

INTERNATIONAL REGULATION ON COMMERCIAL UTILISATION OF GENETIC RESOURCES: ITS IMPLEMENTATION AND IMPLICATION IN SOUTH ASIA

*Amrendra Kumar**

I. INTRODUCTION

Genetic resources have been significant component for the ecological, economic, social and cultural development of a country. The potential value involved with genetic resources has benefited the societies and communities for long time. The rapid growth in science and technology has further added “the commercial value stimulating the trade and commerce among the countries and communities.”¹ Further, it is the “biotechnological industry with help of information technology has widely utilized the genetic resources to develop new and improved crops varieties, medicines, cosmetics and other commodities.”² Generally, the genetic resources are used by the industries, universities, research institutions, botanical gardens and gene banks which have either accessed directly from nature or acquired indirectly from the biodiversity rich nations, indigenous and local communities, intermediaries and individual.³ The economic significance of the genetic resources has further increased “the appropriation by way of bio-prospecting and misappropriation by way of bio-piracy for the commercial and non-commercial purposes.”⁴ This has necessitated the efforts to regulate the access and use of genetic resources and traditional knowledge at international level.

Consequently, the last two decades have witnessed a growing momentum to establish international legal regime for the commercial utilization of genetic resources. At the international level, “the Convention on Biological Diversity (1992), its Bonn Guidelines (2002) and Nagoya Protocol (2010) along with FAO International Treaty on Plant Genetic Resources for Food and Agriculture (2001) have been prominent international legal instruments regulating the commercial utilization of genetic resources and associated traditional knowledge.”⁵ However, FAO regime provides the multilateral legal system specifically for plant genetic resources distinctive to the bilateral legal system for overall genetic resources provided under CBD regime. Under bilateral legal system, “Convention on Biological Diversity (CBD)”⁶ provides the obligations to the member

* Assistant Professor, Law Centre-II, Faculty of Law, University of Delhi, India.

¹ K. ten Kate and S.A. Laird, *The Commercial Use of Biodiversity: Access to Genetic Resource and Benefits Sharing* 15 (Earth Scan, London, 3rd edn., 1999). See also Kate ten K. and S.A. Laird, “Biodiversity and Business: Coming to Terms with the ‘Grand Bargains’ ” 76(1) *International Affairs* 12 (2000).

²*Ibid.*

³ M.S. Suneetha and Balakrishna Pisupati, “Benefit Sharing in ABS: Options and Elaboration” UNU-IAS Report, 2009, *available at*: <https://www.cbd.int/abs/doc/unu-abs-report-2009-en.pdf> (last visited on October 22, 2018).

⁴ Padmashree Gehl Sampath, *Regulating Bioprospecting: Institutions for Drug Research, Access and Benefit Sharing* 24-36 (United Nations University Press, Tokyo, 2005).

⁵ Conference of Parties to the Convention on Biological Diversity: Decision X/1 Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising from the Utilization, 2010; *available on*: URL: <http://www.cbd.int/doc/decisions/cop-10/en.pdf>. (last visited on October 12, 2018).

⁶ Convention on Biological Diversity, 1992. It is framework convention for biodiversity conservation and management adopted on 5 June, 1992 at UN Conference on Environment and Development at Rio de Janeiro, Brazil. It came into force on December 29, 1993 where 193 member countries are currently parties to it. *Available at*: http://www.cbd.int/doc/legal/cbd_un_en.pdf. (last visited on October 12, 2018).

states to establish legal and institutional framework at national level to facilitate and regulate the commercial utilization of genetic resources and benefit sharing arising from their utilization. Recently, the member states adopted 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.”⁷ After the adoption and ratification of the Nagoya Protocol, it became incumbent for the member nations including the South Asian Nations to implement it in their domestic jurisdiction being major repository of the biodiversity.

