

Access and benefit sharing: issues and experiences from India

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Abstract With the Nagoya Protocol on Access and Benefit Sharing (ABS) coming into force on 12th October 2014, national and global debates on ABS shifted towards implementation of this new and challenging international framework at national levels. The time and energy spent on negotiating the framework and its adoption in 2010 by the Conference of Parties to the Convention on Biological Diversity (CBD) would now be reflected in the manner by which countries design their ABS frameworks considering options ranging from administrative to legal regimes. India is one of the few countries that had legislated a framework to deal with ABS in 2002. However, the implementation experience has been uneven and complex. This paper will review the state of play with regard to the Nagoya Protocol on ABS and the way India is responding to the implementation of the Protocol besides addressing challenges of implementing complimentary international obligations such as the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and others.

Keywords Nagoya Protocol · Access and benefit sharing · International treaty · India · ABS frameworks · CBD

1 Introduction

The Convention on Biological Diversity (CBD) was adopted during the United Nations Conference on Environment and Development (UNCED) in 1992 with the focus on conservation, sustainable use of biological resources and fair and equitable

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sharing of benefits arising from such use.¹ The third objective of the CBD on fair and equitable sharing of benefits arising from the utilization of genetic resources is considered an innovative approach adopted by a multilateral treaty where the principle is based on series of discussions on the issue and consensus to recognize and reward people and countries who have contributed to the conservation of genetic resources and share the benefits with such providers.²

Meanwhile, discussions under the Food and Agricultural Organization's (FAO) Commission on Genetic Resources for Food and Agriculture (CGRFA) focused on recognizing the contribution of farmers and farming families across the world to conservation of plant genetic resources for food and agriculture. The discussions focused on the ways and means to recognize the contributions of farmers through the concept of farmers' rights.³ Discussions under the CGRFA and CBD contributed to adoption of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) under the UN Food and Agriculture Organization (FAO) in 2001 and the Nagoya Protocol on Access and Benefit Sharing (ABS) under the CBD (NP) in 2010. While the NP focuses on ABS in relation to genetic resources in general, the ITPGRFA focuses specifically on ABS issues related to plant genetic resources for food and agriculture (PGRFA).

Significant amount of time and energy is spent on assessing the ABS provisions under the ITPGRFA and the NP and how the provisions can be implemented at international and national levels.^{4,5,6,7}

CBD provides countries to control access to its sovereign resources subject to individual ABS agreements (bilateral processes) while the ITPGRFA supports international pooling and sharing of resources for agricultural research and food security through a multilateral system of exchange (multilateral processes).⁸ These two systems of provision of access and sharing of benefits are therefore different, making synergistic implementation of the Nagoya Protocol and International Treaty (IT) a challenge at national level. Countries that are parties to both the CBD and

¹ United Nations Conf. on Env't & Dev.: Convention on Biological Diversity, June 5, 1992, UNEP/Bioprospecting.Div./N7BINC 5/4, 31 I.L.M. 818 (entered into force Dec. 23, 1993).

² Balakrishna Pisupati, pocket guide on access and benefit sharing. UN University-Institute of Advanced Studies, Yokohama, Japan.

³ Farmers'Rights, FAO Res. 5/89, U.N. FAO, 25th Sess. (Nov. 29, 1989).

⁴ Jorge Cabrera Medaglia, et al., the interface between Nagoya protocol on ABS and the ITPGRFA at the international level: potential issues for consideration in supporting mutually supportive implementation at the national level (2013).

⁵ Gurdial Singh et al., food security and access and benefit sharing for food and agriculture (2011).

⁶ Kathryn Garforth & Christine Frison, *Key Issues for the relationship between the Convention on Biological Diversity and the International Treaty on Plant Genetic Resources for Food and Agriculture* (Quaker International Affairs Programme, Occasional Paper No. 2, 2007).

