Determining Access to Genetic Resources and Ensuring Benefit-sharing: Legal and Institutional Considerations for States Providing Genetic Resources

Paper Presented to the Global Biodiversity Forum

Jakarta, 4 November 1995

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by

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I. Introduction

For State's to effectively capitalize on the new relationship created by the Convention on Biological Diversity between Parties providing genetic resources and the users of genetic resources, an integrated approach, in line with attaining the State's development goals, may be desirable. A fundamental consideration for a State which will provide genetic resources is ascertaining the need for new legislation and institutions to determine access to genetic resources, while ensuring benefit-sharing.

The purpose of this paper is to briefly highlight some general legal and institutional considerations for States providing genetic resources which may assist them as they define their approach to the issue. The paper is arranged to provide a broad framework from which national legislation could be fashioned.

II. National Planning

The Convention on Biological Diversity attempts to create a new relationship between the providers and users of genetic resources by creating a *quid pro quo* between the Parties of the Convention which provide genetic resources and potential users: access to genetic resources in exchange for sharing of benefits derived from their use. Whether through a comprehensive treatment of all aspects of biodiversity's conservation and the sustainable use of its components, or through a more focused sectoral treatment, a national planning process should be considered in order to capitalize on the new relationship.

Planning will help the State organize and implement its approach to genetic resource access and benefit-sharing, and may lead to appropriate comprehensive national policies, legislation and institutions. If the State is a Party to the Convention on Biological Diversity, then establishing a planning process would, at least with regard to this issue, satisfy article 6 which requires Parties to develop national, strategies, plans or programmes for the conservation and sustainable use of biological diversity.[2]

The very nature of genetic resources - their wide availability, ease of dissemination and replication - may demand that national policies, legislation and institutions reflect a consensus for action among the various constituencies which are knowledgable about, control or use genetic resources. Therefore, the planning process should be highly participatory and involve the individuals, institutions and economic sectors which will be most affected. Participation in turn becomes a

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[1] Legal Officer (Biological Diversity), IUCN Environmental Law Centre, Bonn, Germany. This paper derives in part from a technical document prepared in 1994 at the request of the Board of the Cartagena Accord (the Andean Pact), as well as *Determining Access to Genetic Resources and Ensuring Benefit-sharing: Legal and Institutional Considerations*, IUCN Environmental Policy and Law Paper, number ___ (forthcoming 1996). The views expressed here do not necessarily reflect those of IUCN or its members.

[2] For more information on planning, *see* Kenton Miller and Steven M. Lanou, NATIONAL BIODIVERSITY PLANNING: GUIDELINES ON EARLY EXPERIENCES AROUND THE WORLD (1995) (World Resources Institute, United Nations Environmental Programme and The World Conservation Union).

mechanism for building the political and social consensus needed to implement policies and, where necessary, legislation.

The list of possible stakeholders will vary with the country but may include:

- governmental agencies (e.g., environment, natural resource, agriculture, technology, health and customs agencies);
- industry (e.g., pharmaceutical, breeding or other biotechnology oriented businesses);
- the scientific community;
- *ex-situ* conservation facilities such as botanic gardens, zoos and microbial resource centres;
- indigenous and local communities or their representative organizations; and
- relevant non-governmental organizations, as well as private individuals.

All of these stakeholders have useful information and perspectives to contribute and will help shed light on the practical realities involved with the exchange and use of genetic resources.

When stakeholders are identified, national goals can be clarified. Mechanisms to attain the goals can be then identified. At this point, a legal and institutional profile could be undertaken to ascertain which laws and institutions within the country apply to genetic resources. International obligations should also be identified.

Once this is completed new legal and institutional arrangements can be contemplated and devised. In the meantime, existing law and institutions might be used as "stop-gaps" until more specific policies, legislation and institutions are established.

III. The Content of National Access Legislation

The final content of access legislation will depend on many State-specific considerations identified in the national planning process. Practical considerations may be the biggest factor shaping any access legislation. These might include:

- the likelihood or anticipated volume of future requests for access;
- past experiences as a source of genetic resources;
- the perceived value of genetic resources within its jurisdiction;
- whether genetic resources are shared with other States;
- capacity to add-value to genetic resources; or
- technical, administrative and financial capacity to create and oversee a regulatory programme.

