Accessing Plant Genetic Resources and Sharing the Benefits: Experiences in India

Rai S Rana*

Member, National Biodiversity Authority, India and Former Director, National Bureau of Plant Genetic Resources, New Delhi-110012

Recent negotiations under the Convention on Biological Diversity and the adoption of Nagoya Protocol on Access and Benefit Sharing have placed biodiversity-rich developing countries in a better position to gain from their bioresources and to enhance their capacity to provide more incentives for conservation and sustainable use of biodiversity. India responded to its national obligations by enacting the Biological Diversity Act, 2002. This legislation, and the Biological Diversity Rules, 2004 framed under it, provide for a three-tier legal framework for regulating access to bioresources (and associated traditional knowledge) while promoting fair and equitable sharing of the resulting benefits. Indian citizens are free to access bioresources for research purpose but they are required to intimate the concerned State Biodiversity Boards (SBBs) prior to obtaining them for commercial purpose. On the other hand, persons other than Indian citizens, as defined under section 3 (2), are essentially required to obtain prior approval of National Biodiversity Authority (NBA) for accessing India's bioresources whether for research use or for commercial purpose. To promote benefit sharing, NBA's prior approval is also required whenever an Indian researcher/institution intends to transfer bioresources or results of research on them to the latter category of users. Furthermore, no person shall apply for seeking IPR protection over any innovative process/product, based on the use of bioresources, occurring in India or obtained from India, without prior approval of NBA and signing the agreement on benefit sharing. Applying for protection of plant variety under PPV&FRA is, however, exempted from this provision. Approvals are granted by NBA on a case by case basis, keeping in view the recommendations of an Expert Committee and imposing terms for benefit sharing in monetary or non-monetary mode. Implementing the Act's provisions presents a challenge since it requires active partnership and effective coordination involving the NBA at the national level, SBBs at the state level and Biodiversity Management Committees at the local level. Also considering that India's national legislation combines the role of the regulator (enforcing authorized access to bioresources) with that of the promoter (promoting conservation and sustainable use of bioresources, benefit sharing provisions, and also creating public awareness), and the advisor (advising the central and state governments on some key issues and national concerns). India's experiences in implementing its national legislation may be of immense regional and international interest.

Key Words: Access and benefit sharing, Access to genetic resources, Access to PGR and benefit sharing, Agro-biodiversity, Farmers' rights in India, Institutional mechanism for ABS in India, Nagoya Protocol and Indian legislation, Regulating traditional knowledge

Biological resources form an essential and continuous input into all crop improvement and animal breeding efforts, including the programmes of public and private sectors, and also sustain livelihood activities of farming communities (FAO, 2010). 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 (Rana, 2004; Gepts, 2006; Suneetha and Pisupati, 2009; Engels *et al.*, 2010; Nair, 2011).

Stimulated by unprecedented technological advances, appreciation of the monetary and non-monetary value of biological resources has grown enormously in recent years leading to increasing conflict over rights and responsibilities for these resources, including both the naturally growing as well as the cultivated forms (Duttfield, 2000; Kamau and Winter, 2009; Gokhale, 2011). The Convention on Biological Diversity (CBD), 1992 recognized sovereign rights of nation-states over their bioresources and also over determining terms of access to them subject to their national legislation. In accordance with this requirement, national governments are framing policies, rules and procedures, through appropriate legislation that regulate access to biological resources and related traditional knowledge within their territorial jurisdiction (Tvedt and Young, 2007; Morgera and Tsioumani, 2011).

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

I. Background

India is a party to several biodiversity-related conventions including CBD and the International Treaty on Plant genetic Resources for Food & Agriculture (ITPGRFA). India is also signatory to international trade agreements including WTO-TRIPS. It has also signed recently the Nagoya Protocol on Access & Benefit Sharing (MoEF, 2011).

To meet its national obligations under CBD, India enacted the Biological Diversity Act, 2002 with clear specification of access regulations for domestic and foreign users of bioresources growing in India or obtained from India (Rana, 2010). 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, however, 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. The Nagoya Protocol on ABS, adopted recently under CBD, is expected to fulfill this task.

The National Biodiversity Authority (NBA), established in 2004 in Chennai, is charged with the overall responsibility of implementing this Act, in partnership with the State Biodiversity Boards (SBBs) and the local Biodiversity Management Committees (BMCs). It is intended that these access regulations will be facilitative, subject to some essential restrictions and appropriate benefit sharing agreements, and the use of bioresources will help in their conservation, sustainable use and sharing of the resulting benefits. There is, however, a growing apprehension that technologies which develop and make use of these resources seem to outpace the ability of social organizations to understand their impact and also the capability of national laws to cope with them (Kamau and Winter, 2009; Oliva, 2010; WFC, 2010).

Under CBD, Article 15 provides for regulating access to genetic resources and ensuring fair and equitable sharing of the resulting benefits with primary stakeholders and other identified beneficiaries. Accordingly, access to bioresources, and associated traditional knowledge, is regulated in India under its national legislation wherein the sharing of benefits is linked to promoting conservation and sustainable use. Obtaining authorised access to bioresources, where applicable, is essential and the offences under this Act are cognizable and non-bailable. IPR issues like the Breeder's Rights, on the other hand, are addressed by provisions under the Protection of Plant Varieties & Farmers' Rights Act (PPV&FRA), 2001 and the Patents Act, 1970 (as amended in 2002 and 2005) to meet the obligations under WTO-TRIPS. There is harmony in implementing these three legislations and it has been ensured that plant genetic resources are made available for research, as well as for commercial use, through well defined procedures under a 3-tier system and subject to certain specified restrictions.

II. The Changing Scenario

India is one of the mega biodiversity-rich countries of the world. With only 2.4% of the land area, it accounts for 7.8% of all the recorded species on this planet. India also ranks 10th in the world and 4th in Asia in plant diversity. It is one of the eight Vavilovian Centres of Origin and Diversity of Crop Plants and an acknowledged centre of rich crop diversity, being home to 167 important cultivated species and 320 species of their wild relatives (Rana and Arora, 1990). Available data show that 45,968 species of plants and 91,364 species of animals have already been documented in India.

India spearheaded the International Undertaking on Plant Genetic Resources in 1980s, supporting the concept that PGR were common heritage of humankind and should be made available for research in an unrestricted manner for developing improved crop varieties to boost agricultural production. During the 1930-1980 period, seed samples of landraces and farmers' varieties were taken away freely by scientists of the developed countries through systematic explorations, without signing any agreements and benefit sharing/technology transfer arrangements. India has also contributed significantly to global gene banks of International Agricultural Research Centres under the CGIAR system (Rana, 2004).

Agricultural biodiversity is an important subset of biological diversity and it has been largely developed, used and conserved through human effort. Access to crop genetic resources, in particular, has now come to occupy centrestage in recent years following the emergence of IPR protection in various forms, particularly the breeder's rights, and enormous growth in seed sector and herbal healthcare business (Laird *et al*., 2005; Kamau and Winter, 2009; Robinson, 2010; Winter, 2011). Disagreeing provisions under some major international agreements, including CBD and ITPGRFA on one hand and WTO-

TRIPS on the other, have further complicated the situation (Dutfield 2000, Carrizosa *et al*., 2004, Feit *et al*., 2005, Pant 2009, Rana 2010, Nair 2011).

It is widely recognized, however, that unrestricted access to biological resources of crop plants, developed initially and conserved mostly by the farming communities, determines largely the pace and success of all plant breeding efforts by both public and private sectors. In this context, provisions of the national legislation, on regulating the access to plant genetic resources (PGR) and realizing the fair and equitable sharing of benefits arising from their sustainable use, is discussed in this paper while keeping in view our national obligations under some relevant international treaties/agreements. The way ahead lies in generating increasingly more benefits through greater use of bioresources, through employment of recent advances in molecular biology and biotechnology, and sharing them with the rightful beneficiaries in a fair and equitable way (Rana, 2004; Tvedt and Young, 2007; Ved and Goraya, 2008; Oli and Dhakal, 2009; World Future Council, 2010, Dewar, 2010; Johnson, 2011).