⁷ Claudio Chiarolla, *The Question of Minimum Standards of Access and Benefit-Sharing Under the CBD International Regime: Lessons from the International Treaty on Plant Genetic Resources for Food and Agriculture*, 10 Asian biotech. Dev. Rev. 3 (2008).

⁸ Michael Halewood et al., *Implementing 'Mutually Supportive' Access and Benefit Sharing Mechanisms Under the Plant Treaty, Convention on Biological Diversity and Nagoya Protocol*, 9 Law, Env't. & Dev. J. 68 (2013).

ITPGRFA are therefore in need to find operational options to implement ABS provisions at national level to honor the commitments on assigning PGRFA under the Treaty (ITPGRFA) Multilateral System while considering issues of sovereign rights over their genetic resources.

This paper provides an overview of implementation of the Biological Diversity Act in India and identify the challenges of implementing the NP and the ITPGRFA at national level and provides a quick assessment of experience from India on the challenges of implementing the two ABS systems since India is a party to both NP and the ITPGRFA.

2 Links between the Nagoya Protocol and the ITPGRFA

With the entry into force of the ITPGRFA in 2001 and the NP in October 2014, there is a need for countries to streamline national implementation of the Protocol and the Treaty in a manner the administrative, legal and regulatory frameworks concerning ABS. While the NP is the general framework concerning access to genetic resources, the ITPGRFA is specific with regard to access to genetic resources pertaining to food and agriculture and for specific purposes (Annex I).⁹

The CBD established a Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches¹⁰ to provide guidance regarding the relevance of sectoral approaches to implement the NP, including the ITPGRFA. This Group concluded that the CBD does not differentiate between different categories of genetic resources or different sectors. However, in practice, several basic distinctions exist that could be used for the development of national or international regulations such as the nature of the application or the intended use (commercial versus non commercial, for food and agriculture, for pharmaceutical purposes, etc.); the physical nature of the resources or their location (marine, terrestrial, higher plants; microorganisms; found ex situ or in situ, etc.). At the international level the ITPGRFA provides an example of a specialized legal regime on ABS in addition to focusing on facilitating multilateral exchange of genetic resources for food and agriculture.

The Standard Material Transfer Agreement (SMTA) of ITPGRFA is a private law contract, between the provider and the recipient. It has been described as “a private contract between individual provider and the recipient, is relied upon as the principle mechanism for the operation of the multilateral system”.¹¹ The ABS agreement envisaged under the NP also is a private contract between the provider of the resource and the user through a strictly bilateral system. While the ITPGRFA, through the SMTA, provides for standardized material transfer and benefit sharing

⁹ International Treaty on Plant Genetic Resources for Food and Agriculture, adopted Nov. 3, 2001, S. Treaty Doc. No. 110–19, [hereinafter International Treaty].

¹⁰ UNEP/CBD/WG-ABS/7/2, Dec.12, 2008.

¹¹ Halewood, *supra* note 8, at 72.

clauses while the NP suggests custom-made contractual clauses for access and benefit sharing.¹²

As described by Cabrera et.al.,¹³ it is the intellectual property rights (IPR) regime operating under the two systems that provide the differential though the genetic resources under the agriculture sector is governed by two ABS frameworks with the one focusing on patents and the other on breeder's rights. However, there has been limited focus on understanding the IPR related issues in implementing the IT though the discussions related to implementation of the NP seem to draw more attention to IPR issues using the debates on “disclosure of source/origin” debates.

The Multi Lateral System (MLS) is a core component of the ITPGRFA as it is further set out in Articles 10 to 13.¹⁴ The ABS system in the MLS covers only certain crops. ITPGRFA Article 11.1 defines the scope of the MLS as “the plant genetic resources for food and agriculture listed in Annex I”, i.e. 35 food crops and 29 forage plants. Annex I crops include major staples crops, as well as a range of other plants widely used for food and agriculture. The scope of the coverage of the MLS is that it covers “all plant genetic resources for food and agriculture listed in Annex I that are under the management and control of the Contracting Parties and in the public domain”.¹⁵ Thus, as described by Cabreara et.al.,¹⁶ linguistically, the paragraph imposes three *cumulative* criteria: PGR being under the *control* of the state; *managed* by the state; and recognized as being considered *public domain*.