Simply put, careful consideration must be given to the anticipated demand for genetic resources and what technical, administrative and financial resources are or will be available to develop and execute a regulatory regime. A well planned approach which is simple and cost-effective to implement will ensure that transaction costs do not outweigh future benefits gained from genetic resources.

In fact, genetic resource access legislation should strive for simplicity of process to avoid cumbersome rules and delays.[3] For Parties to the Convention on Biological Diversity this is an especially important consideration, as article 15(2) requires them to (1) create conditions to facilitate access to genetic resources for environmentally sound uses and not (2) impose restrictions which run counter to the Convention's objectives. This approach may also make good business sense as the supply of genetic resources is elastic.

While every State is different, future access legislation will undoubtedly share many similarities. For example, access legislation is likely to have to:

- specify principles, objectives and definitions;
- identify scope of application;
- establish or designate appropriate institutions to determine and enforce access;
- outline an access determination process; and
- specify means of appeal.

It may also include provisions on export controls, sanctions and penalties, identification and monitoring and financial issues.

In addition, in order to give full effect to the Convention's prior informed consent (PIC) requirement worldwide, legislation focusing on the provision of genetic resources would ideally provide the foundation for more comprehensive legislation treating the State not only as a provider of genetic resources but as a user as well.[4]

A Party to the Convention could consider a range of use-oriented measures aimed at ensuring the interests of other Parties. Such reciprocity could then create a constructive atmosphere for Parties to cooperate in maintaining each others' interests.

For example, importers of biological or genetic resources could be required to demonstrate that export has been pursuant to the prior informed consent of the exporting Party and that mutually agreed terms have been negotiated. Import controls could coincide with existing customs and biosecurity controls (such as phytosanitary or quarantine regulations). Ports of entry could be designated.

Measures on subsequent use could be considered to ensure prior informed consent. These could be expressed through legislative or administratively-based processes to grant intellectual property rights or product approval and licensing. Ideally, approval would not be granted until PIC had

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[3] Lyle Glowka ET AL., A GUIDE TO THE CONVENTION ON BIOLOGICAL DIVERSITY at 81 (1994) (IUCN).

[4] *Id.*

been confirmed. The practical effect of this would be to establish the origin of the genetic resources upon which the product is derived, and perhaps the terms upon which the genetic resources were provided as well. This could be accomplished through an international certificate of origin system.[5]

In addition, potential users of genetic resources within a Party - whether natural or legal - could be required by law to obtain the prior informed consent of other Parties providing genetic resources. Penalties and remedies for importation or subsequent use without prior informed consent could be provided. The effectiveness of the system may also require the Party providers or their intermediaries to have access to the court system of the Party using genetic resources.

Access legislation probably will not at first reflect such comprehensive treatment of the issue. However, legislation may be designed to enable a phased approach.

A. Principles, Objectives and Definitions

Sections on principles, objectives and definitions may be useful features of national legislation. A State may consider including as a forward section of the access legislation a recitation of the principles (or policies) upon which the legislation is founded. A section on objectives may specify the goals the State wants to achieve through the access legislation. These may be one output of the planning process.

Future access legislation might also include a definitions or use of terms section to define and clarify terms used. In many cases, drafters will not need to invent new terms and definitions for the access law. Instead, they will be able to draw on a number of existing documents such as the Convention on Biological Diversity and the FAO International Code of Conduct for Plant Germplasm Collecting and Transfer as sources. Indeed, drafters should be encouraged to draw on these documents as the terms used and definitions provided reflect broad international consensus thereby contributing to the effectiveness of the legislation enacted.

"Access to genetic resources" is one term which is not defined by the Convention. Whether or not legislation actually needs to include a definition for this term is a matter of judgment. At least conceptually, however, a State will need to consider what "access" means.

A possible definition might be "to obtain samples of genetic resources for purposes of research, conservation, commercial or industrial application." There are four important aspects of this definition. First, it is dependent on how genetic resources are defined. Article 2 of the Convention on Biological Diversity could assist here. Second, access means to physically obtain genetic resources. Third, the definition emphasizes samples of genetic resources. This implies obtaining a discrete amount of biological material or a limited number of specimens for subsequent use.

