



## Access to Genetic Resources and Benefit Sharing: Indian Experience

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‘Access and Benefit Sharing’, ABS in short, refers to access to genetic resources (and traditional knowledge associated with them) and fair and equitable sharing of benefits (generated from their use by researchers, breeders and biotechnologists, and also by developers and manufacturers of bioresource-based products) with the country of origin/ rightful owners. This topic, along with its relevance to adaptation to climate change, is centre stage these days. The legally binding Nagoya Protocol on ABS, adopted in 2010 and ratified presently by 87 Parties, has more clearly defined and strengthened this concept derived from Article 15 of the Convention on Biological Diversity.

India is contracting party to several international treaties impacting on ABS.

**International Undertaking on Plant Genetic Resources for Food & Agriculture (PGRFA)**, established by the FAO in 1983, and based on the principle that PGRFA were common heritage of mankind, was the first voluntary international agreement on sharing of PGRFA. India was among the 113 nations who signed and adhered to this International Undertaking. This era was followed by granting of intellectual property rights (IPR) over the products of research on genetic resources. Working mostly in developed countries and making use of PGRFA obtained from developing countries, IPR holders appropriated all the resulting benefits to themselves.

**The TRIPS Agreement under WTO (1995)** provided that the Members may exclude plants and animals (other than microorganisms) from patenting but any country excluding plant varieties from patenting must provide for an effective *sui generis* system for their protection.

**The Convention on Biological Diversity (CBD):** It is a legally binding comprehensive treaty adopted in June 1992, sought to balance the rights of providers of genetic resources with those of their users (including the breeders and other researchers). It also marked the end of the ‘common heritage’ concept of genetic resources by recognising sovereign rights of States

over their natural resources within their boundaries and affirming that the authority to determine access to genetic resources rested with the national governments subject to national legislation. The FAO also revised the text of its 1983 International Undertaking on PGR to bring its provisions in harmony with those of the CBD and then adopted it on 3 November, 2001 as the legally binding **International Treaty on Plant Genetic Resources for Food & Agriculture (ITPGRFA)**. 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 access to genetic resources, this Treaty provides for a Multilateral System (MLS), based on Standard Material Transfer Agreement.

**The Nagoya Protocol to CBD on ABS** is the new legally binding international treaty specific to ABS and provides implementation mechanism for the benefit sharing provision under the Convention’s Article 15, setting out core obligations on the Parties to develop provider as well as user country measures so as to ensure that genetic resources are not used without prior consent of the countries of origin. The ABS-Clearing House offers assistance in monitoring the process.

### Legal Framework for ABS in India

#### *Focus on Conservation and Sustainable Use, Supported by ABS Provisions*

Implementing the CBD gained momentum soon after its entry into force in December 1993 as several nations passed legislation to claim sovereign rights over their natural bioresources. India enacted the Biological Diversity Act (BD Act) in 2002 and framed Rules for its implementation in 2004 in pursuance to its commitments under the CBD. This Act provides legal framework for implementing the CBD and to affirm India’s sovereign rights over granting access to its naturally occurring

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bioresources (and associated traditional knowledge) and for setting terms for sharing of benefits arising from their utilisation.

Four agencies are working in partnership in implementing this Act: the Central Government, the National Biodiversity Authority (NBA), established by the Central Government; the State Biodiversity Boards (SBBs), established by the State Governments; and the Biodiversity Management Committees (BMCs) at the local level, set up by every Local Self-Government body. They have well defined, non-overlapping and mutually supportive roles.

The BD Act follows a common but differentiated approach to deal with applications received from Indian citizens/entities and those from foreign persons/entities for the regulated four activities. 1) A foreign person/entity cannot access bioresources [and associated traditional knowledge (TK)] occurring in India for research/bio-survey and bio-utilisation for research/commercial use without prior approval of NBA. Indian researchers/entities, however, are permitted access for research without any approval but they are required to intimate the concerned SBBs, from where the bioresources are accessed, and enter into a benefit sharing agreement prior to commercial utilisation. 2) All persons/entities applying for intellectual property rights (IPR) on products/processes, based on research on India's bioresources and associated TK, require prior approval of NBA. 3) In addition, all scientists/institutions, intending to transfer results of their research on bioresources occurring in India to foreigners/entities for monetary or other gains, are required to take prior approval from NBA.

4) The foreigners/entities intending to transfer already accessed bioresources to another foreigner/entity (Third Party Transfer) also require prior approval of NBA for this purpose (See Box 1). The differentiation between foreigners/entities and Indian applicants ensures that all the foreigners/entities deal with a single window system.