Against this background, this paper aims to examine the international regulation of the commercial utilization of the genetic resources and associated traditional knowledge especially after the adoption of Nagoya Protocol. It proceeds with analyzing the promises and prospects for its implementation in South Asian nations outlining the physical status of genetic resources and its commercial utilization. It also explores the major implications on the legal system of these South Asian nations fulfilling the obligations for the domestic legislation and regulatory requirements. The paper further proposes that South Asian nations should take initiative and leadership in the implementation of the Nagoya Protocol at regional level by trans-boundary cooperation and at national level by enacting specific legislation or amending existing legislation as well as improving the plans and policies for the commercial utilization of genetic resources and associated traditional knowledge.

II. GENETIC RESOURCES IN SOUTH ASIA

South Asia comprises with eight sovereign states i.e. Afghanistan, Pakistan, India, Nepal, Bhutan, Bangladesh, Maldives and Sri Lanka located in the Hindu Kush Himalayan and Hindu-Malay region. It ranges from the world's highest elevation in the Hind Kush Himalayan region to its river's delta and low laying coastal plains and islands of the Arabian Sea, Indian Ocean and Bay of Bengal. This is immensely diverse region comprising vast and unique variety of ecosystem i.e. Forest, Wetlands, Mountain, Desert and Coral reefs which harbors variety of faunal and floral species of plants, animals and microorganism enriching the biological and genetic resources due to its geographical and geological locations. Individually, “Afghanistan is comprised of eight bio-geographical provinces endowed with several species including 150 species of mammals, 500 species of birds, 100 species of reptiles, 10 species of amphibians, 140 species of birds, 245 species of butterflies and 4000 species of vascular plants.”⁸ In the similar bio geographical realms, “Pakistan has 195 recorded mammals species, 668 of birds species, 177 reptiles species, 12 amphibians and 192 freshwater fish species along with 3500 plant species.”⁹

With only 2.5% of the land area adorned with 10 bio-geographic zones and 26 biotic provinces, India accounts for 8% of the recorded species of the world which includes millions of races, sub- species and local variants of species. It is estimated that “India has approximately 45000 species of plants representing as much as 11 % the world's flora which

⁷ Nagoya Protocol on the Access to Genetic Resources and Fair and Equitable Sharing of Benefits arising from their Utilization to the Convention on Biological Diversity adopted on October 30, 2010, CBD Secretariat: Montreal. Available at: <http://www.cbd.int/abs/text/default.html> (last visited on October 12, 2018).

⁸ B.H. Desai, K.P. Oli, et.al., *Implementation of the Convention on Biological Diversity: A retrospective analysis in the Hindu Kush-Himalayan countries* (ICIMOD, Kathmandu, 2011) available at: http://www.indiaenvironmentportal.org.in/files/implementation_of_the_convention_on_biological_diversity.pdf (last visited on November 2, 2018).

⁹*Ibid.*

includes about 17500 species of flowering parts, 48 species of gymnosperms, 1200 species of pteridophyte, 1980 species of mosses, 845 species of liverworts, 6500 species algal, 2050 species of lichens, 14500 species of fungi and 850 species of bacteria.”¹⁰“The total estimates of animal species in India are about 89,450, out of which insects alone include 59,353 species. Other faunal components include mammals (372 species), birds (1230 species), and reptiles (428 species), over 300 species of amphibians and 500 species of molluscs.”¹¹ However, “Bhutan being small landlocked country situated on the southern slopes of the eastern Himalayan with three distinct ecozones harbors 5603 vascular plant species, 667 bird species, 49 species of fish etc.”¹² Similarly, “Nepal also as landlocked nation has rich biological diversity with 342 endemic plants and 160 endemic animal species.”¹³ Bangladesh is also very rich small geographical regions of Indo-gangatic plain and eastern Himalayan realm provide wide range of plants, animal and marine species in its Sundervan wetlands, Chittagong Hills and Bay of Bengal. Maldives and Sri Lanka as Islands also have similar kind of diverse species in plants, animals, and marine species in their own regions. Being repository of large amount of genetic resources, the member nations of the South Asia has serious concerns over the conservation and commercial utilization of their genetic resources.