Fourth, the purposes of access - research, conservation, commercial or industrial application - are kept broadly defined, yet they help focus the determination on the activities most likely to result in benefit sharing. They can be broadly distinguished along commercial and non-commercial lines although, admittedly, the lines are quite blurry. In effect, however, the intent of the potential user would need to be ascertained. In short, the four purposes of access proposed manifest the intention to exclude from consideration the myriad of other biological resource uses. For example, biological resources which are sold as a commodity for consumption or direct use would not be covered.

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[5] Telephone Interview with Brendan Tobin, Peruvian Society for Environmental Law (July 1995).

B. Scope of Application

A law's scope of application section defines what the law applies to. The primary objective of access legislation is to regulate a potential user's access to genetic resources. Consequently, an access law should focus on the physical act by a potential user to obtain, for a particular purpose, genetic resources from a source within the country. Related to scope of application are fundamental questions pertaining to (1) the genetic resources covered (2) the sources of genetic resources and (3) specific exclusions.

1. Genetic Resources Covered

National legislation should clearly state to which genetic resources - plant, animal or microbial - it applies. This of course will be related to how genetic resources are defined.

An important consideration is whether legislation should apply to "derivatives" of genetic resources. This is not an easy question to answer, especially since the Convention on Biological Diversity does not clearly address the issue. Therefore, the State will need to review it very carefully.

The primary questions appear to be whether access to derivatives needs to regulated *per se* or whether it is adequate to simply regulate access to genetic resources from which the derivatives are derived, ensuring that any benefit-sharing arrangement includes benefits resulting from derivatives. The simple answers appear to be "no" to the first question, and "yes" to the second. The answers may be justified based on the two contexts in which the term "derivative" is used.

In the first context, "derivatives" may be used to denote unimproved or unmodified chemical compounds, other than DNA or RNA, merely associated with the biological material, but formed by the organism's metabolic processes. Like DNA or RNA, these exist in a sample of biological material when it is obtained from an *in-situ* or *ex-situ* source. For example, derivatives of genetic resources might be biologically active chemical compounds found within plant material which is collected, but which are yet to be extracted, modified and used.

In the second context, "derivatives" may refer to DNA or RNA, or a chemical compound, created from materials originally obtained from an *in-situ* or *ex-situ* source. The resulting derivative, for example, might be a breeder's hybrid seed, a traditional healer's medicine or a pharmaceutical company's synthetic version of an extracted biochemical. These, then, are end-products derived from genetic resources through human intervention.

Derivatives of genetic resources are potentially quite valuable, but they may not need to be regulated *per se* for two reasons. First, in the former context, since the ultimate source of the derivative material is likely to be biological material obtained from an *in-situ* or *ex-situ* source within the State's jurisdiction, the State may need to only regulate access to the biological material containing the chemical compounds.

Second, in the latter context, while in theory it is possible to regulate access to all products derived from genetic resources, in practice it would not seem to be realistically feasible. For example, if the government's prior informed consent is required every time derivative material is proposed to be transferred, then it will be practically impossible for the State to control, since the

material is likely to be proprietary and may also be subject to intellectual property rights. Furthermore, there is probably no practical way to monitor the transactions, except by putting all research and development under governmental scrutiny.

In both cases, therefore, "derivatives" may only be relevant in the benefit-sharing context. In other words, instead of regulating access to derivatives *per se*, it may be more expedient to ensure that benefit-sharing agreements cover materials derived from the genetic resources to be accessed.

2. Sources of Genetic Resources Covered

Related to the question of which genetic resources could be covered, is the question of which sources of genetic resources could be covered by the legislation. Genetic resources can be obtained from both *in-situ* and *ex-situ* sources, whether public, privately or communally owned. A pre-requisite to making this determination is knowing what the potential sources of genetic resources are within State jurisdiction. These might be identified in a planning process, from which a decision can be made as to which sources should be reached by the legislation.