International Developments

Access to genetic resources and the sharing of benefits are admittedly complex issues and need to be viewed from at least three distinct dimensions, namely, perspective of the developers and the users, management and governance at the national level, and also the national obligations under international treaties/ agreements. The first category represents the main stakeholders and key beneficiaries like the local farming communities, public sector research institutions, private sector seed companies and multinational corporations. The second group involves policy makers, legislators, managers and administrators concerned with management, governance and regulation. The third dimension reflects the national obligations under multilateral environment and also trade agreements, mainly the legally binding treaties CBD, ITPGRFA and WTO-TRIPS.

The Key Role of CBD

The need to regulate access to genetic resources and ensure a fair and equitable sharing of the resulting benefits was at the core of the adoption of CBD. Access, where granted, shall be on mutually agreed terms (MAT) and subject to prior informed consent (PIC) of the Contracting Party providing such resources. A series of principles and requirements around access and benefit sharing (ABS) were established under its process with a view to increasing transparency and equity in the international flow of genetic resources. Somehow not many countries have been able to effectively implement them and the on-going ABS negotiations are often paralysed by complex challenges.

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), namely, conservation of biodiversity: both in-situ (Article 8) and ex-situ (Article 9), sustainable use of its components (Article 10), and fairly and equitably sharing the benefits arising from such use (Article 15), are inseparable in implementing the CBD. They together provide 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, while also gaining from access to modern biotechnology tools/ techniques and products (Articles 16 and 19). Resorting to unauthorised access to bioresources, including plants with medicinal properties along with traditional knowledge associated with them, or getting patented any innovation/ process/ product based on the use of such resources is sometimes referred to as "biopiracy" (Chaudhury, 2003; Swiderska, 2006; Robinson, 2010).

Nagoya Protocol on Access and Benefit Sharing

The Nagoya Protocol, on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization, is an international agreement under CBD. Its objective is to promote sharing of the benefits arising from utilization of genetic resources in a fair and equitable way, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components. Adopted by the Conference of the Parties to CBD at its tenth meeting on 29 October 2010

in Nagoya (Japan), it will remain open for signature by Parties to the Convention from 2 February 2011 until 1 February 2012 at the United Nations Headquarters in New York. The protocol now has 61 signatories, but will enter into force 90 days after 50 countries, who are Parties to CBD, have consented to be bound by it, which means they must ratify the text. The protocol envisages the setting up of an international regime on access and benefit sharing of genetic resources, which will lay down the basic ground rules on how nations shall cooperate in obtaining genetic resources and sharing the benefits arising from their utilization.

ITPGR: Multilateral System for Global Food Security

The International Treaty on Plant Genetic Resources for Food and Agriculture, facilitated by FAO of the United Nations, entered into force in 2003 bringing conformity in provisions of the International Understanding on PGR and those of CBD, under the UNEP. Its primary objective is to promote global food security and its mandate includes conservation of agricultural biodiversity and sustainable use of plant genetic resources for food and agriculture. To begin with, it has established a multilateral system to facilitate access to genetic resources of 64 crops, listed in Annexes I and II of the Treaty, and seeks to promote fair and equitable sharing of benefits arising from their use. These crops together account for 80 percent of all human food consumption and comprise a pool of genetic resources that are accessible to everyone. Articles 12 and 13 include provisions on access and benefit sharing respectively.

Contracting Parties agree to share designated accessions stored in their national gene banks along with relevant information on them. This gives scientific institutions and private sector plant breeders the opportunity to work with, and potentially to improve, the materials stored in gene banks or even the germplasm collections growing in fields. By facilitating research, innovation and exchange of information without restrictions, this approach cuts down on the costly and time consuming need for breeders to negotiate contracts with individual gene banks. The Multilateral System sets up opportunities for developed countries with technical know-how to use their research laboratories to build on what the farmers in developing countries have accomplished in their fields.

WTO-TRIPS and Breeder's Rights

Plant genetic resources, that serve as the essential building blocks for developing improved varieties of crop plants, were recognized as the common heritage of humankind under the International Understanding on PGR adopted in 1983, facilitated by the FAO Commission on PGR. This scenario changed with the WTO-TRIPS agreement coming in to force in 1995 since its Article 27.3b required its member parties to provide some form of protection as intellectual property rights (breeder's rights), either through patents or an effective sui generis national legislation. Union Ministry of Commerce is the nodal agency for its implementation in India.

Since disclosure of the lineage of improved varieties is not required by the Patent Offices, origin of parental lines (used by the breeders) remains hidden with the result that the CBD principles of PIC and MAT cannot be applied and the obligation for fair and equitable sharing of benefits cannot be met. This inconsistency can be removed through a suitable revision of the provisions of this international trade agreement to bring them in harmony with those of CBD and this is being attempted by the biodiversity-rich developing countries during the on-going negotiations under the Doha Round.

India has taken the lead in this context since its national legislation, the Protection of Plant Varieties & Farmers' Rights Act, 2001 requires the applicants to disclose the information on lineage and origin of the improved variety to be protected and assurance of CBD-compliance. It is also noteworthy that the Indian legislation provides exemption for the farmers' rights and researcher's rights while granting the breeder's rights. This national legislation, however, needs to be recognized under bilateral/ multilateral/ international agreements in order to be effective and the recently adopted Nagoya Protocol on International Regime on Access & Benefit Sharing is a positive development in this direction.

III. Indian Response to International Treaties

National Legislation for Implementing the International Treaties

The Biological Diversity Act, 2002, was enacted in India in response to CBD's provision that the authority to determine access to genetic resources rests with the national governments and it is subject to their national legislation. It also provides further support to other complementary national laws already 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 was 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.

Salient Provisions of the Biological Diversity Act, 2002

Primarily aimed at promoting conservation and sustainable use of all categories of biological 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. Its key provisions are summarized below:

- 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 brief, 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 Biodiversity 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.

- A notable feature of this legislation lays in differentiating the applicants in two categories, namely, persons who are citizens of India and the others including non-resident Indians, persons who are not citizens of India and body corporates, associations or organizations – not incorporated or registered in India; or incorporated or registered in India but having any non-Indian participation in its share capital or management.

Recognising that the Indian citizens owe allegiance to the Indian Constitution and can be called upon in person to the courts to ensure compliance to this Act's provisions, a practical differentiating way has been adopted under which the applicants of the second category are required to obtain prior approval of 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 read with Section 19). They 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. This provision is thus differentiating for the specified purpose but it is not discriminatory since non-resident Indians are also included in this category.

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 and adhering to its directives.

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:

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

Protection of Traditional Knowledge Associated with Bioresources

The subject of protection of knowledge, practices and innovations of local people and communities is quite complex. The informal knowledge available with people presents following difficulties in being recognised for purposes of IPR:

- "Community" as such is not a legal entity.
- Knowledge is quite often in parallel held by individual organisations, groups of people, communities.
- The conditions of novelty and innovative step, necessary for granting of patent, are not satisfied in case of traditional knowledge.

Considering these complex nuances, an enabling provision for protection of traditional knowledge has been made under this legislation. The modalities for protecting indigenous knowledge are still emerging and evolving and therefore the measures for doing so have been left open and flexible under this provision. It provides for inter alia registration of knowledge, and for developing sui generis system for protecting traditional knowledge.

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.

