Regulated Use of Biological Resources and Traditional Knowledge for Sustainable Development: The Experience from India

Pushpa Kumar Lakshmanan
Law Centre – I, Faculty of Law, University of Delhi, Delhi, Delhi- 110007 India.
Corresponding author: pushpaharvard@gmail.com

OIDA International Journal of Sustainable Development, Ontario International Development Agency, Canada.
ISSN 1923-6654 (print) ISSN 1923-6662 (online) www.oidaijsd.com
Also available at http://www.ssrn.com/link/OIDA-Intl-Journal-Sustainable-Dev.html

Abstract: Biodiversity is the base and source of most of the developmental activities. With the advent of modern biotechnology, the utilization of biological and genetic resources for various developmental ventures in medicine, health products, cosmetics, and industrial products increased manifold. Ever since the Convention on Biological Diversity rolled out a blueprint for conservation of biological diversity, sustainable use of its components and equitable sharing of benefits arising out of utilization of genetic resources and traditional knowledge, the Parties to the Convention recognized them as cardinal principles for sustainable development that depends on biological diversity. The Nagoya Protocol on Access and Benefit Sharing for Utilization of Genetic resources and Traditional Knowledge concretized the legal mandate for facilitated access to genetic resources and traditional knowledge for research and developmental purposes. The Protocol ensured equitable sharing of benefits to the indigenous and local communities that have shared traditional knowledge and contributed for the conservation of biological diversity. Being a party to the Convention on Biological Diversity as well as the Nagoya Protocol, India has been implementing the Convention and the Protocol through the Biological Diversity Act, 2002.

The Biological Diversity Act, 2002 provides facilitated access to biological resources and associated knowledge based on prior approval and mutually agreed terms. Even though both the Convention on Biological Diversity and the Nagoya Protocol use the terms "genetic resources," the Indian Biological Diversity Act regulates "biological resources." This gives a broader scope to the regulation and benefit sharing. A three tier-mechanism has been created under the Act to regulate access to biological resources and associated knowledge and to ensure benefit sharing. The National Biodiversity Authority at the federal level provides prior approval to the non-Indian entities for research and commercial utilization of biological resources. This Authority also regulates transfer of research results and transfer of accessed biological resource to a third party. Any application for intellectual property protection for any product or process involving biological resources requires prior approval of the National Biodiversity Authority. The State Biodiversity Boards established in the States regulate access to biological resources by the Indian citizens at the state level. Both the National Biodiversity Authority and the State Biodiversity Boards determine benefit sharing at the time of granting approval. However, the State Biodiversity Boards do not have any clear mandate under the Act to accord approval and fix benefit sharing. This issue has been raised in the case of Divya Pharmacy v. Union of India (2018). The Biodiversity Management Committees established at the grassroots level in the local bodies have major duties of conservation and documentation of biodiversity and the associated knowledge available within its jurisdiction. These Committees also have the power to levy access fees from the persons accessing biological resources within its jurisdiction. The Biological Diversity Rules 2004, and the Access and Benefit Sharing Regulations 2014 aid the implementation of Biological Diversity Act.

Nevertheless, the implementation of the Biological Diversity Act has been entangled with multiple challenges due to convoluted procedures, different enforcement approaches of State Biodiversity Boards and lack of clarity in the law itself. Hesitation of industry stakeholders to comply with the law and lack of participation and awareness about the access and benefit sharing process on the

part of the local communities add the complexity to the implementation of the law. All these issues not only pose threat to the implementation of biodiversity law, but also threat to conservation and sustainable development. This paper will critically analyze the importance of conservation of biological diversity and sustainable use of biological resources globally and in a developing country like India to further sustainable development. It will shed light on the difficulties in implementing the biodiversity law in India. This paper will also examine how access and benefit sharing regime in India impacts research and innovation for sustainable development and how it benefits biodiversity conservation and local communities with the help of case studies.

Keywords: Access and Benefit Sharing; Convention on Biological Diversity; Innovation; Nagoya Protocol; Sustainable development.

Introduction

Biological diversity is complex web of life forms that decide the possibility of sustainability of this planet as a whole. Every species depends on different other species for survival. Human beings depend on biodiversity for every aspect of their life. Besides being affected by the natural causes, biodiversity is threatened by over exploitation of biological resources in an unregulated manner. With the extreme challenges of global climate change and threats to biodiversity in an unimaginable manner, the humanity is in the cross roads now looking for alternative ways of surviving. Consequences of climate change are already noticed in various countries in terms of rapid desertification, significant reduction in agricultural food production, acute water shortage, devastating natural calamities such as changes in rainfall pattern, unmanageable floods and irreversible droughts. One of the major casualties of global climate change is biodiversity. The ecosystems across the world are experiencing unprecedented threats that tell upon the existence of several species of flora and fauna. Significant numbers of species of microorganisms, insects, and plants have already under serious threat. If biodiversity is getting threatened for any reason, it demonstrates the death knell for the humanity as well. Even though use of biological resources for developmental purposes cannot be ruled out due to its increasing demand in industrial processes, drugs manufacturing, cosmetics and health products, prudent use of biological resources is the need of the hour.