3. Specific Exclusions to the Scope of Application

Another aspect of scope of application which could be considered by a State is whether to include specific explicit exclusions to the law's application; that is, what won't be regulated by the legislation. Two possibilities which might be considered are (1) customary use of genetic resources and (2) genetic resources obtained prior to the legislation's enactment (retroactivity).

a. Customary Use

The use and free exchange of genetic resources is integral to the economic, religious and cultural well-being of indigenous and local communities throughout the world. Preambular paragraph 12 of the Convention on Biological Diversity recognizes this. In addition article 10(c) requires each Party to protect and encourage customary use of biological resources compatible with conservation and sustainable use of biological diversity. Use must be in accordance with traditional cultural practices. Notwithstanding that customary uses of genetic resources could be implicitly excluded from the scope of access legislation it may be desirable to make explicit their exclusion. In so doing the validity and significance of customary use to indigenous and local communities will be more widely recognized outside of these communities, and there will be no confusion when the law is applied.

b. Retroactivity

Legal rules as a general rule do not to apply to past actions. This is the principle of non-retroactivity. Incorporating a non-retroactivity clause into access legislation would establish a cut-off date, usually the entry into force of the legislation, before which transactions involving the obtention of genetic resources would not be subject to benefit-sharing.

C. Institutions to Oversee Access to Genetic Resources

An access determination process (see section III.D) represents the procedure by which the State can grant or deny consent to access genetic resources. Governmental institutions overseeing biological diversity exist in almost every State. Their competencies vary with the circumstances but, in many cases, they are divided along sectoral lines, with competencies distributed along national and sub-national lines as well.

Dividing competencies along sectoral lines has fundamentally constrained efforts to conserve and sustainably use biological diversity because the sectoral nature of government encourages a fragmented approach to biological resource management. This, in turn, is accentuated by limited budgetary and staff resources, poor coordination, as well as conflicting mandates and jurisdictions between agencies and levels of government.

Sectoralism extended to the access and benefit-sharing realm may result in the loss of important genetic resources, as well as lost benefit-sharing opportunities. For example, when governmental competencies are divided along sectoral lines there may be instances were some organisms especially attractive in biotechnological applications - such as micro-organisms or insects - literally "fall through the cracks" and are not within the clear competence of any institution. Sectoralism also increases the likelihood that decision-making will be accomplished in a vacuum, without consultation, and may result in one arm of the government not knowing what the other is doing.

Because access and benefit sharing involve issues which cut across sectoral lines, States need to consider how to institutionally approach the issue in a cross-sectoral, integrated manner. Integrating the access determination process could provide a means for better, more integrated decision-making. Integrated decision-making will in turn limit arbitrary decisions and missed opportunities. Access to genetic resources will be facilitated and from this will follow an increased likelihood that benefits can be captured to meet national goals.

1. Designating a Focal Point

An institutional focal point may have to be designated to process applications for access determinations. A threshold question is at what governmental level access will be granted or denied?

The question is especially important for federated States. In federated States, decision making with regard to biological resources may take place at the level of the federated entity, not the federal government. Therefore it will be important to clarify which level of government is competent to determine access to genetic resources.

A primary consideration is also whether the focal point should be a governmental agency at all. It might also be a government or university-related research institution, a private contractor or an independent, private, non-profit organization.

Whether an existing sectoral line agency or a newly created public or private institution is designated will depend on the circumstances within the State. Whatever choice is made, care should be taken to ensure that the focal point's competencies do not conflict with those of other agencies and that it promotes coordination, both within and outside the government.

Depending on its level of expertise, an advisory panel of experts might be created to provide multi-disciplinary advice to the focal point. The advisory panel's competencies might include providing the focal point with scientific, economic and legal advice on requests to access genetic resources. Both might be supported by a secretariat.

The simplest approach may be to create a centralized inter-ministerial or inter-agency governmental body with clear competency over genetic resources. In this case, the focal point could be composed of individuals representing different sectoral governmental ministries or

agencies with relevant competencies in biodiversity and areas related to benefit sharing. Relevant non-governmental or private sector representatives might also be invited to participate and add their perspectives.

This arrangement may be advantageous because it could provide an opportunity for all relevant arms of the government and, ideally, representatives from the non-governmental, private and communal sectors, to be included in the decision-making process. It provides the possibility, therefore, for maximum coordination.

This option is most feasible if the focal point is established within the government. It might be an independent body or set-up within another agency.

The focal point's primary task would be to make access determinations. In this capacity, a primary goal should be to gather information and, in particular, coordinate with and accept for consideration the views of parties inside and outside the government potentially affected by the access determination, prior to making an access determination. This could be undertaken as part of a public interest review (see section III.D.3).

