UNEP

CBD

CONVENTION ON BIOLOGICAL DIVERSITY

Distr.
GENERAL

UNEP/CBD/COP/4/23
19 February 1998

ORIGINAL: ENGLISH

CONFERENCE OF THE PARTIES TO THE
CONVENTION ON BIOLOGICAL DIVERSITY
Fourth meeting
Bratislava, 4-15 May 1998
Item 16.3 of the provisional agenda*

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

Note by the Executive Secretary

I. INTRODUCTION

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

2. The Conference of the Parties has already considered Article 15 in depth at previous meetings. At its second meeting, it considered the compilation of "existing legislation, administrative and policy information on access to genetic resources and the equitable sharing of benefits derived from their use" (UNEP/CBD/COP/2/13) and "information provided by Governments as well as relevant reports from appropriate international organizations regarding policy, legislative, or administrative measures related to intellectual property rights as provided in Article 16 of the Convention and to access to and transfer of technology that makes use of genetic resources" (UNEP/CBD/COP/2/17).

3. At its third meeting, the Conference of the Parties considered a compilation of "views of the Parties on possible options for developing national legislative, administrative or policy measures, as appropriate, to implement Article 15" (UNEP/CBD/COP/3/20).

---

* UNEP/CBD/COP/4/1.

4. At the fourth meeting of the Conference of the Parties, access to genetic resources will be considered under item 16 of the provisional agenda (“Matters related to benefit-sharing”), which includes three sub-items:

(a) 16.1: "Measures to promote and advance the distribution of benefits from biotechnology in accordance with Article 19 ("Handling of biotechnology and Distribution of its Benefits)";

(b) 16.2: "Means to address the fair and equitable sharing of benefits arising out of genetic resources";

(c) 16.3: "Compilation of views of the Parties on possible options for developing national legislative, administrative or policy measures, as appropriate, to implement Article 15 (’Access to genetic resources’)", the issue addressed in the present note.

5. At its third meeting, the Conference of the Parties, in paragraph 1 of its decision III/15, urged “Governments, regional economic integration organizations and other international, regional and national competent organizations to send to the Secretariat, five months before the fourth meeting of the Conference of the Parties, information on:

> "(a) National, regional, and sectoral legislative, administrative and policy measures and guidelines for activities covered by Article 15, and in particular, on access and benefit-sharing, both adopted and under development, including information on their implementation;
>
> "(b) National participatory processes for the activities covered by Article 15, and in particular, ways by which access and benefit-sharing measures and guidelines, including related institutional arrangements are developed and implemented;
>
> "(c) As appropriate, research programmes on genetic resources."

6. By paragraph 2 (a) of the same decision, the Executive Secretary was requested to:

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

7. The present note has been prepared by the Executive Secretary in response to that request. It draws upon the following two previous documents prepared for the second and third meetings of the Conference of the Parties, respectively:

(a) Report by the Secretariat on access to genetic resources and benefit-sharing: legislation, administrative and policy information (UNEP/CBD/COP/2/13); and

(b) Note by the Executive Secretary on access to genetic resources (UNEP/CBD/COP/3/20).

8. The latter note was prepared in response to the request of the Conference of the Parties in decision II/11, paragraph 1 (a), for the Executive Secretary to further elaborate the survey of measures taken by Governments to implement Article 15, including any national interpretations of key terms used in that article with a view to completing the survey in time for circulation at the third meeting of the Conference of the Parties.

9. The present note assumes a familiarity with the contents and ideas of both documents referred to in paragraph 8 above, additional copies of which are available upon request from the Secretariat or can be downloaded from the Internet as <http://www.biodiv.org/cop2/COP2-13> and <http://www.biodiv.org/cop3/COP3-20>.

10. Sub-item 16.3 will provide an opportunity to continue the discussions on the implementation of Article 15 that took place at the second and third meetings of the Conference of the Parties. Likewise, the present note is a continuation of the previous submissions. It does not deal with ex situ collections not acquired in accordance with the Convention as those are subject to the negotiations for the adaptation of the International Undertaking on Plant Genetic Resources. These negotiations are currently being undertaken by Governments within the Commission on Genetic Resources for Food and Agriculture of the Food and Agriculture Organization of the United Nations (FAO) (see decision III/15, para. 7).

