Access and Benefit sharing **

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Biological Diversity

Biological diversity is fundamental to agriculture and food production. From the millions of genes that serve as life's building blocks to the thousands of plants and animals that inhabit the earth, to almost limitless combinations of organisms that make up natural ecosystems, biodiversity makes an essential contribution for feeding the millions of population of the world.

Diversity in Agriculture and its erosion

A rich variety of cultivated plants and domesticated animals serve as the foundation for agricultural biodiversity. Inspite of a large genetic base of animals and plants, human beings depends only on 14 mammal and bird species for 90% of their food supply from animals and four plant species *viz.*, wheat, rice, maize and potato provide half of our food. Modern intensive agriculture has encouraged many farmers to adopt uniform high yielding varieties of plants or breeds of animals. When farming communities abandon diversity, varieties and animal breeds may die out along with their specialized and unique traits. The rapidly diminishing gene pool is serious concern at this point in history due to Climate Change, Urbanisation, Changes in Lifestyles and also the Food Habits and the emergence of new biology, notably Biotechnology and Genetic Engineering.

Importance of Conservation, Traditional and its sustainable use

It has been estimated that about three quarters of the genetic diversity of agricultural crops have been lost over last century. Out of 6300 animal breeds, 1350 are endangered or already in extinction. Since the dawn of human civilization and the birth of agriculture, forest dwellers, fishermen, herders and farmers, have been managing genetic diversity by selecting plants and animals to meet constantly changing environmental conditions and the food requirements of an increasing population. Such societies everywhere possess rich and priceless

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local knowledge including a highly tuned sense of how to match the right variety or the animal breed with particular agro-ecosystem. They are not only aware about the ecosystems but also have developed ways and means of transferring indigenous and traditional knowledge from one generation to the next generation. The genetic variability arrived at through this social process is what allows breeders to develop improved varieties of crops, and livestock and fish. Modern Science has developed techniques to conserve plants and animals in gene banks, botanical gardens and zoological parks as well as in the wild through a network of sanctuaries, national parks and biosphere reserves through National and International networks. While these are vital, it is being increasingly recognized by modern science that biodiversity needs to be maintained on farms, wetlands and in nature, where it can evolve and adapt to the changing conditions of competition and co-existence. Much of such valuable genetic materials are found in the tropical world, where the poorest people live in this region.

CBD Framework on Access and Benefit Sharing (ABS)

Convention on Biological Diversity (CBD) is the first international legal instrument that brought out a radical change from the then prevailing common perception on genetic resources as "common heritage of mankind" to a legally binding regime that confers "sovereign rights" to the States over their own biological resources including genetic resources and traditional knowledge.

CBD provides a fundamental framework for its Parties to develop appropriate national legislations and policy guidelines to facilitate fair and transparent means and mechanisms for access to and equitable sharing of benefits accrued from the use of genetic resources and associated traditional knowledge. The most relevant provisions on access to genetic resources, traditional knowledge and benefit-sharing are stipulated in Articles 8 (j), 15, 16 and 19 of the CBD.

The issue of access and benefit-sharing involving genetic resources and traditional knowledge has however become a rather contentious subject of wide ranging discussions and debates at various international forums under the aegis of CBD, WTO-TRIPS, WIPO, UN-FAO, UNEP, etc. The existing inequities in international legal frameworks particularly of the CBD and WTO-TRIPS, and also the disproportionate distribution of biodiversity and biotechnologies across the world have been the major impediments for implementing a dynamic and transparent mechanism for regulating and monitoring access, benefit-sharing, technology transfers and IPR protection and other relevant activities related to genetic resources and associated traditional knowledge.

FAO-International Treaty of Plant Genetic Resources for Food and Agriculture (ITPGRO (2001) and ABS process

The Treaty, which has come into force since 2001, aims at conservation and sustainable use of plant genetic resources for food and agriculture (PGRFA) and the fair and equitable sharing of the benefits arising out of their use for sustainable agriculture and food security. The Treaty provides for an efficient, effective and transparent multilateral system to facilitate both access to and fair and equitable sharing of benefits arising from the utilization of PGRFA on a complementary and mutually reinforcing basis (Article 10.2).