Other functions of the focal point might be to:

- collect and disburse fees, royalties, other financial returns and benefits on behalf the State;
- reach mutually agreed terms for access (see section III.D.2);
- carry out or coordinate identification and characterization of genetic resources to ascertain their potential use or value;
- seek further legislation in the area; and
- identify and inform potential users of the State's access rules.

D. Prior Informed Consent: The Access Determination Process

Prior informed consent implies that an administrative "access determination" process is created to handle requests for access to genetic resources within the jurisdiction of the State. The process is a manifestation of the State's sovereign rights over genetic resources within its jurisdiction. The procedure's primary goal would be to ensure sufficient information exists for the designated oversight institution to make an informed access determination; that is, whether to grant or deny access.

It is notable that the Convention on Biological Diversity uses the term "prior informed consent" exclusively in relation to the State. Depending on the circumstances, however, the premise of the concept - full knowledge or information prior to access to genetic resources - could also be extended to private or communal sources of genetic resources, for example, indigenous and local communities, individuals and institutions. Requiring the potential user to obtain the informed consent of these providers of genetic resources prior to access could be stipulated in the access legislation. Whether or not this consent has been obtained could be determined within the State access determination process.

The access determination process in its most basic form, could have five basic components:

- application submitted to a designated institutional focal point;
- reaching mutually agreed terms (see section III.D.2);
- public interest review;
- access determination (denial of or consent to access); and
- appeal.

Variations on the basic procedure can be envisioned for (1) expedited access determinations procedures, (2) indigenous and local communities and (3) coastal States.

1. Application to Focal Point

The information required for an access determination can be supplied via an application form. Legislation could outline the broad informational requirements, while more detailed administrative rules and regulations could be promulgated if need be. An access determination application form could be created to standardize the presentation of relevant information and facilitate the access determination process. A fee might be charged by the focal point for processing the application.

2. Reaching Mutually Agreed Terms

Article 15(4) of the Convention states that access to genetic resources is to be on mutually agreed terms. Inherent in the phrase "mutually agreed terms" is the expectation of a negotiation between the Party providing genetic resources and a potential user. A successful negotiation could result in an access agreement for benefit sharing.

The Convention on Biological Diversity appears to use the phrase "mutually agreed terms" exclusively in relation to the State. This, in combination with the call in other Convention articles for benefit-sharing with the Contracting Parties providing genetic resources, appears to create a subtle ambiguity which may require clarification at the national level in States where all genetic resources are not publicly owned by the State.

Article 15(4) does not address ownership of genetic resources. And, while article 15(1) reaffirms the authority of governments to determine access to genetic resources, it does not grant the State a property right over the genetic resources within its jurisdiction. Rather, national law determines questions of ownership.

The State is sovereign over the genetic resources within its jurisdiction in all cases, even though it will not always be the owner. The Convention seems to imply that the State has the sovereign right through the focal point to subject private or communal agreements granting access to non-publicly owned genetic resources to review. Furthermore, it implies that the government then can reach mutually agreed terms with the potential user additional to any private conditions negotiated. This could be in a separate agreement between the State and the potential user, or in a tripartite agreement between the private or communal provider, the potential user and the State. Whether this will actually be the case in State practice remains to be seen however.

In addition to being tasked with access determinations the focal point, therefore, might have associated functions related to reaching mutually agreed terms. There are at least three possible scenarios. First, where the genetic resources are publicly owned, the focal point might reach mutually agreed terms and enter into access agreements with potential users. To do this, the focal point would need to have legal personality to enter into contractual arrangements. Second, it might review access agreements proposed between other State agencies with competence over biological resources and a potential user to ensure terms of access represent the interests of the State in the context of genetic resources and benefit-sharing.

Third, it might review proposed access agreements between a private or communal owner of genetic resources and a potential user. In this case, the review might be undertaken for two reasons. First, to ensure that State interests are secured by reaching mutually agreed terms. Second, to ensure that the best interests of the private or communal source of genetic resources are reflected in the benefit sharing provisions of the agreement.

In order to review proposed access agreements as part of the access determination process, and reach mutually agreed terms either for publicly owned genetic resources or where the genetic resources are privately owned, the focal point would need minimum criteria to serve as a guide. These could represent the State's minimum interests. A State's general policy on benefit sharing will form the basis from which minimum criteria can be derived. Both could be derived from a national planning process which could identify national goals.

