

Biodiversity Monitoring: A Pre-Condition to Access and Benefit Sharing under the Indian Biological Diversity Act, 2002

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The conservation of biological diversity has emerged to be a dominant international discourse due to the issues arising out of appropriation of genetic resources. Bioresource utilization in the form of trade has received increased attention in the recent times. The assertion of private intellectual property rights in innovations based on biological resources and knowledge obtained from developing countries has been a major concern. Post the Nagoya Protocol on Access and Benefit Sharing of Genetic Resources 2010. An important aspect the protocol recognizes is the need for securing the rights of communities over their resources; by restricting biopiracy and protecting the rights of the communities/stakeholders. India announced the Access and Benefit Sharing Guidelines (ABS) 2014 under the Biological Diversity Act 2002. Prior approvals and ABS agreements are mandatory for access to biological resources for certain purposes and for seeking IPR protection. Biodiversity maintenance is important for the sustainable utilisation of biological resources. There are concerns that increased bioresource trade may pose a threat to the conservation of species. It is in this context that the present study attempts to analyse the need for biodiversity monitoring in the ABS process in India. This study highlights the need for including biodiversity monitoring as part of the pre-ABS mechanism in India. Effective ABS implementation in India would be achieved only when it is linked with conservation objectives.

Keywords: Biological resources, biodiversity monitoring, access and benefit sharing

Biodiversity maintenance is important for the sustainable utilisation of biological resources. Its importance can be realised by the amount of natural wealth utilised by humans. The Millennium Ecosystem Assessment (MEA) documented the importance of biodiversity and 'Ecosystem Services' (ESSs) for human well-being and projected that continued supply of these services is threatened by unsustainable human activities which includes overexploitation. Approximately 60% of the ESSs examined during the MEA were found degraded or used unsustainably, including wood, fresh water and the regulation of regional and local ESSs leading to natural hazards.¹ Some other alarming cases include; world's total forest area decrease by 3.1%, current intact habitat of only 1.4% of the land of the 'Biodiversity Hotspots' (that covered 12% of the land's surface)² and fisheries being greatly depleted, with 75% of the world's fish stocks being overexploited.³ Most of the world's agricultural crops have lost genetic diversity due to change in agricultural practices and other factors.⁴

Economic development and overexploitation of ESSs has posed serious challenge to ecosystem and biodiversity conservation. To combat the continuous loss of biodiversity a need for sustainable utilisation of bioresources had been realised at the global level. The conservation of biodiversity and ecosystems emerged as a worldwide mandate at international level leading to the adoption of the U.N. Convention on Biological Diversity in 1992 (CBD). For the first time conservation of biological resources became a global obligation. The CBD was an outcome of the world community's growing commitment towards sustainable development. It was a step forward in the conservation of biodiversity, the sustainable use of its components, and the fair and equitable sharing of benefits arising from the use of genetic resources (the three fundamental objectives of the CBD). Till date 196 states have ratified the CBD.⁵

With the purpose to initiate the third objective of the CBD, the Nagoya Protocol (Protocol) on Access and Benefit Sharing, 2010 was implemented in 2014. It is a supplementary agreement to the CBD to provide transparent legal framework for the effective implementation of Access and benefit Sharing (ABS), thereby contributing to the conservation and

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sustainable use of biodiversity. For effective implementation, the protocol has set out certain compliance obligations that include:

- Specific obligations to support compliance with the domestic legislation or regulatory requirements of the contracting party under mutually agreed terms and prior informed consent, and also take measures in this regard.
- Cooperate in cases of alleged violation of another contracting party's requirements
- Take measures regarding access to justice.
- Take measures to monitor the utilization of genetic resources, by designating effective checkpoints at any stage of the value-chain, research, development, innovation, pre commercialization or commercialization.

So far 89 states have ratified the protocol and India is one among them. India's contributions are significant in the implementation of this international principle. The Indian Government introduced the Environment Information System to decentralized computerized network database. Further, India has implemented the international standards under its national laws. The Biological Diversity Act, 2002 (Act), the Biological Diversity Rules, 2004 (Rules), the Green Tribunal Act, 2010 and the Access and Benefit Sharing Guidelines, 2014 (Guidelines), form the legal ambit of the implementation mechanism in India. India is one of the 17 like-minded mega-biodiverse nations in the world. In the initial COP meetings at the CBD, India presented to the world its unique way of documenting biodiversity using a people participatory approach in the form of People Biodiversity Registers (PBRs). So far approximately 26 State Biodiversity Boards have been established and more than 37,000 Biodiversity Management committees have been formed. It is remarkable to note the progress in the development and cataloging of the People Biodiversity Registers. India has played a decisive role in the development of the International Framework of Access and benefit Sharing. Keeping its commitment to the implementation of the CBD post the Nagoya protocol India has announced the ABS guidelines in 2014. Currently, different SBBs in India are in the process of implementing the guidelines. India has also achieved the first certificate of compliance in relation to the ABS clearing house mechanism in 2015 which has been hailed as an important development. Under this certificate India granted access to ethno- medicinal knowledge of the

Siddi community from Gujarat to a researcher affiliated with the University of Kent in the United Kingdom.