Links to the Protection of Plant Varieties & Farmers' Rights Act and the Patents Act

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 knowledge) obtained from India, is required to obtain prior permission of the NBA [Section 6].

There is no overlap between BDA and the Plant Varieties Protection (PVP) & Farmers' Rights Act and the scope and objectives of these two legislations are different. The PVP legislation accords intellectual property rights to a person for developing a new plant variety. On the other hand, the biodiversity legislation is primarily aimed at regulating access to biological resources and associated knowledge so as to ensure equitable sharing of benefits arising from their use. In order to harmonise both the legislations, an exemption has been provided under Section 6(3) of the Biodiversity Act for applicants seeking protection of varieties under the PVP Act. The intention of Section 6(3) is to ensure that before granting of the IPRs under PVP or the Patents Acts, NBA gets an opportunity to realize equitable sharing of benefits arising out of the use of biological resources and knowledge. As the PVP legislation also has a provision for benefit sharing, an exemption has been provided in the Biodiversity Act for applicants seeking protection under the PVP Act. The Authority under the PVP legislation would be required to endorse a copy of the right granted under this Act to the NBA.

Likewise, 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 repository institution.

Realizing Fair and Equitable Benefit Sharing under the Biological Diversity Act

A schematic diagram is presented in Annex 1 showing how applications submitted to the NBA for grant of access are processed. While showing the mechanism, it also indicates the role played by the Expert Committee on ABS. 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 by the Expert Committee on ABS and followed while making recommendations regarding benefit sharing on a case-by-case basis (Annex 2).

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. Terms and conditions for benefit sharing are finally entered in to the agreement when mutually agreed between the NBA and the Applicant.

Procedure for Applying to NBA for Access to Bioresources

Four kinds of applications forms have been prescribed and fee for each of these categories have been specified. These may be downloaded from NBA's website. Relevant information on these Application Forms and fees is presented in Table 1.

Applying terms for benefit sharing on a case by case basis notwithstanding, a generalized and indicative scheme for sharing monetary benefits, arising from commercialization of innovations/processes/Products based on the use of bioresources, and associated TK, is given below for guidance purpose only (Table 2).

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:

- 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.

Table 1. 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/TK by foreigners/ Commercial Use, Bio-survey/ Bio-utilization.	Rs. 10,000/-
Form II [Section 4, Rule 17].	Transfer of Research Results/ Data.	Rs. 5,000/-
Form III [Section 6, Rule 18].	Seeking IPR	Rs. 500/-
Form IV [Section 20, Rule 19].	Third Party Transfer of Bioresources	Rs. 10,000/-

Table 2. Benefit Sharing Terms for IPR and Commercialisation of the Product

Commercial Use Category	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 5% 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 as a commodity under DGFT permit.	The Applicant shall pay 5% of the total FOB value of the bioresource under export to the Authority.	----------

National Biodiversity Authority

In exercise of the powers conferred by Sub-Section (1) (4) of Section 8 of the Biological Diversity Act, 2002, NBA was established by Government of India in October, 2003 at Chennai, Tamil Nadu under the Section 8 of the Act for pursuing the implementation of the Biological Diversity Act, 2002 at the national level. It consists of a Chairperson, 10 Ex-officio and 5 Non-official members. 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.

NBA has been charged with the overall responsibility of implementing this legislation in partnership with the State Biodiversity Boards and the Biodiversity Management Committees at the grass root level. The provision of mandatory consultation of BMCs by the NBA and SBBs would ensure formalisation of PIC by the communities and the involvement of BMCs in the decision making process.

It is noteworthy that NBA has been assigned three major functions merged together. It is expected to act as the regulator for enforcing the law's provisions under sections 3, 4, 6 and 20. It also has the responsibility to develop and issue guidelines for facilitating access to biological resources and for fair and equitable benefit sharing under Section 21. Its advisory role includes advising the Central Government on matters relating to conservation of biodiversity, sustainable use of its components and

equitable sharing of the benefits arising out of the utilization of biological resources, and associated TK. It is also expected to advise the State Governments towards the selection of areas of biodiversity importance to be notified as heritage sites and the measures for their management. Viewed from this perspective, some situations may arise requiring adjustments in balancing these roles within the provisions of the Biological Diversity Act and the Rules framed under it.

NBA's role is truly challenging as it acts as the regulator and also the promoter of conservation and sustainable use of bioresources in addition to acting as the advisor to the Central and State governments on matters related to biodiversity.

IV. 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 26 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 and making recommendations for their approval or otherwise.
- 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 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 benefit claimers 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 genetic 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'.

BOX 1

Legal Framework for Regulating ABS in India

It comprises a three tiered structure at the national, state and local levels with distinct roles, supportive of each other.

National Biodiversity Authority (NBA): All matters relating to requests for access by foreign individuals, institutions or companies, and all matters relating to transfer of results of research to any foreigner are dealt with by the National Biodiversity Authority.

State Biodiversity Boards (SBB): All matters relating to access by Indians for commercial purposes are under the purview of the State Biodiversity Boards (SBB). The Indian industry is required to provide prior intimation to the concerned SBB about the use of biological resource. The State Board has the power to restrict any such activity, which violates the objectives of conservation, sustainable use and equitable sharing of benefits.

Biodiversity Management Committees (BMCs): Institutions of local self government are required to set up Biodiversity Management Committees in their respective areas for conservation, sustainable use, documentation of biodiversity and chronicling of traditional knowledge relating to biodiversity. SBBs are expected to take decisions in consultation with BMCs where appropriate. NBA and SBBs are required to consult the concerned BMCs on matters related to use of biological resources and associated knowledge within their jurisdiction.

- There is no overlap in the functions of NBA and SBBs. Their domains and functions are very distinct from each other. All matters relating to requests by foreign individuals, companies or institutions and all matters relating to transfer of results of research to any foreigner, are dealt with by NBA. All matters relating to access by Indians for commercial purposes are under the purview of the concerned State Biodiversity Boards. Approvals prior to applying for IPR over innovations, based on the use of bioresources and associated TK, are also accorded by NBA.

V. Some Notable Accomplishments

1. Regular Meetings of the NBA held

The NBA has held 21 meetings so far and their proceedings are available on its website to ensure transparency and also to provide an opportunity to all the stakeholders for their inputs. Several consultations have also been organized at the national level to promote implementation of the BDA and developing guidelines for dealing with traditional knowledge associated with bioresources,

2. Progress in constituting and operationalising the SBBs and BMCs

To establish and effectively operate a 3-tier system presents a great challenge in managing skills. With the constitution of SBBs in 26 states and over 4,000 BMCs in these states until October 2011 (Table 3), the NBA is challenged with supporting these entities with adequate policy and regulatory guidance, provision of much needed tools, methods and guidelines to translate the provisions under the Act, especially those related to ABS provisions, into practice so that such activities can promote better realization of provisions of the Act with respect to ABS issues. Inadequate information on biodiversity and their potential for use, its economic value and potential, tools and guidelines on different provisions under the Act, limited capacities with the implementation structures and awareness about ABS provisions under the Act, are key challenges before the NBA, and also the MoEF. Moreover, the ABS provisions are yet to have an on-ground impact largely due to lack of national guidelines available for ABS, capacities to implement the provisions under the Act and awareness on how to use the Act for the benefit of supporting conservation, sustainable use and sharing the benefits equitably. Efforts are underway to get the SBBs constituted in the remaining states of Bihar and Jammu & Kashmir.

3. NBA-SBBs Interface Workshops

Interactive meetings between the Authority members and SBBs are being regularly organized providing an opportunity to review the progress made in implementing provisions of the Act and also to discuss ways and means of overcoming difficulties faced in this process. Sixth National Meet in this series was held at Chandigarh in September, 2010.

