CHAPTER 19

Regulation of Access to Genetic Resources and Sharing of Benefits from Biodiversity

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INTRODUCTION

The Convention on Biological Diversity (CBD) provides an international legal régime for the regulation of access to and exchange of genetic resources, i.e. genetic material of actual or potential value. While recognising the sovereign rights of States over their natural resources, the CBD in Article 15 urges Parties to facilitate access for environmentally-sound uses and not to impose restrictions that run counter to the objectives of the Convention.[2] However, paragraphs 4 and 5 emphasise that such access should be granted based on 'mutually agreed terms' and should be subject to 'prior informed consent' of the Party providing the resources. Article 15 also requires Parties to put in place legislative, administrative or policy measures aimed at ensuring fair and equitable sharing of the results of research and development, and benefits arising from the commercial and other utilisation of genetic resources. Benefits should not be limited to monetary benefits but should include other benefits such as technology transfer, capacity building, training of professionals (as the case of the National Biodiversity Institute in Ethiopia and INBI in Costa Rica), or training local people to identify indigenous plants and their values.

Before the Convention came into force, the world's genetic resources were treated as a common heritage of humankind and were open to access without restrictions. They were collected and utilised freely by interested persons and institutions, particularly those from the developed countries. Most developing countries were opposed to the principle of common heritage to genetic resources. They argued against a régime that allowed the developed countries to freely or cheaply obtain genetic resources, patent products arising from the genetic material and sell these patented products at high prices to the developing country where the materials was collected. The developing countries argued for sovereign rights over genetic resources. The debate, mainly between the developed and developing countries, on

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2 It should be noted that paragraphs 1 and 2 of article 15 mention "regulation of access" and not "control of access" as has been misinterpreted by some people.

ownership of genetic resources was partly resolved through the negotiations for the Convention on Biological Diversity.[3]

THE CONCEPT OF "MUTUALLY AGREED TERMS"

Article 15 of the Convention requires Contracting Parties to institute measures that strike a balance between national rights to determine access and obligations to facilitate access by other parties on mutually-agreed terms. The Convention elaborates on this basic point by explicitly providing that access shall be subject to prior informed consent. The mutual agreement by parties involved in the access arrangement is based on what we may term transparency which requires the party seeking access to obtain prior consent of the one that holds or owns the genetic material or resource.

Article 15 contains certain phrases that require mutually-agreed interpretation. For example, paragraph 2 of the article requires "each Contracting Party to create conditions to facilitate access to genetic resources for environmentally-sound uses by other Contracting Parties". This provision, it appears, applies to access to genetic material for environmentally-sound use(s). There are two points to note. First, it is the Party supplying the genetic material that determines what constitutes environmentally-sound use. Second, it is assumed that the Party seeking to have access to the genetic material will disclose the nature of the use(s) and both Parties have adequate capacities to determine that the use(s) will have no negative environmental impacts. To effectively enforce this requirement – that of ensuring environmentally-sound uses of the genetic material – both Parties must conduct their affairs in a very transparent manner. "Environmentally-sound uses" can be interpreted to refer to utilisation that gives high regard to conservation and the sustainability of the resource and furthermore, alludes to biosafety. But to date, no consensus has been reached on the concept of biosafety. The Party seeking to have access must disclose all the relevant information on the uses to the supplying Party. Second, access to the genetic material will only be facilitated after the supplying country has received all the information and has granted prior consent.

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3 Sanchez, V. and Juma, C. (1994), *Biodiplomacy: Genetic Resources and International Relations.* ACTS Press, Nairobi.

THE CONCEPT OF PRIOR INFORMED CONSENT

Prior Informed Consent (PIC) refers to the consent by the provider of the genetic resources based on the information (research proposal) provided by the applicant (prospector) including full disclosure of the intent and scope of the bioprospecting activity prior to granting permission to access the genetic resources. The applicant is required to specify the manner in which the resources are going to be used, by whom and the potential outcome of the bioprospecting exercise. Some of the main elements of the PIC model include the following:

- A designated national authority;
- Scope of the PIC;
- Complete information from the applicant:
  - the specific material wanted;
  - the quantities required;
  - the use to which the material will be put;
  - the potential implications for granting access;
- Requirement of licence and fees and financial returns such as loyalties;
- Conditions governing every licence, e.g. sharing of research results;
- Provisions for future uses and exchange of collected genetic resources.

Developing national access policies and legislation

Article 15 of the CBD provides the framework for Parties to assert their sovereign rights over their genetic resources. African countries need to move fast to take advantage of this opportunity provided by the CBD and establish national policies, legislation and institutional arrangements to regulate access to genetic resources under their jurisdictions and tap the benefits from them. In other words, for African countries to effectively enforce the provisions on sovereign rights and access to genetic resources countries they need to formulate policy, legal and institutional measures.

Specific areas that require attention in establishing national access regulation include the introduction of regulations governing the collection of biological resources. Contracts between the collectors, national authorities and the suppliers of biological resources can help ensure that they generate immediate as well as long-term benefits for the countries containing the resources.[4] Since the developing countries are not

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[4] Reid, E. *et al* (1993, *Biodiversity Prospecting*. World Resources Institute, Washington, DC.

in a position to correctly assess the potential value of genetic resources in the initial stages of exploitation (particularly due to a lack of information), it will be important to devise contracts carefully, negotiating the terms for actual commercial exploitation when greater information about the potential value of the resource is available.