However, India faces twin challenges in relation to the implementation of the Biological Diversity Act 2002; Conservation of biological resources while meeting the international obligation of providing access to biological resources. Three different innovative financing mechanisms have been identified in relation to ABS frameworks at the national level. One of the foundational principles identified is that 'ABS must necessarily lead to conservation and sustainable use of biodiversity through an effective combination of rights and incentives'.⁶ The regulation of biological diversity under the Act comes under the purview of functions of the National Biodiversity Authority (NBA) under Section 18, State Biodiversity Boards (SBBs) function under Section 23 and Biodiversity Management Committees (BMCs) function under Section 41 in relation to the regulation of biodiversity for general purposes of bio-survey and bio-utilisation under Section 3 and regulation of biodiversity in relation to intellectual property under the purview of Section 6. India is the first country in the world that has been able to tap into the magnitude of ABS having dealt with seven hundred and eighty ABS applications. An analysis of the extent of implementation of ABS in relation to intellectual property (Section 6) in India revealed several important aspects. The major challenges faced by the NBA are in obtaining the benefit sharing fee or the royalty, the challenge of enforcing contractual obligations under the ABS agreement. Some applicants refuse to give the royalty on the basis that no profit was made on the commercialization of the product. While some amount of royalty has been received from the applicants decision is not yet taken on the manner in which the amount is to be utilized.

The real purpose of ABS is that the benefit arising out of any commercial activity based on biological source should reach the benefit claimers. NBA is yet to develop an effective mechanism in this regard. Another aspect is that information given by the applicants with respect to point 3, 4, 5 (i.e., details of the biological resources, the geographical location and associated traditional knowledge related to the invention) of the Form III is not verified with the PBR information. SBB has a role in the verification of the information given by the applicant. There are severe delays in the approval of applications under the purview of Section 6 which is further delaying the

process of patent grant at the Patent Office. There is a requirement of administrative linking between the NBA and the patent office modules for an effective clearing of biotechnology based patent applications (Smriti Roy and Padmavati M, 2013, unpublished work).⁷ Effective ABS implementation would be achieved when conservation objectives are linked. There is a need to link the PBR information to ABS regulation in India. To what extent the ABS process in India has facilitated the conservation of biological resources adopted in the three tier system (of NBA, SBB and BMC) of the Act. It is in this context that the present study attempts to analyse the need for biodiversity monitoring in the ABS process in India.

Biodiversity Monitoring and ABS – Setting the Background

“Biodiversity monitoring is the repeated observation or measurement of biological diversity to determine its status and trend”.⁸ The concept of biodiversity monitoring in the context of ABS has two perspectives, firstly, in the international context i.e. by interpreting and understanding the framework setup by the CBD and secondly, in the context of commercialization of bioresources.⁹ The challenge in commercialization of bioresources, is identifying the limit for exploitation. Commercialisation of bioresources cannot be forbidden; it provides economic strength to a state and also leads to capacity building and other developing factors. Access and benefit-sharing (ABS) refers to the way in which genetic resources may be accessed, and how the benefits that result from their use are shared between the people or countries using the resources (users) and the people or countries that provide them (providers).¹⁰ After the commencement of the Protocol it has become an obligation to the member states to implement the mandates ABS as well as monitoring measures. In this way the commercialisation of bioresources may now be practiced in a more permissible, systematic and productive manner under the concept of ABS. The activities of trade related to bioresource (including ABS) aim to assure the sustainability of both, the bioresource being used and the ecosystem involved. The aim is to ensure that the use of a species or ecosystem is not higher than its regenerative and/or productive capacity. However, to implement this in a systematic and sustainable way monitoring mechanisms are invoked. Biodiversity monitoring is one such essential initiative and practice, wherein

organizations can define instruments for the application of good management and monitoring practices to guide design and improve the productive processes of the bioresources.¹¹

