Regulating Access to Genetic Resources and Promoting Benefit Sharing in India

RS Rana*

Member, National Biodiversity Authority, India and Former Director, National Bureau of Plant Genetic Resources, New Delhi-110 012

The Convention on Biological Diversity (CBD) recognizes sovereign rights of States over their bioresources and also on determining terms of accessing to them, subject to their national legislation. India is among the 193 Contracting Parties to CBD and enacted the Biological Diversity Act, 2002 to claim sovereign rights over its bioresources, and associated traditional knowledge (TK), and to meet its national obligations on conservation of biodiversity, sustainable use of its components and fair and equitable sharing of benefits arising from their utilization. This legislation, and the Biological Diversity Rules, 2004 framed under it, provide a three-tier legal framework for regulating access to bioresources (and associated TK) while ensuring fair and equitable sharing of resulting benefits. For a national legislation on access and benefit sharing (ABS) to be effective, its recognition at the international level is essential so as to provide enabling legislation in user countries and also to support an effective monitoring mechanism for proper realization of the equity benefits. Adoption of the Nagoya Protocol to CBD on ABS on 29 October, 2010 during the COP-10 meeting, held in Japan, is the first step in this direction. This paper presents salient features of this landmark national legislation, discusses its implications to biodiversity-related international treaties bearing on this subject and also overviews the progress made in implementing its provisions while making some suggestions as the way forward.

Key Words: Implementing CBD in India, ABS in India under CBD, Indian Legislation on ABS, Legal Access to Bioresources with Benefit Sharing in India, India's National Biodiversity Authority, 3-Tier System for Operating ABS Regime in India

Introduction

Sovereign rights of States over their biological resources, reaffirmed in the preamble of the Convention on Biological Diversity (CBD), 1992 and articulated clearly in its Articles 8 (*In-Situ* Conservation) and 15 (Access to Genetic Resources) brought the twin issues of access and benefit sharing (ABS) to the centre stage, linking them inseparably to the conservation of biodiversity and sustainable use of its components. Regulating access to bio-resources is considered the most common mechanism for sharing of benefits, arising from their authorized use, but it is expected that the benefit sharing terms, subject to which approval for access is granted, should be encouraging greater use of these bio-resources rather than posing barriers to their availability to users.

With the emergence of highly restrictive intellectual property rights (IPR) systems, it became imperative to enact national legislation to claim sovereign rights of ownership over bio-resources to ensure realization of fair and equitable sharing of benefits arising from their utilization. When the national access regulations are not properly balanced with provisions of the laws protecting monopolistic patent rights or exclusive breeders' rights, it is likely to have adverse effects on the utilization and management of genetic resources in developing countries (Tvdt and Young, 2007). For a national legislation on ABS to be effective and develop proper monitoring mechanism for realization of equity benefits, however, its recognition at the bilateral/ multilateral or international level is essential (Andersen *et al*., 2010).

The key ethical principles of obtaining prior informed consent (PIC) and equity in benefit sharing, along with the rights of farmers and local communities, brought in focus by the CBD, are also now widely recognized (Engels *et al*., 2010). This development calls for a re-look at our current approach and strategy for conservation, sustainable use and management of bio-resources, adding a new dimension of sustaining livelihoods for local farming communities and forest dwellers, the primary benefit claimers, who even now continue to conserve and use their bio-resources, and also add value to them, under *in-situ* on-farm conditions where they have developed their distinctive traits and where they are still evolving for better adaptation in response to increasing selection pressures exerted by demands of their varying natural growth environments and also farmers' preferences.

*Author for Correspondence: E-mail: rairana@vsnl.net; rairana2006@yahoo.com

Background Information on Agricultural Biodiversity

It is interesting to study human cultures and their preferred plant sources for food, feed, fiber, healthcare, shelter, rituals or aesthetics. Although about 250,000 species of plants (divided into 460 families) have so far been documented worldwide, products from only around 300 species (belonging to 20 families); just a tiny fraction of what's available in nature, are being more commonly used. Again, nearly 3,000 species of plants are used and cultivated by humans under managed conditions but a remarkably small number of these species contribute greatly to the global harvest of food crops. Ranked in order of their annual production, the world's most important 15 food crops are: sugar cane, wheat, rice, maize, potato, sugar beets, barley, sweet potato, cassava, soybean, grape, tomato, bananas, legumes (beans and peas), and oranges.

i. Centres of Origin and Diversity of Crop Plants

Another remarkable fact is that different crop plants were selected and domesticated from their wild relatives by humans in different parts of the globe at different times. Scientific studies have been made to broadly identify these 'Primary Centres of Origin and Diversity of Crop Plants'. Vavilov, the renowned Russian botanist and explorer, recognized the following eight such primary centres (Vavilov, 1926):

I. The Chinese Centre – in which he recognized 138 distinct species of which probably the earlier and most important were cereals, buckwheat and legumes.

II. The Indian Centre (including the entire subcontinent) – based originally on rice, millets and legumes, with a total of 117 species.