Access and Benefit Sharing

CBD and ITPGR, and the Bonn Guidelines provide a broad framework for ABS procedures. The main features of ABS mechanisms include: (i) Prior Informed Consent (ii) Mutually Agreed Terms (iii) Material Transfer, Agreements, and (iv) Benefit - sharing agreements through monetary and nonmonetary means. Apart form the frameworks as suggested in the above policy documents and guidelines, several other national. international, and regional institutions, agencies and community organizations have developed different models of access and benefit - sharing agreements, MTAs, MATs, etc. (Laird, 2002). A few examples of such model agreements on ABS contracts, bioprospecting partnerships include: The Andean Pact Decision 391 and Contracts (1996); The Pew Conservation Fellows Biodiversity Research Protocols (1996); Royal Botanic Garden Policy on Access to Genetic Resources and Benefit Sharing (RBG, Kew 1998); Common Policy Guidelines for Participating Botanic Gardens on Access to Genetic Resources and Benefit Sharing (Cartagena 2000); The Limbe Botanic Garden Policy on Access to Genetic Resources and Benefit Sharing (2001); Community Biodiversity Registers and Honey Bee Network for chronicling and protection of Local People's Innovations (India); Draft Research Policy for Protected Areas in Cameroon etc. Although these frameworks and models are useful in developing appropriate ABS agreements, they cannot serve as absolute or comprehensive mechanisms as the objectives, standards and procedures of ABS will vary considerably from Parties to Parties.

The Biological Diversity Act 2002

The core of the ABS provisions and their effective implementation in the territorial jurisdiction of India is dealt with in the Biological Diversity Act 2002 and in the Biological Diversity Rules 2004. The Biological diversity Act 2002 provides for regulated access to biological and genetic resources by bonafide endusers for different purposes, including scientific research, commercial uses,

biosurvey, bio-utilization, conservation and other sustainable uses, etc. The over all implementation of the Biological diversity, 2002 Act is coordinated by three functional bodies viz. The National Biodiversity Authority (NBA), the State Biodiversity Boards (SBB), and the Biodiversity Management Committee (BMC). NBA is the national competent authority to discharge all decisions pertaining to ABS, including prior informed consent process, approval for access to and transfer of biological resources and scientific research results and technologies to foreign citizens, companies and non-resident Indians (NRIs), prior approval for applying for IPRs based on biological resources or traditional knowledge obtained from India, fixing criteria for benefit sharing, approval of third-party transfer of accessed biological resources and traditional knowledge, and several other matters related to ABS.

Access to biological resources and associated traditional knowledge:

The Biological diversity Act, 2002 stipulates norms for access to biological resources and traditional knowledge based on three ways:

- (i) Access to biological resources and traditional knowledge to foreign citizens, companies and NRIs based on 'prior approval of NBA' (Section 3).
- (ii) Access permits to Indian citizens, companies, associations and other organizations registered in India on the basis of 'prior intimation to the State Biodiversity Board' concerned (Section 7).
- (iii) Exemption of prior approval or intimation for local people and communities, including growers and cultivators of biodiversity, and vaids and hakims, who have been practicing indigenous medicines (Section 7).

The key procedures to be followed for access to biological resources and traditional knowledge are dealt with under Rule no 14 (1-10 sub rules) of the Biological diversity Rules 2004. These provisions are laid down to ensure effective, efficient and transparent access procedures through written agreements and applications in prescribed formats. Applicants seeking access to biological resources and traditional knowledge are required to submit an application in **FORM I** (annexed to the Biological diversity Rules 2004) along with an application fee of Rs.10,000/- The NBA through appropriate consultation mechanisms through an Expert Committee shall dispose of the application and communicate its decision to grant access or otherwise to the applicant within a period of six months from the date of receipt of the application. The Authority is required to communicate the grant of access to the applicant in the form of a written agreement duly signed by an authorized official of the Authority and the

applicant. The Biological diversity Rule 14 also stipulates the Authority to provide reasons in writing in cases of rejection of an application and give reasonable opportunity to the applicant to appeal. The Authority shall publicize the approval granted through print or electronic media and also shall monitor the compliance of the conditions agreed upon by the Party and the applicant when the approval for grant for access was accorded. The access procedures are only regulatory in nature, but are not prohibitive in any manner to any applicant irrespective of their nationalities, affiliations, origin, etc.