Minimum criteria for the State might address (1) the strategic importance of the genetic resource targeted; (2) collection and export restrictions including those based on the conservation status of the target organisms; (3) research participation and publication; (4) provision of duplicate samples; (5) technology transfer; (6) royalties or fees; (7) ownership of samples and derivatives and intellectual property rights; (8) limits on third party transfer; (9) reporting and tracking requirements; or (10) the term of the agreement.

3. Public Interest Review

Ideally, the access determination process should be an opportunity for the focal point to gather information relevant to making an access determination. It may also be the point where the focal point reaches mutually agreed terms, and/or reviews proposed access agreements. With the relevant information at hand, the focal point can review and consider the application and determine whether access is in the public interest. This component of the access determination might be described as a "public interest review".

a. Sources of Information

There are a number of information sources which the focal point can rely upon. The obvious primary source is the potential user applying for an access determination. The applicant will be required to submit an application as well as supplementary information to the focal point. But there may be other sources of important information which the focal point could draw on in its decision-making process.

For example, depending on its technical expertise the focal point may need the advice of a specially created advisory board (see section III.C.1). Also, parties potentially affected by the access determination or with special expertise, such as communities, business, the scientific community, may have useful information to provide. The focal point could be required to

publicize the receipt of an application and its contents to potentially affected parties and accept comments and information, these could then be considered with the application.

b. Consideration of the Application and Comments Received

In its deliberations, the focal point will need criteria with which to measure whether the application is in the public interest. This will help limit arbitrary decision-making, especially if the criteria are made publicly available.

National legislation might specify the general criteria against which the application is to be judged, as well as to what extent the focal point must consider comments received. Criteria might include an assessment of the proposal's environmental or social impact; whether the terms for benefit sharing are in keeping with national development goals developed in the planning process; whether all relevant permits have been obtained or applied for; and, importantly, whether the informed consent of, for example, indigenous and local communities, has been obtained.

4. The Access Determination

The actual access determination will be a decision to deny or grant consent access to genetic resources. It is, essentially, a yes or no answer. But, for purposes of transparency and possible appeal (see section III.D.5), a rationale for the decision should be provided and made publicly available. The criteria against which the application is judged should provide the basis upon which the access determination is made. If access is denied, the State will need to decide whether denial is without prejudice.

Consent should be manifested in writing, perhaps in the form of a permit. Appended to this could be conditions of access, in particular conservation and sustainable use provisions and the mutually agreed terms as part of an access agreement negotiated.

The permit document demonstrates that the potential user has obtained the prior informed consent of the State. Therefore, it could be used as a certificate of origin[6] or proof in other countries that prior informed consent has been obtained and as a possible means to ensure benefit sharing.

5. Appeal

An administrative appeals process could be instituted as part of the access determination procedure. Whether based on procedural or substantive grounds, the appeals process could be accessible to applicants denied consent, as well as potentially affected parties whose views were not adequately considered by the focal point in the public interest review. If a substantive right of action is provided, an appropriate margin of discretion should be maintained for the focal point.

6. Variations on the Basic Procedure

The basic access determination procedure could be modified in any number of ways to accommodate the particular circumstances existing in the country.

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[6] Tobin, *supra* note 5.

a. Expedited Procedures

Reaching mutually agreed terms and obtaining prior informed consent implies a case by case review of access applications. Case by case review will work well in most instances, especially for discrete one time only access to genetic resources. However, expedited procedures may be desirable in two cases where multiple requests for access are expected.

In the first case, there may be situations where an institution needs to undertake field work involving genetic resources on a regular basis. To minimize the burden of multiple access determinations for it and the focal point, it may be desirable for a single access determination and access agreement to be made which could lead to granting access to the institution and its researchers for a particular period of time.

