

Implementing the Biological Diversity Act in India: Focus on ABS and Agro-biodiversity

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Conservation and sustainable use of biodiversity are age old traditions in India, as reflected in our ancient scriptures and the use of numerous indigenous plants in religious rituals, ceremonial offerings and local healthcare practices. The Biological Diversity Act, 2002 (BDA) provides an umbrella legal framework to affirm our commitments for this purpose. In addition, India is recognized as a mega-diverse country, in view of its spectacular biological diversity adapted to a wide range of environments available in its ten distinct eco-geographic zones. Equally significant is the fact that it has generously shared its biological resources in the past with other countries as reflected in the records of collections maintained in national genebanks of USA, Russia and Japan among others and also the international gene banks developed by the International Agricultural Research Centres under the CGIAR System.

Meeting National Obligations under International ABS Agreements

Legally binding international treaties, multilateral agreements and global conventions often function as international laws impacting upon policy and legal framework in countries that have ratified them. India was among the lead nations who joined and adhered to the voluntary International Undertaking on Plant Genetic Resources (PGR) established in 1983, facilitated by the FAO Commission on PGR and based on the principle that PGRs were the common heritage of mankind. This era was followed by aggressive seeking of intellectual property rights (IPR) over the products of research on genetic resources by the users of PGR in developed countries, appropriating all the resulting benefits to themselves and depriving the providers (owners) of those bioresources in developing countries. The legally binding Convention on Biological Diversity (CBD), adopted in June 1992, seeks to balance the rights of providers of genetic resources and their users (including the breeders and other researchers). More recently, the Nagoya Protocol on access to genetic resources and

benefit sharing (ABS), adopted in 2010, has further consolidated this global legal framework.

The 1992 Convention on Biological Diversity (CBD): The Turning Point

The CBD is the first commitment of humankind towards conservation of biological diversity, sustainable use of its components and promoting fair and equitable sharing of benefits arising from their utilization. It marked the end of the 'common heritage' concept of genetic resources by recognizing sovereign rights of States over their natural resources within their boundaries and accepting that the authority to determine access to genetic resources rests with the national governments subject to national legislation. This Treaty is nearly universal with 196 Contracting Parties, the United States being the only major country that has not yet ratified it.

Implementing CBD gained momentum soon after its entry into force in December 1993 as several nations passed legislation to claim sovereign rights over their bioresources and to implement CBD's provisions. For example, the Philippines established a system for access to biological resources by an executive order issued in 1995 and the Andean Community, in its Decision No. 391 taken in 1996, adopted a Common Regime on Access to Genetic Resources. India enacted the Biological Diversity Act in 2002 and framed Rules in 2004 for implementing it, with the Union Ministry of Environment, Forests & Climate Change as the nodal ministry.

The Trade Related Intellectual Property Rights, 1995, WTO

The TRIPS Agreement under WTO, which entered into force on 1 January 1995, is to date the most comprehensive multilateral agreement on IPRs. This treaty requires Member States to make patents available for any invention, whether product or process, in all fields of technology without discrimination, subject to the normal tests of novelty, inventiveness and industrial

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applicability. It has been provided further that the Members may exclude plants and animals (other than micro-organisms) and essential biological processes for the production of plants or animals (other than non-biological and microbiological processes). However, any country excluding plant varieties from patent protection must provide for an effective *sui generis* system of their protection. India has amended its Patents Act, 1970 to permit patenting of products (and also of micro-organisms) and also enacted the Protection of Plant Varieties and Farmers' Rights Act, 2001 to meet its national obligations. Union Ministry of Commerce & Industry is the nodal ministry for implementing this Treaty.

The International Treaty on Plant Genetic Resources for Food and Agriculture

Recognizing the interdependence of countries for crop genetic resources, the FAO revised the text of its 1983 IU on PGR to bring its provisions in harmony with those of CBD and then adopted it on 3 November, 2001 as the legally binding International Treaty. This Treaty presently covers designated accessions of 64 Annex-1 food and forage crops (which are in public domain and managed by the national governments) and upholds the Farmers' Rights subject to national legislation.