11. As of 22 January 1998, the Secretariat had received few official communications by Governments in response to paragraph 1 of decision III/15, although reminders were sent out to the national focal points on 4 February 1997 and 27 October 1997. Information has been provided by the Government of Tunisia, the Government of Turkey, the Government of Costa Rica, on the work of the Central-American Commission on Environment and Development, and the Government of Germany and the European Commission, on a Workshop entitled ‘Towards Best Practices for Access to Genetic Resources', held on 15-16 January 1998 in Córdoba, Spain.

12. The Secretariat has received some informal communication on measures and activities (including initial discussions) related to Article 15 in: the Association of South East Asian Nations (ASEAN); the Andean Pact member States - Bolivia, Colombia, Ecuador, Peru and Venezuela; Angola; Argentina; Australia (including two of its states); Brazil; Cameroon; Egypt; Eritrea; Ethiopia; Fiji; Gambia; Ghana; India; Indonesia; Kenya; Lao People’s Democratic Republic; Lesotho; Malawi; Malaysia (including Sabah and Sarawa); Mauritius; Mexico; Mozambique; Nigeria; Philippines; Seychelles; South Africa; South Korea; Sri Lanka; Thailand; Tunisia, United Republic of Tanzania; United States of America; Yemen and Zimbabwe. It has also received information on access measures and benefit-sharing arrangements in response to its call for case-studies on benefit-sharing (a synthesis report on which is contained in UNEP/CBD/COP/4/INF.7). The status of implementation of

Article 15 varies significantly among the Parties. Whereas some have already adopted comprehensive laws and administrative regulations, others are still in the process of discussing the adoption of appropriate access legislation.

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

II. MEASURES TO IMPLEMENT ARTICLE 15

14. The Convention on Biological Diversity regulates access to genetic resources and sharing of benefits derived from its use in Articles 15, 16, paragraph 3, 19, paragraphs 1 and 2. It is complemented by Article 8(j), in so far as genetic resources are subject to knowledge, innovation and practices of indigenous and local communities, and Article 17.2, which deals with the exchange of information including knowledge which makes use of genetic resources. All Articles require action from “each Contracting Party”. Articles 16, paragraph 3 and 19, paragraphs 1 and 2, ask for special consideration of developing countries in the context of technology transfer, participation in biotechnological research and the sharing of results and benefits from biotechnology (see UNEP/CBD/COP/4/21). Apart from these provisions, the Convention bases the access regime on the parties to genetic-resource transactions: the providing countries, which are countries of origin or those having acquired the genetic resources in accordance with the Convention, and the users of genetic resources provided by other Parties.

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

16. At the international level, measures other than guidelines might be also necessary regarding international legislation touching upon the regime of genetic resources of the Convention, especially on intellectual property rights which should be supportive of and not run counter to the objectives of the Convention (Article 16, paragraph 5). Relevant international instruments include the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPs) and the Union for the Protection of New Varieties of Plants (UPOV). This is, however, an area beyond the scope of this paper and its mandate given by decision III/15.

17. While natural measures might differ considerably, there is a need for harmonization in the interests of both the users and the providers of genetic resources since:

(a) Without harmonized standards, access might be made more difficult rather than facilitated as called for in Article 15, paragraph 2 of the Convention;

(b) Legal and institutional uncertainty hinders access and, hence, benefit-sharing by users;

(c) Access and benefit-sharing measures in one country might turn out to be useless if the user remains uncontrolled in the country of provenance;

(d) The same is true if provider countries with similar biodiversity have lower or no standards: users will choose the country where benefit-sharing requirements are the lowest. The Andean Pact has responded to this problem by establishing a common access regime.

