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In Defense of Local Community Knowledge and Biodiversity: A Conceptual Framework and Essential Elements of a Rights Regime

ial Singh Nijar 26-Sep-97

e Link Between Peoples' Knowledge Systems and Protection of Biodiversity

. Symbiotic Relationship

ughout history, Biodiversity has been familiar among local communities with both resources and vledge being freely exchanged or applied for the common good. Diverse and viable knowledge arms were developed based on the life-support capacities of the Earth's bounty. There was a biotic relationship: people lived off nature even as they helped to sustain it. The life of munities was enhanced, spiritually, culturally and economically even as the communities nced earth's biodiversity.

nowledge and practice relating to forestry and agriculture best illustrates this. In local vledge systems, the plant world is not artificially separated on the basis of separate commodity ets to which they supply raw materials and resources: forest supplying commercial timber and :ultural land supplying food commodities. Instead the forest and the field are in ecological inuum. Activities in the forest contribute to the food needs of the local community, while :ulture itself is modelled on the ecology of the tropical forest. Some forest dwellers gather food :tly from the forest while many communities practice agriculture outside the forest, but depend e forest for the fertility of agricultural land.

life-support and food-giving capacities of the forests have spawned the local knowledge systems. has led to the development of knowledge, practices and lifestyles designed to preserve the rity and diversity of the forest and its sustainable use.

on-tribal areas too, forests provide food and livelihood through critical inputs to agriculture ough soil and water conservation, fodder and organic fertilizer. Indigenous silvicultural practices ased on sustainable and renewable maximization of all the diverse forms and functions of forests rees. This knowledge passed through generations assures the survival of the forest, its onent parts, its sustainability and the people and cultures dependent upon it and the ecosystem hole. Such knowledge has been steadily eclipsed and marginalized, largely by colonialism and nsuing industrialism of the West. The diverse knowledge systems that developed with the rse uses of the forest for food and agriculture were ignored, and substituted with a oculturalized view that valued the forest only in terms of its industrial and commercial timber urce.

ning the value of forests only in terms of its source as commercially exploitable timber reduces /alue of diversity of life in the forest to the value of a few commercially valuable species, and ier, to the value of their dead product. This reductionism is destructive to the integrity of the sts as well as to forest cultures which tap the forests in its diversity for their food, medicine, fibre shelter.

i, forestry science ignores, for example, the knowledge of the Hanunoo in the Philippines of 1,600 t categories; of the Lua Tribe in Thailand of cropping systems based on 160 crops and the life aining food system based on the forest for the Kayan, Kenyah, Punan Bah and Penans of wak. They rely on fungi (23 varieties eaten by Kenyah and 43 by Iban), and sago, which is the :h derived from the pith of a palm tree.

outh India, the Soliga tribe from the Belirangan hills of Karnataka uses 27 different varieties of ' vegetables and a variety of tubers, leaves, fruits and roots for medicinal purposes. The staple

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of rice and lesser millet of the tribes in Madhya Pradesh is complemented with the seeds, grains, roots, rhizomes, leaves and fruits of some 165 trees, shrubs and climbers of the forest.

Diversity and Uniformity

As diversity gives way to uniformity, only aged single species stand. In agriculture, only species whose production can be optimized for commercial interests are advanced. The isolation of characteristics which are "beneficial" results in the reduction of genetic variety. The Green Revolution high-yield response varieties of wheat and rice displace traditional crops, creating vast areas of monoculture.

Biotechnology in crops expedites this tendency towards monoculture as biotechnological-developed strains replace locally adapted strains or the advantages of local planting techniques which are geared towards maintaining diversity rather than productivity. The economic impetus of biotechnology slowly causes a further erosion of the world's biological diversity propelling agricultural production towards greater uniformity.

Similarly the homogenization of livestock populations is resulting in the irreparable loss of diversity. Cross-breeds of Jersey and Holstein cows are replacing the carefully evolved pure breeds of cattle in India such as the Sahiwal, Red Sindhi, Rathi, Tharparkar, Hariana, Ongole, Kankrej and Gir. The local disappears from the farming system and organic fertilizer is substituted by chemical fertilizer. Soil, fauna and flora also become extinct.

Locally specific nitrogen-fixing bacteria, fungi that facilitate nutrient intake through mycorrhizal association, predators of pests, pollinators and seed dispersers, and other species that co-evolved over centuries to provide environmental services to traditional agrosystems have become extinct, or have had their genetic base increasingly narrowed. Soil microbes, deprived of the flora with which they have co-evolved, also disappear.

Biodiversity erosion thus starts a chain reaction which ultimately threatens the life-support systems and consequently the livelihoods of millions of people of the Third World dependent on and co-existing with it.

Value of Knowledge

There is growing appreciation of the value of the knowledge and experience of local and indigenous communities in the use of the medicinal, agricultural and other useful properties of endemic flora and fauna. Between 300,000 and 750,000 plant species are thought to exist in the world with much of the diversity found in tropical zones. While fewer than 1 per cent of this diversity has been documented for their medical or chemical properties, valuable information about these resources is gained within culturally diverse knowledge systems.

It is estimated that three-quarters of the plants that provide active ingredients for prescription drugs have come to the attention of researchers because of their use in traditional medicine. Of the 120 active compounds currently isolated from the higher plants and widely used in medicine today, 74 per cent show a positive correlation between their modern therapeutic use and the traditional use of the plant from which they derive.

Paul Balick of the New York Botanical Gardens found that using traditional knowledge increased the efficiency of screening plants for medical properties by more than 400 per cent. The current value of the world market for medicinal plants derived from indigenous and local communities is estimated at US\$ 43 billion. Furthermore, the value of crop varieties improved and developed by traditional farmers to the international seed industry is estimated to be US\$ 15 billion. In addition to medicines, agricultural products, other natural products developed by indigenous peoples and local communities such as sweeteners, perfumes, fabrics and cosmetics, are in everyday use. With a growing market for natural products the value of these contributions will continue to rise.

Biodiversity Prospecting

Advanced screening techniques and recent advances in biotechnology and genetic engineering have stimulated a rush for biodiversity prospecting, primarily in the South, where most of the world's biodiversity is located. It is reported that of recent bioprospecting projects documented by a governmental organization, Rural Advancement Foundation International (RAFI), 83 per cent was in the South's terrestrial biodiversity.

An additional 11 per cent of bioprospecting projects were for sampling diversity from international waters - again mostly in the South. Only 6 per cent of bioprospecting efforts focused exclusively on the North.

At the same time, Northern Governments and multinational corporations are vigorously seeking to extend their intellectual property rights regimes to plants, animals and micro-organisms through bilateral international trade instruments such as the General Agreement on Tariffs and Trade (GATT) and the World Trade Organization (WTO).

This poses a grave threat to the nurturers of biodiversity - farmers, indigenous peoples and local communities. Their knowledge systems, traditional culture, social and economic lifestyle and

tices are being usurped and undermined by these processes.

International Developments Affecting the Recognition of Rights in Biodiversity of Nations, Farmers, and Indigenous Peoples

IPOV, FAO and Farmers' Rights

A long time in history no concept of sovereign rights of resources or property rights in genetic resources existed. What contributed to the emergence of property rights for commercial benefits in this area was the enactment of an International Convention in the early 1960s - the Union for the Protection of New Varieties of Plant (UPOV). The South wherein the biodiversity was concentrated, tapped freely for source material and farmers' germplasm, on the rationale that it formed the common heritage of mankind. Corporate interests, predominantly from the North, invaded the local commons of the South for free, made "improvements" in the breeding process by modifying the plant variety's characteristics and quality, and claimed property rights on these for a patent of an invention as an industrial product (i.e. novelty, industrial application and originality).

Innovative contribution and knowledge of local communities to the evolution of seeds and genetic resources concerned were ignored. No reward existed for them. This inequitable treatment between breeders of germplasm and owners of technology spawned a debate in the Food and Agricultural Organization (FAO) in the 1970s. Developing countries complained that "the common heritage of mankind" taken from within their borders for free was now returned as a commodity at a price. As a consequence, the FAO at its 22nd session in 1983 adopted an Undertaking. (For status of the Undertaking and the FAO Global System in Plant Genetic Resources, see Appendix 1).

The Undertaking recognized free access to basic source material as well as to improved and elite varieties. Several industrialized countries rejected this undertaking arguing that improved materials do not form part of the common heritage of mankind. In the March 1987 meeting of FAO's Commission on Plant Genetic Resources (CPGR), the South asserted that farmers' rights were based on the basis of their having domesticated their important agricultural crops, and observed, developed and safeguarded the tremendous biodiversity that breeders and the seed industry use as source material. Innovation was thus an integral part of farmers' breeding their seed varieties. The debates finally led to the international recognition of both Plant Breeders' and Farmers' Rights in 1989. This recognition is expressed in resolutions 4/89, 5/89, and 3/91, which were negotiated by the Commission on Plant Genetic Resources and unanimously approved by more than 160 countries at the FAO Conferences in 1989 and 1991.