Sustainable use of biological resources for developmental purposes should be the norm rather than an exception. The Convention on Biological Diversity (CBD) for the first time came out with a road map for conservation of biodiversity; sustainable use of biological resources; and fair and equitable sharing of benefits arising out of the utilization of genetic resources. The CBD recognised sovereign rights of the States over their natural resources and their authority to determine the access to genetic resources through their domestic legislation. In this context, this paper analyses the importance of conservation of biodiversity, prudent use of and regulated access to biological resources for developmental purposes, and equitable sharing of benefits to the indigenous and local communities that have contributed for conservation of biological resources and associated knowledge [1].

The Convention on Biological Diversity and India

The CBD advocated for access to genetic resources should be based on prior informed consent and mutually agreed terms of the member country providing genetic resources. For this purpose the CBD obligated the States to take come out with suitable legislative, administrative or policy measures for sharing the results of research and development and the benefits arising from the commercial and other utilization of genetic resources [2]. The benefits have to be shared with the member country providing genetic resources in a fair and equitable manner on mutually agreed terms.

After ratifying the CBD on 18 February 1994, India has been implementing the CBD with all seriousness. Conservation of biological diversity has been implemented with the help of a slew of legal and policy instruments. The Indian Forest Act 1927, the Forest (Conservation) Act 1980, and the Wildlife (Protection) Act 1972 are the major laws that promote conservation of biodiversity. The Biological Diversity Act 2002 (BD Act) is the law enacted to implement the CBD to implement access and benefit sharing in India.

The BD Act aims at conserving biological diversity available in the country, sustainable use of its components and fair and equitable sharing of benefits arising out of use of biological resources and the associated knowledge. The BD Act was enacted in the background when the world was witnessing numerous biopiracy cases. India itself was a casualty of many biopiracy cases such as the Neem case, Turmeric case and Basmati case wherein India's biological resources as well as the traditional knowledge of local communities have been found to be misappropriated and patented in foreign countries without any permission from Indian authorities or local communities [3]. The parties who have misappropriated and sought patent protection in other countries have neither accessed the resources or

knowledge legally nor shared any benefit with the relevant stake-holders. The Government of India launched legal proceedings in foreign patent offices such as the US Patent and Trademarks Office and the European Patent Office to vindicate India's claims. The BD Act was enacted against this backdrop to prevent misappropriation of genetic resources and the traditional knowledge of local communities in India and to end biopiracy. The BD Act has become model legislation for most of the developing countries to fight against biopiracy and to regulate access and benefit sharing relating to genetic resources and traditional knowledge.

Regulated use of Biological Resources and Associated Knowledge under the BD Act

The regulatory system under the BD Act is built on three-tier system that will take care of access to genetic resources and the associated knowledge at the national level, state level and local level. The National Biodiversity Authority (NBA) functions as the highest level regulatory body in relation to access to biological resources and associated knowledge. It is imperative to clarify here that the CBD as well as the Nagoya Protocol advocates regulatory access to genetic resource and traditional knowledge. However, the BD Act in India regulates access to biological resources in a broader sense. Instead of referring to traditional knowledge, the BD Act refers to associated knowledge in relation to biological resources. This has been frowned upon by many scholars as why should India encompass biological resources broadly, instead of limiting its regulation only with genetic resources. In fact, as per international law, the multilateral treaties only set the minimum standards for the states. A state party is at liberty to go beyond the minimum standards and regulate matters broader than the subject matter dealt with in the multilateral treaties. Associated knowledge relating to biological resources is broad enough to include the traditional as well as the contemporary knowledge prevailing among the indigenous and local communities [3].

Approval Mechanism and Determination of Benefit Sharing

The NBA is the overarching regulatory authority to grant approvals for non-Indian entities. Non-Indian entities mentioned in section 3(2) of the BD Act should obtain prior approval from the NBA before obtaining any biological resource occurring in India or associated knowledge for research or for commercial utilization or for bio-survey and bio-utilization. The NBA may impose any charge or fix royalty against any person mentioned in section 3(2) who intends to access any biological resource available in India or any associated knowledge for research or commercial utilization or for bio-survey and bio-utilization or transferring the results of any research pertaining to biological research from India.