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

19. The present note includes both a section on provider-related guidelines and a section on user-related guidelines. It is up to each Contracting Party to decide which part of the guidelines might be drawn upon first. Those countries that are more a provider than a user might wish to start setting up measures, such as legislation, for providing genetic resources. On the other hand, those countries whose emphasis is more on the user side might wish to establish some regulation or at least guidance on ensuring that when their bodies and their nationals use genetic resources from other countries, they have secured prior informed consent and reached mutually agreed terms which strive for the fair and equitable sharing of benefits.

A. Provider-related guidelines

1. Preparatory process

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

21. The national or regional 1/ planning process can either be built into an overall biological-diversity strategy in accordance with to Article 6(a) of the Convention or be established as a stand-alone process for access and benefit-sharing in relation to genetic resources. After identifying the stakeholders that should be part of the process, the strategic plan should include an assessment of the natural-resources-related industrial, administrative, institutional and legal status quo, as well as the identification of parameters for access legislation and the implementing process.

(a) Identification of stakeholders

22. Stakeholders vary from country to country. As an initial step, there is a need to identify those stakeholders within the country who should be included in the planning process. They may include:

(a) Ministries and government agencies concerned with natural resources, agriculture, including fisheries and forestry, customs, protected areas, health, research, justice;

(b) The industrial sector, in particular pharmaceutical, plant-health horticultural, personal care and cosmetics, flavouring and fragrance, food and beverage, and other biotechnological companies;

(c) The scientific and academic communities, such as universities and research institutions dealing with genetic material;

(d) Ex situ conservation facilities, such as botanical gardens, zoos, microbial resource centres, universities and research institutions;

(e) Indigenous and local communities or their representative organizations;

(f) People's organizations;

(g) Traditional healers or their associations;

(h) Non-governmental organizations working in the field of genetic resources.

23. For example, Australia, Malaysia, the Philippines and South Africa had or have set up a national committee, with Malaysia, the Philippines and South Africa including stakeholders from all sectors of society.

(b) Assessment of the status quo

24. As part of the law-making process, a country should assess its own needs, opportunities, resources, and capacities (“stock-taking”). This exercise should include a review of:

1/ The following text describes the national process and legislation. It applies equally, however, to regional processes and legislation as well, with the modifications that derive from the nature of such an exercise at the regional level.

(a) What kind of biological resources are available in the country;

(b) What information related to genetic resources and derived products is available in the country, including information related to scientific and traditional knowledge;

(c) The types of commercial uses to which genetic resources might be applied;

(d) Existing legislation related to biological diversity and, in particular, genetic resources, including legislation on natural resources, such as constitutional norms on biodiversity, natural resources etc., wildlife laws, conservation legislation, sectoral laws related to fisheries, forestry and agriculture, laws on protected areas; land-tenure law, intellectual property law, regulations on research (permit requirements), phytosanitary regulations and import and export regulations for biological resources, including regulations related to the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES);

(e) Country capacity in human resources for access and development projects, scientific and technological know-how (taxonomists, biochemists, etc.), in order to get an idea of the country's potential to participate in the product-development phase;

(f) What institutions are carrying out which functions related to genetic resources and what their capacities are.

2. Elements for legislation

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

26. Whatever approach is chosen, it might be useful to review existing legislation and policy in order to make it compatible with new access legislation and to avoid conflicting laws and regulations. This is especially important regarding other natural resource laws; for example, while licences or research permits should not proliferate, the access-and-benefit-sharing arrangement should cover all requirements, including the sustainability of the access activity and environmental impact concerns.

27. Since the third meeting of the Conference of the Parties, new stand-alone legislation has been adopted by Bolivia (Supreme Decree No. 24676 of 21 June 1997 implementing Decision 391 of the Andean Pact, on the Common Regime on Access to Genetic Resources), Brazil (Bill of Law No. 306/95 of 19 November 1997 on Access to Genetic Resources) and India (Bill on Access to Genetic Resources).

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

(a) Scope of application

29. Various criteria can determine the scope of application. Standard criteria include:

(a) Types of genetic resources;

(b) Ex situ and in situ conditions; and

(c) Indigenous and local knowledge, innovations and practices (intangible components related to genetic resources.