Farmers' Rights were in recognition of "the enormous contribution that farmers of all regions have made to the conservation and development of plant genetic resources"(Resolution 4/89). Farmers' rights were defined as "rights arising from the past, present and future contribution of farmers in conserving, improving and making available plant genetic resources, particularly those in the centres of origin/diversity". These rights were declared by this resolution to be vested in the International Community, as trustees for present and future generations for the purpose of ensuring full benefits to farmers and supporting the continuation of their contributions.

The envisages that the implementation of these rights would ensure that farmers, farming communities and their countries receive a just share of the benefits derived from plant genetic resources which they have developed, maintained and made available. It thus sees Farmers' Rights not only as a matter of justice and equity, but by providing incentives and means for the conservation and further development of these plant genetic resources by farmers, will "ensure that genetic resources on which we all depend are conserved and continue to be made available."

The contribution of the traditional farmer in developing the plant was acknowledged. But the right was not vested in the individual farmer. Instead it accrued to the farmers' governments to receive assistance in the maintenance of genetic resources. It is essentially a general obligation of the North to help the South, tied into the context of aid and dependency.

The international gene fund, administered by FAO for the conservation and utilization of plant genetic resources was set up to consolidate these "farmers' rights". However, the lack of contributions from Northern corporations and their governments rendered this fund inoperative. The debate did not end there. This was because of: the extension of patent rights to genetic materials; and, the growing importance of biotechnology.

In addition to the conflicts between agro-business and farmers' right, pharmaceutical companies were enjoying free access to genetic materials from the forest (especially tropical rain forests), and mining the vast knowledge of forest peoples, again for free.

The viability of FAO's 1989 Undertaking itself came into question because of several developments in international negotiations. These were: the revision of the UPOV Convention; Trade-related Intellectual Property Rights Agreement (TRIPs) negotiations in the Uruguay Round of GATT; and the Convention on Biological Diversity.

The first two substantially broadened the gap between source materials and improved varieties in terms of value and ownership rights attached to them. The rights of breeders/inventors over improved varieties are given greater recognition at the expense of rights of local communities over source materials which themselves are the results of innovation and improvements by generations of

ers.

the 1991 UPOV Revision

1991 revision of UPOV further restricted the farmers' rights. The protected variety may still be used as an initial source of variation for the creation of new varieties but such new varieties cannot be marketed or sold without the plant breeders' rights (PBRs) holder allowing it. As the PBRs holder wants to maximise his sales and profit, his authorization will almost certainly not be given. Breeders' rights have also been extended to cover not only production for sale, but also reproduction, multiplication, conditioning for the purpose of propagation, and exporting/importing and stocking for the same purposes.

Developing countries have the option to adopt in their national law the right of the farmer to use his seed for planting. It is unlikely, however, that developing countries will do so. They are under extreme pressure from the Northern countries to harmonize their legislation with the IPRs standards promoted in the North. So if the United States or the European Community do not make use of this option, the developing countries will also be excluded from authorizing their farmers to reuse their own seeds. Another restriction is that harvested material cannot be sold or marketed without the breeders' authorization. If royalties are not paid, the breeder can interpose to prevent the farmer from selling his produce. These changes have made PBRs to offer the same kind of iron-clad protection as do patents for industrial inventions.

RIPs in GATT

Article 27(3)(b) of the TRIPs Provision of the GATT Final Act obliges Members to provide for the protection of plant varieties. They may do this either by patents or an effective *sui generis* system or a combination of these. The only such system available now is that under UPOV which favours plant breeders. Each country is free to set up its own system.

Developing countries may exclude from patentability plants and animals which are not considered to be biologically improved varieties. Again a distinction is drawn between genetic material developed in the North by technologists and that which has been developed in the South by farmers or indigenous populations.

the Convention on Biological Diversity

The impetus for the Convention came from Northern conservation groups and the biotechnology industry, to protect disappearing tropical forests and to ensure biological capital for the generation of profits. The South which holds most of the biological resources and diversity of the world argued that access and IPR protection for the North created an unequal and unfair exchange. In this context Southern governments looked forward to an international recognition of their ownership rights in genetic resources, and accessing advanced technologies of the North (especially biotechnology) in exchange for granting access to their genetic resources to Northern enterprises. For this reason the Convention on Biological Diversity was important for Southern countries.

The Convention recognized that the States have sovereign rights over their natural resources. They reserve access to their genetic resources. It is subject to their national legislation. Thus, the "common heritage principle" is abandoned in favour of "sovereignty over natural resources". The Convention thus regulates access and can deny it if it is inimical to its national interest. The Convention enables States to endeavour to "create conditions to facilitate access for environmentally sound uses" to other States and not to impose restrictions that run counter to the Convention's objectives. Its objectives are declared to be:

- ▶ conservation of biological diversity;
- ▶ the sustainable use of its components; and
- ▶ the fair and equitable sharing of the benefits arising out of the utilization of genetic resources (Article 1).

Authority to determine access rests with the State, it is the State's legislation which will determine what constitutes "environmentally sound uses".

The Convention stipulates conditions (in addition to those set out by national legislation) for the grant of access to its genetic resources. Thus access shall be:

- ▶ on mutually agreed terms (Article 15.4); and
- ▶ subject to prior informed consent of the State of the resource (Article 15.5).

The Convention expressly recognizes that both access to and transfer of technology are essential elements for attaining its objectives. Each party undertakes to provide and/or facilitate access for and transfer of technologies to others that are relevant to the conservation and sustainable use of biological diversity, or make use of genetic resources and do not cause damage to the environment (Article 16.1).

In regard to technologies which make use of genetic resources, the Convention obliges States to take legislative, administrative or policy measures to give access to and transfer of technology on mutually agreed terms to other States, especially the developing countries which provide the genetic

urces. The technologies include those that are protected by patents and other intellectual property rights (Article 16.3). The whole of this Article 16 on the transfer of technology and IPRs is from clear. It is therefore open to interpretation and definition.

Convention calls upon contracting Parties to ensure that such IPRs are supportive of and do not counter to its objectives. In view of recent trends through TRIPs in GATT to oblige developing countries to strengthen intellectual property rights protection, the Convention may offer an opportunity to reject the establishment of a regime which will be incompatible with its objectives.

Convention recognizes the role of indigenous and local communities in conserving and sustainably using biological diversity, and states that the benefits arising from their knowledge and innovation should be equitably shared and urges States to initiate methods for the development and use of indigenous and traditional technologies in pursuance of conserving and using biological diversity. It further exhorts Parties to protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements.

What emerges from a brief review of these international developments and debates is that there is an acknowledgment that farmers' and indigenous peoples' rights are essential for the conservation and promotion of biological diversity. This emanates from a recognition of their diverse systems of knowledge and innovation in biological resource improvement and utilization, and that equity demands a sharing of benefits. However, what emerges equally clearly is that the existing international mechanisms are not entirely supportive of this understanding. The search for a coherent legal framework advancing this understanding is therefore of crucial importance for the preservation and protection of these critical values.

Search for a Legal Framework for Regulating Access

Article 15 of the Convention on Biological Diversity recognizes that States have sovereign rights over their natural resources. They determine access to these genetic resources and their national legislation will prevail.

Such clear recognition will undoubtedly prompt States to amend, modify or even promulgate national legislation to regulate access to such resources. The terms and conditions for the grant of access are usually within the domain of national legislation. The Australian State of Queensland, for example, proposed an amendment to its Nature Conservation Act "to give the State outright ownership of flora and fauna and guarantee that it shares in any profits made from exploiting them", an action it sees as essential to "halt a systematic search of our biota by foreign laboratories and pharmaceutical companies".

Often there is no single coherent legislation to govern access in most countries. Instead it is spread in a plethora of legislation over different sectors of the bureaucracy. This often makes regulation and management difficult, uncoordinated and cumbersome. Often the legislation is sector-based: fisheries, wildlife and forests. Moreover, sometimes the authority to legislate constitutionally is distributed between the Federal (central) authority and the respective States. This creates serious problems such as an absence of integrative approach across the sector due to the limited scope of various enactments in relation to biological diversity conservation, a lack of comprehensive coverage of biological diversity issues, and the constitutional distribution of legislative process between the State and the Federal Governments that result in areas of overlap and non-implementation between them.