It is important that countries who are parties to the ITPGRFA take the legal and administrative steps to identify the materials in their countries that are part of the multilateral system. From the implementation angle of ABS mechanism under the NP and the ITPGRFA, clarifying the legal and operational boundaries of access and benefit sharing is of crucial interest, because PGR outside the MLS are covered in principle by sovereign rights and in the absence of national level policy and regulatory frameworks to deal with ITPGRFA. Stakeholders interested in accessing and providing genetic resources may be left in the dark as to use the appropriate ABS principles. Until the notification issued by the Ministry of Environment, Forests and Climate Change (MoEFCC) in December 2014, germplasm exchange for PGRFA, including the ones covered by ITPGRFA was under the purview of the Biological Diversity Act.

¹² Tvedt, *Beyond Nagoya: Towards a Legally Functional System of Access and Benefit-sharing*, in *Global governance of genetic resources access and benefit sharing after the Nagoya protocol 30* (Oberthür & Rosendal eds., 2014).

¹³ Cabrera Medaglia, *supra* note 4.

¹⁴ Selim Louafi & Shakeel Bhatti, *Efforts to Get the Multilateral System Up and Running*, in *Crop genetic resources as a global commons: challenges in international law and governance 194* (Michael Halewood et al. eds., 2013).

¹⁵ ITPGRFA, art. 11(2).

¹⁶ *Id.*, art.11.

3 Implementation of ABS provisions under the CBD: the Biological Diversity Act in India

India enacted the Biological Diversity Act (BDA) in 2002¹⁷ and notified the Rules in 2004¹⁸ in response to its commitments under the CBD. The Act focuses on issues of conservation, sustainable use of India's biological diversity and provides specific provisions on ABS issues, including implementation options using a decentralized approach. The Act is implemented through a decentralized, three tier structure that consists of the National Biodiversity Authority (NBA), the State Biodiversity Boards (SBBs) and the local level Biodiversity Management Committees (BMCs). Sections 3, 4, 6, 7 and 21 of the BDA are in essence the regulatory provisions under the ABS mechanism envisaged by the Act.

Biological resources and associated knowledge, under the BDA, can be used for purposes such as bio-survey, bio-utilization, research and commercial purposes. Section 2 (f) of the BDA defines what is meant by commercial utilization.¹⁹ The BDA makes it mandatory for such persons to apply for prior approval from NBA in cases where they fall within the regulatory jurisdiction of the NBA under section 3 of the Act.

Further, certain activities, namely, the transfer of research results relating to any biological resource occurring in or obtained from India, by any person to any person who falls within the purview of the NBA²⁰; and application to obtain any Intellectual Property Right (IPR) for any invention based on research or information relating to any biological resource obtained from India, are regulated under the ABS mechanism.²¹ For the purpose of the above mentioned activities, the National Biodiversity Authority is vested with the power of regulation.

India is one of the countries that continues to argue the need for disclosure of source of genetic resources in patent applications under the World Intellectual Property Organization (WIPO) since 2000. In line with this, the Patent Act was amended in 2005 that specifically requires all patent applications filed in India to disclose the source of material if biological resources are used in the patent application. Section 6 of the BDA mandates previous approval of NBA when Indian biological resources are used in the innovations and inventions subject to patent applications both in India and outside India. Rule 18 of the Biological Diversity Rules (BDR) specify the procedure for seeking approval from NBA for applications related to intellectual property protection. The Controller General of Patents and Trademarks (CGP&TM) of India issued specific guidelines on

¹⁷ Biological Diversity Act, 2002, No.18 of 2003.