Biodiversity monitoring is also essential not just for conservation or sustainable ABS but also for development. The fostering of green economy and using of environmentally friendly goods and services, environmentally sound technologies helps in increasing resource efficiency, generating economic opportunities and employment, further contributing to poverty eradication.¹² However, the unsustainable practices led to the continuous loss of biodiversity and degradation of ecosystem services. The importance of Biodiversity Monitoring had been observed through various sectors, for e.g. the Agricultural sector, where the role of monitoring has been proved imperative. It has been observed that in the absence of a strong monitoring system the level of accountability by stakeholders within proper business, legal and regulatory environment cannot be set up.¹² Whereas, monitoring helps in highlighting the environmental impacts to encourage sustainability in resources management in the agricultural sector (for e.g. increase in number of small scale farmers and sales revenue).¹³

Biodiversity monitoring is imperative in order to achieve global targets of conservation. With the adoption of the international regime on ABS it is increasingly clear that biodiversity rich countries will need to meet obligations of the Nagoya Protocol. The linking of biomonitoring mechanism in all ABS initiatives is an important step. India being a mega diverse nation and a ratified member to the CBD and the protocol is also under obligation to implement the mechanism.

Implementation of Access and Benefit Sharing under the Biological Diversity Act 2002

The Indian government has been working for biodiversity conservation even prior to the commencement of the CBD. The Indian Govt. initiated the Environment Information system i.e. (ENVIS) i.e. a decentralized computerized network database system consisting of the focal points in the Ministry and chain network partners, known as ENVIS centres located with potential organisations throughout the countries.¹⁴ It is a scheme for environmental information collection, collation, storage, retrieval and dissemination to policy planners, scientists, environmentalists, researchers etc., India also envisaged the National Conservation

Strategy and Policy Statement 1992, where the Indian government proposed for actions in relation to biodiversity conservation and protection.¹⁵ In 2006, the National Environment Policy was introduced by the government. The policy highlights the importance of biodiversity conservation in relation to other components of the environment. It emphasises the need to formulate an appropriate system for Prior Informed Consent and Fair and Equitable Benefit sharing in respect of biological material and traditional knowledge of use of such biological material to enable the country and local communities respectively to derive economic benefits for providing access. The Indian biodiversity law comprises of the Biological Diversity Act, 2002, the Biological Diversity Rules, 2004, the Green Tribunal Act 2010 and the Access and Benefit Sharing Guidelines 2014. Currently, the access to bioresources for research and for commercial utilisation including Intellectual Property Rights (IPR) is regulated under the Biological Diversity Act 2002 (Section 3 in general and Section 6 in relation to IP respectively).

The Act primarily addresses the issues concerning access to genetic/biological resources and associated traditional knowledge by foreign nationals, institutions or companies, and equitable sharing of benefits arising out of the use of these resources and associated knowledge by the country and its people. ABS governance is through a three tier system, i.e., NBA at the national level, the State Biodiversity Board (SBB) and Biodiversity Management Committees (BMCs) at local levels. The NBA deals with the requests for access to bioresources and associated traditional knowledge by foreign nationals, institutions or companies, and all matters pertaining to the transfer of research findings to any foreign national, imposition of terms and conditions to secure equitable sharing of benefits, establish sovereign rights over the bioresources of India and approval for seeking any form of Intellectual Property Rights (IPRs) in or outside India for an invention based on research or information pertaining to a biological resource and associated traditional knowledge obtained from India. SBBs deal with matters relating to access to bio-resources by Indians for commercial purposes and restrict any activity which violates the objectives of conservation, sustainable use and equitable sharing of benefits.¹⁶ the functions of the BMCs include conservation, sustainable use, and documentation of biodiversity and chronicling of