Revocation of access

Revocation of access or approval granted to an applicant will be done only on the basis of any complaint or *suo motto* under the following conditions:

- violation of the provisions of the Biological diversity Act 2002 or conditions on which the approval was granted
 - (ii) non-compliance of the terms of the agreement
 - (iii) failure to comply with any of the condition of access granted
 - (iv) on account of overriding public interest or for protection of environment and conservation of biodiversity (Rule 15, Sub rule 1).

After having withdrawn the access permit, the Authority is required to send an order of revocation to the concerned Biodiversity Management Committee and the State Biodiversity Board for prohibiting the access and to assess the damage, if any, caused, and steps to recover the damages (Rule 15, Sub rule 2).

Restriction for access

The Biological diversity Act 2002 imposes certain restrictions on request related to access to biological resources and traditional knowledge if the request is on:

- (i) endangered taxa
- (ii) endemic and rare taxa
- (iii) likely adverse effects on the livelihood of the local people
- (iv) adverse and irrecoverable environmental impact
- (v) cause genetic erosion or affect ecosystem function
- (vi) use of bioresources for purpose contrary to national interests and other related international agreements to which India is Party (Rule 16, Sub rule 1).

Transfer of research results

The Biological diversity Act 2002 does not permit any person to transfer the results of any research relating to biological resources obtained form India for monetary consideration to foreign nationals, companies or NRIs without the prior approval of the Authority. Approval for such transfers shall be done on the basis of an application to authority in FORM II along with the payment of an application fee of Rs.5000/-. The Authority within a period of three months from the receipt of an application shall take a decision on it. As in the case of access permits the Authority shall communicate the approval for transfer of research results to the applicant in the form of a written agreement duly signed by an authorized official of NBA and the applicant. The authority shall communicate the reasons in case a request for transfer of research results was not granted and shall give reasonable opportunity and time to the applicant for an appeal, if any (Rule 17, Sub rule 1-6).

Prior approval before applying for IPR: (Rule 18, Sub rules 1-6):

All the conditions for granting approval for transfer of research results shall be applicable to any person desirous of applying for a patent or any other intellectual property rights, based on the biological resources and associated knowledge obtained form India. The Format for making such applications in FORM III with a payment of Rs. 500/-

Third-party transfer of accessed biological resources or knowledge: (Rule 19, Sub rules 1-6):

The Biological diversity Act 2002 permits transfer of accessed biological resources or traditional knowledge to a third party on the basis of the prior approval of the Authority through a process of submitting an application in FORM IV along with the payment of an application fee of Rs.10,000/-. The other procedures remain the same as those stipulated for access to biological resources and traditional knowledge under Rule 14.

Criteria for benefit sharing

The Biological diversity Act 2002, subject to Section 21 and Rule 20 of the Biological diversity Rules-2004 insists upon including appropriate benefit sharing provisions in the access agreement and mutually agreed terms related to access and transfer of biological resources or associated knowledge occurring in or obtained from India for commercial use, bio-survey, bio-utilization or any other monetary purposes. The Authority shall develop guidelines and shall notify the specific details of benefit sharing formula in an official gazette on a case-to-case

basis. The suggested benefit sharing measures may include "monetary benefits" such as royalty, joint ventures, technology transfer, product development, and "non-monetary benefits" such as education and awareness raising activities, institutional capacity building, venture capital fund, etc. The time frame and quantum of benefits to be shared shall be decided on case-to-case based on mutually agreed terms between the applicant, Authority, local bodies, BMC, SBB and other relevant stakeholders, including local and indigenous communities. One of the suggested mechanisms for benefit sharing includes direct payment to persons or group of individuals through district administration, if the biological material or knowledge was accessed from specific individuals or organizations. In cases where such individuals or organizations could not be identified, the monetary benefits shall be paid to the National Biodiversity Fund. Five percent of the benefits shall be earmarked for the Authority or State Biodiversity Board towards the administrative service charges (Rule 20, Sub rule -9).