Unlike the bilateral system of agreements under CBD for accessing PGRs, this Treaty provides for a Multilateral System (MLS) of ABS to facilitate exchange of PGRs which are in public domain, covering initially only 35 food crops and 29 genera of forages. Union Ministry of Agriculture & Farmers Welfare is the nodal Ministry for implementing the ITPGRFA, assisted by the DARE and NBPGP. A notification has been issued exempting the exchange of designated accessions of genetic resources of crops listed in Annex-1 of the ITPGRFA from the provisions of Sections 3 and 4 of the BD Act for research, breeding and training purposes.

The Nagoya Protocol to CBD on ABS, 2010

The Nagoya Protocol to CBD, the new legally binding international treaty specific to ABS, elaborates implementation of benefit sharing provisions under the Convention's Article 15 and sets out core obligations for its contracting Parties to take appropriate measures related to access to genetic resources, benefit sharing and compliance. The provider Parties need to create legal certainty, clarity and transparency for access to genetic resources; provide fair and non-arbitrary rules

and procedures for such access; establish clear procedures for prior informed consent and mutually agreed terms; and provide for issuance of an internationally acceptable certificate when access is granted. The user Parties are also required to ensure that their researchers and other users of genetic resources must comply with the national legislation of provider countries by monitoring through the ABS-Clearing House mechanism operated by the CBD Secretariat.

The National Biodiversity Authority (NBA) has been designated as the National Competent Authority for implementing this Protocol and the format for the Internationally Recognized Certificate of Compliance has also been approved. A Core Expert Group has also been constituted to designate the Check Points and notify the user and provider country measures.

National Legislation in India for Implementing the International Treaties on ABS

Under the CBD, the Sovereign 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 to fulfill this requirement. It also provided suitable linkage to the provision for patenting of products and processes/technologies, based on the use of bio-resources and associated traditional knowledge (TK), under Section 10 (4) of the Patents (Amendment) Act, 2002. 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. For major achievements in implementing the national obligations under the CBD, please see Box 1.

This Act has adopted a common but differentiated approach [Sections 3 and 19], as adopted by the CBD principle on responsibilities of the developing and developed countries, under which the following categories of persons/body corporate/associations/organizations 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:

"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

Box 1. Implementing national obligations under CBD in India: Major Achievements at a Glance

1. Enacted the Biological Diversity Act, 2002 and the Rules, 2004
2. NBA established in 2003 and SBBs constituted in all the 29 States at present.
3. BMCs formed in nearly 4,000 local bodies across 17 States.
4. Guidelines for preparing People's Biodiversity Registers updated in 2013 and 2485 PBRs prepared by BMCs across 17 States. NBA has been providing financial support towards setting up of BMCs and also for preparation of PBRs.
5. Biodiversity Rules and Regulations on ABS notified by 17 States.
6. Sixteen SBBs have been supported for ABS activities under 4 externally funded projects.
7. Notified Guidelines on International Collaborative Research Projects, 2006.
8. Notified Guidelines for the identification of Biodiversity Heritage Sites and **seven** BHS sites have been notified in three States u/s 37.
9. Threatened species have been notified in 16 States and 2 Union Territories u/s 38.
10. Notified Exemption for 385 Normally Traded Commodities u/s 40, 2014.
11. Notified Guidelines on Access and Benefit Sharing Regulations, Nov 2014.
12. Notified Exemption of ITPGRFA, Annex-1 Crops, Dec 2014.
13. Fifteen institutions have been notified as the national designated repositories u/s 39 and Guidelines on their mandates and safekeeping of deposited specimens/samples issued in March, 2016.
14. ABS Awareness and Sensitization Workshops conducted in 6 States.
15. Two media workshops attempting increased awareness conducted.
16. Number of IRCCs submitted to ABS-CH: 25 out of the total of 27 so far.
17. Winners and Runners-up of India Biodiversity Awards 2016 (including the new category on Good Practices for ABS Mechanisms) honoured on the International Day for Biodiversity 2016, organized in Mumbai on 22 May.
18. Number of complete Applications received for Forms I to IV: 1218.
19. Number of applications approved: 865.
20. Number of Benefit Sharing Agreements signed: 270.
21. Amount of monetary benefit sharing received by NBA: Rs. 34.26 Crores.
22. Amount of monetary benefit sharing received by SBBs: Over Rs. 4 Crores.