IIa. The Indo-Malayan Centre (including Indonesia, Philippines, etc.) – with root crops (*Dioscorea* spp., *Tacca*, etc.) preponderant, also with fruit crops, sugarcane, spices, etc., some 55 species.

III. The Inner Asiatic Centre (Tadjikistan, Uzbekistan, etc.) – with wheats, rye and many herbaceous legumes, as well as seed-sown root crops and fruits, some 42 species.

IV. Asia Minor (including Transcaucasia, Iran and Turkmenistan) – with more wheats, rye, oats, seed and forage legumes, fruits, etc., some 83 species.

V. The Mediterranean Centre – of more limited importance than the others to the east, but including wheats, barleys, forage plants, vegetables and fruits -especially also spices and ethereal oil plants, some 84 species.

VI. The Abyssinian (now Ethiopian) Centre – of lesser importance, mostly a refuge of crops from other regions, especially wheats and barleys, local grains, spices, etc., some 38 species.

VII. The South Mexican and Central American Centre – important for maize, *Phaseolus* and Cucurbitaceous species, with spices, fruits and fibre plants, some 49 species.

VIII. South America Andes region (Bolivia, Peru, Ecuador) – important for potatoes, other root crops, grain crops of the Andes, vegetables, spices and fruits, as well as drugs (cocaine, quinine, tobacco, etc.), some 45 species.

VIIIa. The Chilean Centre – only four species – outside the main area of crop domestication, and one of these (*Solarium tuberosum*) derived from the Andean centre in any case. This could hardly be compared with the eight main centers.

VIIIb. Brazilian-Paraguayan Center – again outside the main centers with only 13 species, though *Manihot* (cassava) and *Arachis* (peanut) are of considerable importance; others such as pineapple, *Hevea* rubber, *Theobroma cacao* were probably domesticated much later.

Notwithstanding the unending human migrations and trade exchanges over the past nearly ten millennia, these Vavilovian Primary Centres can still be broadly defined because putative ancestral species and wild relatives continue to evolve there where they developed their recognizable distinctive traits (Auer, 2009). Zeven and de Wet (1982) further elaborated this concept enlarging them into 12 regions. These areas are rich in genes for valuable traits like resistance to diseases and pests, adaptations to specific stress environments and also tastes and qualities preferred by the local communities. And, these are essentially the target genes most commonly sought after for their identification, characterization, cloning and manipulation by the researchers using modern tools and techniques of biotechnology (Rana, 2004).

ii. Pre-CBD Movement of Genetic Resources

Seed samples of these landraces and farmers' varieties were taken away freely from these areas, mostly the

developing countries, through systematic explorations and collections by scientists of developed countries in general, and researchers of International Agricultural Research Centres in particular, and stored subsequently in their gene banks. These operations were undertaken mostly during the 1930-1980 period without signing any agreements and benefit sharing/ technology transfer arrangements. This was done by technology-rich countries and international organisations under the pretext that all global biological resources were shared heritage of mankind and needed to be safeguarded by storing them under ex-situ conditions, both for their protection from unforeseen calamities and also for promoting their greater use in crop improvement programmes (Rana and Arora, 1990). The International Undertaking (IU) on Plant Genetic Resources (PGR), voluntary in nature and facilitated by the FAO, supported this movement.

Following the recognition of sovereign rights of States over their biological resources by the CBD in 1992, biodiversity-rich developing countries pressed for repatriation of their seeds to their national programmes and demanded adoption of appropriate procedures to ensure authorized access to their bio-resources, subject to fair and equitable sharing of benefits arising from their use. Unauthorised taking away of genetic resources and their use without sharing benefits with the country of their origin was considered 'biopiracy'. These discussions led to referring of two issues by the CBD to the FAO for further deliberation and finding acceptable solutions to them. These included matters related to the fate of genetic resources collected (and taken away) prior to CBD and the realization of Farmers' Rights as developers, conservers and primary users of agricultural bio-resources (MSSRF, 1996). The FAO revised the text of the IU on PGR and adopted it in November 2001 as the legally binding International Treaty on Genetic Resources for Food and Agriculture (ITPGRFA). Farmers' Rights were recognized under this Treaty but their realization was left to the national governments in their jurisdiction. The issue of collecting genetic resources from countries of their origin, prior to CBD, still hangs on but the designated accessions stored in CGIAR's International Gene Banks have been brought under the operative jurisdiction of the FAO.

iii. Management and Governance Systems for Access and Benefit Sharing

Management and governance of genetic resources need to be looked from three dimensions, namely, perspective of developers and users, governance at the state and national levels, and national obligations under international treaties/agreements.

The first dimension of developers and primary users comprises local farming communities, public sector research institutions, private sector seed companies and multinational corporations. They represent the main stakeholders and key beneficiaries. The second dimension involves policy makers, legislators, managers and administrators. The third dimension relates to national obligations under multilateral environment and trade agreements. Under the last category, three major international agreements, namely, CBD, ITPGRFA and WTO-TRIPS have impacted the management systems of genetic resources globally and also at the national level, more so in the developing countries (Andersen, 2008). The first two treaties highlight the conservation of bio-resources, their sustainable use, regulated access and fair and equitable benefit sharing while the third focuses mainly on patenting/protection laws that grant monopolistic/exclusive rights to IPR holders/breeders to the exclusion of the rights of farmers and other primary beneficiaries. These three are legally binding treaties and India is a contracting party to all of them. Considering that agro-biodiversity is a subset of the total biological diversity, and a very important one, it is imperative that all these international agreements need to be implemented in harmony with each other.