Biodiversity Management Committee

The formation of BMC at local body level is for the purpose of

- · Promoting conservation
- · Sustainable use
- · Documentation of Biological diversity including
 - · Preservation of habitats
 - · Conservation of land races
 - · Folk varieties and cultivars
 - Domesticated stocks and breeds of animals and microorganisms
 - Chronicling of knowledge relating to biological diversity

The main function of the Biodiversity Management Committee (BMC) constituted under each local body as per section 41 (1) of the Biological diversity Act and Rule 22, Sub rules 1-11 of Biological diversity Rules, is to prepare People's Biodiversity Registers, which shall contain comprehensive information on the availability and knowledge of local biological resources and medicinal or any other traditional knowledge associated with them. Another important functions of the BMC are to advise the State Biodiversity Board and the National Biodiversity Authority on matters for granting approval, to maintain data about the local vaids and practitioners using the biological resources, besides maintaining a register containing information on access to biological resources and knowledge

granted, details of collection fee received and details of benefit sharing derived and mode of the sharing.

The ABS procedures stipulated under the Biological diversity Act, 2002 are in line with the provisions of International laws and polices, particularly CBD and the Bonn Guidelines. The entire procedures as described in the Biological diversity Act 2002, can contribute substantially to facilitate an international regime of ABS on genetic resources and traditional knowledge.

The Protection of Plant Varieties and Farmer's Rights (PPVFR) Act, 2001 (Act 53 or 2001)

The PPVFR Act 2001 and the Rules framed under this Act, called the PPVFR Rules 2003, deal primarily with the protection of plant breeder's rights over the new varieties developed by them and the entitlement of farmers to register new varieties and also to save, breed, use, exchange, share or sell the plant varieties, which the latter have developed, improved, and maintained over many generations. The Act is a deviation from the 1991 UPOV Model and can be regarded as an alternate 'sui generis' system that accord protection of the rights of the formal innovations of a plant breeder and the informal knowledge system and traditional plant varieties of the farmers as well (Sahai, 2003). The important provisions contained in this Act relevant to ABS are those on the protection of farmers rights and the mechanisms suggested for compensation or benefit-sharing (Brahmi et al., 2004) for the contributions of local communities or farmers in the development of a new plant variety (Sections 39, 40 & 41 of the Act and Rules 33 and 66). The section 40 of the Act requires that the breeder or any applicant for registration of a new plant variety shall disclose any information regarding the use of genetic material conserved by any tribal or rural families in the breeding or development of such variety. Willful non-disclosure of such information will lead to rejection of the application for registration. Similarly, the Act also ensures compensation of the contributions of any village or local communities to the development of a variety registered under this Act. Such compensation will be deposited to National Gene Fund. Another important provision in support of the farmers' conservation efforts is the recognition or rewards for a farmer who is engaged in conservation of genetic resources of land races of wild relatives of economic plants and their improvement through selection and preservation. The rewards will be made from the National Gene Fund.

Benefit Sharing: "TBGRI Model" or "Kani Model"

India has the distinction of being the first country in the world in experimenting a benefit-sharing model that implemented the Article 8(j) of CBD, in letter and spirit. It was the Tropical Botanic Garden and Research Institute

(TBGRI) in Kerala that demonstrated indigenous knowledge system merits support, recognition and fair and adequate compensation (Dr. P. Pushpangadan, 2002). The model, which later on came to be known as: "TBGRI Model" or "Kani Model" or "Pushpangadan Model", relates to the sharing of benefits with a tribal community in Kerala, the Kanis, from whom a vital lead for developing a scientifically validated herbal drug (Jeevani) was obtained by scientists of TBGRI. The TBGRI Model has got wider acclaims, acceptance and popularity the world around, because it was the first of its kind that recognized the resource rights and IPR of a traditional community by way of sharing equitably the benefits derived out of the use of a knowledge that has been developed, preserved and maintained by that community for many generations (Gupta, 2002, Mashelkar, 2003). Further, it demonstrates the vast and as yet under-explored or untapped potentials of the Indian traditional knowledge systems, particularly the traditional health care practices of the local and indigenous people in India.

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