Source: NBA Secretariat, Chennai.

India; or incorporated or registered in India but has any non-Indian participation in its share capital or management”.

All users are also required to seek prior approval of NBA for transferring results of research on bioresources to users of the above defined category, for applying for IPR over products of research on bioresources and also for third party transfer of the already accessed bioresources, by submitting applications in specified

formats and after payment of prescribed fee for each of the above mentioned purposes [See Box 2].

Access of Indian citizens to bio-resources for research is not restricted. However, Section 7 under the Act 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

Box 2. Activities covered under the BD Act and the authorities for granting approval

Purpose for use of bio- resources and/or traditional knowledge associated thereto	Application Form to be used	Authority for granting approvals	
		For Indian Citizens/ For Persons/ entities defined u/c 3(2)	Entities
1. a) Research b) Bio-survey & Bio-utilization c) Commercial Utilization	Form I Prescribed Fee: Rs.10,000/- No Fee	No approval required	NBA NBA
Special Forms: 1A, 1B, 1C		No approval required	NBA
2. Transfer of Results of Research on Bio-resources to entities defined u/s 3(2)	Form II Fee: Rs. 5,000/-	SBB NBA NBA	NBA
3. Seeking Intellectual Property Rights	Form III Fee:Rs.500/-	NBA	NBA
4. Transfer of the already accessed bio-resource to entities defined u/s 3(2)	Form IV Fee: Rs.10,000/-	Not relevant	NBA

Source: www.nbaiindia.org

to the concerned State Biodiversity Board (SBB) with the expectation that a BS Agreement may have to be signed.

Implementing Mechanism for the Biological Diversity Act

A 3-tier system for implementing the BD Act has been established comprising the National Biodiversity Authority (NBA) at the national level (established by the central government), State Biodiversity Boards (SBB) at the state level (constituted by the state governments) and Biodiversity Management Committees (BMC) at the local level (constituted by the local bodies). Their roles are well defined under the Act. The Act is being implemented by NBA in partnership with SBBS and BMCs.

Established by the Central Government on 1st October, 2003, the NBA comprises the Chairperson, 10 ex-officio members representing union ministries/ departments and 5 experts nominated by the Central Government. NBA, which is essentially an inter-ministerial body assisted by five technical experts, has held 38 meetings till 4 July, 2016. SBBs have also been constituted in all the 29 States and over 4,000 BMCs have also been formed across 17 States.

Funds and grants accruing to these three partners in implementing the Act are operated under the National, State and Local Biodiversity Funds. The mechanism for passing on the monetary benefits from the National and State Biodiversity Funds to BMCs and benefit claimers where identified, as provided under the Regulations on ABS guidelines, is shown in Box 3.

NBA has constituted several Expert Committees and Core Expert Groups from time to time to provide recommendations on specific issues. Eight such ECs

and CEGs are functioning at present involving a pool of 174 experts drawn from different specializations across the country.

EC on Agro-biodiversity has played a lead role in implementing the national obligations under the ITPGRFA and exempting designated accessions of Annex-1 crops from provisions of Sections 3 & 4 of the BD Act. Its recommendations on facilitating the mandate of IARCs and some other important issues are under consideration by the Authority for follow up actions.