State sovereign rights in resources accords the right to regulate access. Indeed Article 15.2 obliges the States to facilitate access to genetic resources for environmentally sound uses and not to impose restrictions that run counter to the objectives of the Convention. Access is made subject to prior informed consent of the contracting party providing such resource unless otherwise determined by party (Article 15.5). Access has to be on mutually agreed terms (Article 15.4).

The cumulative effect of these provisions appears to be:

State may set up legislation regulating access;

Considerations on regulating access can also include:

Denial of access if it is inimical to its national interest;

Facilitating access for "environmentally sound uses", a term which will need to be defined;

Access on mutually agreed terms should include the right of the State to participate in research and development activities (Article 15.6), and, the right to share in a fair and equitable way the benefits arising from their commercial and other utilization (Article 15.7).

The use of the expression "mutually agreed terms" seems to suggest an ad hoc contractual arrangement. But this does not necessarily preclude the enactment of legislation which incorporates minimum terms and conditions consistent with the Convention and furthering its objectives which must be adhered to by both the provider and the collector of the genetic resources. This kind of legislation is often promulgated to ensure the orderly development and management of an activity,

to protect a particular class of people, often a weaker party. On this basis, countries have enacted Acts relating to Employment (to stipulate minimum terms and conditions of employment), Purchase (to regulate the commercial hire purchase of consumer goods) the Sale of Goods (relating generally with express and implied terms relating to the sale of goods) and Housing Development (to control and regulate housing developers as well as the contents of Sales and lease agreements between developers and consumers). Licensing laws often also exist to regulate the conduct and activity of certain categories of entrepreneurs on the rationale that their activity impacts on the public.

protection of biological diversity is particularly amenable to such legislation. Its importance has been underlined. If allowed ad hoc private contractual arrangements much would depend on the strength of the respective negotiating parties, in this case between industry (often transnational corporations) and a Third World State with the biodiversity. Experience has shown that transnational corporations (TNCs) are more able to assert their terms and with a strong IPR regime favouring industry, "mutually agreed terms" may not necessarily be mutually beneficial in reality. Corporations often negotiate with little accountability. Even the National Cancer Institute (NCI) of the US which between 1986-1991 collected some 10,000 samples representing more than 2,500 species from just six Third World countries alone, has had its standard collectors' contract severely criticized. New Scientist of 3 July 1993 reported that:

NCI has a standard agreement which it offers countries in which its collectors hunt plants. The agreement is meant to encourage such cooperation. Australia, however, refused to sign the standard agreement when asked by the NCI in 1990. "It is a legally vacuous document", claimed the Western Australian official who is negotiating the agreement. "It would not guarantee the outcomes we desire, and unless it guarantees them, why should we sign the document?"

Australians, he says, will not agree to any deal that does not build in protection for the plant in the wild, include Australian scientists in the research and development, and guarantee a "fair and equitable share of any commercial benefits from development of the plant".

NCI collects in 25 nations, but only 4 countries "have forced the NCI into formal agreement".

Proposed Collector's Act

It is then suggested is a system of licensing collectors of biological diversity as a means of regulating them. The applicant will be vetted to ensure his ability to fulfill the obligations under the Act. The licence is then given for a prescribed period and subject to conditions. Any contravention of obligations will expose the offender to penal sanctions and a withdrawal of the licence. Directors and employees of companies may be liable to imprisonment for any contravention of the Act. Licensed collectors will also be required to sign an agreement with the State (or any one it may designate or authorize on its behalf) which impose obligations on the collector before during and after collection.

Provisions include the collector furnishing the State with plans for prospecting, the types of material to be collected in terms of species and quantities, the evaluation, storage and use of the collected material, including the uses to which it would be put, and, the benefit the host country or community may derive from the collection of the germplasm. This is a consolidation of "the prior informed consent" of the State to which access is subjected by Article 15.5 of the Convention. By this provision consent must be given with full knowledge of its implications for the resource as well as for sovereign rights of the State granting it.

During the collection the collector is limited to the quantum of the resource collected, and he has to inform the local community and farmers informed of his mission and supply them with duplicate samples if required. Upon collection, he has to record the most complete data as to the plant collection, its diversity, habitat and ecology sufficient to provide curators and users of germplasm an understanding of its original content; as well as document methods and technologies of using and caring the collected material.

After collection, a series of obligations requires processing the plant samples and pathogens for preservation, depositing all collections, associated materials and records of information with the government, transferring the samples timeously to conditions which optimize their viability, and warning the authorities of any impending threat to plant populations or evidence of accelerated genetic erosion together with recommendations for remedial action. Significantly all prospecting activities and experimentation have to be done with a collaborator (individual or institution) from the host country, such person/institution to be approved by the State.

Income representing not less than a fixed percentage of any income arising from the supply of germplasm extracts to commercial organizations is payable by the collector. An amount is similarly payable for royalties obtained as a result of the creation or invention of a marketable product. Significantly, the collector must obtain his country's endorsement agreeing to indemnify the source country for any losses it sustains by the collector's breach of the agreement, and to deliver up the results of any report made of studies or experimentation made on the collected specimen. To prevent usurpation of innovations of local communities or indigenous people, a comprehensive obligation is imposed on the collector. It reads: "No patent application shall be filed within or outside the source country in respect of the collected specimens or any part thereof, its properties or activity or any

atives which utilize the knowledge of indigenous groups or communities in the commercialization of a product as well as to a more sophisticated process for extracting, isolating or synthesizing the active chemical in the plant extracts or compositions used by indigenous peoples or if the same process respects the intellectual right of the indigenous communities".

agreement covers situations where although the organism is freely available from different countries, the phenotype providing an active agent from a plant is found only in the country from which it is collected.

Voluntary contracts of this kind do not preclude parties from negotiating other terms (not in conflict with these terms) and tailoring them to their specific needs. The advantage of obliging parties to sign contracts with the Government instead of enacting subsidiary legislation to implement the Act, is that contracts are usually more easily enforceable outside the source countries. Many countries primarily have reciprocal enforcement arrangements with other countries. By this a civil judgment issued in the source country is enforceable in the reciprocating country upon fulfillment of certain conditions. Legislation of a country, on the other hand, has no extra-territorial effect.

Ex-situ Collections

The Convention excludes from its scope and ambit genetic resources obtained from source countries before the Convention came into force. This has major implications for biodiversity, especially for agriculture. Worldwide holdings of crop germplasm in *ex-situ* collections (including wild relatives) amount to about 4.2 million accessions, including over two million accessions of cereals and about half a million of food legumes. The number of unique accessions is thought to be about 50 per cent of the total number.

In fact, for certain major crops they may for practical purposes represent nearly all of the world's remaining diversity. Furthermore, the actual and potential value of these collections is generally considered to be superior to most of the diversity not yet collected for the crops concerned. In addition the North effectively controls 85 per cent of all fetal populations of domesticated livestock and 86 per cent of global microbial culture collections, the bulk of which originates from the South.

Over 100 crop germplasm collections have been established in about 130 countries. Over half (53 per cent) of the accessions are located in developed countries, one-third (36 per cent) in developing countries and about 12 per cent in international centres. However it is estimated that about 35 per cent of the unique samples are held in the International Centres of the Consultative Group of International Agricultural Research (CGIAR). These probably comprise the most significant collection.

Who Owns These Ex-situ Genetic Materials?

The opinion of FAO's Legal Office in 1987 was that regardless of where the material may have been collected from, ownership of genetic material held in government genebanks or held in public institutions was, in most cases, considered to be vested in the State in which these genebanks are located. For materials held in the International Agricultural Research Centers (IARCs) the legal position was unclear. Since 1988, the IARCs have jointly stated that they do not regard themselves as owners of the germplasm but consider that they hold them in trust for the benefit of the international community, in particular the developing countries. This formalizes the status of the germplasm under which the IARCs received the genetic material. The Consultative Group for International Agricultural Research (CGIAR) under which the IARCs are run, state that as they hold the collections in trust, they have a duty to distribute the germplasm for these collections to any researcher who demonstrates a legitimate interest. The IARCs make no attempt at controlling subsequent commercial uses (and claiming of IPRs) of germplasms.

The Commission on Plant Genetic Resources finding this position unsatisfactory, has called for the setting up of an International Network of base collections in genebanks under the auspices or direction of the FAO, thereby implementing FAO's International Undertaking (Article 7.1(a)). Countries and institutions which voluntarily decide to place collections in their genebanks within this network agree to ensure that the genetic material is safely conserved and will be made available for plant breeding and research purposes, while respecting the rights of the providers of the germplasm. Countries and the IARCs, collectively holding 46 per cent of the world's germplasm, have indicated their willingness to make their genebanks part of this International Network. International Plant Genetic Resources Institute (IPGRI) has also signed agreements with those national and international institutions registered with it to conserve specified germplasm and make it available to the international community. IPGRI has agreed to merge its register with the International Network. The combined Network will cover about 70 per cent of global accessions. The IARCs collections have now been placed under FAO's International Plant Genetic Resources Institute.