knowledge relating to biodiversity (however, not specifically mentioned in any provision). In order to safeguard the interests of the local people and to allow research by Indian citizens within the country, free access to biological resources for use within India for any purpose other than commercial use for Indian people has been given to the traditional physicians and other citizens—India has a bottom up approach, with the NBA (at central level),¹⁷ SBBs (at state level)¹⁸ and BMCs (at district/block level),¹⁹ their roles have been elaborated further: NBA is the highest Authority to implement the Act. “Section 3 of the Act”²⁰ deals with the regulation of access to bioresources. A person or a body corporate, not an Indian shall have to seek approval from the NBA for obtaining any bioresource occurring in India or knowledge thereto for research, ‘commercial utilisation’, ‘bio-survey and bio-utilisation’.²¹ Under this provision the NBA restricts the access of bioresources. To access any bioresource and associated traditional knowledge, the procedure mentioned in Rule 14 shall apply accompanied with Form I application. Similarly, to seek approval in relation for applying for IPR, the procedure mentioned in Rule 18 shall apply accompanied with Form III. Till date, NBA has granted approvals to 247 applications, out of which 68 are Form I applications and 131 are Form III applications.²² In this procedure of granting or rejecting approvals, status of bioresource is enquired in a top bottom approach (i.e. from NBA, SBBs & BMCs) and only after the official communication the approval is granted. However, conservation or protection is not a part of this procedure, it has been mentioned as a part of function of SBBs and BMCs. The direct provision for ABS is Section 21 of the Act. It evokes the role of the NBA in determination of equitable benefit sharing.²³ NBA while granting approvals under Section 19 or Section 20 ensures that the terms and conditions subject to be approved^{24, 25} secures equitable sharing of benefits arising out of the use of accessed biological resources, their by-products, innovations and practices associated with their use and applications and knowledge relating thereto, however, in accordance with mutually agreed terms and conditions between the person applying for such approval, local bodies concerned and the benefit claimers.²⁶ Further, the NBA, subject to any regulations made in this behalf, determines the benefit sharing which shall be given effect in certain other manners as well.²⁷ The criteria

for equitable sharing of benefit has been elaborated under Rule 21 of the Biological Diversity Rules 2004. According to it, the formula for benefit sharing shall be determined on a case to case basis.²⁸ In any case, 5% of the accessed benefit shall be earmarked for the NBA or boards, as the case may be for administrative charges.²⁹ However, with the commencement of the Guidelines in 2014, there have been various changes in the benefit sharing mechanism.

Role of State Biodiversity Boards in Implementation of ABS

SBB have a very important role in the ABS process. As per Section 6 of the Act, unless the NBA has provided approval, no application on IPR shall be entertained in relation to any bioresource originating in India. This read with Section 7 of the Act mentions, any Indian citizen or organisation shall not be allowed to obtain any bioresources for commercial utilisation, except prior intimation to the concerned SBB (exception to vaida and hakims for indigenous medicine). It is the function of the SBB to regulate the granting of approvals for commercial utilisation or bio-survey and bio-utilisation of bioresources by Indians.³⁰ Further, it is the function of the SBB to restrict certain activities violating the conservation objective of the Act.³¹ On receipt of intimation, the SBB in consultation with the local bodies and after making enquiries as it deems fit, shall order, prohibit or restrict the access of the bioresource, in contrary to the objectives of the Act. Though conservation is a priority, India has not been able to achieve its conservation targets.³² The Act provides the power to the SBBs, to restrict activities that violate the conservation objective. But it does not introduce conservation as a function for the SBB.³³ The function of the SBBs is to advise the State Govt., in relation to regulating approvals for ABS applications (by Indian) and other functions for the implementation of the Act.³⁴ However, for 'conservation and promotion of bioresources' and a list of other initiatives, State biodiversity Fund has been constituted, which makes conservation the responsibility of the SBBs.³⁵ Conservation as a function in general and for ABS (specifically, with the co-ordination of the BMCs). Till date 37769 BMCs have been constituted under the Act.³⁶

Role of BMCs in ABS implementation in India

For a successful ABS mechanism there is need for multi-stakeholder frameworks discussing the scope of

access, value addition and benefit-sharing.³⁷ Further, the rights and duties of the community also need to be distinguished in benefit-sharing arrangements in consonance with the local Authorities. The Act established the BMCs in this regard. BMCs shall be established for the purpose of promoting conservation, sustainable use and documentation of biodiversity including preservation of habitats, conservation and other aspects relating to biodiversity.³⁸ The NBA and SBBs consult the BMCs while taking any decision relating to the use of bioresources and knowledge associated with such resources occurring within the territorial jurisdiction of concerned BMC.³⁹ Here the BMC may levy charges in form of fee from any person for accessing or collecting bioresource for commercial purpose, within its territorial jurisdiction.⁴⁰ However, the BMCs have their own funding mechanism, the Act provides the provision of Local Biodiversity Funds that shall be granted by the State Govt. to be utilised by the BMCs for the implementation of the Act.⁴¹

Apart from all this the BMC has a very important function i.e. documentation of the PBRs.⁴² PBR is an important document because it is the authentic database on local biodiversity, on availability and knowledge of local bioresources, their medicinal or any other use and traditional knowledge associated with them.⁴³ The techno-legal aspects of PBRs have been discussed from the point of view of implementation as well as validation of the information and harmonizing traditional knowledge related information.⁴⁴