¹⁸ Biological Diversity Rules, 2004, G.S.R. 261 (E).

¹⁹ Commercial utilization means end uses of biological resources for commercial utilization such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours, extracts and genes used for improving crops and livestock through genetic intervention, but does not include convention breeding or traditional practices in use in any agriculture, horticulture, poultry, diary farming, animal husbandry or bee keeping. *See* Biological Diversity Act, 2002, § 2(f).

²⁰ Biological Diversity Act, 2002, § 4.

²¹ *Id.*, § 6.

procedures for approvals related to patents using Indian biological resources in 2012.²²

The BDA also provides approval procedures for ABS under Forms I, II, III and IV.²³ The BDR specifies the use of Form I for access to biological resources and associated traditional knowledge.²⁴ Form II provides for seeking prior approval of NBA for transferring the results of research to foreign nationals, companies, non-resident Indians, for commercial purposes.²⁵ Form III provides for seeking prior approval of NBA to apply for patents.²⁶ Form IV mandates seeking approval of NBA for third party transfer of the accessed biological resources and associated traditional knowledge.²⁷

4 Linkages between ITPGRFA and the Nagoya Protocol on ABS

With the adoption of NP on ABS in October 2010 countries are besieged with two international frameworks to respond to ABS. The NP is a general framework covering genetic resources, other than human genetic resources, that occur in the territorial boundaries of countries (sovereign rights) while the ITPGRFA is a specialised instrument that focuses on a set of genetic resources for food and agriculture (Annex I crops).

While the NP is a bilateral framework, the ITPGRFA operates using a multilateral approach and covers designated germplasm available in public domain. Cabrera et.al. outline the issues regarding the interface between the NP and the ITPGRFA with regard to their ABS provisions.²⁸

5 Linking ABS issues at national level

In India, until December 2014, all ABS related issues, including the germplasm covered under the ITPGRFA (Annex I) was under the purview of BDA. This created several challenges in implementing national obligations under the ITPGRFA in India. The National Biodiversity Authority in 2012 made detailed analyses of the implementation hurdles related to the above and submitted a recommendation to the MoEFCC to bring out a notification that recognizes the need to provide facilitational access to Annex I crops under the ITPGRFA. Considering this, the MoEFCC in December 2014 notified that Annex I crops will no longer come under the purview of

²² Office of the Controller General of Patents Designs & Trademarks, *Guidelines for Processing of Patent Applications Relating to Traditional Knowledge and Biological Material*, (Dec. 18, 2012), http://www.ipindia.nic.in/iponew/TK_Guidelines_18December2012.pdf (Accessed 30 May 2014).

²³ Biological Diversity Rules, 2003, Rules 14, 17, 18, 19 & 20.

²⁴ Biological Diversity Act, *supra* note 20, at § 3 & 19(1).

²⁵ *Id.*, § 4 & 19(1).

²⁶ *Id.*, § 6 & 19(2).

²⁷ *Id.*, § 20(2).

²⁸ Cabrera Medaglia, *supra* note 4.

the BDA and requested the Ministry of Agriculture (MoA) as the focal Ministry for implementing the ITPGRFA to work closely with the NBA on implementation of complementary ABS frameworks.²⁹

6 Challenges in implementing the ABS provisions in India

As mentioned previously, India is a signatory to both the CBD and the ITPGRFA. However, until 2014 no specific guidelines were issued for implantation of the ITPGRFA while the ABS provisions under the CBD were implemented using the BDA. In the absence of specific guidelines on implementation of the IT, the BDA is used de facto to deal with access and benefit sharing aspects related to genetic resources for food and agriculture. The guidelines issued by the MoA in 2014 also do not focus on issues of benefit sharing nor do they provide guidance on how to implement the ABS provisions under the IT and NP in a synergistic manner.