It is crucial to understand that the granting of sovereign rights to States in their biological resources under the Convention could be effectively undermined if they are not accorded the same rights to the genetic resources collected from their territory and now located in these genebanks. FAO has undertaken a major revision of the International Undertaking on Plant Genetic Resources (IUPGR) to make it more compatible with the Convention on Biological Diversity. This would be presented in Geneva in 1996 at the 4th International Conference on Plant Genetic Resources. It will take the form of the FAO's first report on the State of the World's Plant Genetic Resources and a Global Plan of Action. The terms of access to agricultural genetic resources (including the issue of IPR) and the

ept and the implementation of Farmers' Rights is being renegotiated.

in situ collections ought to be brought within the Convention and countries and communities nationally providing the germplasm accorded sovereign rights which should entitle them to regulate access and obtain benefits on the same basis as for *in-situ* collections.

Community/Indigenous Peoples' Intellectual Rights

Members of indigenous peoples, knowledge and determination of the use of resources are collective and inter-generational. No indigenous population, whether of individuals or community, nor government can sell or transfer ownership of resources which are the property of the people and in which each generation has an obligation to safeguard for the next.

Agreement by the Coordinating Body of Indigenous Peoples of the Amazon Basin (COICA), 1994.

State has sovereign rights over its tangible biological resources insofar as regulating access to it, but not over the intangible knowledge pertaining to its properties and the development of that knowledge informally, accretionally and over time, by a community.

As stated earlier, the TRIPs provisions in GATT 1994 seek to globalize the dominant patent paradigm of industrialized countries, mainly that of the USA. These provisions guarantee ownership rights in products made in the laboratories of the North from the knowledge of indigenous peoples and local communities. The knowledge system of these communities, their innovations, the societal and cultural context in which they produce and innovate, and the purpose for which they do so - all these are denied recognition. Only the North's industrial model of innovation is recognized; the cumulative collective system of innovation of traditional communities is excluded by the TRIPs provisions.

The generally accepted legal position is that the intangible right in the genetic resource, that is the knowledge in the resource, of indigenous peoples and local communities is deemed to be in the public domain. It can therefore be accessed freely. This undoubtedly exacerbates the usurpation of the knowledge of indigenous peoples and local communities with serious consequences for them and for biodiversity conservation and sustainable use.

There are no legal instruments or standards that protect indigenous peoples and local communities from biopiracy of their knowledge. There has not been a lack of declarations and pious exhortations recognizing these rights. Examples are: the Convention on Biological Diversity [Article 8(j)], Convention 169 of the ILO [preamble, Articles 7 and 13(1)], Resolution 1990/27 of the Working Group on Indigenous Populations created in 1982 by the UN Economic and Social Council (ECOSOC), Report of the Secretary-General of the UN to the Commission on Human Rights Sub-Commission on Prevention of Discrimination and Protection of Minorities (44th session), and the Declaration at the International Conference on Indigenous Peoples and the Environment, Chile, 1992. Farmers' rights have not been recognized in the FAO by the International Undertaking on Plant Genetic Resources.

There are now two distinct possibilities on the question of protecting the knowledge of indigenous peoples and local communities. The first is to do nothing, on the premise that to provide any kind of "protection" of rights is to bring indigenous communities and their resources into the fold of the market economy, which with its subversive influences of materialism and consumerism, could overwhelm and ultimately destroy these societies. The second is to formulate a rights regime which respects the cultures and value-systems of these communities as a device to prevent the usurpation, commoditization and privatization of their knowledge and ward off any threats to the integrity of these societies.

Doing nothing in the face of active assaults to the biological resources and the knowledge systems of indigenous societies by pharmaceutical companies and other sectors of the industrial society, is to maintain the status quo. And this is to perpetuate the present continued destruction of indigenous societies and their natural environment.

Doing nothing really leaves little option but to consider the formulation of a rights regime which is able to protect and preserve the fundamental values and the social and cultural cohesiveness and integrity of these societies which are largely responsible for conserving and sustainable using biological diversity.

The main elements of such a regime need to be identified. But first some remarks to clarify the conceptual framework that informs this rights regime.

The Conceptual Framework

The claim "ownership" rights to intellectual knowledge, is not to adopt the IPR model of the industrialized North. In particular, the concept of privatized, individualized or corporatized knowledge and concepts of creativity is clearly rejected. Indigenous communities create collectively. This necessarily means that the whole community will be deemed the rightful owner of such creativity or innovation.

Further rejected by this alternative rights regime, is the notion of a one-shot concept of innovation which typifies industrial innovations. The creation of indigenous communities is often accretional, incremental, and over time. The knowledge is continuous as it modifies, adapts and builds upon the existing knowledge. A redefinition of "innovations" would pave the way for the recognition of

ulative innovations and knowledge. This will also mean that the innovation cannot be dealt with out regard to the past, present and future "owners" and beneficiaries of the knowledge. The right therefore inure in perpetuity and cannot be extinguished or its integrity impaired as this would deprive the present and future owners/beneficiaries access to and use of the right. This would ensure individuals purporting to act in the name of a community cannot impair the status and integrity of the right, as it "belongs" to the community and its members. Also rejected is the notion that for an innovation to be recognized, it must have an industrial use; or that it must be trade-related. Innovations of domestic, common and social value, all hallmarks of community creativity, must be accorded recognition.

Importantly, the entire ethos of the industrial patent regime will be entirely excluded from, and form no part of, the regime establishing indigenous and local community rights. So establishing a community rights regime will be really an attempt at formulating a wholly new sui generis regime to reflect the ethos of the communities and the way they relate to themselves as well as to biodiversity.

The main concern, as is readily discernible, does not relate to the lack of equitable compensation for the community. It is in fact the usurpation of community intellectual knowledge, although this is indeed a valid complaint. The underlying assumption that informs this new regime is that indigenous communities should be protected from commoditization of their knowledge and their resources. As noted, the influence of the market economy is subversive to indigenous communities. It breaks up communities. Individuals from amongst them barter the societies' interest and ultimately destroy the fabric of the community.

The main thrust of this rights regime is that the whole of the indigenous peoples' and local communities' knowledge system must be protected. This means that their creativity in the form and manner in which the communities understand this term and practise it, must be accorded formal recognition. Implicit in the rights regime is a recognition that indigenous peoples and local communities have a right to self-determination and to safe-guard their cultures, lifestyles and practices in the broadest sense. It gives them complete control to regulate access, including the right to deny any such access, to their traditional resources.

Importantly, the knowledge systems of indigenous communities are denied recognition. Only the western, industrial model of innovation is accorded recognition. It may be suitable for industrial products, but it is antithetical to the ethical and social values and needs of many Third World countries and peoples. It is critical, therefore, to redefine "innovation" in a manner which is protective of the creativity of local communities and indigenous peoples. This is crucial to the preservation of biodiversity itself, as recognizing and protecting their knowledge systems means, as well, a recognition and preservation of the cultural and social life of traditional societies which embodies knowledge and practices supportive of biodiversity. It is also in accord with social justice as it recognizes the true creator and respects diverse cultures and different traditions of knowledge.

In addition to the definitional devices, various sophisticated contrivances exist in the present patent law to marginalize indigenous knowledge and accord recognition and patent rights to products, incorporating the knowledge of indigenous peoples and local communities, for example, by "inventively" describing the products as "non-obvious derivatives" or the process as "a more sophisticated process for extracting, isolating, or synthesizing the active chemical in the plant or natural extracts or compositions". It was thus that the US has granted patent rights to US "inventors" in respect of the use of neem plant. Indian traditional knowledge of the use of the neem as a pesticide, dentrifice, etc. dates back 5,000 years. It is part of their Ayurved knowledge system.