4. Capacity Building at the State Level

NBA is trying to strengthen capacity of SBBs at various levels by utilizing the opportunity provided by fund support under the India-UNDP/GEF/UNEP (Biodiversity) Programme. Two projects are under implementation at present and these are briefly described below:

Table 3. Setting up Biodiversity Management Committees

S. No.	State	No. of BMCs
1.	Andhra Pradesh	35
2.	Goa	5
3.	Gujarat	11
4.	Himachal Pradesh	2
5.	Karnataka	3,592
6.	Kerala	200
7.	Madhya Pradesh	50 district Panchayats, 313 Janpad Panchayats, 23043 Gram Panchayats, 237 Nagar Panchayats, 14 Nagar Nigams, 86 Nagar Palikas, 3969 Gram Sabhas (in progress)$^{+}$
8.	Manipur	15
9.	Mizoram	234
10.	Nagaland	10
11.	Punjab	51
12.	Tamil Nadu	1
13.	Tripura	13
14.	Uttar Pradesh	1
15.	Uttarakhand	37
16.	West Bengal	33
	Total	4,240 +

A 3-year project (2009–2012), under Small Grants Programme, is being implemented on strengthening institutional structures for implementing the Biological Diversity Act in Jharkhand and Madhya Pradesh states with the broad objective of capacity building at various levels and bringing in behavioral changes to manage natural resources in an integrated, participatory and sustainable manner. Owing to the close link between the Biological Diversity Act 2002, National Environmental Policy 2006, Schedule Tribes and other Traditional Dwellers (Recognition of Forest Rights) Act 2006, National Biodiversity Action Plan 2008 and India's Fourth National Report to the CBD, inclusion of natural resource dependent tribal and marginalized population, particularly women, in the planning and decision making process is one of the critical and vital elements of the strategy. This intervention has a focus mainly in Jharkhand and Madhya Pradesh states known for their rich biodiversity. The project will help to address the challenges in implementation of the Biological Diversity Act by strengthening the SBBs and BMCs through capacity building, public awareness activities, developing databases and their networking. The initiative in the two states is on the pattern of a pilot project that will function as a template in strengthening the other SBBs in India.

This has been followed by a 4-year Full Scale Project

(2011-2014), with fund provision of USD 6,278,000, on capacity building in 5 more states for strengthening the implementation of the Biological Diversity Act & Biological Diversity Rules, with a focus on Access & Benefit Sharing Provisions, in Andhra Pradesh, Gujarat, Himachal Pradesh, Sikkim and West Bengal.

One 3-year project (2010 -2013, funded by the World Bank, is also being implemented by the MoEF and ICAR on National Agriculture Innovations, with a strong component on biodiversity and livelihoods, in three economically backward districts in Himachal Pradesh, Rajasthan and Andhra Pradesh.

5. *Expanded Role of the Expert Committee on Access and Benefit Sharing*

NBA was established in October, 2003 but the decision for constituting the Expert Committee, on scrutinizing applications received by the NBA for granting approval and making its recommendations, was taken by the 4th meeting of the Authority held on 6 October, 2005. To begin with, two expert committees were set up; one dealing with applications received for access on a case by case basis and the other on recommending the terms for benefit sharing in each case recommended for approval. On gaining some experience, these two committees were merged into one committee in 2009 and named as the Expert Committee on Access and Benefit Sharing. This expert committee has 22 members at present, representing different areas of specializations. Two member secretaries of SBBs have also been made members to gain experience and participate in decision making. Five more member secretaries of different SBBS are also invited to attend meetings of the EC on a rotational basis. This Committee, treated by the NBA as a Standing Committee, has evolved over the years by gaining from its experience and has now become a strong institutional mechanism for implementing the benefit sharing provisions of the Biological Diversity Act and the Rules framed under it. On recommendations of this Committee, 359 applications have been granted approval by the Authority and 93 agreements on benefit sharing on mutually agreed terms have been signed so far (Table 4).

6. *Documenting Biodiversity in People's Biodiversity Registers (PBR)*

Documenting bioresources, and associated traditional knowledge, is among the responsibilities assigned to the BMCs. Model format and guidelines for preparation of such registers have been developed and uploaded on the Authority's website. Workshops are being organized to assist BMCs in this effort and 932 PBRs have been documented so far under different SBBs (Table 5).

Table 4. Status of Applications as on 13.10.2011

Category of Forms	Received	Cleared	Under Process	Closed	Agreements Signed
Form I	101	27	52	22	16
Form II	35	14	21	0	11
Form III	458	298	143	17	50
Form IV	50	20	25	5	16
Incomplete	13	0	0	13	0
Total	657	359	241	57	93

7. *Designation of Repositories under the BDA*

In exercise of the powers conferred by Section 39(1) of the Biological Diversity Act, 2002, the Ministry of Environment & Forests designated 13 institutions to act as repositories for different categories of biological resources (Table 6). These designated repositories shall also keep in safe custody the representative samples, as voucher specimens of the biological material accessed in accordance with the provisions of Section 19 (Persons other than Indian citizens accessing any bioresource or any person seeking IPR on innovation based on the use of bioresources and associated TK.

8. *Normally Traded Commodities Notified*

Under Section 40, bioresources normally traded as commodities are exempted from provisions of this Act. As per the notification issued by the Union Ministry of Environment & Forests on 26 October, 2009 and subject to the subsequent clarification issued on 16 February, 2010, 190 bioresources (species) have been designated as normally traded commodities and so exempted. This list, however, remains contested and it is likely to be revised considering that some known threatened species happen to be included in it.

9. *Commercial Use of Medicinal Plants by Herbal Industry*

Global demand for herbal products in recent years

Table 5. Preparation of People's Biodiversity Registers

S. No.	State	No. of PBRs Documented
1.	Andhra Pradesh	5
2.	Karnataka	212
3.	Kerala	74
4.	Madhya Pradesh	480
5.	Uttarakhand	139
6.	West Bengal	17
7.	Manipur	2
8.	Jharkhand	3
	Total	932

Table 6. Repositories designated under the BDA

S. No.	Name of the Institution	Category of Bioresources
1	Botanical Survey of India, Kolkata	Flora (Angiosperms, Gymnosperms, Pteridophytes, Bryophytes, Lichens, Macrofungi, Macroalgae)
2	National Bureau of Plant Genetic Resources, New Delhi	Plant genetic resources
3	National Botanical Research Institute, Lucknow	Flora (Angiosperms, Gymnosperms, Pteridophytes, Bryophytes, Lichens, Macrofungi, Macroalgae)
4	Indian Council of Forestry Research and Education, Dehradun (Forest Research Institute, Dehradun; Institute of Forest Genetics and Tree Breeding, Coimbatore; and Tropical Forest Research Institute, Jabalpur)	Flora (Angiosperms, Gymnosperms, Pteridophytes, Bryophytes, Lichens, Macrofungi, Macroalgae). For TFRI only: Fauna (Termites, butterflies, moths)
5	Zoological Survey of India, Kolkata	Fauna
6	National Bureau of Animal Genetic Resources, Karnal	Genetic resources of domestic animals
7	National Bureau of Fish Genetic Resources, Lucknow	Fish genetic resources
8	National Institute of Oceanography, Goa	Marine flora and fauna
9	Wildlife Institute of India, Dehradun	Faunal resources in Protected Areas
10	National Bureau of Agriculturally Important Microorganisms, Mau Nath Bhanjan	Agriculturally important microorganisms
11	Institute of Microbial Technology, Chandigarh	Microorganisms
12	National Institute of Virology, Pune	Viruses
13	Indian Agricultural Research Institute, New Delhi	Microbes/ Fungi

has experienced a quantum jump in volume of plant material traded within and outside the countries of origin. International market of medicinal plants has been estimated at US$ 60 billion per year, growing at a rate of 7% annually. India is one of the richest countries in the world as regards genetic resources of medicinal and aromatic plants. Medicinal plants, as a group, comprise about 8,000 species and account for nearly half of all the higher flowering plant species documented in India. Even though over 105 plants provide the basic raw materials used in modern medicine the world over, the number of plants used on a sizeable scale is just around 40 in India. Furthermore, marketing of raw herbal drugs is highly unorganized and unregulated, often without any premium on quality (Robinson, 2010).