Restrictions Imposed on Granting Access to Bioresources

Certain restrictions have been imposed under Rule 16 on NBA's, and also SBBs', approvals for access to bio-resources, requiring to take necessary steps to restrict or prohibit access when the request relates to any endangered taxon or endemic and rare species or it may result in adverse effect on the livelihoods of the local people or adverse environmental impact which may be difficult to control and mitigate, may cause genetic erosion or adversely affect ecosystem functioning or 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:

- Indian citizens/entities accessing bio-resources for research/ bio-survey and bio-utilization for research in India.
- Provisions of Section 3 (access to bio-resource) and Section 4 (transfer of research results), read

Box 3. Mechanism of passing on the accrued monetary benefits by NBA/ SBBs to BMCs or the benefit claimers where identified

A. When approvals are granted:

1. 5.0 % of the total amount goes to the NBA, of which 2.5% is retained by NBA and 2.5% is passed on to the concerned SBB as administrative charges.
2. 95.0 % of the amount is passed on to the concerned BMCs and / or benefit claimers where identified.

B. When approvals are granted by SBBs

1. 5.0 % of the total amount is retained by the SBB as administrative charges.
2. The rest 95.0 % of the amount is passed on to the concerned BMCs and/ or benefit claimers where identified.

C. Utilization of funds

1. For supporting conservation and sustainable use biological resources and development of areas from where such biological resources or knowledge associated thereto have been accessed;
2. For promoting socio economic development of areas from where the biological resources and knowledge are accessed, in consultation with the local bodies concerned.

Source: Guidelines on ABS Regulations, 2014.

with Section 19, shall not apply to international collaborative research projects, conforming to the guidelines issued by the Central Government on 8 November, 2006.

- Provisions 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.
- Accessing bioresources for conventional breeding or traditional practice in use in any agriculture, horticulture, poultry, dairy farming, animal husbandry, bee keeping, etc. in India is exempted from provisions of this Act. However, "End Uses" of biological resources for "Commercial Utilization" (such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours, extracts and genes used for improving crops and livestock through genetic interventions are not exempted.
- 'Value added products', which may contain portions or extracts of plants and animals in unrecognizable and physically inseparable form are exempted for trade.
- Provisions of prior intimation to SBB for commercial use shall not apply to local people and communities including village healers/vaids, farmers and other traditional growers.
- Items such as normally traded commodities, notified by the Central Government u/s 40, would be exempt so long as these are traded as commodities.
- Exchange of designated accessions of genetic resources of crops listed in Annex-1 of the ITPGRFA

has been exempted from provisions of Sections 3 and 4 of the BD Act.

Notification on Guidelines on Access and Benefit Sharing

Notification on ABS Guidelines Regulations under the Biological Diversity Act was issued on 21 November, 2014. These Guidelines provide for legal certainty, clarity and transparency, simplified procedure for the Indian researchers/Govt. institutes to carry out basic research outside India, options for benefit sharing for different users, graded benefit sharing system, supply chain system from source to the manufacturer, upfront payment on high economic valued bioresources (like Red sanders and Sandalwood), apportioning of the accrued benefits to the BMCs/benefit claimers and options for sharing benefits in monetary or non-monetary mode. For the module on terms for BS, please see Box 4.

Facilitating Non-commercial Research on Bioresources by Indian Researchers/Government Institutions in Other Countries

- Through the Guidelines on ABS Regulations, NBA has introduced a special Form A for the supply chain stockists, traders and manufacturers accessing bioresources from BMCs and Form B for the Indian researches/scientists/institutes to carry/send samples of bioresources outside India for conducting research including taxonomic studies. Government institutes can also send bioresources outside the country to carry out research work abroad in face of emergencies like epidemics, natural disasters, etc.
- Another special Form C has also been introduced for deposition of microbial type cultures in any

Box 4. Module showing benefit sharing in monetary mode under the Guidelines on ABS