Under US patent law, section 101 of Title 35 of the US Code, for any product or process to be patentable, must satisfy the triple requirements of novelty, utility, and non-obviousness. No patent can be granted for discovering a product of nature. For a process using the newly discovered product of nature, a patent claim may be made. The point is that it must be an "invention". The US Court decisions on whether a product is, or is not, a product of nature are very fact-specific, and as a consequence judicial guidelines have proven difficult to delineate. This leaves the field wide open to make "convenient" decisions. This is demonstrated clearly in relation to the patent claims made of the neem. As regards the seeds of the neem tree, they are held not to be patentable because they are a product of nature. So the knowledge pertaining to it is not patentable too. (Generally, by this model patent law, ideas/knowledge are/is not patentable, although the application of the ideas may be.) However, the methods of scattering ground neem seeds as a pesticide is not a patentable process, because it has "been known and practised for centuries and would be deemed obvious." But patents have been granted for:

- ▶ extracts from pre-treated neem bark shown to be effective against certain cancers (US Pat. No. 4,537,774). These extracts are distinguished from the prior art as it is said that the process involved the pre-treatment of the bark rather than a direct extraction method. The pre-treatment is said to result in extracts with a higher degree of purity;
- ▶ neem-seed extracted azadirachtin in a stable storage form (US Pat. No. 4,556,562); and azadirachtin-derivative insecticides (US Pat. No. 5,047,242). In all these, azadirachtin is the significant active component.

What this shows is that the knowledge and use of the knowledge of indigenous communities is denied recognition. But the use of that same knowledge by western laboratories is accorded recognition by stating the definitions in a way prejudicial to the indigenous peoples and local communities. Thus,

synthetic form (referred to as a "derivative") of the neem incorporating the knowledge of traditional peoples, is described as "technically not a product of nature" and hence patentable! Similarly, the process by which the compound is synthesized, is patentable. The "stable storage formula" is also patentable. The derivatives are said to be "synthesized in the laboratory, not merely extracted from nature"! And they are "more stable than the azadirachtin found in nature"!

There is, of course, a serious flaw in these self-serving definitions. Traditional uses, although based on natural products, are not "found in nature" as such. They are products of human knowledge. To transform a plant into medicine, for example, one has to know the correct species, its location, the best time of collection (some plants are poisonous in certain seasons), the part to be used, how to prepare it (fresh, dried, cut in small pieces, smashed), the solvent to be used (cold, warm or boiling water; alcohol, the addition of salt, etc.), the way to prepare it (time and conditions to be left in the sun), and, finally, the posology (route of administration, dosage).

Essentially, these conflicts as to what can and cannot be recognized as "creative" and "innovative", present a clash of the definitions of knowledge systems. The present unidimensional definition of knowledge cannot be accepted as it allows for the usurpation of traditional knowledge by deft definitional maneuvers. It reduces the pool of human cultures by a reductionism which denies recognition to the diverse and varied knowledge systems of local communities and indigenous peoples. It is of the first importance then to reclaim the right by reformulating a definition which explicitly recognizes the knowledge systems of indigenous peoples and local communities. Accordingly, it is proposed to define "innovation" to:

include any collective and cumulative knowledge or technology of the use, properties, values and uses of any biological material or part thereof, rendered of any, or enhanced, use or value as a result of the said cumulative knowledge or technology whether documented, recorded, oral, written or howsoever otherwise existing including any alteration, modification, improvement thereof; and also include derivatives which utilize the knowledge of indigenous peoples and local communities in the commercialization of any product as well as to a more sophisticated process for extracting, purifying, or synthesizing the active chemical in the biological extracts or compositions used by the indigenous peoples and local communities.

Definition of Community

A rights regime is in relation to both indigenous communities and farmers. Often indigenous communities are also farmers. While it is readily acknowledged that indigenous communities have distinctive and unique characteristics, and significant cultural, social and political heterogeneity (even and amongst) them such that their interest comes into direct conflict with that of farmers, especially in relation to land, there exist powerful and strong factors unifying the two groups.

Among the unifying factors are that indigenous peoples and local (farming) communities are marginalized, dependent on the ecosystem, have a common demand and need for self-management control of their resources, make claims to land rights and collective rights, have in some cultures a long tradition of free exchange and transmission of knowledge and resources between communities and generations, and, finally, both are threatened by the same forces. In relation to the knowledge that is sought to be protected by this rights regime, farmers and indigenous communities share the same interest and face the same challenge. Both have had their interests marginalized by the same forces and in like fashion. The knowledge of generations of farmers in developing, refining and adapting the seed, their genius in so doing and preserving biodiversity in the process, denied recognition by restrictions in definitions now being globalized by GATT. Similarly the creative, informal, and accretional creativity of indigenous communities is eclipsed.

In recognition of these strong unifying factors, in the proposed draft of this rights regime, indigenous peoples and local (farming) communities are referred to as "local communities". The term is defined as follows:

group of people having a long standing social organization that binds them together whether in a defined area or howsoever otherwise...

The Role of the State

The proposed rights regime necessarily follows the route of the State as the central authority through which the rights of indigenous peoples and local communities are established, validated and claimed. This is because the regime is being proposed within the parameters of WTO/TRIPs, which allows for the establishment of a *sui generis* system of protection of plant varieties, and the Convention on Biological Diversity, which establishes the sovereignty of States over the biodiversity within their geographical boundaries. This is also a pragmatic approach as in international law, the enforcement of rights established by international instruments is through nation states.

Nevertheless, it is acknowledged that many States have been a hindrance to indigenous peoples. The State could hardly then be an appropriate channel for the vindication of the rights of indigenous peoples.

The legal framework then has to be adapted. The nation state should be seen as the authority *vis-à-vis* international enforcement only. The governments claiming sovereign rights are, in fact,

ing those rights in trust for their communities. They exercise what is described in juridical terms "higher trust". This also means that within the State, the real authority in relation to the control these rights is accorded to and should be vested with the local community leaders or duly appointed local representatives of indigenous peoples. Once the international community formally appoints indigenous peoples as legal entities in their own right, with a status equivalent to nation states, they will then claim, enforce and defend their own rights.

Key Main Elements

Ownership Rights: Rights of Custodianship, Inalienable, Not Subject to Exclusive Monopoly Rights

A community is declared the "owner" of its knowledge. The people exercise complete control over it collectively. They hold it in trust for themselves as well as for the beneficiaries of their ancestors, and they also hold it in trust for future generations. The community therefore holds this right as custodians or stewards and it is thus held in perpetuity. The knowledge therefore always remains in the community and its integrity cannot be impaired. This also means that it cannot be extinguished or divested. Moreover, no exclusive monopoly rights or any other rights can be created in respect of the knowledge, for to do so is to impair its integrity and to violate the basis on which it is held. Otherwise, future members of the community, for whom the right is being held in trust for, will be denied access to it and to its enjoyment. The elemental covenant within and between members of the community is undermined, if not destroyed, by any such divestment or impairment. It is in this sense the right is referred to as being inalienable. No rights inconsistent with this right can be created or claimed by anyone in relation to it. In this way any permanent impairment, say, by TNCs, is subject to challenge by members of the community. In the same way that land was said by indigenous communities to "own them", and for this reason inalienable, so too their knowledge systems is an integral component of their culture of being and survival. So it neither can be usurped from them nor can they alienate themselves from it.

A proposed rights regime seeks to preserve this crucial facet by:

- ▶ declaring indigenous communities as custodians of the innovation;
- ▶ prohibiting a kind of dealing in the right which will have the effect of impairing its integrity (example: transferring, leasing, or assigning the right); and
- ▶ declaring as void, any transaction which has the effect of destroying the integrity of the right.

Free sharing and transmission of knowledge between communities and generations, a tradition existing amongst some communities, does not amount to an impairing of the right. Nor does any dealing in the knowledge which does not amount to a divesting of the right in effect. So communities, in their exercise of the right to self-determination may commercialize the innovation if they choose to do so.

A legal mechanism for this "ownership" holding will need to be identified, for example, a trust or the incorporation of a body recognized as representing the collective interest of the community.

If more than one community owns this knowledge, then it is deemed to be vested in both, or all, of the communities.

II Elements of Culture, System and Practices of Communities Formally Recognized

A rights regime formally incorporates and recognizes all the elements of the culture, system and practices of local communities, and bestows them the status of "rights" which then become enforceable. The right is recognized in the form and manner in which it is recognized by the local community itself. The entire identity and integrity of the knowledge system replete with its values, beliefs and sacredness is accorded recognition. In the case of genetic resources and local seeds, for example, recognition extends to the whole livelihood system and the system of production by which ruralized communities make a living. One such specific value relates to the cultural practices whereby communities freely exchange knowledge or products incorporating this knowledge amongst themselves. This is expressly preserved and recognized in this rights regime.