III. GENETIC RESOURCES AND ITS’COMMERCIAL UTILIZATION

Our Earth is endowed with different types of natural and non-natural resources. Among the natural resources, genetic resources are most significant which are found as genetic material in animal, plant, microbial or other organisms. These are generally distinguished from their source of nutrition, structure and mobility, however the genes are found in all of them. “‘Gene’ denotes a group of organism sharing number of heritable characteristics which are reproductively isolated for another parts or forms.”¹⁴ But in legal sense, it is defined as “genetic material of actual or potential value containing functional units of heredity.”¹⁵ However, it has been defined in simple words as “genetic resources are primary resources and raw materials in the form of genes, chemicals, gems, resins, enzymes and proteins etc. These are generally found in animal, human, plant and marine substances within their natural ecosystem and habitats, or outside their natural habitats like seed banks, gene banks, and botanical gardens.”¹⁶ Such genetic resource may be accessed by either acquiring the genetic resource and information from the nature directly or exploring other sources such as gene banks, seed banks, research institutions and botanical gardens. There are multiple stakeholders who play dominant role in providing or facilitating the access to such genetic resources as providers like “nation states, research institutions, universities, intermediaries, indigenous and local peoples, and individuals.”¹⁷ These genetic resources are used by different types of users such as researchers, scientists, industries in different sectors such as “pharmaceutical, biotechnology, seed, crop protection, horticulture, cosmetic and

¹⁰ K. Venkataraman, “India’s Biodiversity Act 2002 and its role in conservation” 50(1) *Tropical Ecology* 23-30 (2009).

¹¹ *Ibid.*

¹² *Supra* note 8 at 12.

¹³ *Ibid.*

¹⁴ Peter Johan Schei and Morten Walløe Tvedt, “ ‘Genetic Resources’ in the CBD : The Wording, The Past, The Present and The Future” FNI Report 4/2010, *available at*:<https://www.fni.no/getfile.php/131744-1469869059/Filer/Publikasjoner/FNI-R0410.pdf> (last visited on October 15, 2018).

¹⁵ *Supra* note 6, art. 2.

¹⁶ Sarah Laird and Rachel Wynberg, *Access and Benefit Sharing in Practice: Trends in Partnership across Sectors*, CBD Technical Series No. 38 (Secretariat of CBD, Montreal, 2008). *Available at*: <https://www.cbd.int/doc/publications/cbd-ts-38-en.pdf> (last visited on October 16, 2018).

¹⁷ *Supra* note 1 at 30.

personal care, fragrance and flavor, food and beverage industries for basic research and commercial utilization.”¹⁸ Their utilization of genetic resources has been recognized as “to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology.”¹⁹ Further, the biotechnology has been applied as “any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.”²⁰ Such commercial application and utilization of the genetic resources through biotechnology has been largely done by the above said industries unhindered and unregulated which has further stimulated for the strong and binding legal instrument for access and benefit sharing system at national and international level.

IV. INTERNATIONAL REGULATION ON COMMERCIAL UTILIZATION OF GENETIC RESOURCES

At international level, regulation on genetic resources has been addressed at different times and occasions through different legal instruments such as CBD, ITPGRFA, TRIPS, UPOV and UNCLOS.²¹ Among these, “the Convention on Biological Diversity (1992) has been one of the pioneer international legal instrument which deals with the conservation, sustainable utilization, access and benefit sharing of the biological resources i.e. genetic resources.”²² The CBD not only has given the fundamental principles and obligations as framework convention, but also demanded “a nationally implemented ABS legal regime for commercial utilization of genetic resources.”²³ Even though, the implementation on the ABS mechanism at national level remained unsatisfactory across the member nations. For the implementation of its objective and principle on ABS for the commercial utilization of genetic resources, Conference of Parties (COP) of the CBD further led to recourse under Article 28 to initiate the deliberations for an effective legal instrument for the implementation of ABS regime on commercial utilization of genetic resources.