(i) Types of genetic resources

30. The scope of application can be distinguished first of all according to the taxonomic origin and classical kingdoms: animals, plants and micro-organisms. For example, the Costa Rican and the Philippines regulations apply only to wild fauna and flora.

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

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

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

34. Genetic resources from human origin are often explicitly excluded from the scope, as, for example, with the Andean Pact, Brazil and the Eritrean draft.

(ii) In situ and ex situ conditions

35. Provisions on access and benefit-sharing include material from both in situ as well as ex situ conditions (Brazil, Andean Pact, Costa Rica). If ex situ collections are not covered, there is a risk that provisions related to in situ genetic resources are circumvened in approaching the institution holding ex situ collections. Furthermore, the ex situ facility might have special knowledge regarding the use and characteristics of the genetic resource.

(iii) Local and indigenous knowledge, innovations and practices

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

(b) Property rights and ownership clauses

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

38. This is done in order to avoid giving those owning the physical natural resource as such ownership of the genetic component or a potential derivative. What was formerly total ownership can thus be divided into two parts: genetic resources and related material are subject to a qualified regime in relation to the ownership of the physical entity which forms the biological resource; and the genetic resource is subject to different rights for its information value, which is different from the direct-use value of the biological resource.

39. Where the genetic component is subject to a specific regulation, the physical owner is not entitled to transfer its use without the consent of the respective owner or the authority representing the owner (for example, the law declares the genetic component to be a national patrimony). Only by an access and benefit sharing arrangement can a user obtain the right to use the genetic component or the derivatives. This right is subject to the conditions in the arrangement, which include the sharing of benefits and sustainability (see below).

(c) Definitions

40. Stand-alone laws on access and benefit-sharing contain a series of definitions of legally important terms, the content of which goes beyond normal usage. These definitions draw partly on those in the Convention and partly define terms in a broader sense. Terms defined include: access to genetic resources; intangible property; traditional knowledge; competent national authority; biotechnology; access contract; derivative/derived product.

(d) Requirements for prior informed consent (PIC)

41. Prior informed consent (PIC), required by Article 15, paragraph 5, of the Convention, is the central procedural device enabling the provider of genetic material or related knowledge to negotiate the terms of the access and benefit-sharing agreement (which may be a bioprospecting arrangement or, in general, the "mutually agreed terms"). It enables the providers of genetic resources or related knowledge to negotiate on a more equal basis with the users of those resources. Requirements for information to be provided by the user of the material or related knowledge set up in the legislation include:

(a) Quantity and kind of material to which access is sought;

(b) Duration of the access activity;

(c) Locality or area of access, including the geographical coordinates;

(d) Assessment of the impact of the access activity on conservation and sustainable use of biological diversity;

(e) Purpose of the research and expected result.

(e) PIC procedure

(i) General

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

43. Provisions regulating the involvement of stakeholders in the decision-making process should balance the rights with the interests of the applicant and the practicability of the PIC procedure in order to facilitate access. To meet those concerns, some legislation (e.g. the Andean Pact Regime and the Brazilian Bill) establishes time-frames within which access must be denied or granted Countries have been criticized for not being practical and providing disincentives for potential private-sector partners in access-and-benefit-sharing arrangements or non-governmental organizations

involved in conservation whose work is impeded as access has become more difficult.

(ii) Use-related distinctions

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

45. Some legislation foresees the possibility of framework or umbrella agreements, such as the Andean Pact or the Philippine Executive Order. Such an arrangement facilitates access for specific purposes by a specific institution or person and avoids the need to negotiate an individual agreement in each instance, thus lightening the bureaucratic burden.