CBD

Article 15 of CBD on 'Access to Genetic Resources' recognises sovereign rights of States over their natural resources and also affirms that the authority to determine access to genetic resources rests with the national governments, subject to national legislation. Access, where granted, shall be on mutually agreed terms (MAT) and subject to prior informed consent (PIC) of the Contracting Party providing such resources.

CBD also points to the importance of cultural diversity and traditional knowledge (TK). Article 8(j) of CBD on Traditional Knowledge, Innovations and Practices, calls on Parties to "respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising

from the utilization of such knowledge innovations and practices".

It needs to be appreciated that the three main objectives of the CBD (stated under Article 1), conservation of biodiversity: both in-situ (Article 8) and ex-situ (Article 9), sustainable use of its components (Article 10), fairly and equitably sharing the benefits arising from such use (Article 15), access to and transfer of technology (Article 16) and Handling of biotechnology and distribution of its benefits (Article 19) are inseparable in implementing the CBD and form the foundation of biodiversity-rich developing countries' expectations to gain substantially from their genetic resources (and associated TK) by providing them to users, based on PIC and MAT, and gaining from access to modern biotechnology tools/ techniques and products.

It is not only that genetic resources form a necessary and continuous input into all crop improvement and animal breeding efforts, including the on-going programmes of the public and private sectors, they also sustain livelihood activities of farming communities. Developing more insect-resistant and herbicide-tolerant crop varieties, employing new tools and techniques of modern biotechnology, also requires bio-prospecting to locate target genes, cloning their DNA and injecting them into locally adapted high yielding varieties hoping that the projected expression and stability of the added genetic information from exotic sources will dramatically increase the yield and, hence, marketability of their proprietary crop varieties/livestock breeds (Gepts, 2006).

ITPGRFA

The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) was intended to bring conformity in provisions of the International Undertaking, facilitated by the FAO, and the CBD, under the UNEP. After lengthy negotiations, delegates from 116 countries adopted the text of this treaty in November 2001, with the American and Japanese delegates abstaining. This treaty, serviced by the FAO in the interest of global food security, mandates conservation and sustainable use of plant genetic resources for food and agriculture, seeks to promote fair and equitable sharing of benefits arising out of the use of these resources and also establishes a multilateral system to facilitate access to 64 crops listed in Annexes I and II of the Treaty so as to share benefits derived from such facilitated access under the terms of a Standard Material Transfer Agreement (SMTA), based on mutually agreed terms. Thus, ITPGRFA is in harmony with the CBD and upholds the objectives of conservation, sustainable use and equitable benefit sharing with respect to agricultural bio-resources. Union Ministry of Agriculture is the nodal implementing ministry in India.

There is, however, still a lack of consensus regarding "fair and equitable" benefit sharing. It is also somewhat hazy how the benefits will be shared under this Treaty when the products are IPR protected and not freely available to farmers and researchers.

Unlike the CBD, which provides for bilateral negotiations to establish the terms of access and benefit sharing for each specific exchange of materials, all germplasm exchanges under the multilateral system will be subject to the standard MTA. Monetary benefits will be paid to a fund established by the Governing Body (FAO, 2009). This fund, as the Global Crop Diversity Trust Fund, will be used primarily to support farmers who conserve and sustainably use plant genetic resources for food and agriculture, especially such farmers in developing countries or in countries with economies in transition. The financing of germplasm conservation has been addressed only in general terms, making this aspect of the treaty potentially difficult to implement. The overall impact of the treaty also seems to be limited because of the omission of soybeans, peanuts, and some other important food crops from the list of 35 crops covered in its Annex I.

WTO-TRIPS

Another international agreement, namely, the Trade Related Intellectual Property Rights (TRIPS), under the World Trade Organisation (WTO), 1995, also impacts the access and benefit sharing processes as it requires under its Article 27.3b that plant varieties must be given some form of protection to intellectual property rights, either through patents or an effective *sui generis* national system. This article is now due for revision based on the experience gained so far from implementing its provisions. Doha Round of negotiations is, however, underway though the progress made so far is much below the developing countries' expectations.

National Legislation for Implementing the International Treaties

Under CBD, the authority to determine access to genetic resources rests with the national governments and it is subject to their national legislation. The Biological Diversity Act, 2002, was enacted in India in response

to this requirement (NBA, 2004) and also to provide further support to other complementary national laws in force, namely, the Wildlife (Protection) Act, 1972 as amended in 1991, and the Protection of Plant Varieties & Farmers' Rights (PPVFR) Act, 2001. It also provides suitable linkage to the provision for patenting of products and processes/ technologies, based on the use of bio-resources and associated indigenous traditional knowledge (ITK), under Section 10 (4) of the Patents (Amendment) Act, 2002. The stage is thus set for developing a national movement for implementing these combined provisions for access and benefit sharing to ensure food and livelihood security based on conservation, development and sustainable use of bio-resources.