An Indian citizen or any body corporate, association or organization which is registered in India should give prior intimation to the State Biodiversity Board (SBB) concerned before obtaining any biological resource for commercial utilization, or bio-survey and bio-utilization for commercial utilization [4]. This provision will not apply to local people and communities of the area, including growers and cultivators of biodiversity, and *vaids* and *hakims*, who have been practicing indigenous medicine.

Transfer of Research Results

Prior approval of the NBA is required for transfer of the results of any research relating to any biological resources occurring in, or obtained from India for monetary consideration or otherwise to any non-Indian entity referred to in section 3(2) of the BD Act. According to the explanation to this section, the term "transfer" does not include publication of research papers or dissemination of knowledge in any seminar or workshop, if such publication is as per the guidelines issued by the Central Government [5].

Application for Intellectual Property Rights

Any person who wishes to apply for any intellectual property right within or outside India for any invention based on any research or information on a biological resource obtained from India shall obtain the prior approval of the NBA before making such application [6]. However, if a person applies for a patent, permission of the NBA may be obtained after the acceptance of the patent but before the sealing of the patent by the patent authority concerned. The Biological Diversity Act provides that the NBA should dispose of any such application within ninety days from the date of receipt of the application. While granting the approval under this section for IPR based applications, the NBA may, impose benefit sharing fee or royalty or both or impose conditions including the sharing of financial benefits arising out of the commercial utilization of such rights.

For any person, whether Indian or non-Indian, prior approval of NBA is necessary to apply for a patent or any other form of IPR within India or outside India; or for transfer of any biological resource or associated knowledge. As per the provisions of sections 19 and 20 of the Biological Diversity Act, the NBA may grant approval subject to any conditions that may include imposition of any charge or royalty.

On behalf of the Central Government, NBA can take any measures to oppose the grant of IPR in any country outside India on any biological resource obtained from India or knowledge associated with such biological resource which is derived in India.

Application under Protection of Plant Varieties Farmers' Rights Act

The Protection of Plant Varieties and Farmers' Rights Act, 2001deals with protection of breeders' rights and farmers' rights [7]. Section 6(3) of the Biological Diversity Act states that prior approval is not required for any person making an application for any right under the Protection of Plant Varieties and Farmers' Rights Act, 2001 because benefit sharing will be fixed by the Plant Varieties and Farmers' Rights Authority while deciding such cases. Whenever, any such right is granted by the Plant Varieties and Farmers' Rights Authority, the Authority has to endorse a copy of such document granting the right to the NBA.

Determination of Benefit Sharing

NBA determines equitable benefit sharing arising out of the use of accessed biological resources, their by-products, innovations and practices associated with their use and applications and knowledge relating to them in accordance with mutually agreed terms and conditions between the person applying for such approval, local bodies concerned and the benefit claimers [8]. NBA is the apex body that has the power to formulate guidelines for access to biological resources and for fair and equitable benefit sharing. NBA determines benefit sharing subject to any regulations made under the BD Act.

Rules 14 to 20 of the Biological Diversity Rules, 2004 prescribe the procedure for access to biological resources and associated traditional knowledge, transfer of results of research, for seeing prior approval before applying for IPR protection, third party transfer of accessed biological resources, and criteria for equitable benefit sharing.

The 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 to the Convention on Biological Diversity (hereinafter Nagoya Protocol) was adopted on 29 October 2010 in Nagoya, Japan under the Convention on Biological Diversity [9]. Adoption of the Nagoya Protocol is undoubtedly a much awaited milestone achievement of the international community, particularly the Contracting Parties of the CBD.

The Nagoya Protocol on ABS is the instrument for the implementation of the access and benefit sharing provisions of the CBD. The Nagoya Protocol applies to genetic resources within the scope of Article 15 of the CBD and to the benefits arising from the utilization of such resources. The Protocol also applies to traditional knowledge associated with genetic resources within the scope of the Convention and to the benefits arising from the utilization of such knowledge.

The Contracting Parties are obligated to take appropriate national legislative, administrative or policy measures for access and benefit sharing for genetic resources and the associated traditional knowledge. In order to ensure proper compliance with the domestic legislation on ABS, the Protocol obligates the Parties to designate National Focal Points, Competent National Authorities and Check Points. The Protocol also suggests the establishment of the ABS Clearing House and information sharing mechanism. It also provides for special considerations for certain research activities and global multilateral benefit sharing mechanism.

Article 5 and 6 of the Protocol reflects the CBD's approach to access and benefit sharing based on the principles of prior informed consent (PIC) and mutually agreed terms (MAT). According to Article 6, access to genetic resources for their utilization shall be subject to the PIC of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the CBD, unless otherwise determined by that Party. This will be done according to the domestic access and benefit-sharing legislation or regulatory requirements of the Party.