In the CBD COP fourth meeting in 1998, “a regionally balanced expert panel on ABS was set up which formally initiated the work on international instrument on ABS for commercial utilization of genetic resources.”²⁴ In year 2000 at Nairobi, CBD COP fifth meeting further formalized the ongoing ABS negotiations by constituting an “Ad-Hoc Open Ended Working Group (AHWG) with a mandate to develop guidelines on ABS.”²⁵ It presented the “Bonn Guidelines on Access to Genetic Resources and Fair and Equitable

¹⁸ Thomas Greiber, Sonia Peña Moreno, *et.al.*, “An Explanatory Guide to the Nagoya Protocol on Access and Benefits Sharing” *IUCN Environmental Policy and Law Paper No. 83* 4 (2012), available at: https://cmsdata.iucn.org/downloads/an_explanatory_guide_to_the_nagoya_protocol.pdf (last visited on October 28, 2018).

¹⁹ *Supra* note 7, art. 2.

²⁰ *Ibid.*

²¹ Silke von Lewinski, *Indigenous Heritage and Intellectual Property: Genetic Resources, Traditional Knowledge and Folklore* 212 (Kluwer Law International, The Netherlands, 2nd edn., 2008); See also, G. Kristin Rosendal, “Regulating the Use of Genetic Resources: Between International Authorities” 16(5) *Environmental Policy and Governance* 265-277 (2006).

²² Ananda Mohan Bhattarai, *Protection of Himalayan Biodiversity: International Environmental Law and A Regional Legal Framework* 6 (Sage India, Delhi, 2010).

²³ *Supra* note 6, art. 15.

²⁴ CBD COP Decision IV/8: *Access and Benefit Sharing*, May 04-15, 1998 (Bratislava, Slovakia), available at: <https://www.cbd.int/decision/cop/?id=7131> (last visited on October 20, 2018).

²⁵ CBD COP Decision V/26: *Access to Genetic Resources*, May 15-26, 2000 (Nairobi, Kenya), available at: <https://www.cbd.int/decision/cop/?id=7168> (last visited on October 20, 2018).

Sharing of Benefits arising out of their Utilization”²⁶ which was subsequently adopted in year 2002 at CBD COP sixth meeting at The Hague. It was basically adopted to assist the parties, governments and other stakeholders in developing ABS agreements, plans and strategies for commercial utilization of genetic resources. It was also formulated to help the member states in establishing legislative, administrative and policy measures on access and benefit sharing and/or when negotiating contractual arrangements for commercial utilization of genetic resources. However, the guidelines became controversial among the states being non-binding and voluntary in nature. Then, the World Summit on Sustainable Development (2002) held in Johannesburg in its plan “called for consensus and action by the international community to have an effective legal instrument on ABS within the framework of the CBD taking into account the Bonn guidelines.”²⁷ In view of this, CBD COP seventh meeting in 2004 at Kuala Lumpur adopted “the term of references of AHWG for negotiations on an international regime on ABS.”²⁸ Then, the CBD COP ninth meeting instructed the AHWG “to finalize the international regime for consideration and adoption by the conference of parties at its tenth meeting on an instrument to effectively implement the provisions in Articles 15 and 8(j) of the convention and its three objectives.”²⁹

At the end, CBD COP tenth meeting in 2010 at Nagoya (Japan) adopted 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.”³⁰ This protocol has 27 preambular paragraphs and 36 Articles with an annexure having list of monetary and non-monetary benefits. The objective of this Protocol primarily consist of “the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over these resources and to technologies, and by appropriate funding.”³¹ It basically applies to “genetic resource and traditional knowledge associated with it as well as the benefits arising from their commercial utilization.”³² The basic obligations under this protocol have been assigned on the access to genetic resources and associated traditional knowledge, benefit sharing on their commercial utilization along with compliance measures in several provisions such as:

Access to Genetic Resources: It has been the first pillar of ABS mechanism explained in several provisions of this protocol. First of all, Article 6 reaffirms the sovereign rights of states over their national resources as per the domestic legislation and regulatory requirements and further clarifies that “access to genetic resources are subject to prior

²⁶ CBD COP Decision VI/24: *Access and Benefit Sharing as Related to Genetic Resources*, April 08-19, 2002 (The Hague, Netherlands) which adopted Bonn Guidelines. Available at: <https://www.cbd.int/decision/cop/?id=7198> (last visited on October 23, 2018).