Five critical challenges can be identified in implementing the ABS provisions under the IT and NP. Firstly, there is lack of clarity on jurisdiction with regard to access to genetic resources and benefit sharing under the ITPGRFA and CBD (NP). Secondly, there are conflicting interpretations of provisions under the BDA and BDR by the MoEFCC such as the provisions related to exemptions under conventional breeding and traditional practices (section 2j), role and meaning of collaborative research (section 5). Thirdly, limitations for research, collaboration and development under the current provisions of BDA and BDR that keep all collaborative research efforts, other than those under government led collaborations is hindering implementation of IT. Fourthly, there are limitations with regard to legal and administrative operational issues in the absence of specific guidelines to implement the provisions under the NP and IT. Lastly, there are challenges related to lack of capacities and awareness on issues related to ABS, IPR and obligations under the ITPGRFA.

7 Options for implementation of Nagoya Protocol on ABS at national level

India ratified the NP in October 2012 but is yet to come up with effective implementation mechanism for the Protocol. The consideration made by the MoEFCC under the BDA covers relevant implementation needs of the NP. However, several gaps exist in the BDA with regard to key provisions in the NP for effective implementation of the Protocol.

Such gaps include absence of user country measures (as required under Article 15 of NP), non designation of check-points (Article 17), mechanism for seeking prior informed consent (Article 6 and 7), providing special consideration for non-commercial research (Article 8), mechanism for transboundary cooperation (Article 11), dealing

²⁹ Ministry of Environment, Forests & Climate Change, Notification F. No. 28-5/2008-CS(NBA), Dec. 17, 2014.

with traditional knowledge (Article 12), designation of National Competent Authority (Article 13), provision of information to the ABS clearing house mechanism (Article 14) and development of model codes of conduct and best practices (Article 20). Government of India needs to immediately address the gaps mentioned above to effectively comply with the provisions of the NP.

Additionally, it is important that more clarity on current ABS frameworks, approval granting processes and predictable and rationale benefit sharing frameworks need to be developed. Using a one-size-fit-all approach to benefit sharing with no consideration for sector specific issues of commercialization and profit making (as provided through the ABS guidelines notified in November 2014) will seriously jeopardize implementation of ABS in India under the Act.

For India to enhance compliance to the Protocol, it will be appropriate to consider focusing on the issues related to economic valuation for ABS purposes; building legal capacities at national level for ABS; exploring ABS as an innovative financing mechanism at national level; supporting development of synergistic frameworks at national level on ABS (linking NP, ITPGRFA, WIPO discussions and others) using development of ABS contracts, multi-layered compliance systems and establishment of cohesive national competent authorities; mainstreaming ABS across CBD work programmes such as forests, protected areas and marine biodiversity.

8 Conclusion

Considering the above, the following issues are suggested for further consideration by relevant agencies, including the NBA, MoEFCC and MoA to effectively implement the NP. (1) It is necessary to focus on developing user country measures in India for discouraging misappropriation of resources accessed from other countries by Indians and used in India. Design mechanisms for seeking the consent of communities in India for ABS purposes. (2) Currently, the BDA requires the communities to be “consulted” when seeking access. (3) Address the need for revising the BDA (2002) since the Act has several provisions that are conflicting and those that need updating (such as section 3). (4) Develop clarity to users on provisions regarding ABS, especially on what the Act covers and what it exempts. (5) Reduce undue regulatory oversight as interpreted by various bodies under the Act that has negatively impacted research and cooperation by Indians. (6) Remove impediments for compliance of ABS provisions by providing predictable and flexible approaches to access and benefit sharing, and ensure clarity on the roles and responsibilities of Central Government, NBA, SBBs and BMCs.

India is one of the few countries in the world that has an operational legal framework to deal with the objectives of the CBD, including ABS. It needs to ensure the objective of the BDA is appropriately understood and effectively implemented. Collaboration with relevant ministries and stakeholder groups is perhaps the best option to realize the potential of ABS in India that contributes to conservation, sustainable use and improvement of local livelihoods.