According to Article 7 of the Protocol, each Party shall take national measures *in accordance with domestic law*, *as appropriate*, with the aim of ensuring that traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with the PIC or approval and involvement of these indigenous and local communities, and that MAT have been established. The terms, national measures "*in accordance with domestic law" and "as appropriate"* provide sufficient leeway to the Parties to choose the level of PIC and MAT as per their convenience.

Under the Nagoya Protocol, PIC is not mandatory to regulate access to genetic resources. It is up to the Party, whether or not, to provide for PIC procedure through domestic legislation. If a Party decides to regulate access to genetic resources for their utilization subject to the PIC of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention, it has to provide for necessary legislative, administrative or policy measures, as appropriate. If a Party does not want to regulate access to genetic resources based on PIC, it need not enact such legislation.

If a Party chooses to regulate access to genetic resources thorough PIC, it must enact a domestic law and such law must provide for a mechanism for PIC or approval system with the help of a Competent National Authority and it should provide for a mechanism that ensures legal certainty, clarity and transparency of the domestic access and benefit-sharing legislation or regulatory requirements. The domestic measures should also provide for fair and non-arbitrary rules and procedures on accessing genetic resources. The procedures should apply for prior informed consent, criteria and processes for obtaining prior informed consent or approval, and clear rules for establishing MAT The terms should set out a dispute settlement clause, terms on benefit-sharing, including in relation to IPR, terms on subsequent third-party use, if any; and the terms on changes of intent, if applicable.

Where the indigenous and local communities have established right to grant access to genetic resources, their involvement is required for access to genetic resources. The law should provide for the criteria and/or processes for involvement of indigenous and local communities for access to genetic resources. The domestic law should provide for a written decision or certification by a competent national authority, in a cost-effective manner and within a reasonable period of time. All details of PIC and MAT should be notified by the Competent National Authority to the Access and Benefit-sharing Clearing-House.

Annex to the Protocol lists ten monetary benefits and seventeen forms of non-monetary benefits, but does not limit the scope of benefits with those mentioned in the Annex. The Parties are at liberty to apply any other form of benefit sharing. The Protocol has given life to the provisions of the CBD pertaining to ABS through an internationally legally binding instrument. The success of this Protocol will depend on how the State Parties and different stakeholders give life to its provisions by effective compliance and implementation.

Fulfilling the Legal obligations of the Nagoya Protocol under the Biological Diversity Act

Having established a well regarded legislative framework, India stands on a strong footing to implement the Nagoya Protocol. India plans to implement the Nagoya Protocol through the Biological Diversity Act. However, India needs to make some necessary changes in the BD Act.

Article 6, 7 and 12 of the Protocol stipulates that accesses to genetic resources and traditional knowledge should be based on prior informed consent (PIC) or with the approval and involvement of indigenous and local communities.

Annex to the Nagoya Protocol lists ten monetary benefits and seventeen forms of non-monetary benefits, but does not limit the scope of benefits with those mentioned in the Annex. The Biological Diversity Act or the Rules may be amended to include those forms of monetary and non-monetary benefits provided in the Annex to the Protocol that will broaden the scope of determination of benefit sharing by the NBA. Alternatively, the NBA may elaborate the monetary and non-monetary benefits in the benefit sharing guidelines.

Prior Informed Consent

Articles 6, 7 and 12 of the Nagoya Protocol stipulate that accesses to genetic resources and traditional knowledge should be based on prior informed consent (PIC) or with the approval and involvement of indigenous and local communities.

The existing PIC mechanism under the Biological Diversity Act may not meet the requirements of the Nagoya Protocol as it does not involve local communities directly. At present access to genetic material is given by the NBA in consultation with the SBBs and BMCs. The participation or involvement of local communities is not ensured appropriately, though one can argue that the involvement or voices of the local communities are expressed through the BMCs. To be specific, access to genetic resources held by the local communities, where they have the established right to grant access to such resources, PIC or approval and involvement of indigenous and local communities is to be obtained as per Article 6.2 of the Protocol. In India, the Scheduled Tribes and other Traditional Forest Dwellers (Recognition of Forest Rights) Act, 2006 protects the rights of scheduled tribes and traditional forest dwellers in the community right to intellectual property and traditional knowledge related to biodiversity and also empowers the holders of forest right to regulate access to community forest resources through Gram Sabha. In such a case, PIC or approval and involvement of the scheduled tribes and other traditional forest dwellers has to be

obtained.