(iii) Nationality-related distinctions

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

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

48. Another in-country example of bioprospecting is the case of the biotechnological company Diversa, which has signed and access-and-benefit-sharing agreement with the authorities of Yellowstone National Park in the United States. The Park receives a package of economic, scientific and technical benefits that includes an annual financial contribution to the Park creditable against future royalties, based on revenues generated by the commercialization of enzymes for valuable applications, and research training. As this example shows, benefit-sharing can also take place between different sectors of society within one country, thus creating incentives for conservation and sustainable use. Countries

might wish to strive for in-country benefit-sharing and not differentiate between users on the basis of their origin but rather on the basis of the purpose of the use. Some legislation, such as the Andrean Pact Regime, wisely exempts from its provisions trade in genetic resources among indigenous and local communities and small-scale farmers.

(f) Requirements for mutually agreed terms

49. “Mutually agreed terms” is the second pillar of the access-and-benefit-sharing regime set up by the Convention. Mutually agreed terms presuppose prior informed consent to negotiate the access-and-benefit-sharing-arrangement (ABA). 2/ Inherent in the phrase "mutually agreed terms" is the expectation of a negotiation between the party providing genetic resources and a potential user. Mutual agreement does not, however, imply complete liberty in what might be agreed upon. Every access-and-benefit-sharing-arrangement is embedded in the regime of the Convention. This implies that some features are keys to the agreement and might be required by the access legislation.

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

(a) Kind, quantity of prospected material and location of prospection;

(b) Deposit of specimens and registered knowledge with the competent national authority of country of origin;

(c) Research participation;

(d) Benefit-sharing, e.g., immediate benefits in cash and kind exceeding normal salaries and reflecting the economic value of genetic resources; payment of royalties; flow-back of benefits into conservation and sustainable use of biological diversity; technology transfer, capacity-building in different areas, adding value inside the country of origin;

(e) Confidentiality of information;

(f) A clause allowing renegotiation during the project;

(g) Ownership of the resource;

2/ The term "access-and-benefit-sharing arrangement" (ABA) describes an agreement which is in line with the provisions of the Convention. The term “material transfer agreement” is generally used for every exchange of genetic resources on a contractual basis, regardless whether benefit-sharing is part of that agreement; for example, the private sector has been using the term for a long time for all transactions of genetic material. It is therefore proposed that the term "access-and-benefit-sharing agreement" be used to describe contracts that take the provisions of the Convention on Biological Diversity into account.

(h) Agreement on whether the material can be passed on to entities not party to the mutually agreed terms;

(i) Time limitation of the agreement.

(j) Recognition of the origin of related information, for example, in publications or the description of the marketed product.

51. The kind of benefit-sharing to be included in the agreement can be stipulated in the access regulation. However, the amount and scope of the benefits to be shared should be decided during the negotiations. The kind of benefits which are possible are elaborated upon in notes by the Executive Secretary on measures to promote and advance the distribution of benefits from biotechnology in accordance with Article 19 (UNEP/CBD/COP/4/21) and on means to address the fair and equitable sharing of benefits (UNEP/CBD/COP/4/22).

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

(g) Partners to the mutually agreed terms

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

(a) Agreement between the competent authority/institution responsible for the PIC procedure and the user;

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

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

(d) Quadripartite agreement between the competent authority, the user, the agency of access and the provider of traditional knowledge.

(h) Monitoring and enforcement

54. It is difficult to monitor agreements on access and benefit-sharing. One possibility is a regular report requirement on advances made in research and development conducted on genetic-resource accessions. Some legislation (e.g., Brazil, Philippines) foresees penalties or the cancellation of the agreement in case of violation of its provisions. There is a need for more case-studies and information on best practices on monitoring and enforcement.

3. Institutional arrangements

55. During the process of preparing access measures, there is a need to identify the most appropriate kind of institution or administrative structure to handle bioprospecting. The responsibilities might well go beyond the negotiation of access-and-benefit-sharing arrangements but include:

(a) The development and implementation of an efficient, simple and transparent process for bioprospecting arrangements;

(b) The provision of legal and business expertise to providers of genetic resources, organizing capacity building activities, including, for example, drawing on GEF funding for such activities;

(c) The coordination of the consultative policy process surrounding bioprospecting and the examination of the macropolicy context in which it operates (e.g. other laws, government incentives);

(d) The development of a strategic approach for promoting biotechnology research and capacity in the country providing genetic resources;

(e) The monitoring of the bioprospecting arrangements together or in collaboration with other stakeholders, such as the patent office or research related institutions;

(f) The receipt and disbursement of revenues/benefits from bioprospecting arrangements that are not dedicated to local and indigenous communities or other direct stakeholders, such as the national park management.