Access and Benefit Sharing under India's Biological Diversity Act, 2002

Following an extensive and intensive consultation process involving all major stakeholders, the Central Government enacted the Biological Diversity Act, 2002 with the following salient features:

- to regulate access to biological resources of the country with the purpose of securing equitable share in benefits arising out of the use of biological resources; and associated traditional knowledge (TK) relating to biological resources;
- to conserve and sustainable use of all biological diversity components;
- to respect and protect traditional knowledge of local communities related to biodiversity;
- to secure sharing of benefits with local people as developers and conservers of biological resources and holders of knowledge and information associated with their use;
- to promote conservation and development of areas of importance from the standpoint of biological diversity by declaring them as biological diversity heritage sites;
- to provide support to on-going programmes on protection and rehabilitation of rare, endangered and threatened species;
- to ensure increasing involvement of institutions and state governments in the broad scheme of implementing the Biological Diversity Act, through constitution of appropriate committees.

In addition to promoting conservation and sustainable use of all categories of bio-resources, this umbrella legislation regulates access to them while determining mode/quantum of fair and equitable benefit sharing, and signing agreements with the users based on mutually agreed terms.

In exercise of the powers conferred by Sub-Section (1) (4) of Section 8 of the Biological Diversity Act, 2002 (No.18 of 2003), the Central Government established a body called the National Biodiversity Authority (NBA), on 1st October, 2003. The main functions of this Authority are:

1. To lay down procedures and guidelines to govern the activities provided under Section 3, 4 and 6. (Permission to foreigners/non-resident Indians and foreign companies).
2. To regulate activities and advise the government of India on research/ commercial use of bio-resources, bio-survey and bio-utilization.
3. To grant approval under Section 3, 4 and 6 based on the following considerations:

- Certain persons not to undertake Biodiversity related activities without approval of National Biodiversity Authority (Section 3) (Access to biological resources or Associated knowledge).
- Results of research not to be transferred to certain persons without approval of National Biodiversity Authority (Section 4) (Transfer of Research Results).
- Applications for seeking IPR rights not to be made without prior approval of the NBA (Section 6).

4. To grant approval to certain persons seeking transfer of already accessed biological resource/ associated traditional knowledge (Third Party Transfer) (Section 20).
5. To determine and impose terms of equitable benefit sharing, arising out of the use of accessed biological resources and associated traditional knowledge (Section 21).
6. To advise the State Governments in the selection of areas of biodiversity importance to be notified under Section 37 (1) as heritage sites and measures for their management.
7. To take any measure, on behalf of the Central Government, necessary to oppose the grant of IPR in any country outside India on any bioresource obtained from India or knowledge associated with it which is derived from India.

To sum up, this Act seeks to regulate access to

India's biological resources, and associated TK, with a view to securing equitable sharing of benefits arising from their use. Its primary objectives include promoting in-situ conservation of bio-resources and their sustainable use and linking them to the goals of food security, healthcare, livelihoods and eco-friendly development concerns through suitable applications of the National Gene Fund. It also addresses supportive mechanisms like documenting and protecting biodiversity-related TK, conservation and development of designated areas as biological diversity heritage sites and also the protection of threatened species and their habitats.

Recognising that the Indian citizens owe allegiance to the Indian Constitution and can be called upon in person to ensure compliance to this Act's provisions, a practical differentiating way has been adopted under which the following categories of persons/ body corporate/ associations/ organizations are required to obtain prior approval of the NBA for seeking access to India's bio-resources (and associated TK) for research and commercial use or engaging in bio-survey and bio-utilization activities (Section 3 and Section 19):

- A person who is not a citizen of India
- A citizen of India, who is non-resident
- A body corporate, association or organization – not incorporated or registered in India; or incorporated or registered in India but has any non-Indian participation in its share capital or management.

All the entities in this category are also required to seek prior approval of the NBA for transferring research results abroad (Section 4), for applying for IPR (Section 6) and also for third party transfer of the granted approval (Section 20), by submitting applications in specified formats and after payment of prescribed fee for each of the above mentioned purposes. As explained earlier, the provisions of this law are differentiating but not discriminatory.

Access of Indian citizens to bio-resources for research is unrestricted and free. However, the Section 7 states that no person, who is a citizen of India or a body corporate, association or organization which is registered in India, shall obtain any biological resource for commercial utilization, or bio-survey and bio-utilization for commercial use except after giving prior intimation to the concerned State Biodiversity Board.

Restrictions Imposed on Granting Access

Certain restrictions have been imposed under Rule 16 on NBA's approvals for activities related to access to bio-resources, requiring the Authority to take steps to restrict or prohibit requests for such access on considering the following reasons:

i. The request for access is for any endangered taxa;
ii. The request for access is for any endemic and rare species;
iii. The request for access may result in adverse effect on the livelihoods of the local people;
iv. The request for access may result in adverse environmental impact which may be difficult to control and mitigate;
v. The request for access may cause genetic erosion or adversely affect ecosystem functioning;
vi. When the use of resources is for purposes contrary to national interest and other related international agreements entered into by India.