Likewise, Article 7 of the Protocol mandates that access to traditional knowledge associated with genetic resources that is held by indigenous and local communities is to be obtained with PIC or approval and involvement of these indigenous and local communities. This provision will apply to all local communities who possess traditional knowledge at their disposal whether they live in forest land or not; and also to forest dwellers as protected under the Scheduled Tribes and other Traditional Forest Dwellers (Recognition of Forest Rights) Act, 2006.

The Biological Diversity Act of India does not mention PIC explicitly in the Act or the Rules though the approval system does the similar function. Under the Biological Diversity Act, access to genetic material is given by the NBA *in consultation with* the SBBs and BMCs. The participation or involvement of local communities is not ensured appropriately, though one may argue that the involvement or voices of the local communities are expressed through the BMCs. However, the provisions of Nagoya Protocol are very clear and categorical that each Party requiring prior informed consent shall establish necessary legislative, administrative or policy measures, as appropriate, to set out criteria and/or processes for obtaining prior informed consent or approval and involvement of indigenous and local communities for access to genetic resources.[3] Thus, the existing PIC mechanism under the Biological Diversity Act does not meet the requirements of the Nagoya Protocol as it does not involve local communities directly in cases (i) where they have established rights to grant access to genetic resources and (ii) where the local communities have traditional knowledge associated with genetic resources that is sought to be accessed. This aspect requires suitable changes in the Biological Diversity Act.

As far as the mutually agreed terms (MATs), the NBA has already developed model ABS agreements for the purpose of fixing benefit sharing under the Biological Diversity Act. These are the MATs as contemplated under the CBD. The Protocol also prescribes MATs for the purpose of access to genetic resources and benefit sharing. These aspects are already in place in India under the Biological Diversity Act. The MATS under the agreements may require modifications for strengthening them.

Check Points

India needs to designate check points for the purpose of monitoring the utilization of genetic resources and to increase transparency as provided in Article 17 of the Protocol. In a country like India with vast genetic resources, a single check point will not be able to check the movement of genetic resources. It is also not feasible for the Ministry of Environment and Forests to function as a Check point as it requires a great number of administrative staff with technical skills. The viable option is to designate the NBA as the Apex Check Point with other designated check points in different departments/offices such as the Patent Office, Customs office in Ports in Airports, GEAC, and the Chief Wildlife Warden in the Forest Department. If required, the NBPGR and ICMR may also be designated as Check points if there is a need to monitor the utilization of genetic resources through their approvals.

All the approvals from the Patent Office involving genetic resources or materials have to be intimated to the NBA before the granting of patent or ceiling of patent. Customs department at very port/harbour or airport in the country should be equipped with two technical experts from the NBA to monitor the movement of biological materials and to collect or receive the information related to the utilization of genetic resources. In the same manner the NBPGR and the ICMR should be posted with two technical experts each to monitor the export/import of genetic materials or utilization of genetic materials for any research or development purposes.

Given the fact that India is a biodiversity rich country and also a technologically progressive state, it is amongst those few countries which are capable of both, acting as a user as well as a provider nation in the ABS process. Therefore, it is required that Indian laws should have provisions for fulfilling its international obligations both as a user and a provider.

With regard to the benefits arising out of utilization of genetic resources the Indian BD Act contains sufficient provisions to meet the requirements under the Nagoya Protocol. As a provider country, the first and foremost thing that India needs to set out is to clarify the criteria for PIC in relation to TK associated with the biological resources. Accordingly, The Rules to the Biological Diversity Act should also be amended to include the procedure for PIC mechanisms in clear terms in relation to the TK associated with genetic resources.

The Nagoya Protocol also demands that the user state should honour and comply with the legal and regulatory requirements of the provider country. To be in conformity with the above requirements, India needs to amend its BD Act to incorporate adequate provisions to ensure that the genetic resources and TK obtained from other countries into India for research or commercial purpose shall comply with regulatory requirements of provider countries.

In order to broaden the scope of the forms of benefit sharing provided under the BD Act, it along with it corresponding rule should be amended to include the additional forms of monetary and non-monetary benefits provided under the annex to the Nagoya Protocol. As an alternative, the NBA may also elaborate the monetary and non monetary benefits in the benefit sharing guidelines.

The Protocol also mandates the user countries to ensure that the benefits arising from the utilization of genetic resources obtained from other Parties as well as the subsequent applications and commercialization of such resources are shared in fair and equitable manner as per the domestic laws of the providing Party and based on MAT. Articles 15.2 and 16.2 of the Protocol specifically urge the Parties to enact adequate measures to the address cases of non-compliance.