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

B. User-related guidelines

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

58. At the same time, there is a growing uncertainty from the user side regarding access to genetic resources. Users need clear contact points in the country of origin and authorized institutions to grant access. There is a need for legal certainty on access, ownership, tenure and related rights in the provider country so that the user can comply with the provider's national laws and regulations. Where there is legislation and policy in place, the lack of capacity on the provider countries to implement it and to negotiate access and benefit-sharing arrangements creates another uncertainty from the point of view of the user.

59. Article 15, paragraph 7, of the Convention, refers to legislative, administrative, or policy measures to ensure the fair and equitable sharing of benefits. Some user countries have already taken policy measures, such as setting up programmes for joint research on genetic resources between institutions in the provider and user countries or developing economic incentives for their nationals to negotiate access-and-benefit-sharing arrangements.

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

61. As the discussions on user-related guidelines are still in their infancy, the following guidelines will need to be further developed by the Parties.

1. Preparatory process

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

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

(a) Access regulations to ex situ facilities;

(b) Import regulations related to species protection, phytosanitary regulations, etc.;

(c) Intellectual property rights, in particular conditions for granting patent applications, plant breeders rights, trademarks, appellations of origin;

(d) Food-and-drug-administration laws and other official authorization systems;

(e) Natural-resources law.

2. Legislative and administrative measures

64. Once an analysis has been completed on which part of the legal and administrative system is the most appropriate for incorporating access-and-benefit-sharing regulations, the relevant area or areas, which might vary from country to country, should be changed accordingly to ensure that the user of a genetic resource has negotiated a bioprospecting arrangement based on prior informed consent according to the law of the country of origin of the genetic resource or knowledge.

3. Conclusions and recommendations

65. The access-and-benefit-sharing regime set up by the Convention is still under development. Best practice is just emerging and no final conclusions can be drawn from the experience which has been gained so far. It is therefore important to review and readjust measures to implement Article 15 on a regular basis. There is also a need to develop some guidelines for users in the event that no access legislation has been put in place.

66. The Conference of the Parties is invited to adopt the following decisions regarding the implementation of Article 15:

The Conference of the Parties:

1. Decides to make access to genetic resources and benefit-sharing a standing item on the agenda of its meetings;

2. Requests the Subsidiary Body on Scientific, Technical and Technological Advice, drawing upon emerging practices and case-studies on benefit-sharing, to develop guidelines to assist Parties;

3. Requests Parties and Governments:

(a) To include in their national reports information on legal and policy measures adopted concerning access to genetic resources and benefit-sharing;

(b) To provide to the Secretariat copies of relevant legal instruments, including constitutional provisions and modifications, laws and executive orders;

4. Requests Parties and Governments, regional economic integration organizations, and other competent international, regional and national organizations to provide the Secretariat on a regular basis with updated information on experiences on the implementation of Article 15 and access-and-benefit-sharing arrangements at the national or regional level;

5. Requests the financial mechanism to give special emphasis to the following programme priorities for assistance to developing country Parties (as further described in documents UNEP/CBD/COP/4/21 and 22):

(a) Stock-taking activities;

(b) Formulation of access legislation and incentive measures;

(c) Implementation of specific benefit-sharing initiatives;

6. Requests the Executive Secretary:

(a) To compile information on bioprospecting arrangements, material-transfer agreements, and access-and-benefit-sharing arrangements, and to disseminate such information in a standardized format through the clearing-house mechanism;

(b) To disseminate other information received in accordance with paragraphs 3 and 4 above through the clearing-house mechanism;

(c) To improve upon the guidelines, using the information and experiences submitted by Governments and relevant bodies, and to report to the Conference of the Parties thereon a regular basis.