Exemptions Provided under the BD Act

The following exemptions have been provided under this Act to promote bona fide use of bioresources for research and non-commercial use:

- Provisions of Section 3 (access to bio-resource) and Section 4 (transfer of research results) shall not apply to the approved collaborative research projects, conforming to the policy guidelines issued by the Ministry of Environment and Forests (MoEF) vide its notification dated 8 November, 2006.
- Provision of Section 6 shall not apply to any person making an application for any right under the Protection of Plant Varieties and Farmers' Rights Act, 2001. Where any right is granted under this law, the concerned authority granting such right shall endorse a copy of such document (granting the right) to the NBA.
- Provisions of Section 7 (prior intimation to SBB for commercial use) shall not apply to the local people and communities including village healers/ *vaids*, farmers and other traditional growers and also to Indian users of these bio-resources for research.
- Normally traded commodities, 190 bio-resources as notified by the MoEF vide its notification dated 26 October, 2009, subject to the clarification issued on 16 February, 2010, would be exempt from purview of this Act provided they are traded as commodities.

Link to the Patents Act

Section 6 (1) of the BD Act links to the requirement under Section 10 (4) of the Patents (Amendment) Act, 2002 that requires disclosure of the source and geographical origin of the biological material, used in developing an invention/innovation. A sample of the bioresource is also required to be deposited in the designated national depository institution.

Authorised Access to Biological Resources Required Prior to Seeking IPR

Any person seeking any kind of IPR in or outside of India for any invention/technology/product or process based on any biological resource (or associated information) obtained from India, is required to obtain prior permission of the NBA (Section 6). In addition, the Patent (Amendment) Act, 2002, requires the patent applicant to disclose the source and geographical origin of the used biological material in the patent application, when used in an invention (Section 10(4)).

Realizing Fair and Equitable Benefit Sharing under the Biological Diversity Act

The NBA is required to develop and notify guidelines for imposing terms for fair and equitable benefit sharing and efforts in this context are going on. A National Consultation was also organized on 23 April 2010 at Chennai to obtain further inputs from different experts and stakeholders for this purpose. Until these guidelines are finalized and notified, some working guidelines have been developed and followed while making recommendations regarding benefit sharing on a case-by-case basis.

Options for sharing non-monetary benefits, adopted from the non-binding Bonn Guidelines, are provided under Section 21 as listed below:

- Transfer of technology
- Location of production, R&D units in areas inhabited by 'benefit claimers'
- Associating Indian scientists and benefit claimers with the R&D activities
- Setting up of venture capital
- Payment of monetary [and royalty] benefits
- Product development
- Institutional capacity building
- Education and awareness raising activities

For sharing benefits in monetary form, consideration is given to potential commercial value of the innovation/ product/ process/ technology, expected volume of potential business and the capacity to pay of the applicant. Applying terms for benefit sharing on a case by case basis notwithstanding, a generalized and indicative scheme for sharing monetary benefits, arising from use of biorsources and associated TK, is given in Table 1 for guidance purpose only.

Approval for accessing bioresource, bio-survey & bio-utilization, transfer of research results, seeking IPR and third party transfer of already accessed bioresource is given by NBA by signing a written agreement with the applicant as required under Rule 14 (5).

The amount realized by the NBA through fees, royalties and other sources goes to the National Biodiversity Fund that is used for the following purposes:

Table 1.

Category Commercial use	Benefits from direct commercial use	Benefits from commercial use after licensing to a licensee (third party)
The Applicant commercialises the process/product	The applicant shall pay royalty @ up to 3% of the highest ex-factory sale price of the product sold or used for captive consumption (in such cases, the price would be determined on the basis of the price which the product would get if sold in the market).	The applicant pays a mutually agreed upfront amount until the product/ innovation enters into commercial production.
The Applicant licenses the process/product to a licensee	The Applicant shall pay up to 5% of the license fee received from the Licensee as one-time benefit sharing at this stage. The Applicant shall also provide a copy of the contract, entered into, to the Authority.	Upon commercialization, the applicant shall further pay, in addition to the payment made earlier, up to 4% royalty on the amount received by him as his royalty-charges from the licensee on an annual basis.
The Applicant collects the bioresource from its natural populations, with prior approval of the concerned SBB/BMC/State Wildlife Board, and exports it under DGFT permit.	The Applicant shall pay 5% of the total FOB value of the bioresource under export to the Authority.	

– Channeling benefits to the 'benefit claimers'.
– Helping the conservers and developers of biological resources/ local communities in support of their on-location efforts towards conservation and sustainable use.
– Promoting conservation of bio-resources and development of areas from where these are accessed.
– Supporting conservation efforts for the designated 'Biodiversity Heritage Sites'.
– Capacity building.