Access and Benefit Sharing Guidelines

In the 12th meeting of the NBA there was a proposal to introduce a set of Guidelines on ABS.⁴⁵ It was further proposed that the guidelines must be made simple and pragmatic and shall include provisions in relation to the commercial exploitations of the bioresources. In 2014 the ABS Guidelines came into existence. These guidelines mainly focus on the commercialisation of the bioresources and ABS related to it. They provide a mechanism in which the financial obligation of the user of genetic resources is to be determined for each of the activity identified earlier for which bioresources are obtained, it also indicates how these benefits are to be shared.⁴⁶ However, the measures to be taken in relation to monitoring the access are in process under the SBBs. The guidelines mainly focus on the financial obligations of the users of the bioresources, how they

shall be determined and the percentile of benefits to be shared. It is an extension of the Section 3 of the Act dealing with the process for access of the bioresource and associated traditional knowledge.⁴⁷ The Act derives that the benefit sharing obligation on traders shall be 1.0 to 3.0 % and for manufactures it shall be 3.0 to 5.0 % of the purchase price of the biological resource.⁴⁸ In case of bioresources having high economic value the benefit sharing shall be not less than 5.0%.

Further, the ABS Guidelines states that the stakeholders, in case of commercializing the IPR obtained on inventions related to genetic resources need to pay to the NBA such monetary and/or nonmonetary benefit, as agreed between the applicant and the NBA.⁴⁹ As per the ABS guidelines, benefit sharing may be done in monetary and/ or non-monetary modes, as agreed upon by the applicant and the NBA/SBB concerned in consultation with the BMC/ Benefit claimer, etc. Determination of benefit sharing is to be based on considerations such as commercial utilization of the biological resource, stages of research and development, potential market for the outcome of research, amount of investment already made for research and development, nature of technology applied, time-lines and milestones from initiation of research to development of the product and risks involved in commercialization of the product. Interestingly, the amount of benefit sharing is to remain the same whether the end product contains one or more biological resources. Once the biological resource use obtains approval from the NBA the mode of benefit sharing is prescribed such that 5.0% goes to NBA and 95% of the go to concerned BMC(s) and/ or benefit claimers, where approval is granted by SBB, the SBB may retain a share, not exceeding 5% of the benefits accrued while the remaining share is to be passed on to the BMC concerned or to benefit claimers.⁵⁰ Currently, all the states are in the process of implementing the guidelines. Notices are being issued by the SBBs to initiate ABS with the Indian companies.

Biodiversity Monitoring to be an Integral Part of ABS Mechanism

Commercial utilisation is the essence of ABS, and the absence of a systematic monitoring mechanism shall lead to an unsustainable ABS. ABS cannot be performed in isolation or at the cost of conservation. Therefore, monitoring of Biodiversity has to be a part of the ABS mechanism. So far, in relation to the ABS

agreements reached in India there has been no specific obligation imposed in relation to biodiversity monitoring. To that extent, in view of the post Nagoya implementation, India will need to recognize “monitoring” as one of the conditions. A review of the Form I and Form III of the Act reveals the need to strengthen the context of biodiversity monitoring. In the recent past many SBBs have notified to industries to disclose the extent of use of bioresources. Institutions have also received such notices. One of the enabling mechanisms under the Act would be to integrally link biodiversity monitoring with ABS. Some of the proposals that could be implemented in this regard are given below:

- To recognise “Biodiversity Monitoring” as a pre-condition to ABS.
- To initiate “Biodiversity Monitoring” as a part of the ABS Agreement by invoking conservation obligations for the users and the providers, both.
- To convey to the users that benefit-sharing does not release them of their responsibility of sustainable utilisation for bioresources used for commercial purposes.
- SBBs will need to have a regulatory role in such biodiversity monitoring by strengthening the institutional mechanism.
- BMCs should work as agencies for local biodiversity monitoring.
- Financial mechanisms must be made available for effective conservation. Academic institutions can play a vital and supportive role in this endeavor.
- Social objectives in terms of contribution to biodiversity monitoring must be outlined in approvals for research grants related to use of bioresources. Utilising this as a non-monetary basis of implementation of ABS will be desirable.

Conclusion

This study highlights the need for including biodiversity monitoring as part of the pre-ABS and post ABS mechanism in India post the Nagoya Protocol. India is one of the eight primary centres of the origin of cultivated plants which highlights the important role of conservation and sustenance of species. This assumes importance in light of the concerns on loss of biological diversity in India. By making biodiversity monitoring an integral part of the implementation of the ABS guidelines and for ABS agreements a common responsibility/will to conserve biological diversity can be achieved.

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