About 90% of the medicinal plants, used by herbal industry in India, are collected from the wild source and more than half of these collections involve destructive harvesting. As a result of such exploitative practices combined with excessive collections, many important medicinal plants are becoming endangered or threatened. NBA is currently engaged in consultation with the Ayurvedic Drug Manufacturers Association and several other major players to address this problem with a view to promoting sustainable use practices and registration of bulk users of herbal materials for healthcare, cosmetics and food supplements.

Draft guidelines for commercial use of India's natural and biological resources and traditional knowledge, developed by NBA, is facing opposition from some industries that deal in products such as herbal drugs, cosmetics and nutritional supplements (Unnikrishnan, 2010). NBA's EC-ABS has constituted a sub-committee to critically review the draft guidelines and suggest improvements for developing recommendations for further consideration of the NBA.

VI. An Overview of the Implementation and also Some Concerns

1. Ownership Rights/Sovereign Rights and the Primary Beneficiaries

Habitats/ Ecosystems	Ownership Rights and Beneficiaries
Natural bioresources in protected areas (PA) network	Sovereign rights acknowledged to the State (Government of India). Monetary benefits expected to be flowing to the claimants and beneficiaries through the channel of Biodiversity Fund at the national, state and BMC levels.
Natural bioresources outside the PAs (Forest Areas)	Tribal communities and Forest Dwellers' Rights granted over their lands and also for collection of NTFP.
Agricultural/ Cultivated bioresources	Farmers and Farming Families
Communities' common lands	Local Communities

2. Three Major Functions of the NBA

A. NBA Functioning as the Regulator

S. No.	Concerns	Remarks
i.	Enforcement of the provisions under sections 3, 4 and 6.	Procedures and guidelines for this purpose need to be laid down to ensure clarity and transparency.
ii.	Enforcement of the Act's provisions with an effective system for reporting for violations and follow up actions.	There is need for a separate wing having trained cadres for enforcement of legal provisions and reporting of violations. Example of enforcement under Wildlife Act, 1972: Case of Petr Svacha and Emil Kucera, Czech entomologists, caught collecting butterflies in Darjeeling area in 2008 and sentenced by the court (Mitra, 2008). Svacha paid his fine but Kucera jumped bail and sneaked out of India.
iii.	Capacity at the national level with adequate support base at the state and local levels.	The NBA is expected to be centre of excellence on all matters dealing with biodiversity, including scientific, policy matters and legal affairs. Biodiversity databases need to be developed at both the national and state levels with an efficient networking system.
iv.	Constitution, strengthening and functioning SBBs	Many SBBs have part-time non-technical chairmen. Member-secretaries are on mostly on deputation and get transferred frequently. There is need for adequate infra-structure and technical staff at this level.
v.	NBA as an autonomous national organization.	There is need to strengthen the organization with sufficient funding allocations made under the 12th Plan. More project-based funding needs to be encouraged.
vi.	Inspecting capacity at the exit points [Custom Department]	There is an urgent need for preparation of working manuals and organizing proper training for the custom officials manning the exit points.
vii.	Effective regulation and monitoring of bulk use by the herbal and other user industries.	It is important to bring the major pharmaceuticals and herbal drug manufacturers in the fold through proper monitoring mechanism. The bulk users need to declare quantity/location and timing of collections to promote sustainable use.
viii.	Conservation of threatened species.	Section 38 provides for notifying threatened species and prohibits or regulates their collection while also taking appropriate steps to rehabilitate and preserve those species. National database on threatened species needs to be developed on priority, enabling the NBA to develop suitable management plans. Some states have already notified their lists of threatened species and the rest should be encouraged to do so at the earliest.
ix.	Designated Repositories under the Act.	Thirteen institutions have been designated as repositories for different categories of biological resources but no guidelines for their roles have been notified as yet. There is also no follow up and monitoring. There is also a glaring gap since no internationally recognized repository has been designated for microorganisms, which is a requirement for the patent system.
x.	Notification of normally traded commodities	A list of 190 species (bioresources) has been notified but inclusion of several threatened species has been protested. The list needs an early revision.
xi.	Restrictions on granting access by SBBs under Section 24 read with Rule 6.	There is need for the NBA to take a lead by developing and notifying suitable guidelines to assist the SBBs and also organize training workshops for capacity building.
xii.	Monitoring of implementing the benefit sharing terms.	The agreement signed by the applicant with the NBA contains mutually agreed terms for benefit sharing. Applicant is required to submit reports on an yearly basis along with supportive documents but proper mechanism of monitoring need to be developed for follow up action.
xiii.	Protection of traditional knowledge associated with bioresources.	National consultations notwithstanding, this remains the weak link. It is a complex and highly debated topic and deserves high priority to move forward.

B. NBA Functioning as the Promoter

Concerns		Remarks
i.	Conservation of bioresources	National Biodiversity Action Plan has indicated broadly some activities that should be undertaken by the NBA. This needs to be followed up by developing a suitable work-plan that may be linked up to the projects that are being implemented by the NBA in several states, focusing on *in-situ* on-farm conservation and related activities with the involvement of self-help groups and local NGOs.
ii.	Sustainable use of bioresources	NBA has not yet been able to notify the much awaited guidelines for this purpose with the result that exploitative practices, combined with excessive collections, are continuing putting a large number of species at risk, particularly the medicinal and aromatic plants. NBA is currently engaged in consultation with the bulk users, like the Ayurvedic Drug Manufacturers Association, and several other major players to address this problem with a view to promoting sustainable use practices. To begin with, bulk users, particularly in herbal healthcare and food supplements sector, are being encouraged to provide information on the quantities, location, source and timing of collections, and also to register themselves with the concerned SBBs. Even when such information is declared, there is no effective monitoring of such extractions from the wild populations. Voluntary checks do not seem to be working and there is need to develop and enforce and effective system with proper checks an balances.
iii.	Fair & equitable sharing of profits arising from the use of bioresources	This is the most critical element in implementing the provisions on ABS but the expected guidelines to deal with this topic, at the national as well as state levels, have not been notified as yet. This needs to be done without further delay. It is, however, commendable that the Expert Committee has developed a working module for this purpose (Annex-2) and this may be used after suitable refinements where required.
iv.	National Biodiversity Fund (Section 27)	All charges and royalties received by the NBA, and also the grants, are to be credited to this Fund which shall be applied for: – Channeling benefits to the benefit claimers; – Conservation and promotion of biological resources and development of areas from where such bio-resources or knowledge associated thereto have been accessed; – Socio-economic development of areas referred to above in consultation with the local bodies concerned. About Rs.50 lakhs have been received in this Fund so far and there is an urgent need to notify the guidelines for channeling this amount. An Expert Committee has been constituted for this purpose and this process needs to be completed at the earliest.
v.	Responding to Stakeholders' grievances	On receiving inputs from some stakeholders about the difficulties that they were facing because of their reservations regarding some items contained in the formats of different categories of agreements, the NBA promptly constituted an Expert Committee for this purpose and formats of all the four kinds of agreements were suitably revised.
vi.	Partnerships with major sectors	The NBA continues to hold consultations with major stakeholders including the seed industry and the herbal healthcare sector to promote sustainable utilization of bioresources and greater generation of benefits for sharing with the beneficiaries. More active partnerships with major sectors need to be developed.
vii.	Institutional support	Need to identify and involve leading institutions, particularly at the local level, and also the local NGOs to assist the BMCs.
viii.	Promoting research on key issues and engage consultants.	NBA is required to commission studies and engage consultants to assist the Authority in the effective discharge of its functions.
viii.	Creating awareness and promoting people's participation.	Much more effort is required in this direction with proper planning, funding support and media coverage.