²⁷ See Plan of Implementation of the World Summit on Sustainable Development, Chapter IV, para. 44(o): *Access and Benefit Sharing*, available at: https://www.un.org/esa/sustdev/documents/WSSD_POI_PD/English/WSSD_PlanImpl.pdf (last visited on October 20, 2018).

²⁸ CBD COP Decision VII/19: *Access and Benefit-Sharing as related to genetic resources*, February 09-20, 2004 (Kuala Lumpur, Malaysia), available at: <https://www.cbd.int/decision/cop/?id=7756> (last visited on October 20, 2018).

²⁹ CBD COP Decision IX/12: *Access and Benefit Sharing*, May 19-30, 2008 (Bonn, Germany), available at: <https://www.cbd.int/decision/cop/?id=11655> (last visited on October 20, 2018).

³⁰ CBD COP Decision X/1: *Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization*, October 18-29, 2010 (Nagoya, Japan), available at: <https://www.cbd.int/decision/cop/?id=12267> (last visited on October 20, 2018).

³¹ *Id.*, art. 1.

³² *Id.*, art. 3.

informed consent (PIC) for their utilization.”³³ The above said consent is required from the providers which is either in the country of origin of such resources or the country that has acquired the genetic resources in accordance with CBD. In one circumstance, the country of origin indicates the country where those genetic resources are found in-situ conditions or within its ecosystem and natural habitats. In alternate circumstance, a party would have acquired genetic resources in accordance with PIC and MAT granted under CBD. For the genetic resources held by the ILCs, the protocol provides that “each party is also under obligation to ensure in accordance with domestic law that PIC or approval and involvement of ILCs is obtained for such access to genetic resources as well where they have the established rights to grant access to such resources.”³⁴ Further, it requires the party “to take necessary legislative, administrative and policy measures for information, cost and criteria for obtaining PIC at domestic level.”³⁵ For the access to traditional knowledge associated with genetic resources held by the ILCs, “states have to take measures in accordance with domestic law aiming to ensure that such traditional knowledge associated with genetic resources held by ILCs is accessed either with their PIC or with their approval and involvement.”³⁶ Additionally, it also required that mutually agreed terms have to be established with the ILCs on acquiring the genetic resources and associated traditional knowledge and information in such cases. But, there has to be given special consideration “while granting access to genetic resources in the case of promotion of non-commercial research particularly in developing countries and in the matter eminent or present emergencies threatening to human, animal or plant health i.e. pathogens and the importance of genetic resources for food and agriculture.”³⁷ Not only this, the member states have also obligation to cooperate with each other and with involvement of their ILCs on the access of such resources and knowledge which is shared by more than one countries and communities in the trans-boundary situations to achieve the objective of this protocol.³⁸

Benefit Sharing on its Commercial Utilization: After the access to genetic resources, Article 5 specifically deals with second pillar of the ABS mechanism demanding the fair and equitable benefit sharing on the basis of the mutually agreed terms. For this purpose, it provides that “benefits have to be shared in fair and equitable way arising from the utilization of genetic resources as well as its subsequent application and commercialization.”³⁹ Such benefits have to share with the country or community providing such resources from in-situ situations or that has acquired the genetic resources in accordance with CBD. However, “the benefits may be monetary and non-monetary which has been referred in the Annexure.”⁴⁰ Now, it depends upon the member states to take legislative, administrative or policy measure to facilitate, regulate and implement the benefit sharing mechanism in their domestic jurisdiction. The benefit sharing mechanism has to be established through contractual agreements or arrangements under mutually agreed terms (MAT).⁴¹

In the specific case where the ILCs have established rights over the genetic resources, the same benefit sharing mechanism has been prescribed on the basis of mutually agreed terms through contractual arrangements with them. The member states have to ensure that

³³ *Id.*, art. 6(1).

³⁴ *Id.*, art. 6(2).

³⁵ *Id.*, art. 6(3).

³⁶ *Id.*, art. 7.

³⁷ *Id.*, art. 8.

³⁸ *Id.*, art. 11(1).

³⁹ *Id.*, art. 5(1).