Implementing Access and Benefit Sharing under the Biological Diversity Act

Biodiversity is a multi-disciplinary subject, involving diverse activities. Its major stakeholders include the Central Government, State Governments, institutions of local self-government, local communities, farming communities, research institutions, industry and civil society organizations. Notwithstanding the fact that the Contracting Party to the CBD is the national government and the Union Ministry of Environment & Forests is the nodal ministry, biodiversity is essentially a state subject. Even at the Central Government level, several union ministries have overlapping authority in managing different components and concerns of biodiversity. Thus, implementing the Biological Diversity Act requires effective coordination among all the concerned authorities and also other major stakeholders.

The Act provides for its implementation through a 3-tier system comprising the National Biodiversity Authority (NBA), the State Biodiversity Boards (SBBs) and the Biodiversity Management Committees (BMCs) at the local communities level. Functions of this system at all the three levels have been well defined. There is a provision for setting up of a Committee on Agriculture and also some expert committees as needed. The NBA has been established and it is operating from Chennai. SBBs have also been constituted in 24 States though they often lack the guidance of technical experts at the top. The task of setting up of BMCs remains a challenge although some states have gone ahead notably in this direction and 31,542 BMCs have already been constituted. Over 400 People's Biodiversity Registers are under preparation. However, infrastructure still remains poor and there is lack of adequate capacity at the lower two levels, particularly at the level of local communities. There is an urgent need for generating awareness at all levels about the Act's main provisions and objectives and also about the benefits that are likely to accrue following its effective implementation.

The NBA has also constituted the following expert committees to assist in its functioning:

- Expert Committee on Access and Benefit Sharing for processing all the Applications.
- Expert Committee for framing the guidelines for determining contributions to and utilization of National Biodiversity Fund.
- Expert Committee on preparing guidelines on ameliorative measures for biodiversity rich areas that are threatened by overuse, abuse or neglect.
- Expert Committee on Agro-biodiversity
- Expert Committee for implementing the Project for establishing "Indian Biodiversity Information System (IBIS)".
- Expert Committee for the preparation of Training Module for Officers staff and various stakeholders on legal, social, technical aspects of implementation of various provisions of Biological Diversity Act, 2002.
- Expert Committee for preparation of guidelines on creating structures, running administration and maintaining of accounts and other related matters pertaining to Biodiversity Management Committees
- Expert Committee on reviewing the agreements' formats.

There is an urgent need at present to develop a strong National Biodiversity Information System, suited to the needs of our country and to serve as a referral facility for networking. Although several options are available for securing equitable sharing of benefits, arising from the use of bio-resources (and associated

Prescribed Application Forms and Fees for Seeking Approval of NBA

Application Format	Purpose	Application Fee
Form I[Sections 3 and 19, Rule 14].	Access to Bioresources/TKby foreigners/Commercial Use, Biosurvey/Bio-utilization	₹ 10,000/-
Form II [Section 4, Rule 17].	Transfer of Research Results/Data.	₹ 5,000/-
Form III [Section 6, Rule 18].	Seeking IPR	₹ 500/-
Form IV [Section 20, Rule 19].	Third Party Transfer of Bioresources	₹ 10,000/-

ITK) but there are not many case studies available as yet to provide learning experiences. Furthermore, some progress in this direction notwithstanding, there is still no adequate monitoring mechanism in place to ensure proper compliance of the contracting agreements, signed between the NBA and the users on mutually agreed terms. Another major limitation is that provisions of our national legislation on ABS do not yet have international recognition and compliance abroad.

Several National Bureaus, mandated with the conservation and sustainable use of bio-resources under the ICAR, are currently engaged in systematic registration of elite genetic resources of crop plants, livestock and fish. Over 800 elite plant genetic resources and nearly 130 elite livestock breeds have already been registered. There is need to provide legal protection to such registered elite genetic stocks by invoking relevant provisions under the Protection of Plant Varieties Act, the Biological Diversity Act and other relevant legislation and administrative measures. Some ground work has already been done but some hazy areas still remain awaiting clarity. Issues relating to beneficiary claimants and farmers' rights require more attention. These discussions need to be continued and supported to reach some meaningful conclusions and well laid out procedures. As it appears, beginning may have to be made with documenting them in relevant communities' Biodiversity Registers, duly endorsed by the concerned SBBs, and finally by the NBA, in partnership with the ICAR.

Our crop and livestock **g**enetic resources are still evolving under *in-situ* on-farm conditions, moving gradually towards better adaptation to situations in which they are grown in the face of emerging outbreaks of pests and diseases and also non-biotic stresses. These evolutionary processes, abruptly cut off by the *ex-situ* conservation strategy, need to be continued and strengthened under the *in-situ* on-farm conditions, managed by the farming communities who are living with their bioresources under different agro-ecosystems. *In-situ* conservation and sustainable use of bioresources is strongly supported under the Biological Diversity Act. Considering that effective implementation of this Act requires joint effort and active collaboration of several union ministries of the central government and also the state governments, it is proposed that this challenging task be undertaken as a standalone national mission on 'Implementing the Biological Diversity Act for Adaptation to Climate Change'.