C. NBA functioning as the Advisor to the Central and State Governments

S. No.	Concerns	Remarks
i.	Meeting the national obligations under CBD.	NBA is required to advise the Central Government on any matter concerning conservation of biodiversity, sustainable use of its components and promoting fair and equitable sharing of benefits arising out of the use of biological resources and associated traditional knowledge. There is need to further develop the National Biodiversity Action Plan and ensure its implementation by the concerned departments/ institutions and organizations.
ii.	Extending support to SBBs.	NBA is expected to provide technical assistance and guidance to SBBs, coordinate their activities and sanction grants-in-aid to SBBs and BMCs.
iii.	Respect and protect the knowledge of local people relating to biological resources.	NBA to develop suitable recommendations for this purpose, including measures which may include registration of such knowledge at the local, state or national levels and legal protection through *sui generis* system.
iv.	Planning and organizing suitable training/ capacity building programmes.	NBA is expected to plan and organize training of personnel engaged or likely to be engaged in programmes for the conservation of biodiversity and sustainable use of its components.
v.	IPR protection of India's bioresources and associated TK in other countries.	NBA to take necessary measures, including appointment of legal experts to oppose grant of IPR in any country outside India on any biological resource and associated knowledge obtained from India in an illegal manner.

To sum up, the 3-tier structure for implementing the Biological Diversity Act, and the Rules framed under it, poses formidable challenges but also offer great opportunities to work in partnership for promoting conservation and sustainable use of biological resources linked to fair and equitable sharing of benefits arising from their utilization. There are more than six major union ministries who exercise authority on different components of biodiversity and decisions have to be taken on evolving consensus on a case by case basis. The central and state governments are also required to work in unison even when their priorities often differ. The required infrastructure and capacity are still inadequate, particularly at the states' and grass root levels where conservation and sustainable use practices need to be strengthened and where primary beneficiaries of the benefit sharing mechanism are striving to earn their livelihoods, often based primarily on bioresources around them. This situation led to a slow tempo of implementation but the pace has picked up in recent years. Notification of guidelines on ABS and several other basic components of the implementation plan need to be issued on priority to assist the SBBs, BMCs and users of bioresources. It is equally important to keep simplifying the procedures for granting access to bioresources and to address the common grievances of the users. It may be desirable to make some policy adjustments to permit sector-wise approach to suit requirements of bulk users in sectors like herbal pharmaceuticals, cosmetics, food supplements and seeds among many others. Even when the delegation of regulatory function to some other central government departments (like the ICAR/DARE for agricultural biodiversity) may not be considered feasible until some minimum conditions are met, developing selective partnerships may be helpful in promoting implementation of the provisions on access and benefit sharing.

VII. The Way Ahead

The National Biodiversity Authority, constituted under India's national legislation on regulating access to bioresources, and the associated traditional knowledge, has been charged with the responsibility of implementing this legislation in partnership with the State Biodiversity Boards and the Biodiversity Management Committees at the grass-root level. It has been assigned three major functions merged together. It is expected to act as the regulator for enforcing the law's provisions under sections 3, 4, 6 and 20. It also has the responsibility to act as the promoter for creating public awareness and also developing and issuing guidelines for facilitating access to biological and for fair and equitable benefit sharing under section 21. It also has an advisory role that includes advising the Central Government on matters relating to conservation of biodiversity, sustainable use of its components and equitable sharing of the benefits arising out of the utilization of biological resources, and associated TK. It is also expected to advise the State Governments towards the selection of areas of biodiversity importance to be notified as heritage sites and the measures for their management. Thus, NBA's role is truly challenging as it acts as the regulator and also the promoter as well as the advisor. Viewed from this perspective, some situations may arise requiring adjustments in balancing these roles

within the provisions of the Biological Diversity Act and the Rules framed under it. For example, preference may be accorded to creating awareness rather than going for enforcing punitive measures.

It needs to be appreciated that India's CBD-compliant sui generis national legislation has a judicious mix of commendable provisions that link up conservation and sustainable use of bioresources with fair and equitable sharing of benefits arising from their authorized use. Notwithstanding some infirmities, it was expected to strengthen, realign and converge its on-going programmes to meet national obligations under CBD based on an all-inclusive and vibrant system (Rana, 2004; Bala Ravi, 2006; Rana, 2010). The pace of its implementation has picked up in recent years but its effectiveness is still considered very low. The major factor responsible for this below expectation performance appears to be the lack of adequate awareness about its provisions, not only among the general public but also among the policy makers and managers alike, more particularly those concerned with access and benefit sharing. This limitation is further compounded by poor infrastructure and little capacity building at the grass-root level. Institutional support is mostly missing at the local level, affecting adversely the scientific content of crucial conservation activities. On the positive side, SBBs have been constituted in 26 of the 28 states and they are being increasingly involved in decision making by the NBA, even though the much needed guidelines on ABS have not yet been notified. It is now the turn of the BMCs to be empowered to play an active role in this process. The Expert Committee on ABS has also evolved over time into a capable institution, streamlining its procedures and operations.

There is also an urgent need for developing partnerships with the lead institutions, and also the private sector, in conserving, sustainable use and managing bioresources based on suitable terms of scientific cooperation and principle of reciprocity (Rana, 2010).

Promoting sustainable use practices deserve more attention and high priority, particularly by the herbal healthcare, cosmetics and food supplements sector (Ved and Goraya, 2008). It is widely known that around 90% of the medicinal plants, used by herbal industry in India, are collected from the wild source and more than half of these collections involve destructive harvesting. As a result of such exploitative practices combined with excessive collections, many important medicinal plants are becoming endangered or threatened. NBA is currently engaged in consultation with the Ayurvedic Drug Manufacturers Association and several other major players to address this problem with a view to promoting sustainable use practices and registration of bulk users of herbal materials (Brindavanam and Agarwal, 2010).

The ICAR/DARE also needs to develop and finalise its own policy and guidelines on access to and exchange of plant genetic resources, in consultation with the NBA, to meet national obligations under the ITPGRFA and bilateral agreements.

Adoption of Nagoya Protocol to CBD on Access and Benefit Sharing during the COP-10 meeting last year is a positive development 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 fair and equitable sharing of benefits, while also 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. With the adoption of this 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 even though the realization of benefit sharing is linked basically to provisions of national legislation and regulatory mechanisms adopted by countries providing the bioresources. However, this lead needs to be developed further through pro-active negotiations under CBD (Schei and Tvedt, 2010).

The United Nations has declared 2010-2020 as the Decade of Biodiversity and COP-11 meeting of the Parties to CBD will be held in Hyderabad in October, 2012. With India ascending to the presidency of the CBD for the period 2012-2014, there will be vast opportunities ahead for playing significant lead role towards promoting equitable and fair sharing of benefits arising from the use of biological resources, even in the face of growing trend toward protecting/ patenting of improved crop varieties and elite genetic stocks. The 2010 Nagoya Protocol on ABS, expected to enter in to force by the next year, is likely to pave the way for rapid progress in this direction (WFC, 2010, Glowka, 2011; Morgera and Tsioumani, 2011; Nair, 2011). With these positive developments, it may well be that disagreeing provisions under the WTO-

TRIPS and CBD may also get reconciled and provide synergy in implementation of these important international agreements on trade and environment (Nair, 2011; Johnson, 2011; Winter 2011, Glowka 2011).