### Some Exemptions Provided under the BD Act

- Local people and communities of the area including growers and cultivators of biodiversity and persons practicing indigenous medicine.
- Accessing bioresources for conventional breeding or traditional practices in use in any agriculture, horticulture, poultry, dairy farming, animal husbandry, bee keeping, etc.
- International Collaborative Research Projects conforming to the guidelines issued by the Central Government in November, 2006 for this purpose.
- Breeders applying for variety protection under the PPV&FR Act, 2001.
- Normally Traded Commodities, notified u/s 40, when traded as commodities.
- Access to designated accessions of notified Annex-1 crops under the ITPGRFA.

The NBA takes help of several Expert Committees (ECs)/Core Expert Groups who provide guidance on specific issues/topics. Eight such committees/core groups are functioning at present involving a pool of over 170 experts drawn from different specializations across the country. EC on ABS, for example, scrutinises applications

**Box 1. Activities covered under the BD Act and the authorities for granting approval**

Purpose for use of bio-resources and/or traditional knowledge associated thereto	Authority for granting approvals	
	For Indian citizens/entities	For persons/entities as defined u/c 3(2) [foreigners]
1. a) Research	No approval required	NBA
b) Bio-survey & Bio-utilisation	SBB	NBA
c) Commercial utilisation		
<b>Special Forms:</b>		
<b>1A</b> For a trader/manufacture	NBA	NBA
<b>1B</b> For emergency research abroad		
<b>1C</b> For depositing microbial sample in a foreign repository		
2. Transfer of results of research on bio-resources to entities defined u/s 3(2)	NBA	NBA
3. Seeking intellectual property rights on bioresource-based products	NBA	NBA
4. Transfer of already accessed bio-resource to entities defined u/s 3(2)	Not relevant	NBA

for access by foreigners/entities, IPR, research results transfer and third party transfer of accessed bioresources. EC on agrobiodiversity has helped in implementing the facilitated access to designated accessions of notified Annex-1 crops under the ITPGRFA and a Core Group is presently assisting implementation of the Nagoya Protocol.

### Implementing the BD Act

Following NBA's establishment in 2003, SBBs have been constituted in all the 29 States. Nearly 40,000 BMCs have also been formed across 26 states and guidelines for preparing People's Biodiversity Registers were updated in 2013 leading to preparation of over 2,500 such registers by BMCs staking claim on their bioresources. Threatened species have been notified in 16 states and two union territories u/s 38 while the Guidelines for Identification of Biodiversity Heritage Sites have been developed and seven such sites have been notified in three states u/s 37.

Responding to the suggestions from stakeholders, formats for the four broad categories of legal agreements have been revised. Out of 1,221 applications received by the NBA so far including 219 that were closed, 814 have been approved under different categories and 247 benefit sharing agreements have been signed with the applicants on mutually agreed terms. National Biodiversity Fund and State Biodiversity Funds, amounting to nearly INR 360 million, are now available for claim of the identified beneficiaries to support conservation related activities including capacity building and raising awareness about the BD Act (See Box 2). In addition, SBBs have also received nearly INR 40 million through registration fees

and benefit sharing.

Guidelines on Access and Benefit Sharing Regulations were notified in November, 2014 accelerating the benefit sharing process. Seventeen States have now framed their *sui generis* Biodiversity Rules and Regulations and 16 SBBs have been supported for ABS activities under 4 externally funded projects. Winners and runner ups of India Biodiversity Awards, 2016 (including the new category on Good Practices for ABS Mechanisms) were honoured on the International Day for Biodiversity this year (See Box 3).

### Some Notable Features of the Indian ABS System

NBA is an autonomous public-funded institution and it has received full support from the Central Government, particularly in policy guidance and making rules and regulations. It is essentially an inter-ministerial apex decision-making body assisted by five technical experts (as non-official members) and has been meeting at regular intervals with its 39<sup>th</sup> meeting held on 14 October, 2016.

Regular consultations, held by the NBA with different relevant ministries (having jurisdiction over various components of biodiversity) and major stakeholders, have helped in clarifying several contested issues and in developing implementable procedures. Dialogues with the DIPP and the Indian Patent Office, the CSIR, the ICAR and the DBT have proved to be particularly useful. Active partnership developed by NBA with 29 SBBs, aided by national and regional level workshops, has also helped greatly in accelerating the ABS system in recent years.

In addition, the Guidelines on ABS Regulations (2014), well received by most of the stakeholders, have really galvanised the ABS system. Responding to requirements of the business organisations (and also many other sectors like agriculture, biotechnology, herbal drug manufacturers and pharmaceuticals) and issuing helpful notifications, like those on Guidelines on ABS and Normally Traded Commodities, have turned out to be a win-win situation.