In the second case, *ex-situ* conservation facilities may process hundreds of requests a year for genetic resources. Case by case access determinations for every request would quickly strain the administrative capabilities of the focal point and the facility. Therefore, it may be possible and desirable for the focal point to make a single access determination and agreement with the *ex-situ* conservation facility which requires the facility to ensure that in its material transfer agreements the interests of the State are maintained. The extent to which this can be accomplished may be limited by national law; it may only be a solution for publicly owned facilities.

b. Special Considerations for Indigenous and Local Communities

In some cases, indigenous and local communities will be the ultimate providers of genetic resources and related knowledge. Mechanisms might be explored which guarantee respect for the wishes of communities in whose territory collecting activities are proposed. Mechanisms might include (1) identifying the communities living in areas where collecting will occur; (2) consultation by the government or by a designated NGO with the communities to ascertain their interest in allowing collecting in their territories and in negotiating an agreement with the potential user; (3) assisting communities to negotiate terms of access and benefit-sharing; and (4) reviewing the agreement between a community and a potential user of genetic resources to ensure conformity with relevant access criteria.

To supplement these mechanisms, legislation might specify that prior to a potential user's access to their territories, indigenous and local communities must provide their consent, based on full knowledge and information supplied to them. It might also specify that access and benefit-sharing must be consistent with the communities' beliefs, traditions, practices or laws. This could be taken one step further by requiring positive proof of informed consent before the State can make an affirmative access determination.

c. Special Considerations for Coastal States

Coastal States Party to the Convention on Biological Diversity which are contemplating access legislation may have special considerations with regard to the law of the sea. The Convention on Biological Diversity is to be implemented with respect to the marine environment consistently with the law of the sea, whether customary or conventional (article 22(b)). In effect, the requirement of consistent application means that measures to implement the Convention may not contradict or undermine national rights and obligations deriving from the law of the sea.

The 1982 United Nations Convention on the Law of the Sea (UNCLOS) is the primary source of newer law of the sea which sharpens and helps clarify ambiguities found in earlier treaties,

codifies customary law and, as between parties, introduces new rights and obligations. It does not mention genetic resources. However, it would appear to apply to them through its references to "natural resources", "living marine resources", "living organisms" and "sedentary species".

It is clear that coastal States have absolute authority over genetic resources within their territorial sea. For purposes of their exploration and exploitation, activities characterized by commercial intent, the coastal State exercises sovereign rights over the genetic resources found in the exclusive economic zone (EEZ) or on the continental shelf.

However, it is unclear whether a coastal State's sovereign rights over marine genetic resources in the EEZ or on the continental shelf are qualified for purposes of marine scientific research - an activity considered to be non-commercial, though its results may be commercially valuable. Therefore, implementing article 15 consistently with the marine scientific research consent regime for the EEZ and the continental shelf in Part XIII (Marine Scientific Research) of the UNCLOS may require careful consideration.

In normal circumstances, consent for marine scientific research in the EEZ and on he continental shelf is to be granted, except where the marine scientific research "is of direct significance to the exploration and exploitation of natural resources, whether living or non-living" (UNCLOS article 246(5)). For marine scientific research in the EEZ and on the continental shelf, UNCLOS attempts to carefully balance the needs of coastal States, researching States as well as land-locked and geographically disadvantaged States. UNCLOS sets the standard and balance. Measures taken pursuant to the Convention on Biological Diversity which undermine the standard and balance could be deemed inconsistent.

While there are a number of potential conflicts, coastal States particularly need to carefully consider Part XIII's provisions on implied consent (UNCLOS article 252) as well as the participation of neighbouring land-locked and geographically disadvantaged States in marine scientific research in the EEZ and on the continental shelf and perhaps the supply of samples to them (UNCLOS article 254). Another area which will have to be considered carefully is identifying when marine scientific research is of direct significance to marine genetic resource exploration and exploitation.

Beyond the possible conflicts with article 15, the marine scientific research provisions are useful for coastal States even if they are not UNCLOS parties, since they are generally accepted as customary international law.[7] For example, article 248 provides that researching States have a duty to provide information to the coastal State with regard to the proposed activity.

Furthermore, article 249 requires, the researching State or competent international organization to (1) ensure coastal State participation or representation in the marine scientific research if it so desires, without obligation to contributing to the costs of the project; (2) provide preliminary reports and final results at the coastal State's request; (3) undertake to provide access to the samples and data collected, at the coastal State's request, and furnish copiable date and samples capable of being divided without diminishing their scientific value; (4) provide, at the coastal State's request, sample and data assessment and research results or assist in their assessment or interpretation; and (5) ensure international availability of research results, subject to the prior

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[7] Alfred H.A. Soons, *Implementation of the Marine Scientific Research Regime in the South Pacific*, Final Report to Forum Fisheries Agency (Report 95/14) and SOPAC (SOPAC Joint Contribution 101) at 8 (1994).

agreement of the coastal State. In instances where there is no duty to grant consent, but consent is granted, a coastal State may impose any other conditions.