References

Bala Ravi S (2006) Infirmities and inconsistencies of Indian legislation on access and benefit sharing. *Curr. Sci.* **90:** 15-19.

Berglund M (2005) The protection of traditional knowledge related to genetic resources: The case for a modified patent application procedure. http://www.law.ed.ac.uk/ahrc/script-ed/vol2-2/TK.asp.

Brindavanam NB and RK Agarwal (2010) Partnership in implementing the Biological Diversity Act. Presentation to the 13th meeting of the NBA-Expert Committee, held in Chennai on 17-18 May, 2010, Ayurvedic Drugs Manufacturers Association, Mumbai.

Carrizosa S, SB Brush, D Brian, BD Wright and NcGuire PE, Eds. (2004) Accessing Biodiversity and Sharing the Benefits: Lessons from Implementing the Convention on Biological Diversity. IUCN Environmental Policy and Law Paper No. 54. IUCN, Gland, Switzerland.

Chaudhury SK (2003) Microbial piracy in India: How to fight back? *J. Intellectual Property Rights* **8:** 389-399.

CBD Secretariat (2002) Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization. SCBD, Montreal.

Dewar D (2010) Seed Industry Applauds Adoption of International Treaties. Crop Life International. Seed World, Nov. 2010. Grand Forks, ND 58201, USA.

Dutfield G (2000) Intellectual Property Rights, Trade and Biodiversity, Seeds and Plant Varieties. Earthscan Publications, London.

Engels, JMM, H Dempewolf and V Henson-Apollonio (2010) Ethical Considerations in Agrobiodiversity Research, Collecting and Use. Springer Netherlands and Bioversity Library, Rome.

FAO (2010) Access to Plant Genetic Resources, the Sharing of Benefits, arising out of their Utilization and the Realization of Farmers' Rights. Chapter 7: State of the World's Plant Genetic Resources for Food and Agriculture: The Second Report. FAO, Rome. 2010.

Feit U M von den Driesch and Lobin W (Eds.) (2005) Access and Benefit Sharing of Genetic Resources. Report of an International Workshop held in Bonn (Germany) on 8-10 November, 2005.

Gepts, P (2006) Plant Genetic Resources and Utilization: The Accomplishments and Future of a Societal Insurance policy. *Crop Sci.* **46:** 2278-2292.

Glowka L (2011) The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization. CBD Secretariat, Montreal.

Gokhale Y (2011) Access and Benefit Sharing in Indian Context: A Developing Country Perspective. TERI Special Paper Series, 2011.

Johnson R (2011) Bridging the Gap Between the Biodiversity Convention and TRIPs: A New Way to Approach Technological Innovation and Economic Development. *Gonzaga J. Internatl. Law* **14:** 1-29.

Kamau EC and Winter G (2009) Genetic resources, traditional knowledge and the law: Solutions for access and benefit sharing. Earthscan, London. 494p.

Ministry of Environment & Forests (2011) Approval for signing of the Nagoya Protocol on Access and Benefit Sharing. PIB, GOI, MoEF, New Delhi, 20 April 2011.

Mitra P (2008) Czech butterfly smuggler helped by embassy to flee India. The Times of India, Oct 30, 2008.

Morgera E and E Tsioumani (2011) Yesterday, today and tomorrow: looking afresh at the Convention on Biological Diversity. In: 21 Yearbook of International Law, Edinburgh School of Law, University of Edinburgh, UK.

Nair MD (2011) GATT, TRIPS and CBD – Relevance to agriculture. *J. Intellectual Property Rights* **16:** 176-182.

Nature-on-line (2008) Court fines entomologists for illegal collecting in India. *Nature* **455:** 276. 17 September, 2008.

Oli KP and TD Dhakal (2009) Access and Benefit Sharing from Genetic Resources and Associated Traditional Knowledge. ICIMOD, Kathmandu.

Oliva MJ (2010) Nagoya Protocol on Access and Benefit Sharing -Technical Brief. Union for Ethical Bio Trade, Geneva, Switzerland. 2010.

Rana RS (2004) Emerging trends in managing and using rice genetic resources. *Asian Biotech. Dev. Review* **7:** 49-66.

Rana RS (2010) Regulating access to genetic resources and promoting benefits sharing in India. *Indian J. Plant Genet. Resour.* **23:** 253-264.

Rana RS and RK Arora (1990) Indian National Plant Genetic Resources System – An overview. Bioversity International Publications, Rome. Web-version/174/ch18.

Robinson DF (2010) Confronting Biopiracy: Challenges, Cases and International Debates, Earthscan, London.

Schei PJ and MW Tvedt (2010) 'Genetic resources' in the CBD: The wording, the Past. The Present and the Future. FNI Report 4/2010. Lysaker, FNI, 2010.

Suneetha MS and Pisupati B (2009) Benefit Sharing in ABS: Options and Elaborations. UNU-IAS, Yokohama, Japan.

Swiderska K (2006) Banishing the Pirates: A New Approach to protecting the Traditional Knowledge. IIED, London, UK.

Tvedt MW and T Young (2007) Beyond Access: Exploring Implementation of the Fair and Equitable Sharing Commitment in the CBD. IUCN, Gland, Switzerland.

Unnikrishnan CH (2010) Industry opposes draft guidelines for use of bio resources: Concern at ambiguity over centralized licensing system and valuation of revenue potential. Mint, e-Paper, Corporate News. Posted: Wed, Mar 3, 2010.

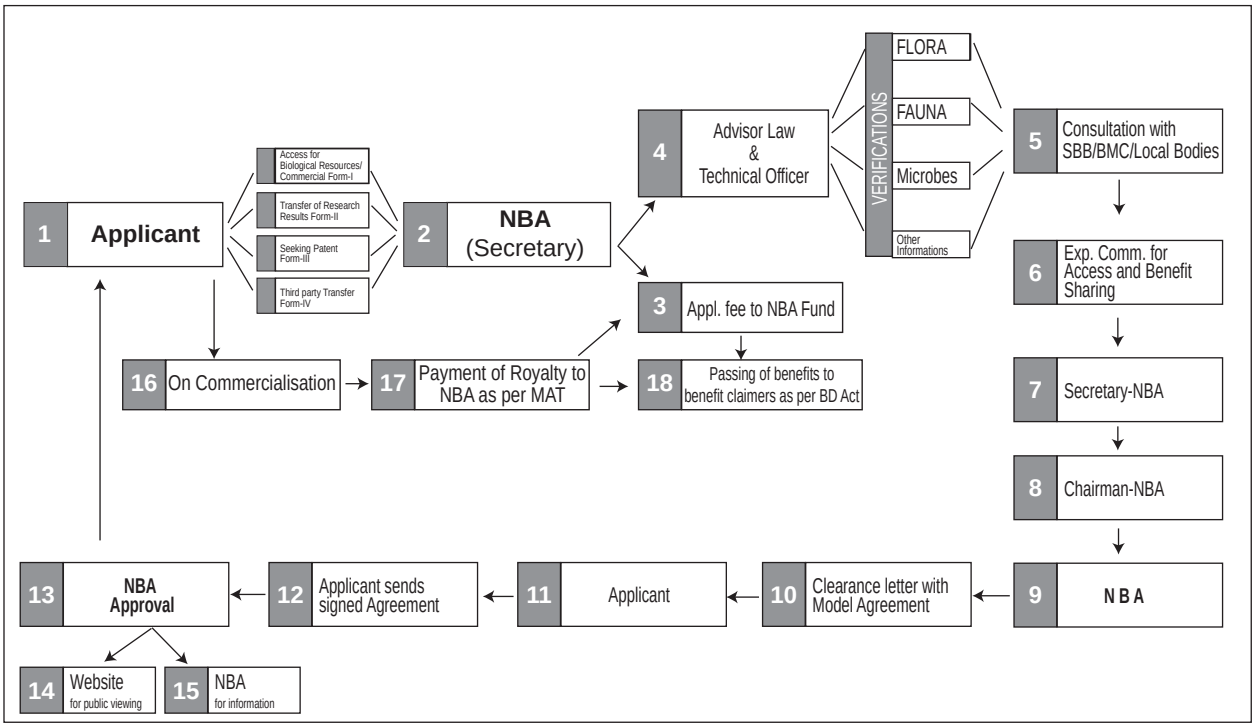
Ved DK and GS Goraya (2008) Demand and Supply of Medicinal Plants in India. Bishen Singh and Mahendra Pal Singh, Dehradun & FRLHT, Bangalore.