⁴⁰ *Id.*, art. 5(4).

⁴¹ *Id.*, art. 5(2).

“benefits arising from the utilization of genetic resources that held by the ILCs are shared in a fair and equitable way with the communities concerned based on the mutually agreed terms.”⁴² In the case of traditional knowledge held by the ILCs, the benefits arising from the utilization of the traditional knowledge have to be shared in the same way on the basis of MAT with the ILCs concerned. However, it has been directed also that “member states will utilize those shared benefits towards the conservation and sustainable use of the biological diversity.”⁴³ There has been also prescribed for giving consideration on the need and modalities of global multilateral benefits sharing mechanism. The basic purpose to establish such mechanism in future would address the issue of “fair and equitable sharing of benefits arising from the utilization of genetic resources and traditional knowledge associated with genetic resources that occurs in trans-boundary situations and where the granting and obtaining the PIC is not possible.”⁴⁴ The member states as parties to this protocol shall also encourage the other countries which are non-parties to promote the ABS system and contribute appropriate information in regard to ABS process.⁴⁵

Compliance Measures for Access and Benefit Sharing: Third pillar of the ABS system is the compliance measures which build the necessary backbone of the Nagoya Protocol. There has been given bunch of provisions in this protocol for the compliance measures for ABS to be established by both provider countries and user countries in their domestic jurisdiction. First of all, Article 15 basically asks for the compliance with domestic legislation or regulatory requirements of the provider countries for the user of such resources and knowledge. For this purpose, “the parties are obliged to take measure to provide that genetic resources utilized within their jurisdiction has been accessed in accordance with the PIC and MAT has been established as required by such legislation regulation.”⁴⁶ Along with this, they are also obliged “to take measures to address situations of non-compliance of these obligations and cooperate in the cases of alleged violation of the domestic legislation or regulatory requirements of the other party.”⁴⁷ In regard to the traditional knowledge associated with genetic resources, Article 16 especially obliged that “the parties have to take measures to provide that traditional knowledge associated with genetic resources utilized within their jurisdiction has been accessed in accordance with PIC or approval and involvement of ILCs and MAT has been established as required under the domestic ABS legislation or regulatory requirements.”⁴⁸ In same the same manner, they will also “to take measures to address situations of non-compliance of the above obligations as well as possible cooperation in the case of alleged violation of the domestic ABS legislation or regulatory requirements of the other party.”⁴⁹ Apart from this, Article 18 specifically included to promote the compliance and enforcement of MAT between individual user and provider of the genetic resources and/or traditional knowledge associated with genetic resources through private contractual arrangements. For this purpose, it refers the parties to include the obligations in their private contract for appropriate dispute resolution mechanism, opportunity to recourse to their legal system and justice system through mutually agreed terms.⁵⁰

⁴² *Id.*, art. 5(5).

⁴³ *Id.*, art. 9.

⁴⁴ *Id.*, art. 10.

⁴⁵ *Id.*, art. 24.

⁴⁶ *Id.*, art. 15(1).

⁴⁷ *Id.*, art. 15(2).

⁴⁸ *Id.*, art. 16(1).

⁴⁹ *Id.*, art. 16(2).

⁵⁰ *Id.*, art. 18(1).

Institutional Mechanism on Access and Benefit Sharing: In support of the above compliance provisions, Article 17 provides for institutional monitoring system on the utilization of genetic resources through establishment or designation of one or more checkpoints in domestic jurisdiction. Not only this, these checkpoints would provide and share the information to the users by using the cost effective communication tool and system for monitoring and transparency.⁵¹ For the purpose of monitoring and compliance, there has been prescribed for the “internationally recognized certificate of compliance”⁵² as evidence of compliance. It would be available at the ABS Clearing House consist of detail information, function and authority issuing such certificate. It has been also asked to establish other domestic institutional mechanisms such as National Focal Points (NFP) and Competent National Authorities (CNA) to facilitate and implement the ABS principles and procedure in domestic jurisdiction.⁵³ These institutional arrangements would work together for the regulation and implementation of the ABS principles on commercial utilization of genetic resources with more legal clarity, certainty, transparency.