In the light of these provisions, the Biological Diversity Act needs to be amended to incorporate adequate provisions to ensure that the genetic resources and traditional knowledge obtained from other countries into India for research or commercial utilization shall comply with the regulatory requirements of provider countries. Suitable penal provisions should also be introduced in the Biological Diversity Act for any such violations. Section 60 of the Norwegian Nature Diversity Act, 2009 provides an example of user country law which can be considered in the Indian context [10].

Special Considerations

Article 8 of the Protocol deals with three special considerations, rather in a loose language, and expects the Parties to make suitable legislative, administrative and policy measures at their discretion.

Simplified measures for non-commercial research activities

Article 8(a) of the Protocol makes a provision for simplified measures for access to genetic resources for research activities meant for non-commercial purposes that contribute to conservation and sustainable use of biological diversity. The regulatory mechanisms of a Party that provide for simplified measures may take into account the subsequent change of intent of such research and may apply the normal regulatory procedures if the research activity does not fall under Article 8(a) of the Protocol.

The Biological Diversity Act of India does not have any different provision for access to genetic resources for research activities meant for non-commercial purposes that may contribute to conservation and sustainable use of biological diversity. But Article 8(a) of the Protocol brings in a very important point that requires favourable consideration of the Parties. Any non-commercial research that contributes to conservation and sustainable use of biological diversity needs special treatment. It is recommended that India may consider introducing a provision in the Biological Diversity Act to provide for simplified measures for such research activities.

Expeditious ABS to meet imminent emergencies

In order to meet imminent emergency situations at the national or international level that may threaten or damage human, animal or plant health, Article 8(b) insists on expeditions access to genetic resources and fair and equitable benefit sharing mechanism including access to affordable treatments by those in need, especially in developing countries. This will mean access to pathogens and other microorganisms that can be used to prevent or cure the epidemic spread of diseases among the human beings, animals or plants. This provision argues for a very genuine situation that requires prompt action by the Parties. Indian interests will not be affected in any manner by honouring this provision.

It is suggested that suitable provisions may be introduced in the Biological Diversity Act to facilitate expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatment by those in need, especially in developing countries as dealt with by Article 8 (b) of the Protocol..

Genetic resources for food and agriculture and food security

Article 8 (c) of the Protocol invites the Parties to consider the importance of genetic resources for food and agriculture and their special role for food security. Even though it is a persuasive provision and there is no compulsion for the Parties to make provision to implement it, taking into consideration the increasing demand for food and agricultural production and the stable increase of population in our country. It is suggested that India needs to incorporate some safeguard provisions in the Biological Diversity Act while providing access to genetic resources for different purposes of research and utilization. This can be incorporated as one of the grounds in Section 34 of the BD Act for refusal/restriction of access to biological resources in the Biological Diversity Act.

Guidelines on ABS regulations 2014

Even though Section 21 BD Act and Rule 20 of Biological Diversity Rules (BD Rules) provide powers to NBA for determining benefit sharing, that section has not given any specific guidelines to assist and finalize the quantum of benefit sharing in different situations. The Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations issued by NBA on 21 November 2014 provide guidelines for fixing benefit sharing [11]. The ABS regulations introduced provisions for special considerations to meet the requirements of the Nagoya Protocol.

Case Studies on Access and Benefit Sharing

A. Benefit Shairng for Access to Seaweed

In one of the benefit sharing cases, about 2000 metric tones of seaweeds collected through self help groups of coastal districts of Tamil Nadu (Ramanathapuram, Tuticorin, Pudukottai and Tanjore) by M/s. Pepsico India Holdings Pvt. Ltd. and M/s. Ganesan & Sons and exported to Malaysia, Philippines and Indonesia for commercial purpose. The NBA fixe a royalty @ 5% of FoB (Free on Board) amounting approximately Rs.39.09 Lakhs from the exporter.

B. Access to Neem Leaves

In another case of access to biological resources, the NBA approved an export of about 2000 Kilograms of Neem to Japan by Bio India Biologicals and determined a royalty @5% of FOB amounting to Rs. 55,035.00 from the exporter as benefit sharing. A part of the royalty amount was transferred to Amarchinta BMC for their contributions in planting more neem saplings in that area and for creating of awareness about biodiversity conservation. In this case, the Amarchinta BMC in Mahboobnager District, Andra Pradesh collected the neem leaves from Amarchinta village and dried them through special method by the villagers of Amrchinta before supplying to the exporter.

C. Divya Pharmacy Case

In the Divya Pharmacy Case, a question was raised in the Uttarakhand High Court as to whether the SBBs have the power to grant approvals for Indian nationals or body corporates when they access biological resources. Section 7 of the BD Act mentions that the Indian citizens should intimate the SBBs while accessing biological resources for commercial purposes. The court had held that section 7 has to be read with section 23(b) and 24(2) that mentions the powers of the SBBs to grant approvals. The court held that the spirit of law has to be looked into while interpreting the individual provisions of the Act [12].