The Way Forward

India's Biology Diversity Act has commendable provisions for not only conservation and sustainable use of bioresources but those on fair and equitable sharing of benefits arising from their authorized use. The key bottleneck in properly implementing this national legislation appears to be the lack of adequate awareness, not only among the general public but also among the policy makers and managers alike, about the provisions of this Act bearing on access and benefit sharing. It is further compounded by poor infrastructure and little capacity building at the grassroots level. There are also not many case studies available on the subject of granting access and benefit sharing methods to learn from the relevant experiences.

There is a growing need for extending partnership to the private sector in conserving, sustainable use and managing bioresources in the country subject to suitable terms of scientific cooperation and principle of reciprocity as recommended by the Brainstorming Session on this aspect, organized in New Delhi in 2005 (Anonymous, 2005). While developing its own policy on access to and exchange of genetic resources, the ICAR make like to take suitable note of the relatively open policy adopted by some leading developed countries, formulated to promote greater use of the collected genetic resources by researchers and breeders. For example, the volume of seed samples distributed annually by the National Plant Germplasm System of the United States has expanded steadily, to a current average of about 120,000 per year, free of charge or restriction (Bretting, 2006).

Pharmacy industry and herbal food sector deserve greater attention in the context of conservation and sustainable use of raw bio-resources used by them. India has the potential of becoming a major global player in market for medicinal plants based herbal formulations, medicines and products. According to WHO, the international market of herbal products is estimated to be US $ 62 billion which is poised to grow to US $ 5 trillion by the year 2050, but India's share in the global export market of medicinal plants related trade is just 0.5 per cent. Out of around 6,000 plant species used in Indian systems of medicine, data on only 960 have been recorded in trade and 179 of them are used in volumes of more than 100 MT per annum (Ved and Goraya, 2008). Given the extent of biodiversity in India, a major task of all concerned, including the policy makers and planners, has to be the identification and guided development of new products with large export potential.

India has set a vision regarding its medicinal plants sector and some major policy initiatives have been taken in this direction. A new beginning may be made by promoting on-farm cultivation of medicinal and aromatic plants, focusing on priority species as reported by various high-level expert committees (Brindavanam, 2010). At the same time, the industry estimates for raw material demand should be made available well in advance so as to regulate demand-supply scenario optimally. In addition, the role of middlemen in the supply chain needs to be streamlined by making them declare their sources of supply and also the areas from where the bioresources have been collected by their primary suppliers.

The Indian government has developed some outstanding policy measures and has also enacted legislation for promoting conservation and sustainable use of country's biological resources (and associated TK) while also meeting national obligations under international agreements like CBD, ITPGRFA, and WTO-TRIPS. Though these initiatives are highly appreciable, there exists enough scope for making these measures better focused and more effective.

A promising development in this context is the adoption of Nagoya Protocol to CBD on Access and Benefit Sharing during the COP-10 meeting, held in October this year in Japan, since it is likely to provide a fillip to developing a much awaited international regime with a framework that balances access to genetic resources on the basis of PIC and MAT with the fair and equitable sharing of benefits while taking into account the important role of TK. The agreed definition of 'genetic resources', adopted under the Nagoya Protocol on ABS, now includes 'derivatives' and this augers well with the position taken by the biodiversity-rich developing countries on this issue. However, this only provides a lead that needs to be developed further through pro-active negotiations under CBD (Schei and Tvedt, 2010). The Biological Diversity Act defines 'biological resources' as plants, animals and micro-organisms, or parts thereof, their genetic material and byproducts (excluding value added products) with actual or potential use or value, but does not include human genetic material.

The Nagoya Protocol is expected to enter into force by 2012 when the next COP meeting would be held in India. Significant developments are then likely to follow in this direction during India's presidency. This Protocol on ABS is a landmark in the international governance of biodiversity as it proposes a global multilateral benefit sharing mechanism. The CBD had already established the concept of fair and equitable sharing of benefits as one of the three main objectives and outlined basic principles including PIC and MAT. Yet, these principles remained largely unimplemented owing largely to a range of difficulties and different views on ways of overcoming them. With the Nagoya Protocol, the fair and equitable sharing of benefits has been reaffirmed as a fundamental component of biodiversity-dealing strategies and a set of rules has been agreed upon to facilitate, promote and ensure its effective implementation. This Protocol has also brought in TK, associated with biorsources, under the ambit of benefit sharing. However, realization of benefit sharing is linked basically to provisions of national legislation and regulatory mechanisms adopted by countries providing the bioresources.

It may be noted that only those countries, who are already Contracting Parties to CBD, are eligible to sign and ratify the Nagoya Protocol. It also needs to be pointed out in this context that the text of The Nagoya Protocol is based on intense negotiations and compromises and, as a result, its content is hazy on several highly contested issues, even excluding the use of some controversial terms despite their adoption based on consensus (UNEP-CBD document, 2010 and ENB, Summary and Analysis, 2010). Considering that some of its provisions are open to interpretation, a lot will depend upon on further development of these provisions in the context of the CBD, as well as its implementation at the national level.