Enforcement Mechanism on Access and Benefit Sharing: The actual success of the ABS legal regime as embodied in the CBD and its Nagoya Protocol would depend upon the proper implementation and enforcement at international and national level. For this purpose, the member states have been given options “to take appropriate, effective and proportionate measures in the form of legislative, administrative and policy measures for the implementation and enforcement of the ABS obligations in domestic jurisdiction.”⁵⁴ To support the enforcement mechanism, the Nagoya Protocol additionally provides for international monitoring, reporting, dispute resolution and review mechanism in compliance of the ABS legal regime. Besides, the public participation, empowerment and education have also been considered essential for the effective implementation and enforcement of the ABS legal regime. However, “the implementation and enforcement could vary among the member states depending upon their legal, political and social system.”⁵⁵

In sum, all these obligations provided by the CBD and its Nagoya Protocol have to be complied with present and future challenges and opportunities by the member states at national, regional and international level. This could also be in consonance to or conflict with crucial developmental needs, technological advancements and ecological concerns affecting the existence of priceless genetic resources in any nation and region.

V. IMPLEMENTATION OF NAGOYA PROTOCOL IN SOUTH ASIAN NATIONS

At the regional level, most of the nations of the South Asian region are parties to the Convention of Biological Diversity. Consequently, they may also become parties to the Nagaya Protocol after signing it. Recently, the protocol has come in to force which would require further “legislative, administrative and policy measures to implement it as provider

⁵¹ *Id.*, art. 17(1).

⁵² *Id.*, art. 17(2).

⁵³ *Id.*, art. 13(1).

⁵⁴ *Supra* note46.

⁵⁵ Jorge Cabrera Medaglia, “The Implementation of the Nagoya Protocol in Latin America and Caribbean: Challenges and Opportunities”, in Elisa Morgera, Matthias Buck, *et.al.*(eds.), *The 2010 Nagoya Protocol on Access and Benefit Sharing in Perspective: Implications for International Law and Implementation Challenges* 356 (Martinus Nijhoff, London, 2013).

and/or user of the genetic resources and associated traditional knowledge.”⁵⁶ Being as provider and user both, they have the options to implement this protocol through ABS legislation or any other regulatory instruments. The Nagoya Protocol requires the member state as provider country to establish the ABS mechanism for genetic resources based on prior informed consent (PIC) or as otherwise agreed by the parties. Not only this, there has to be certain prescribed criteria for PIC and focal point for giving information on how to apply for PIC to the potential user of the genetic resources. There has been also prescribed the establishment of competent national authority for granting clear and transparent written decision or permit which would be the evidence of compliance within given jurisdiction. Besides, “they have to make change or amend the existing law for the inclusion of the prior and informed consent or approval and involvement of the indigenous and local communities on the basis of their established right to grant access to such resources.”⁵⁷ Similarly, their prior and informed consent or approval and involvement are also required to be placed in the new law for the access of traditional knowledge related with genetic resources. In compliance to this protocol, they have been also called for “to create legal, administrative and policy measures to share the benefits arising from the utilization of genetic resources as well as utilization of traditional knowledge in a fair and equitable way. Such rules and procedures have to be fair and non-arbitrary on Mutually Agreed Terms (MATs).”⁵⁸

For the user countries, this protocol also provides obligation “to make legal, administrative and policy measures to ensure that the genetic resources or traditional knowledge utilized within its jurisdiction has been accessed in accordance with PIC and MAT as required by domestic ABS law or regulations of the other party.”⁵⁹ Accordingly, they have to now ensure that “benefits arising from the utilization of genetic resources as well as subsequent application and commercialization of such resources are shared in fair and equitable manner with the providers as per the domestic ABS legislation and other regulatory requirement of the providing country.”⁶⁰ It has been also asked to evolve measures to address the cases of non-compliance and violation of their ABS rules and regulations on commercial utilization of genetic resources. For all these purposes, new legislation would be required to be enacted or existing legislation would be amended in South Asian nations to meet the requirement of the obligations and promises provided under the Nagoya Protocol.