Winter G (2011) Access and benefit sharing for genetic resources: history, rationale, objectives and instruments. Multi-stakeholder Expert Dialogue on ABS for Genetic Resources for Food and Agriculture, Workshop, 25-26 January, 2011, Brussels.

World Future Council, CISDL (2010) Crafting future just biodiversity laws and policies. Paper Presented in the First Meeting of Intergovernmental Committee on the Nagoya Protocol, 9 June, 2011, Montreal, Canada.

ANNEX 1

Schematic Presentation of Processing of Applications under Biological Diversity Act, 2002 and Rules 2004



* For details please go through Biological Diversity Act, 2002 & Rules, 2004

Source: NBA

National Biodiversity Authority: Expert Committee on Access & Benefit Sharing

Access to Bioresources/TK in India for Research/ Bio-survey & Bio-utilization, Commercial Use, Transfer of Results of Research relating to Indian Bioresources, Seeking IPR on innovation based on Bioresource/TK, Third Party Transfer of the Accessed Bioresource or for Obtaining Bioresources for Export

An Indicative Template for Benefit Sharing under the Biological Diversity Act, 2002 (Actual terms are determined on a case-to-case basis)

Purpose of Access	Procedure for Applying and Terms for Benefit Sharing
Access for research: **For Indian citizens:**	Free access, guided by rules and regulations notified by NBA and SBBs. Applying for IPR, on any process/ product based on the accessed bioresource and associated traditional knowledge, shall require prior approval of NBA and entering into benefit sharing agreement.
For others:	Application in Form I is to be submitted to NBA along with payment of prescribed fee of Rs.10,000/- [Section 19, Rule 14]. Quantity of bioresource and its location, and also the objective, are to be specified. An agreement on benefit sharing, as provided under Section 21, is to be entered into with NBA. In case of bioresource of high economic value, upfront payment may be imposed by the NBA. Yearly reports on the progress of research /bio-survey & bio-utilization are also to be submitted to NBA. Applying for IPR, on any process/ product based on the accessed bioresource and associated traditional knowledge, shall require prior approval of NBA and entering into benefit sharing agreement.

B. Access for Commercial utilization/Bio-survey and Bio-utilization **For Indian citizens** **For others**	Free access, guided by rules and regulations notified by NBA and subject to prior intimation to the concerned SBB who may impose some conditions for such access. Quantity of bioresource and location are to be specified. Yearly reports on the progress of research are to be submitted. Applying for IPR, on any process/ product based on the accessed bioresource and associated traditional knowledge, shall require prior approval of the NBA. Application in Form I to be submitted to NBA along with payment of prescribed fee of Rs.10,000/- [Section,19, Rule 14]. Quantity of bioresource and location are to be specified. The Applicant shall pay an upfront amount as benefit sharing, to be decided on a case-to-case basis. An agreement is also to be signed by the applicant. Yearly reports on the progress of research are to be submitted. Applying for IPR, on any process/ product based on the accessed bioresource and associated traditional knowledge, shall require prior approval of NBA and entering into benefit sharing agreement.
C. Transfer of Results of Research relating to bioresources occurring in, or obtained from India, for monetary consideration to foreign nationals/companies and NRIs.	Application in Form II to be submitted along with payment of prescribed fee of Rs.5,000/-.[Section 19, Rule 17]. Transfer of data/ information only and not the bioresource. For persons/ companies, other than Indian citizens/ companies, evidence of authorized access to the bioresource shall be provided. Complete information on commercial value of the research results is also to be provided. Yearly reports on the progress of research are to be submitted to the NBA. Commercialisation of the transferred results of research to be done with the prior approval of NBA. Seeking of IPR shall also be on prior approval of NBA and on entering into benefit sharing agreement.
D. Seeking IPR over Innovation/ ProductBased on the Use of Indian Bioresources/TK **Options:** The Applicant commercialises the innovation/ product. **The Applicant assigns/ licenses the process/ product to a third party for commercialization.**	Application is to be made in Form III with fee payment of Rs.500/- Benefit sharing terms shall be decided on a case-to-case basis. Equitable benefit sharing may be done in monetary or non-monetary mode; options provided under Section 21 and Rule 20. Benefit sharing shall be in any of the options of non-monetary benefits, as provided under Section 21 read with Rule 20, on mutually agreed terms. OR Benefit sharing shall be in monetary form as stated below: The Applicant shall pay royalty @ 3% of the highest ex- factory sale price of the product sold or used for captive consumption. Regular reports on the progress of commercialization and sale of the product, along with verifiable documents, shall be submitted to the NBA with supportive documents by 30th April every year. In case the applicant assigns/ licenses the process/ product to a third party, the licensee, for commercialization, the applicant shall pay to NBA 5% of the license fee received by him from the licensee. The licensee shall also enter into a fresh agreement with NBA and agree to pay royalty @ 5% of the ex-factory sale price of the product sold, and also kept for captive consumption, annually throughout the term of the agreement.. Additional terms will be as follows: The applicant shall undertake to inform NBA within 90 days from the date the patent is granted. The applicant, if he is an Indian citizen, shall give prior information to the concerned SBB regarding the location and quantity of the bioresource to be accessed by him, and shall follow the benefit sharing terms and also the restrictions, if any. Imposed by the SBB (and BMC, where applicable) in the interest of promoting conservation and sustainable use. In case the applicant is covered under Section 3(2) of BDA, he shall apply to NBA for access to the required bioresource in Form I, with the prescribed fee. No further transfer of the license shall be permitted without prior approval of NBA.

E. Transfer of the already accessed bioresource to third party abroad for research purpose	Application to be made in Form IV with fee payment of Rs.10,000/-. [Section 20]. Specific purpose for third party transfer shall be stated in the application and adhered to [Rule 19]. Terms for benefit sharing shall be as follows: No product/ process, coming out of the proposed research project, shall be commercialized without entering into benefit sharing agreement with NBA. No IPR shall be applied on any product/ process coming out from the proposed research project without prior approval of NBA and without signing of agreement with NBA for sharing benefits. No further transfer of the bioresource shall be permitted without prior approval of the NBA (and entering into fresh agreement with NBA on benefit sharing terms). Reports on the progress and final outcome of the proposed research shall be submitted to NBA.
F. Indian citizens/ organizations/ companies seeking export of bioresource, obtained from India, for commercial purpose.	Application to be made to NBA in Form IV with payment of Rs.10,000/-. Prior approval of the concerned SBB/ BMC/ State Wildlife Board for export shall be required. Objective of exporting the bioresource shall be stated and adhered to. The Applicant shall pay royalty @ 5% of the total FOB value of the bio-resource under export as benefit sharing. This amount shall go to the concerned SBB for promoting conservation and development activities at the source location. The bioresource to be used for the specified purpose only. Applying for IPR, on any process/ product based on the accessed bioresource, shall require prior approval of NBA and entering into benefit sharing agreement.