Commercial Utilization

If there is any commercial utilization intended of the knowledge, then the provisions of free exchange do not apply. No use can be made of the knowledge except with the consent of the community which has the custodianship of this knowledge. If the knowledge belongs to more than one community, then the consent of all the communities must necessarily be obtained. If any commercial use is made of this knowledge, without any such consent, then a certain fixed percentage (representing the profits made or that could be made by the use of that knowledge) is payable by the user, whether demanded or not. The right arises upon its commercial use and this right can be exercised by the community whose knowledge is so used. In certain prescribed circumstances, for example, where the community is unable to act on its own initiative, the Government or any NGO may act on its behalf, provided that the community has the first and prior right of enforcement.

Proof of Claim

To facilitate evidentiary proof, any declaration by the elders or other duly recognized members of the community in a manner and form accepted by the cultural practices of that community will be

cient evidence of the existence of the right to that knowledge. The onus will then be on the on/corporation contending otherwise to prove its claim.

Conclusion

ough the proposed rights regime in defence of indigenous knowledge systems is discussed in the ext of the patents debate, it is apparent that the model itself has very little in common with the ern IPR patent regime. For a start, there is no need to file a patent application to establish the : to the innovation. Protection arises once the innovation exists. The existence itself is established ie norms and practices of the particular community. A "Registry of Invention" is set up purely to ate registration by the community of their invention by the simple expedient of declaring to the stry the existence of the invention. Failure to register does not defeat the rights to the vation. Protection of the innovation covers any use or any product made of the knowledge of enous peoples and local communities. This will encompass processes such as extraction, ication, or synthesis. All the US patent claims in relation to the neem, as described earlier, would ndered void by this rights regime.

onus would be on those seeking to defeat the innovation of local communities and indigenous oles to establish that their invention is in no way derived from the indigenous knowledge. Proof of existence of their innovation shall be in a manner acceptable by their cultural and traditional tices. This could include proof by folklore, oral accounts, or such mode.

ally, as challenges are made to this rights regime, the cost of defending the system or particular vations may well be high. But as the main elements of this rights regime are understood and blished and an increasing number of countries of the South accept it as a desirable and effective of protecting the knowledge systems of their indigenous populace and local communities, the should be minimal. Industry will have to take the existence of this regime into account prior to arking on research or production of anything based on the knowledge of indigenous peoples and communities.

Index 1

Anatary Notes on FAO Global System

983 the member countries of FAO established:

- ▶ a permanent intergovernmental forum on plant genetic resources - the Commission on Plant Genetic Resources (CPGR), and
- ▶ a legal framework - the International Undertaking on Plant Genetic Resources (Undertaking or IU).

constitutes the FAO Global System for the Conservation and Utilization of Plant Genetic ources. It initially covered food and agriculture and later extended to animal and fish biodiversity. system is coordinated, overseen and monitored by the CPGR.

objectives of this Global System are to ensure the safe conservation and to promote the ability and sustainable utilization of plant genetic resources for present and future generations by iding a flexible framework for sharing the benefits and burdens. The system covers both *ex-situ* *in-situ* conservation, and plant genetic resources covers genes, genotypes and genepools.

countries are formally part of the System, 123 are members of the Commission and 110 have red to the International Undertaking (IU). This IU was adopted by the FAO Conference olution 8/83, with 8 reservations - USA, United Kingdom, France, Germany, Switzerland, Canada, Zealand and Japan. It was the first comprehensive international agreement concerning plant etic resources.

Undertaking is not legally binding. Its object is to "ensure that plant genetic resources of omic and/or social interest, particularly for agriculture, will be explored, preserved, evaluated made available for plant breeding and scientific purposes".

der to overcome the reservations to the IU, it has been further qualified and interpreted by a ber of complementary resolutions which were negotiated by countries through the CPGR and ted unanimously by the FAO Conference. These resolutions are:

1: provided an agreed interpretation of the IU affirming that PBRs as provided by UPOV /vention of 1978 were not inconsistent with the IU. It simultaneously recognized "Farmers' ts".

2: defined Farmers' Rights.

3: reaffirmed the "common heritage of mankind" concept subject to the sovereign rights of ons over their genetic resources and agreed that Farmers' Rights will be implemented through an national fund based with CPGR.

4: countries agreed that the IU would be revised.

Index 2

Collectors of Biological Resources (Control and Licensing) Act

Act to provide for the control, regulation and licensing of collectors of biological resources and for matters connected therewith.

This Act may be cited as the Collectors of Biological Resources (Control & Licensing) Act.

In this Act unless the context otherwise requires:

Body of persons" means a group of persons not being an incorporated body or group;

Collector" means any individual body of persons, company or firm or institution or any one or more of them engaged or involved in the collection of biological resources whether as a business or otherwise (within the jurisdiction of Malaysia).

Company" means any company incorporated, formed or registered under any written law for the time being in force in Malaysia relating to companies and includes any body incorporated or established under any law in force in Malaysia.

Controller" means the Controller of Biological Resources appointed under this Act.

Convention" means the Convention on Biological Diversity.

Firm" means an unincorporated body of persons associated together for the purpose of carrying on business.

Inspector" means an inspector appointed under this Act.

Licensed collector" means any collector licensed under this Act to engage in or carry on or undertake the collection of biological and plant genetic resources whether as a business, on a one-off basis or howsoever otherwise.

Prescribed" means prescribed by the Minister under this Act.

For the purpose of this Act the Minister may appoint an officer to be styled the Controller of Biological and Plant Genetic Resources and such number of Inspectors of Biological and Plant Genetic Resources and other officers and servants as the Minister may deem fit.

No collection of biological resources shall be engaged in, carried on or undertaken except by a collector in possession of a licence issued under the Act.

A collector who desires to engage in or carry out or undertake the collection of biological resources shall apply to the Controller for a licence and any such application shall be made in the prescribed form in the case of any applicant listed in Column (1) of the Schedule the application shall be accompanied by the document listed against him in Column (2), every such document being verified by means of a statutory declaration made by the person listed in Column (3) of the said Schedule.

On receiving an application for a licence under this section, the Controller may grant the licence applied for or refuse to grant such a licence; and in granting such a licence the Controller may impose thereon such conditions (including the period during which the licence shall be valid) as he may deem fit and proper.

Subject to Section 8, the Controller may at any time vary, cancel or alter the conditions aforesaid and impose any new or additional conditions; or, where the licence is not subject to any condition, impose thereon such conditions as the Controller may deem fit for carrying out the provisions of this section provided that no restrictions/conditions shall be imposed which run counter to the Convention.

Subject to the exercise of power of waiver by the Minister under subsection (2), the licence applied for under Section 4 shall not be granted if the Controller is satisfied that:

(a) the collector is financially sound;

(b) the collector is in a position to meet his obligations under this Act;

(c) unless the applicant is not himself nor is any member or partner thereof a person convicted of an offence involving fraud or dishonesty or an undischarged bankrupt, if the application is made collectively by a person or a body of persons or a firm; and

(d) no one who is convicted of an offence involving fraud or dishonesty or who is an undischarged bankrupt holding office as director, manager or secretary or other similar office or position, if the application is made by a company, or is holding office as president, secretary or treasurer or other similar office or position, if the application is made by a society.

The Minister may in his absolute discretion waive any or all of the conditions set out in section 5.1, (a), (b) or (d) or substitute any or all of the said conditions or such other conditions as he may consider fit and proper.

The Minister may give to a licensed controller such directions as he considers fit and proper for the

ose of ensuring compliance with this Act, and any such direction shall be made in writing and be binding on the licensed controller to whom the direction is made.

any licensed controller:

s carrying on his undertaking, in the opinion of the controller, in a manner detrimental to the rest of the public;

has insufficient assets to cover his liabilities;

s contravening any of the provisions of this Act; or

has ceased to carry on the undertaking

Controller may, subject to the provision of section 8 relating to the giving of opportunity of being heard, revoke the license issued to the licensed Collector or suspend for such period as the Controller determine.

efore revoking or suspending a license under Section 7 or before varying, cancelling or altering conditions imposed on a license or before imposing thereon any new or additional conditions under Section 4(4), the Controller shall notify the collector who is affected by the action proposed to be taken by the controller of the aforesaid proposed action and shall give the licensed collector an opportunity to submit reasons or an explanation why the aforesaid proposed action should not be taken.

an applicant applying under Section 4(3) or a licensed collector, as the case may be, who is affected by the action or decision of the Controller

in refusing to grant a license to him under Section 4(3);

in varying, altering or cancelling any conditions of his licence or imposing thereon any new or additional conditions under Section 4(4);

in revoking or suspending his licence under Section 7;

within fourteen days after having been notified of the action or decision of the Controller appeal against that action or decision to the Minister; and the decision of the Minister made thereon shall be final and shall not be questioned in any Court.