A few countries, such as the Philippines and the Andean Pact countries, have initiated processes of formulating national régimes to enable them implement Article 15.[5] The Philippines has adopted a specific legal régime for regulating access to genetic resources, i.e. the Executive Order No. 247 and has developed a manual for implementing the Order. However, most countries do not have régimes to regulate access to genetic resources or have not initiated processes to establish such régimes. African countries will have to undertake major efforts to formulate national legal measures and establish suitable institutional arrangements for regulating access to genetic resources. These countries need to mobilise various forms of expertise and new capacities to be able to effectively implement the access provisions.

National legislation on access should, at the minimum:

- assert national sovereignty over genetic resources within the national boundaries;
- require bioprospectors to obtain PIC;
- require benefit-sharing as a condition for obtaining a collection permit;
- establish a national biodiversity board or its equivalent to administer access regulation;
- provide protection for indigenous people's knowledge and innovations;
- require that the rights of PIC and benefit-sharing extend to local communities;
- identify requirements for reporting and enforcement;
- encourage technology transfer;
- require use of contracts such as material transfer agreements, commercial research agreements or academic research agreements;
- require that any collection does not endanger biological diversity.

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5 Mugabe, J. *et al* (1995), *Regulating Access to Genetic Resource: National Policy, Legal and Administrative Regimes.* Background paper prepared for the Secretariat for the Convention on Biological Diversity, Geneva.

One of the main obstacles to formulating access policies is the lack of effective methods for valuing biodiversity.[6] Developing countries can enhance their ability to derive benefits from biological resources by seeking new ways to add value. The value of such raw materials is relatively low. Value can be added by establishing or encouraging institutions to undertake identification, collection and screening of biological resources. This will enable the developing countries to share the benefits of biotechnological research and strengthen their scientific, technological and institutional capacity. Such technological capacity could be applied in the development of other sectors of the economy.

BIOPROSPECTING AND ACCESS AGREEMENTS

Bioprospecting refers to the research, collection and utilisation of biological and genetic resources for purposes of applying the knowledge derived therefrom to scientific and/or commercial purposes resources.[7] Bioprospecting has to be done in line with the provisions of Article 15 of the CBD. Research agreements must be signed between the prospector and the Principal (i.e. the agency or regulatory body) granting access to the genetic resources.

There are different types of Research Agreements. The most common ones include:
(i) Academic Research Agreements (ARA);
(ii) Commercial Research Agreements (CRAs); and
(iii) Material Transfer Agreements (MTAs).

These agreements require the prospective candidates to satisfy certain requirements and undergo an application process, managed and enforced by an authorised agency.

Academic Research Agreements are intended purely for academic or scientific purposes. Commonly, developed country universities, botanic gardens or research institutions sign research agreements with collaborators from developing countries. These agreements sometimes include specific provisions for return of benefits to the developing country collaborators and biodiversity conservation programmes in biodiversity-rich areas. Some of the benefits include: publications; literature searches; equipment; lab supplies; access to international funding; building of

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6 See Brown, K. and D. Moran. 1994 in Sanchez, V. and Juma, C. *Biodiplomacy: Genetic Resources and International Relations.* ACTS Press, Nairobi.

7 Reid, E. *et al* 1993, *Biodiversity Prospecting.* World Resources Institute, Washington, DC.

infrastructure; fellowships or training of local scientists; deposit of research results, etc.

Commercial Research Agreements (CRA) are used if the bioprospecting is intended directly or indirectly for commercial purposes.[8] Many research institutions and botanical gardens, such as the Kew Gardens of UK, have developed collaborations with private companies (e.g. pharmaceutical companies) who help them to underwrite the costs of the research programmes, especially those with potential commercial outcomes. In some cases, agreements for commercial collections are signed with developing country collaborators. CRAs include other elements not included in ARAs such as loyalties; intellectual property rights or patenting issues; future supplies of raw materials; exclusivity for sole use samples; confidentiality; advance payments; and the disbursement of commercial revenues.

Material Transfer Agreements (MTAs) are a form of contractual agreements, ranging from letter statements to detailed negotiated contracts, often used for transfer of genetic materials between public sector laboratories to private sector laboratories or biotechnology industries. MTAs have the advantage of binding the parties involved and their successors to an agreement regardless of the status of a patent. The key elements included in MTAs include: what materials are being transferred; the nature of compensation (fees or loyalties); and the scope of the licence (non-exclusive, non-transferable or revocable).

ADMINISTRATIVE ARRANGEMENTS

National policies and legislation on access will be ineffective if they do not have clear provisions for institutional arrangements necessary for their enforcement. Key elements include: designation of the responsible agency (authority); outlining of clear procedures and mechanisms for handling the access applications; determination of PIC and for monitoring the implementation of the various research agreements and contracts. It is necessary to create National Biodiversity Boards, or their equivalents, to oversee the development and implementation of the access policies and to administer and monitor the various bioprospecting relationships. The participation of various stakeholders, including the affected local communities, is critical. They must be informed of all the discoveries and the development of any commercial products from the collections.

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8 The distinction between commercial and academic research agreements is difficult since the latter often leads to commercial application.

CONCLUSION

As a matter of priority, African countries should embark on implementing Article 15 of the CBD (on regulation of access to genetic resources and the equitable sharing of benefits from the use these resources). This will require putting in place regulatory framework (policies and laws); clear access guidelines; institutional mechanisms; and equitable benefit-sharing arrangements. Furthermore, it will require building national capacities in 'Biodiversity Prospecting' such that there are national experts who are capable of negotiating favourable terms and working very closely with the biodiversity prospectors to ensure that African countries reap maximum benefits from their biodiversity. The way forward to regulate access to genetic resources in African countries should take a gradual incremental approach. All existing human potential (experts) and the policy, legal and institutional régimes should be considered and utilised before seeking for new ones.

REFERENCES/FURTHER READING

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