1. Commercial Utilization	
Annual gross ex-factory sale of product	Benefit sharing component
Up to Rupees 1,00,00,000	0.1 %
Rupees 1,00,00,001 up to 3,00,00,000	0.2 %
Above Rupees 3,00,00,000	0.5 %
2. Transfer of Results of Research on Bio-resources	3.0 to 5.0% of the monetary consideration received
3. Intellectual Property Rights	
• If applicant himself commercialize the process/product/innovation	• 0.2 – 1.0% of Annual Ex-factory gross sale (minus govt. taxes)
• If applicant assigns / licenses the process /product / innovation to a third party for commercialization	• 3.0 – 5.0 % of the fee received in any form. And 2.0 – 5.0 % of Royalty
4. Third Party Transfer by u/s 3(2) received from the transferee	2.0 to 5.0% of any amount and /or royalty Persons/Entities

Source: Guidelines on ABS Regulations, 2014.

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- Submission of these special Forms does not require payment of any fee and such requests are usually cleared within two weeks.

Experiences Gained from Implementing the BD Act and the Way Forward

Following a great effort by the drafting committee, chaired by the renowned scientist Dr. M.S. Swaminathan, the process of enacting the BD Act took several years of intense consultations among different government agencies, including the Parliamentary Standing Committee, and other stakeholders to evolve in its final form in 2002, vetted by the Law Commission. Section 3, adopting the CBD principle of common but differentiated responsibilities, was included for access to GRs by the Indian citizens/entities and foreigners in view of the prevailing strong apprehensions regarding what was termed '*biopiracy*' to indicate unauthorized access (mostly relating to pharmaceuticals and industrial applications) by some users without any commitment of sharing the benefits generated from the utilization of India's bioresources and associated traditional knowledge. Some differing views notwithstanding, it is indeed a tribute to the Drafting Committee (and others who contributed to this process) that the text of this Act has stood the test of time when we compare Indian experience with those of some other countries like the Philippines, Brazil, South Africa and the Andean Community. In addition, this Act also served as the umbrella legal framework for implementing the ITPGRFA and also the Nagoya Protocol on ABS in India. Specific Guidelines on ABS Regulations, notified under this Act in November 2014, have been widely welcomed as they impose low benefit sharing terms along the supply chain while offering a slab-system and sectoral approach for benefit sharing.

Some reservations had been expressed by some government departments, and also some other major user sectors about the interpretation of some of the Act's provisions but sustained dialogues with them (including

ICAR, CSIR, DBT, PPV&FRA and the Indian Patent Office) helped the NBA in resolving the difficulties. NBA gained immensely from these meaningful dialogues at the highest level and succeeded in developing strong partnerships. Similar consultation process is presently in progress with several other sectors like seed industry and pharmaceuticals. Partnership with SBBs has also been remarkably strengthened in recent years, sparked by implementation of several externally funded projects by NBA, involving more than fifteen SBBs at present. Strong competition witnessed among the contestants for India Biodiversity Awards 2016 in the category of 'Good Practices for ABS' has brought out the supportive role played by several SBBs towards capacity building of BMCs in this context.

To sum up, the BD Act stipulates norms for access to bioresources and associated TK in two broad categories. While foreign access is subject to prior approval of NBA, domestic access is based on prior intimation (approval) from the concerned SBB. Recent experience reveals that bulk users of bioresources are now better motivated to enter into ABS agreements with the concerned SBBs as compared to those who access the required bioresources only once and work afterwards with their cultures grown in laboratories. This increasing acceptability of the ABS Guidelines notwithstanding, incorporating biodiversity concerns within the natural capital framework and mainstreaming biodiversity in achieving global goals still remain major challenges for the policy makers and planners in public as well as private sectors. It needs to be appreciated, however, that 'biodiversity conservation with sustainable use' and 'inclusive sustainable development' are increasingly recognized to be mutually supportive. This is strongly reflected in the Natural Capital Protocol, launched in London in July 2016 by representatives from over 160 organisations, suggesting the way that businesses may evaluate their operations. In this context, NBA has adopted a positive approach in implementing the BD Act and remains open to suggestions/feedback from all the stake holders.