program	• Training in isolation and identification of compounds, and in the growth, extraction and processing of plant materials; infrastructure and equipment • Sharing of scientific data • Sharing of monetary benefits from future derived products; 50% of royalties from licensed derived product will go to trust fund in country of origin, plus additional 5% if discovery process uses local knowledge
Intended Uses of Resources	• Pharmaceuticals • Phytomedicines	• Pharmaceuticals • Biotechnological • Agricultural
Sources	(3), (6), (7), (16)	(3), (4), (14), (16)

Examples of Institutional Policies on Access and Benefit-Sharing Arrangements

	National Cancer Institute Letter of Collection	Glaxo Research & Development Group
Description of Arrangement	The National Cancer Institute (NCI) is a United States Government research institution engaged in the development of cancer and AIDS treatments. Over the past several years, NCI has developed a standard agreement, the Letter of Collection (LOC), for obtaining access to samples of organisms in other countries for use in developing new pharmaceuticals. NCI signs the LOC as a legal agreement, either with a government agency of the country in which collecting will take place, or with a partner research institution there (as determined by the source country's authorities).	Glaxo Research and Development Group, the research arm of Glaxo Pharmaceuticals (a multinational corporation based in the United Kingdom*) conducts biodiversity prospecting for plants with potential pharmacological uses. Under this policy, Glaxo has entered into agreements to obtain samples from Peru and China. **The United Kingdom ratified the Biodiversity Convention on 3 June 1994.*
Participants and Their Roles	**Collector Under Contract with NCI** • May be either a United States or providing country institution • Collection of plant and/or marine organism specimens **Source Country Government and/or Source Country Institution or Organization** • Collection of specimens • Giving permission for collecting **National Cancer Institute, Division of Cancer Treatment, Developmental Therapeutics Program** • Screening extracts • Product development	**Glaxo Research and Development Group** • Screening • Product development
Resources from Providing Country	• Sample of plants or marine organisms, including initial supply and supplementary samples if NCI requests them • Traditional knowledge may be obtained	• Samples of randomly collected organisms • Guaranteed additional supplies, if possible
Benefits to Providing Country	• Efforts to transfer knowledge, expertise, and technology related to drug discovery and development • Possible benefits for indigenous or local communities (at option of source country Government) • Training • Scientific data & reports • Possible reliance on source country resources for large scale production of commercial product • If NCI grants a company the right to develop a product derived from a sample, it will require the company to negotiate an agreement providing for a share of benefits for the source country	• Cash payments for collectors • Reimbursement for collecting samples • Scientific training and education • Royalties will be paid to suppliers in source countries, equal to a percentage of sales of derived products • Glaxo requires suppliers to pay at least 40% of any royalties they receive to the "source group" most closely associated with the source species
Intended Uses of Resources	• Pharmaceuticals	• Pharmaceuticals
Sources	(15)	(2), (9)

Explanatory Note 1. Most of the arrangements highlighted in the annex are International Cooperative Biodiversity Groups (ICBGs). The ICBGs are collaboration arrangements for development of pharmaceutical products from natural sources in developing countries. The collaborations include both public and private institutions in the United States and developing countries. The ICBG program is funded jointly by the United States National Institute of Health, National Science Foundation, and Agency for International Development. The stated goal is to promote conservation and sustainable use of biological resources through sustainable development of natural drug products. While the United States is not a Party to the Convention, these arrangements are nevertheless useful illustrations of how the Convention might be implemented through mutually agreed terms.

There are two other ICBGs in addition to the three highlighted in annex I above. The Cornell/INBio ICBG studies insects and other species from dry tropical forests of the Guanacaste Conservation Area in Costa Rica. It involves INBio, the University of Costa Rica, Cornell University (United States), and Bristol-Myers Squibb

Pharmaceutical Research Institute (a research arm of a United States-based multinational pharmaceutical corporation). The Washington University/Peru ICBG, now in renegotiation, examines plants used in traditional medicine in Andean tropical rainforests in Peru. It involves Washington University in St. Louis (U.S.), the Natural History Museum (Peru), the Cayetano Peruvian University, the Central Organization of Aguaruna communities of the Alto Marañon (Peru), and Searle Pharmaceuticals (a U.S.-based pharmaceutical firm).

Explanatory Note 2. Descriptions of ABS arrangements and policies are based on publicly available information, which does not always include all relevant details and may exclude certain confidential information. For example, participants in most ABS arrangements do not disclose how large a percentage of profits from derived products is designated as a royalty for the source country or source country institutions.

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Annex II

THE CORE ELEMENTS OF PIC:

A BRIEF EXAMINATION OF RELEVANT INTERNATIONAL INSTRUMENTS

1. Scope of PIC procedure

The international instruments on wastes and chemicals contain provisions to limit the application of the PIC procedure and determining to whom it is to apply. Under the **London Guidelines for the Exchange of Information on Chemicals in International Trade**, "PIC is a procedure which operates in addition to information exchange and export notification" and countries can participate in this without electing to participate in PIC (Article 7). The Guidelines set out a procedure for identifying which chemicals should be subject to the PIC procedure. Likewise, the **Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal** defines the categories of waste subject to control (annex I), those needing special consideration (annex II) and includes a list of hazardous characteristics (annex III). As noted in section III, A, 2, of the attached report, different categories may warrant different regulatory regimes. This may or may not affect how Parties decide to apply their PIC procedure under the Convention on Biological Diversity.