Finally coastal States have the right to require suspension or cessation of marine scientific research particularly where research is not being conducted pursuant to the information upon which consent is based (UNCLOS article 253(1)(a)). Researching states and competent international organizations are responsible for ensuring that marine scientific research conducted by them or on their behalf is conducted in accordance with UNCLOS (UNCLOS article 263(1)). In instances of dispute, States party to the 1982 UNCLOS can avail themselves of the Convention's compulsory dispute settlement procedures (UNCLOS article 264). Disputes involving issues of a coastal State's right or discretion regarding marine scientific research (UNCLOS article 246) are exempt from binding results (UNCLOS article 297(2)).

E. Export Restrictions

Export restrictions could be used by the State providing genetic resources to ensure that prior informed consent requirements, both with the State and with others, have been fulfilled. In many cases, existing mechanisms such as export permits and biosecurity controls for quarantine or phytosanitary purposes could be modified to ensure prior informed consent. New mechanisms may need to be developed as appropriate, particularly for micro-organisms. There are a number of measures States could take.

First, and most importantly, a formal coordination mechanism could be established between the focal point and customs authorities to ensure that customs officials are aware of access determinations. The authority of border officials to ensure prior informed consent could be clarified and the power of seizure could be provided. General restrictions or limits could be imposed on the kinds and amount of biological material exported from the country. Ports of exit could be designated. Penalties for exporting genetic resources without prior informed consent could be established.

F. Sanctions and Penalties

The prior informed consent requirement will be difficult to enforce primarily because of the nature of genetic resources; it will be impossible to ensure enforcement of prior informed consent for all genetic resource transactions. The threat of sanctions and penalties can help bring credibility to the access determination procedure and the need to obtain prior informed consent prior to access. Civil remedies and criminal penalties could be provided. In addition, the access legislation may indicate whether consent, or the access agreement, can be revoked, modified or suspended. If so it should provide the grounds or condition for these actions and could require more detailed procedures to be enacted.

G. Identification and Monitoring

Identification and monitoring of genetic resources will play a critical role in negotiating mutually agreed terms for benefit sharing. The negotiating position of the State will be enhanced if it can independently determine (1) the potential uses for genetic resources within its jurisdiction and (2) how a potential user might use or value a particular genetic resource. And, since collecting pressures can threaten genetic resources, identification and monitoring efforts will contribute to the conservation and sustainable use of genetic resources. In addition, to support indigenous and

local communities and ensure benefit-sharing, inventories[8] of their genetic resources and knowledge, innovations and practices may be undertaken as well, provided they are undertaken with their approval and involvement (see article 8(j) of the Convention on Biological Diversity).

Therefore access legislation might commit the State to undertake identification and monitoring. The focal point might be designated to coordinate this, especially if it is an inter-agency body.

H. Financial Issues

Financial resources may be the most critical consideration in a State's development of a regulatory scheme to determine access to genetic resources and ensure benefit-sharing. In short, an effective access determination process will require funding. A State will have to weigh the financial burden of establishing a regulatory programme against the probability that there will be a possible pay-off in benefits in the future, and explore cost-effective options as part of the planning process.

Where it is feasible, it may be desirable to establish a national fund within which financial benefits derived from genetic resources may be deposited. The planning process could identify how the money could be best spent.

IV. Conclusion

States providing genetic resources are confronted with a number of complex legal and institutional considerations as they seek to determine access to genetic resources and ensure benefit-sharing. Each State will need to determine the best way forward taking into consideration its national and regional circumstances. A national planning process will clarify a legal and institutional approach which, for States providing genetic resources, will enable them to capitalize on the new relationship between the providers and users of genetic resources created by the Convention on Biological Diversity.

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[8] M.S. Swaminathan, *Farmers' Rights: Fair Shares for All in Progress Towards Saving India's Genetic Diversity*, PLANT TALK, October 1995, at 16.

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