No action shall lie against the Government, the Minister, the Controller, Inspector or against any member of the Government or any person acting under the direction of the Minister, the Controller or Inspector for damages in any civil court for anything bona fide done, ordered or omitted to be done pursuant to this Act; and all actions which may lawfully be brought in respect of anything done, ordered or omitted to be done pursuant to this Act shall be instituted within six months from the date of the act of omission complained of, and not afterwards.

Any collector who:

in contravention of Section 4(1) engages in, carries out, or undertakes collection of biological and natural resources without having been duly licensed under that section;

fails to comply with any of the conditions imposed on the license granted under Section 4;

fails to comply with any direction given by the Minister under Section 6;

removes any biological material out of the country without the prior written authorization of the appropriate authority

be guilty of an offence and shall, on conviction, be liable to a fine not exceeding twenty thousand dollars or to imprisonment for a term not exceeding five years or to both.

Where any offence against any provision of this Act has been committed by a licensed collector, person who at the time of the commission of the offence was a director, manager or secretary or in any similar office or position or was an agent, clerk or servant of the licensed controller shall be deemed to be guilty of that offence, unless he proves that the offence was committed without his consent or connivance and that he exercised all such diligence to prevent the commission of the offence as he ought to have exercised, having regard to the nature of his functions in that capacity and to all the circumstances, and shall, on conviction, be liable to imprisonment for a term which shall not be less than twelve months but which shall not exceed three years and shall also be liable to a fine not exceeding ten thousand dollars.

Any person liable under this Act to any punishment or penalty for any act or omission shall be equally liable to the same punishment or penalty for any such act or omission by:

his partner;

his agent acting on his behalf;

is clerk or servant acting in the course of his employment; or

he clerk or servant of his partner or agent acting in the course of employment in circumstances had the act or omission been committed by the partner or agent the aforesaid person would have been liable under this subsection:

vided that nothing herein shall relieve the partner, agent, clerk or servant of that partner or agent of his liability to prosecution.

The Minister shall prescribe the form of contract which shall be entered into for a licensed collector, his agent nominee or the party/institution or body responsible for the resources both as a condition of the grant of a licence under this Act or otherwise.

In the said contract the Minister shall regulate the conditions and terms of any such contract as may be prescribed in sub-section(1) hereof.

No amendment to any such contract shall be made except on the ground of hardship or injustice and with the prior approval in writing of the Controller.

Every such contract shall be as prescribed in Schedule I.

Annex 3

Schedule 1

Contract between the Collector and the Government Parties

Agreement made this day between of (hereafter referred to as "Collector") and of on behalf of the Government of Malaysia (hereafter referred to as "Government").

Recitals

WHEREAS The Collector is desirous of engaging in or carrying on or undertaking the collection of biological resources and has been duly licensed to do so by the Government.

WHEREAS the Government has the sovereign right *vis-à-vis* the Collector of the biological resource to be collected and is desirous of permitting the Collector to collect the said resource.

WHEREAS all parties hereto

observe International Conventions (including the Convention on Biological Diversity) and Codes of Conduct including the Code of Conduct for Plant Germplasm Collecting and Transfer of the Commission on International Genetic Resources), and,

have regard to the sustainable collection of specimens while conserving the biological diversity of the country and respecting and acknowledging the cumulative communal and traditional knowledge, innovations and practices relevant to the conservation of biological diversity and the sustainable use of its components and the close and traditional dependence of many indigenous and local communities embodying traditional lifestyles on biological resources.

Definitions

"Active ingredient" means the constituent element which is responsible for a known effect when the material containing it is used.

"Biological diversity" refers to the varieties of all life forms - plants, animals and micro-organisms, and the genes they contain and the ecosystems of which they form a part.

"Caretakers" means local communities and/or local farmers, who maintain genetic diversity in their environments and farming systems.

"Collaborator" means the national party, organization or institution named by the Collector in consultation with whom the Collector shall engage in the activity referred to in clause 1.

"Collector" means any corporation, organization or person licensed under the laws of this country to collect biological resources and related information.

"Curator" means a person or organization, within the host country or elsewhere, that conserves and manages biological resources and related materials and information.

"Appropriate Designated Authority" means the Government of Malaysia acting through the Minister of Agriculture or such other Ministry, organization, body or person as shall be designated by the Government.

"*Ex-situ* conservation" means the maintenance of organisms or their genetic material away from their natural habitat.

"Farmers' rights" means rights arising from the past, present and future contributions of farmers

conserving, improving, and making available biological resources, particularly those in the centres of origin/diversity.

Genetic erosion" means loss of genetic diversity.

In-situ conservation" means the maintenance of organisms in their natural habitat, or, in the case of domesticated organisms in the area where they developed their distinctive properties.

Natural product" means an object or material produced naturally, without manipulation by man.

"Plant genetic resources" or "plant germplasm" means the reproductive or vegetative propagating material of plants.

The Government" means, where the context so admits, the Government of Malaysia acting through its Ministries or agents or servants.

The foreign Government" means, where the context so admits, the Government of the country where the Collector ordinarily resides and which endorses this contract under Clause 8(1) hereof.

by this Deed it is Hereby Agreed as Follows:

The Government hereby authorize the Collector to engage in the collection of biological resources locally for the period beginning on and ending on

The Collector shall upon the execution of this agreement

furnish the Government with plans for the collector's activity including in particular:

the types of material to be collected in terms of species and quantities;

the plan for the evaluation, storage and use of the material collected;

the use or uses to which the collected material will be put;

the benefit the host country/community may derive from the collection of the germplasm; and

financial arrangements for the collection.

Provide the Government with the names, addresses and particulars of their collaborators from a list drawn up and approved by the Government and which may include:

National scholar(s);

Scientist(s);

Non-governmental organization(s);

Institution(s).

Supply details of any agreement made with the said collaborator, the names of persons who will assist in the said collection and in any event the names and complete particulars of 2 persons nominated by the collaborators to accompany the collection mission.

Undertake to abide by the country's natural product policy and quarantine procedures, and the moral practices, traditional values and customs of local communities and all relevant laws and regulations.

The Collector shall, in the period during collection:

Not collect more than 100-150 grammes (dry weight) of the resource for initial screening save with the permission in writing of the Government.

Inform local communities concerned as to

the purpose of the mission;

how and where samples of the collected biological resource could be obtained by the local community; and

their entitlement to obtain from the Collector duplicate samples.

Whenever samples for bioactivity screening are collected, keep a written record which describes in detail the biological resource particularly its conservation status, locality, its diversity, habitat and ecology such as is sufficient to provide curators and users of the resource an understanding of its natural context.

The Collector shall, after collection

process within weeks thereafter, within the jurisdiction unless otherwise agreed to in writing, the biological samples that have been collected for conservation;

prepare in writing the relevant written record;

deposit duplicate sets of all collections and associated materials and records of information, including that referred to in Section 3(3) hereof, with the Government and the following additional persons/institutions, namely,

obtain the phytosanitary certificate(s) and other documentation necessary for transferring the material collected, where such transfer is permitted by the Government;

inform the appropriate authorities about any impending threat to plant populations, or evidence of accelerated genetic erosion, and make recommendations for remedial action;

supply to the Government a consolidated report on the collecting mission, including:

the localities visited,

the confirmed identification and other relevant data of the biological samples collected; and

any other information as required when the agreement between the two parties was made.

The Collector shall, in addition

at all times, wherever possible, make any study and experimentation involving the specimens in the country and with full participation of the collaborator, save as otherwise agreed to in writing by the collaborator and the Government;

submit to the Government any report or writing concerning studies or experimentation made on specimen collected; and

ensure that the collaborators or, in the case of NGOs or Institutions, their duly nominated persons, shall join in the work in the laboratories or trial sites where any specimen collected is the object of any experimentation or study. In such event the Collector shall finance the participation as aforesaid of the collaboration upon terms mutually acceptable to the Collector on the one part and the collaborator and the Government on the other part.

sum representing not less than 60 per cent of any income arising from the supply of natural products or extracts to commercial organizations shall be paid:

in the case of resources held in custody by local communities as set out under the Community Intellectual Rights Act (CIRA), to the Community or such organizations or authority designated by the Act; and

in all other cases, to the Government.

VIDED that if a greater sum is set out under CIRA the said sum shall be substituted for the sum payable under this section; and

VIDED FURTHER that payment shall be made equally to instances as set out in clause 9(4) of.

sum representing not less than 51 per cent of any royalties obtained as a result of the creation or production of a marketable product is payable in the same manner as clause 6(a) and (b) hereof and subject to the same proviso as set out in clause 6 hereof and provided also that payment shall be made equally to instances as set out in Clause 9(4) hereof.