The BD Act, though basically designed for implementing provisions of the CBD, has come out as an overarching ABS legislation by providing effective linkages to other relevant national Acts and also for working as the enabling legislation for several international treaties and protocols.

**Box 2. Some outstanding contributions to the National Biodiversity Fund**

Contributors paying the Benefit Sharing	Amount (INR in million)
Seaweed: PepsiCo India Holdings (P) Ltd., Gurgaon PSS Ganesan & Sons, Tuticorin Britto Sea Foods, Chennai	4.250
Cattle embryos: Brasif S. A., Brazil	10.764
Neem leaves: Bio India Biologicals, Hyderabad	0.055
Red Sander Wood: 35 Bidders in public auction of Red Sander Wood seized by the Andhra Pradesh state government under the Wild Life (Protection) Act [CITES]	339.600

**Box 3. India Biodiversity Awards 2016: Successful and Replicable Mechanisms for ABS**

In India, nearly 300 million people are dependent on biodiversity for subsistence and livelihoods. This dependence is particularly critical for the tribal people who reside in forest areas and collect non-timber forest produce, including plants of medicinal value, to augment their income. India Biodiversity Awards 2016 included a category on 'Successful Mechanisms for Access and Benefit Sharing' to identify good practices that have been developed and adopted in this context.

The Award Winner was the Gram Moolgai Co. Ltd. who, working in Katni District of Madhya Pradesh, had developed and successfully adopted a fair benefit sharing mechanism, much earlier to the Central Government's notification of Guidelines on ABS Regulations in November, 2014. This company traded in medicinal plants by purchasing them from the collectors, mostly the poor tribal families living on the fringe of Bandhavgarh National Park, and supplying to a well known drug manufacturer. These collectors were registered by the company for this purpose and were shown the price paid by the manufacturer. Raw bioresources were purchased by the company from the collectors at that rate after a deduction of 30%, as the overhead charges including the profit margin, and this offered price was nearly 20% higher than the prevailing market rate. The company also employed these local communities in cleaning, grading, packaging and storing them prior to their supply to the manufacturer promoting thereby sustainable use practice with fair benefit sharing.

Guidelines on International Collaborative Research Projects, notified in 2006, have helped the researchers in availing the exemption provided for this purpose u/s 5 of the Act. Exemption for designated accessions of Annex-1 crops was also notified in December, 2014 to facilitate access under the ITPGRFA. To assist the commerce sector, 385 Normally Traded Commodities were exempted from the Act in April, 2016 u/s 40 as long as they are traded as commodities (not as bioresources for research). **Fifteen institutions have also been notified** as the national designated repositories u/s 39 and Guidelines on their mandates and safekeeping of deposited specimens/samples have been issued in March, 2016. All these guidelines and notifications are available on NBA's website for easy access to them.

**The Way Ahead**

While national ABS legislations of most other biodiversity-rich countries appear to target primarily the bio-survey and bio-utilisation of their bioresources by foreign companies, the Indian national legislation focuses on promoting conservation and sustainable use of bioresources linked to fair and equitable sharing of benefits generated from their commercial utilisation. The BD Act has stood the test of time as an umbrella legislation for not only implementing the CBD and its Nagoya Protocol on ABS but also the ITPGRFA. Its implementation has been effectively linked with other relevant national legislations like the Patents Act, 1970 and the PPV&FR Act, 2001. An on-line application system is to be launched soon to further improve efficiency and effectiveness of the national ABS system.

Notification of the ABS Guidelines Regulations in November, 2014 has remarkably speeded up the Act's implementation process as also the notification on exempting a large number of plants, normally traded as commodities (not as bioresources), u/s 40 to support the foreign trade sector. More effort is underway to include animal and marine products under this exemption.

There are still some areas where interpretation/perceptions about the BD Act's provisions differ among the stakeholders such as the interpretation of certain terms defined under the Act and the scope of exemptions provided therein. To create increasing awareness, however, a section on 'Frequently Asked Questions' is displayed on the NBA's website for guidance and 'sensitisation workshops' are also being organized regularly. The Act's implementation is still weak where it matters most, i.e., in involving and empowering of the local communities for decision making but an Expert Committee's recent suggestions on this aspect are expected to help energising the national ABS system at the grass root level.

Investing in biodiversity conservation is the first step to safeguard the natural bio-wealth for use of future generations. According to an estimate prepared by the BIOFIN project team, India funded core biodiversity schemes and related projects amounting to nearly INR 108 billion during the year 2012 and launched the India Business & Biodiversity Initiative offering avenues for investment to the corporate sector as part of its social responsibility.