Conclusion

The Biological Diversity Act is the key legislation in India that was enacted to implement the provisions of CBD for the purposes of conservation of biological diversity, sustainable use of its components and fair and equitable sharing of the benefits arising out of the use of biological resources and traditional knowledge. In the past fifteen years of its working, the BD Act has indeed significantly established the system of access and benefit sharing in India. However, the current system of actualizing ABS in India suffers from many procedural hurdles. This is prominently observable in some stages of implementation of the Act, such as, obtaining PIC, determining the quantum of benefit sharing, deciding monetary and non-monetary benefits and post-access motoring. A trend has also been seen in the current ABS procedure in the country that the benefit that is being agreed in various ABS agreements is largely monetary in nature. This undermines the potential of non-monetary benefits in national capacity building. Therefore, certain changes are required in the current ABS legal framework especially in the manner in which it is being implemented in the country to maximize the utility of biological resources and traditional knowledge of people for the development of the country.

The BD Act has indeed lost the golden opportunity to incorporate some robust provisions for biodiversity conservation when it was enacted. Its primary focus is to regulate utilization of biological resources and traditional knowledge through access and benefit sharing process. Taking cue from the Nagoya Protocol, the NBA has to set a trend to realize the goal of conservation of biodiversity through a part of benefits accruing out of benefit sharing and engaging the local people and the users in biodiversity conservation.

Another important agenda for the NBA should be to convert the ABS mechanism as a tool of transforming the lives of local people with monetary and monetary benefits. Instead of giving more emphasis on monetary benefits, efforts

should be taken to apply non monetary benefits to transform the lives of the people. Again, the benefits should reach the local communities and the benefits have to benefit conservation of biological diversity. Conservation needs to pick up in all areas where biological resources are exploited.

Adoption of Nagoya Protocol on Access and Benefit Sharing marks a landmark development in ensuring equity with the conservers and traditional knowledge holders while utilizing biological resources and the associated knowledge.

The Protocol thoughtfully provides for flexible mechanisms for access to genetic resources and fair and equitable sharing of benefits through PIC and MAT. The Protocol bestows sufficient leeway to the provider and user countries to fix their own terms in access and utilization of genetic resources and traditional knowledge and hence national sovereignty of Parties over biological resources are effectively respected. The Protocol also contains provisions to encourage users and providers to direct benefits arising from the utilization of genetic resources towards the conservation of biological diversity and the sustainable use of its components.

The Protocol contains provisions that will immensely benefit our national interests. It protects the interests of conservers of biological resources and traditional knowledge holders on the one hand, and provides for conservation of biological diversity and the sustainable use of its components on the other hand. With the legal mechanisms already in place like the Biological Diversity Act, India is truly in an advantageous position to implement the Nagoya Protocol.

The BD Act of India meets with most of the international legal obligations created by the Nagoya Protocol. Nevertheless, involvement of local and indigenous peoples in the access and benefit sharing process needs to be strengthened in a more viable and effective manner. Compliance of user country measures need to be taken into account seriously and legal provisions need to be introduced to reflect this aspect.

Considering the huge repository of biological resources and traditional knowledge in India and the large potential of bio-prospecting opportunities, a mammoth task lies before NBA, SBBs and BMCs in regulating access to biological/genetic resources and the related traditional knowledge and ensuring fair and equitable sharing of benefits. The divisions of NBA need to be enlarged with the induction of legal, technical and scientific experts to effectively deal with the challenges involved in addressing techno-legal issues of ABS. Likewise, the SBBs in the States need to enlarge their size and capacities to meet the demand of task before them. The technical, legal and scientific skills of the staff of NBA, SBBs and BMCs need to be regularly strengthened.

Capacity Building and training for institutions, officials and relevant stakeholders involved in negotiations and implementation of ABS provisions should be given top priority. Article 22 of the Protocol supports this view and advocates involvement of local communities and relevant stakeholders, including non-governmental organizations and the private sector. Capacity building for officials and training and awareness programmes for local communities and other stakeholders to negotiate mutually agreed terms and to promote equity and fairness in ABS negotiations will be the challenging task to be addressed.

In this context, issues such as monitoring and enforcement of compliance; development and use of viable valuation methods; bio-prospecting, associated research and taxonomic studies; technology transfer, and infrastructure and technical capacity to make such technology transfer sustainable; channelizing ABS activities towards conservation of biological diversity and the sustainable use of its components; increasing the capacity of local communities and other relevant stakeholders with emphasis on enhancing the capacity of women within those communities in relation to access to genetic resources and/or traditional knowledge associated with genetic resources need special attention.