Next step should be to harmonise provisions for benefit sharing under CBD and WTO-TRIPS. For implementing the two main principles of ABS mechanism under CBD, namely, "Prior informed consent" and "Mutually agreed terms", legal requirement of a CBD-compliance certificate needs to be adopted as an essential attachment with applications submitted to patent offices for seeking patents on products or processes based on bio-resources and associated TK. This may be in the form of a 'certificate of origin' issued by the national authority of the provider country as the proof of CBD-compliance.

To sum up, the stage appears to be set now for embarking on a global movement for adoption of fair and equitable sharing of benefits arising from the authorized use of genetic resources and also for generating more benefits by promoting greater use of bioresources along with expanded application of modern tools and techniques

of biotechnology. It is important for India to take a lead in this direction if this movement is to make a real headway and this can be done by setting an example through more effective implementation of the national legislation on ABS and by setting up appropriate checks and balances while putting in place an efficient monitoring system.

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ANNEX I

International Treaty on Plant Genetic Resources for Food and Agriculture

List of 64 Crops Covered Under the Multilateral System

A. Food Crops (35)

Crop	Genus	Observations
Breadfruit	*Artocarpus*	Breadfruit only
Asparagus	*Asparagus*	
Oat	*Avena*	
Beet	*Beta*	
Brassica complex	*Brassica* et al.	Genera included are: *Brassica, Armoracia, Barbarea, Camelina, Crambe, Diplotaxis, Eruca, Isatis, Lepidium, Raphanobrassica, Raphanus, Rorippa*, and *Sinapis*. This comprises oilseed and vegetable crops such as cabbage, rapeseed, mustard, cress, rocket, radish, and turnip. The species *Lepidium meyenii* (maca) is excluded.
Pigeon Pea	*Cajanus*	
Chickpea	*Cicer*	
Citrus	*Citrus*	Genera *Poncirus* and *Fortunella* are included as root stock.
Coconut	*Cocos*	

Contd.

Crop	Genus	Observations
Major aroids	*Colocasia, Xanthosoma*	Major aroids include taro, cocoyam, dasheen and tannia.
Carrot	*Daucus*	
Yams	*Dioscorea*	
Finger Millet	*Eleusine*	
Strawberry	*Fragaria*	
Sunflower	*Helianthus*	
Barley	*Hordeum*	
Sweet Potato	*Ipomoea*	
Grass pea	*Lathyrus*	
Lentil	*Lens*	
Apple	*Malus*	
Cassava	*Manihot*	*Manihot esculenta* only.
Banana / Plantain	*Musa*	Except *Musa textilis*.
Rice	*Oryza*	
Pearl Millet	*Pennisetum*	
Beans	*Phaseolus*	Except *Phaseolus polyanthus*.
Pea	*Pisum*	
Rye	*Secale*	
Potato	*Solanum*	Section tuberosa included, except *Solanum phureja*.
Eggplant	*Solanum*	Section melongena included.
Sorghum	*Sorghum*	
Triticale	*Triticosecale*	
Wheat	*Triticum* et al.	Including *Agropyron, Elymus*, and *Secale*.
Faba Bean / Vetch	*Vicia*	
Cowpea et al.	*Vigna*	
Maize	*Zea*	Excluding *Zea perennis, Zea diploperennis*, and *Zea luxurians*.

B. Forages (29)

Genera	Species
Legume Forages	
Astragalus	*chinensis, cicer, arenarius*
Canavalia	*ensiformis*
Coronilla	*varia*
Hedysarum	*coronarium*
Lathyrus	*cicera, ciliolatus, hirsutus, ochrus, odoratus, sativus*
Lespedeza	*cuneata, striata, stipulacea*
Lotus	*corniculatus, subbiflorus, uliginosus*
Lupinus	*albus, angustifolius, luteus*
Medicago	*arborea, falcata, sativa, scutellata, rigidula, truncatula*
Melilotus	*albus, officinalis*
Onobrychis	*viciifolia*
Ornithopus	*sativus*
Prosopis	*affinis, alba, chilensis, nigra, pallida*
Pueraria	*phaseoloides*
Trifolium	*alexandrinum, alpestre, ambiguum, angustifolium, arvense, agrocicerum, hybridum, incarnatum, pratense, repens, resupinatum, rueppellianum, semipilosum, subterraneum, vesiculosum*
Grass Forages	
Andropogon	*gayanus*
Agropyron	*cristatum, desertorum*
Agrostis	*stolonifera, tenuis*
Alopecurus	*pratensis*
Arrhenatherum	*elatius*
Dactylis	*glomerata*
Festuca	*arundinacea, gigantea, heterophylla, ovina, pratensis, rubra*
Lolium	*hybridum, multiflorum, perenne, rigidum, temulentum*
Phalaris	*aquatica, arundinacea*
Phleum	*pratense*
Poa	*alpina, annua, pratensis*
Tripsacum	*laxum*
Other Forages	
Atriplex	*halimus, nummularia*
Salsola	*vermiculata*