The Collector shall obtain the endorsement of this contract by the duly constituted authority of the Government of his country/sponsor organization, signifying, inter alia,

its agreement that in the event of a breach of any terms of this agreement it shall indemnify the Government of Malaysia, or the appropriate community in respect of any losses, expenses, damages thereby occasioned;

its agreement that it shall deliver up to the appropriate designated authority the results of any report or any writing as referred to in Section 5(2) hereof.

The Government of Malaysia shall certify in writing to the Collector its acceptance of the authenticity of the endorsement referred to in sub-clause (1) hereof.

The consent referred to in sub-clause (1) hereof and its certification referred to in (3) hereof shall be conditions precedent to the validity of this agreement.

No patent application shall be filed within or outside the country in respect of the collected specimens or any part thereof, its properties or activity or any derivatives which utilize the knowledge of indigenous groups or communities in the commercialization of any product as well as to a more sophisticated process for extracting, isolating or synthesizing the active chemical in the plant extracts or composition used by indigenous peoples and local communities, or, if the same is the intellectual property of indigenous communities. The provisions of the CIRA shall govern the said collected specimens, any part thereof, its properties or activity where the specimen is an innovation of the

igenous community as defined and set out by the CIRA.

All licenses granted on any patents arising from this agreement shall contain a clause referring to agreement and shall indicate that the licensee has been apprised of this agreement.

In the event of the licensing of any marketable product the payments as set out in clauses 6 or 7, whichever is applicable, shall be made.

Such payment terms shall apply equally to instances where the invention is the actual isolated natural product, or where the invention is a product structurally based on the isolated natural product (i.e., where the natural product provides the lead for development of the invention) or where the invention is an innovation as defined by the CIRA, unless otherwise agreed to in writing by the parties.

The provisions of this clause shall apply notwithstanding that an organism is freely available from other countries, but a phenotype/genotype producing an active agent from a plant is found only in this country.

The collaborators may screen additional samples of the raw materials for other biological activities and develop them for such purposes as they may deem fit (including the patenting thereof) independently of this agreement; provided that the right for the collaborators to do so will arise six months after collection of the samples by the collector.

The Government shall have the right, in the event of the breach of any of the terms herein and subject to Clause 8(2) hereof, to call upon the Collector(s) and/or the sponsor organization(s) to explain the cause why action should not be taken against them for the breach.

This agreement and the rights hereunder shall not be assigned, transferred or in any way encumbered without the consent in writing of the Government and subject always in such event to the assignee or transferee accepting all rights and obligations under this contract and provided that the Government of the Collector's origin duly consents in writing to the said assignment/transfer and confirms that its endorsement of this contract also enures and attaches to the new arrangement.

Annex 4

Community Intellectual Rights Act

to establish a *sui generis* system for the protection of the innovation and the intellectual property of the local communities.

Preamble

In this Act the following terms shall bear the following meanings:

"biological material" refers to the material or any part thereof of plants, animals, microorganisms, the genes they contain, and in relation to plants or plant varieties, animals and animal varieties, microorganisms and microorganism variants, shall include the species or category of a lower level or part thereof or germplasm therein, whether domesticated or not, which is used in accordance with established customs, practices and laws by local communities for a particular purpose that requires a prior knowledge of a particular property of the species, variety or variant, for example as in agriculture, medicine, dye and in producing any of the same.

"commercial utilization" occurs when the innovation and any process relating to it or embodying it are made available for sale in the modern market sector.

"innovation" shall include any collective and cumulative knowledge or technology of the use, properties, values and processes of any biological material or any part thereof rendered of any, or discovered, use or value as a result of the said cumulative knowledge or technology whether documented, recorded, oral, written or howsoever otherwise existing including any alteration, modification, improvement thereof and shall also include derivatives which utilize the knowledge of local communities in the commercialization of any product as well as to a more sophisticated process of extracting, isolating, or synthesizing the active chemical in the biological extracts or compositions developed by the local communities.

"traditional knowledge" is recognized complete with its rituals and sacredness as practised by the community.

"innovator" shall mean the local community responsible for the innovation.

"local community" refers to a group of people having a long standing social organization that binds them together whether in a defined area or howsoever otherwise and shall include indigenous peoples, and local populations, and shall where appropriate refer to any organization duly registered under the provisions of this Act to represent its interest.

"the State" shall refer to the appropriate government ministries or the government as a whole where the context so admits.

Indigenism

The local community shall at all times and in perpetuity be the lawful and sole custodians and stewards of an innovation.

No innovation shall be sold, assigned, transferred or dealt with in any way whereby the status of the local community as custodians and stewards of the innovation is impaired.

The purposes of removing doubt, any exclusive monopoly rights given in respect of the innovation shall constitute an impairment of the said right.

Any impairment of the right to the innovation shall be void as against the local community.

Free Exchange Amongst Communities

A local community shall be entitled at all times to grant free access to its innovation(s) and process(es) in relation thereto to other communities wherever situated without any payment or reward provided always that such an innovation is not so acquired for commercial utilization.

Such acquirer shall make the said innovation available to any other community on the same basis and terms as set out in section 3.1 hereof.

Restrictions for Commercial Purposes

Any person, body, organization or corporation using any innovation or any part thereof for commercial utilization shall

1. seek the written consent of the local community; and

2. pay to the local community which is the custodian or steward of the said innovation a sum representing not less than per cent of the gross sales of any product or process incorporating said innovation.

The sum as aforesaid shall be payable even if the said person, body, organization or corporation is using the said innovation or any part thereof for commercial utilization without the prior consent in writing of the community PROVIDED always that this is without prejudice to the right of the community to enforce its right to the innovation or any part thereof by injunctive or any other relief it may deem fit to pursue, to prevent or prohibit such commercial utilization without its consent.

Nothing in this section shall affect the fact that any commercial utilization without the prior consent of the local community is wrongful.

Any local community may opt to be paid a non-monetary equivalent as may be determined by the local community in accordance with its customs, practices and usages.

Nothing in this section shall prevent more than one person, body, organization or corporation from using any innovation or any part thereof for commercial utilization and at the same or any other time.

The payment shall be made:

1. to an organization duly registered under the provisions of this Act as representing the local community;

2. where no such organization exists, to the State which shall hold it in trust for the local community pending its registration under the provisions of this Act;

3. in respect of an innovation which is, as at the date of the coming into force of this Act, developed by the local community, to the State which shall then apply any such monies for the protection, development and maintenance of its genetic resources PROVIDED ALWAYS that if it is possible to identify the innovator, the payment shall be made to the said innovator.

All monies or their equivalent received by the local community or the State as its trustee shall be applied for such purpose as the local community may decide including but not limited to the protection, development and maintenance of its genetic resources.

Registration of Local Community

Any local community may apply to be registered as an organization to represent its interests provided that its failure to do so will not prejudice its status as custodian or steward of its innovation(s) under Section 1.1 hereof.

Registration shall be effected by the duly authorized representative of the local community applying at the Registry set up under this Act and providing and completing particulars as set out in Form I (not given here).

The community may change the particulars by attending at the Registry and filing Form II (not given here).

Registry of Innovation (ROI)

Community may register its innovation in the Registry of Invention (ROI) provided always that registration will not mean that the community was/is not the custodian or steward of the innovation under the innovation under the innovation under Clause 1 hereof.

Proof of Invention

Upon the duly constituted representatives of the Community declaring or acknowledging in a form and manner valid by their laws, customs or practices that they have been using and are the custodians or stewards of an innovation, the innovation shall be deemed to vest in the Community.

Anyone wishing to challenge this will bear the legal and evidentiary burden of proof for doing so.

Technical Institution

One or more may be nominated by the community(ies), technical institutions or any other body, person or persons to assist the community to identify and characterize their innovation(s), as and when they deem it necessary to do so.

Co-ownership

Nothing in this Act shall prevent any other community or communities wherever situated from exercising their rights to the custodianship or stewardship of an innovation.

In such event, the community shall be co-stewards or custodians of the innovation.

The co-stewardship will carry with it the same rights, duties and obligations as hereinbefore set forth, save that they shall be co-terminous and enjoyed together with the co-stewards or custodians.

All benefits that accrue to one co-steward shall enure to the benefit of the other co-steward or stewards.

Each co-steward shall hold in trust all rights, obligations, rewards, remunerations etc. for the benefit of the other co-steward or co-stewards.

Right to enforce, monitor or further the innovation

Any State, non-governmental organization or the local community and /or its duly registered organization shall have the locus to enforce, monitor and further the local community's innovation in any matters in relation to its utilization, exchange or impairment, whether in Court or elsewhere, provided always that the duly registered organization of the local community shall take precedence and that the local community shall be informed at every stage of the progress of the same.

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