References

[1] The Convention on Biological Diversity (1992). The Convention on Biological Diversity (CBD) was adopted in the Nairobi Conference on 22 May 1992 and opened for signature on 5 June 1992 at the United Nations Conference on Environment and Development at Rio de Janeiro. The CBD entered into force on 29 December 1993. Retrieved from https://www.cbd.int/convention/articles/default.shtml?a=cbd-02

[2] Lakshmanan, Pushpa Kumar. (2018). Implementing the Convention on Biological Diversity and its Protocols in India. In Burra Srinivas and Rajesh Kumar (Eds), *Locating India in the Contemporary International Legal Order*, Springer India, New Delhi.

[3] Lakshmanan, Pushpa Kumar. (2018). Implementing Nagoya protocol on Access and Benefit Sharing in India. In Usha Tandon et al (Eds), *Biodiversity: Law, Policy and Governance*, Routledge – Taylor & Francis, Oxon and New York.

[4] The Biological Diversity Act (2002). Act 18 of 2003. Section 7.

[5] The Biological Diversity Act (2002). Act 18 of 2003. Section 4.

[6] The Biological Diversity Act (2002). Act 18 of 2003. Section 6.

[7] Lakshmanan, Pushpa Kumar. (2008). The Protection of Plant Varieties and Farmers' Rights Act, MS Swaminathan Research Foundation, Chennai.

[8] The Biological Diversity Act (2002). Act 18 of 2003. Section 21.

[9] The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arisingfrom their Utilization to the Convention on Biological Diversity, 2010. Retrieved from www.cbd.int/abs/text/

[10] The Norwegian Nature Diversity Act, 2009. Section 60.

[11] The Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations (2014). Rule 4.

[12] Divya Pharmacy v. Union Of India and Others (2018). Uttarakhand High Court . Writ Petition (M/S) No. 3437 of 2016. Decision dated 21 December, 2018.

About the author:

Dr. Pushpa Kumar Lakshmanan is a Senior Assistant Professor in Law Centre-I, Faculty of Law, University of Delhi. He earned his LL.B. and LL.M. from Pondicherry University and Ph.D. from University of Delhi, India. As a Fulbright scholar he pursued Post-Doctoral research at Harvard Law School, Harvard University, USA. He worked at Nalanda University as Associate Professor during 2015-2018.

Pushpa is a multidisciplinary scholar who specializes in international environmental law with special focus on the Convention on Biological Diversity, the UN Framework Convention on Climate Change, the Paris Agreement on Climate Change, global environmental governance and sustainable development. He teaches environmental law, intellectual property law and international law for LL.B. and LL.M. in the Faculty of Law, University of Delhi. In addition to the above subjects, he taught *"Law and Justice in the global world"* for LL.M. and *"Fundamental Perspectives in Law"* for doctoral students which is a part of their Ph.D. course work.
Pushpa's research scholarship focuses on legal and policy solutions to sustainable development, biodiversity conservation, global climate change, access and benefit sharing for the utilization of genetic resources and traditional knowledge, regulatory approaches to biotechnology, Cartagena Protocol on Biosafety, and Liability and Redress relating to living modified organisms. His other research interests include global governance for climate change; and protection of traditional knowledge, intellectual property rights and world trade, international law and hum an rights with a broad focus on promotion of rule of law, global justice and international peace. He has published over 25 research publications and delivered more than 75 invited lectures and paper presentations in international and national conferences.

He has many academic honours to his credit. He was invited to participate in the International Visitors Programme on "Urban Environmental Issues" in the USA, organized by the US Department of State in August 2003. He was a Visiting Scholar at Cardiff Law School, Cardiff University, UK (2006); a Research Fellow at the Max Planck Institute for Comparative Public Law and International Law, Heidelberg, Germany (2009); and a Visiting Scholar at the University of Washington School of Law, University of Washington, Seattle, USA (2012). He served as a Faculty Associate at the Berkman Klein Center for Internet and Society, Harvard Law School, Harvard University, USA (2013-2016).

He advises the Indian Central Government and national bodies on legal issues and serves as a member of expert committees on environmental matters. Presently, he serves as a Biosafety Expert in the International Roster of Experts for the Biosafety Clearing House, under the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.

Name: Prof. Dr. Pushpa Kumar Lakshmanan
Professor of Law

Mailing address:
Law Centre – I, Faculty of Law,
University of Delhi, Delhi,
Delhi- 110007, India.

Mobile: +91 9871820771
e-mail : pushpaharvard@gmail.com