2. Designated national authorities

The international instruments dealing with the control of trade in hazardous wastes and chemicals each call for a designated, functioning and comprehensively competent authority to be in charge of managing the PIC procedure from beginning to end.

Article 5 (1) of the Basel Convention requires Parties to designate or establish one or more competent authorities, defined in article 2 (b) as a "governmental authority designated by a Party to be responsible, within such geographical areas as the Party may think fit, for receiving the notification of a transboundary movement of hazardous wastes ... and any information related to it, and for responding to such a notification ...". Parties are also required to designate one focal point, defined in Article 2 (7) as an "entity of a Party referred to in Article 5 responsible for receiving and submitting information as provided for in Articles 13 and 16", that is, mostly, communicating with the Secretariat to the Basel Convention.

The London Guidelines make similar recommendations by providing, for example, that each State "designate a national governmental authority (or authorities) competent to perform the administrative functions related to the exchange of information and decisions regarding importation of chemicals included in the PIC procedure" (Article 5.4). The Guidelines go on to provide that the "designated national authority should be authorized to communicate, directly or as provided by national law or regulation, with designated national authorities of other States and international organizations concerned, to exchange information, to make and communicate decisions regarding chemicals included in the PIC procedure and to submit reports at the request of such States or organizations or on its own initiative" (Article 5.5).

Article 6 of the **FAO International Code of Conduct for Plant Germplasm Collecting and Transfer** recommends that Governments "designate the authority competent for issuing permits" to collectors.

The **functions of designated national authorities** vary from instrument to instrument. A core layer of tasks emerges from a close examination. These include overall coordination and communication concerning the following:

- receiving notification of imports/intended exports;
- requiring further information on a proposed import, if necessary;
- contacting all internal Ministries and sectors that might be closely involved;
- keeping in touch with the Secretariat of the Convention or relevant international body (see below);
- informing other agencies of proposed or approved transfers to which their jurisdiction or expertise is relevant;
- keeping in touch with non-governmental organizations and/or relevant international bodies;
- issuing import/export certificates;
- provision of information to public and affected industries;
- building technical capacity;
- enforcement action to ensure compliance.

3. Establishing an international database

The key to an effective PIC procedure is the timely provision of information from one country's designated national authority to another's. To assist the collection and dissemination of such information a number of instruments establish and maintain an international database. In the London Guidelines, the information exchange system is operated by UNEP and FAO, which utilize the existing International Register of Potentially Toxic Chemicals (See Articles 5, 6 and 9 of the Guidelines). The Basel Convention requires Parties to inform the Secretariat about its hazardous wastes legislation and requirements related to transboundary movements and require the Secretariat to convey this information to all Parties (see Articles 3 and 16.1 (g of the Basel Convention). The Conference of the Parties may wish to consider the desirability and potential role of the clearing-house mechanism of an international database of types of genetic resources for which PIC is required, as well as a list of PIC grants/denials by Parties.

Similarly, the International Atomic Energy Agency (**IAEA) Code of Practice for International Transactions involving Nuclear Waster** provides for the IAEA to collect and disseminate information on the laws, regulations and technical standards pertaining to radioactive waste management and disposal (see Article IV).

4. Minimum standards of information

Most of the existing PIC instruments set out the kind of information that must be provided to the importing (or host) country to enable it to give consent. Some of the instruments, such as the Basel

Convention and the London Guidelines, contain extremely detailed provisions on the kind of information to be provided and the time-frame within which it should be processed (see annexes V A and V B of the Basel Convention, and Part II, Article 6 and Annexes I, III and IV of the London Guidelines)

By contrast, the FAO Plant Germplasm Code sets out in very general terms the kind of information an intending collector should provide when submitting a permit application (Article 7). The Code does provide guidance on the information the national authority should give in response to such a request which should be treated "expeditiously" (Article 8).

5. Monitoring and enforcement

All of the PIC instruments contain elements to assess their practical effect and promote observance. The most detailed and institutionally developed provisions are to be found in the Basel Convention and the London Guidelines. The Basel Convention requires the Conference of the Parties continuously to review and evaluate the effective implementation of the Convention. The Convention specifically defines "illegal traffic" in Article 9 and creates obligations on Parties to check such traffic and punish it through criminal sanctions. The Secretariat of the Convention plays an important role in this respect, as it is specifically required "to assist Parties upon request in their identification of cases of illegal traffic and to circulate immediately to the Parties concerned any information it has received regarding illegal traffic" (Article 16.1 (i)).

The London Guidelines provide that UNEP and FAO periodically review the implementation of the PIC procedure (Article 5) and call upon designated national authorities to provide the IRPTC with information and feedback on any difficulties they have experienced using the Guidelines (Article 10). Similarly, the FAO Plant Germplasm Code provides for monitoring and evaluation of the Code (Article 16) and calls upon the FAO Commission on Plant Genetic Resources "to periodically review the relevance and effectiveness of the Code". It suggest that "relevant professional associations and other similar bodies ... may wish to establish peer review ethics committees to consider their members' compliance with the Code."

Enforcement requires penalties, the authority and ability to track activities and collect information. The PIC procedure could create categories of criminal and civil offenses for violations of PIC procedures and access agreements. Taking the Basel Convention as an example, the following situations should be covered:

- export of genetic resources without any PIC at all;

- export of genetic resources not obtained in compliance with the prior agreement;

- forgery of export certifications confirming the 'correct' acquisition of genetic material.