VI. IMPLICATIONS OF NAGOYA PROTOCOL IN SOUTH ASIAN NATIONS

Being the member of the CBD, most of countries in South Asia have signed and ratified its Nagoya Protocol. However, some of them have promulgated the national legislation on the biodiversity conservation and commercial utilization of the biological (genetic) resources and some are in the process of doing the same. For example, Afghanistan and Pakistan regulate conservation and management through different forms of environmental legislation and regulation. Afghanistan under its “Environmental Law (2007)”⁶¹ addresses conservation, use and benefit sharing of genetic resources. Now, Afghanistan has to amend this law to incorporate the obligations of the Nagoya Protocol for

⁵⁶ CBD, “Government Fulfil Their Commitment: Access and Benefit Sharing Treaty receives required number of Ratifications to Enter into Force”, Press Release, July 14, 2014, *available at*: <https://www.cbd.int/doc/press/2014/pr-2014-07-14-Nagoya-Protocol-en.pdf> (last visited on October 25, 2018).

⁵⁷ *Supra* note 42.

⁵⁸ *Supra* note 41.

⁵⁹ *Supra* note 39.

⁶⁰ *Ibid.*

⁶¹ Environment Law, 2007, Islamic Republic of Afghanistan, *available at*: https://momp.gov.af/sites/default/files/2019-03/Environmental_Law.pdf (last visited on October 30, 2018).

permitting the access for the commercial utilization of genetic resources. Pakistan with its “Environmental Protection Act (1997)”⁶² provides the principles and procedure for the conservation, use, access and benefit sharing over genetic resources. However, Pakistan has also come with “National Biodiversity Strategies and Action Plan (2015)”⁶³ which includes the provisions of PIC and MAT given under the Nagoya Protocol.

In Bhutan, “Biodiversity Act of Bhutan 2003 explicitly provides for biodiversity conservation, sustainable use, access and benefit sharing of genetic resources along with indigenous rights over them.”⁶⁴ Bhutan has also now proposed the “Biodiversity Bill, 2016”⁶⁵ in consonance of the provisions of the Nagoya Protocol. India has been pioneer in the implementation of the CBD provisions by enacting the “Biological Diversity Act, 2002”⁶⁶ and subsequently framed the rules and procedures in “Biological Diversity Rules, 2004”⁶⁷ to regulate access and benefit sharing for the commercial utilization biological resources. Recently, there has been also issued new “Guidelines on Access to Biological Resources and Associated Knowledge and Benefit Sharing Regulations, 2014”⁶⁸ in pursuance of the Nagoya Protocol for access requirements and benefit sharing mechanisms in India. Bangladesh has enacted “Biodiversity Act, 2017”⁶⁹ in compliance with the Nagoya Protocol to create appropriate legal system for access to biological resources based on PIC for fair and equitable sharing of the benefits arising out of their commercial use. Nepal, Maldives and Sri Lanka are in the process of formulating the national legislation, plans and strategy on the access and benefit sharing for commercial utilization of the genetic resources. Above all, all the countries in South Asia are custodian of more than two third biodiversity of the world. Hence, they are highly responsible as provider countries in the implementation of the international regulation on commercial utilization of genetic resources in their domestic jurisdiction.

VII. CONCLUSION

After the adoption of new international regulation on the commercial utilization of genetic resources, implementation measures are required to be adopted in the domestic jurisdiction by translating the international commitments into national program of actions. The mode of national implementation could be legislative, administrative or policy measures for achieving the intended results or objectives of the international legal instruments agreed upon. Accordingly, South Asian nations have to adopt suitable legislation, administrative rules and policy measures to implement the Nagoya Protocol. Afghanistan and Pakistan have to evolve and enact the specialized ABS legislation for the commercial utilization of genetic

⁶² Pakistan Environmental Protection Act, 1997, *available at*: <http://extwprlegs1.fao.org/docs/pdf/pak115821.pdf> (last visited on October 30, 2018).

⁶³ National Biodiversity Strategy and Action Plan 2015, Pakistan, *available at*: <https://www.cbd.int/doc/world/pk/pk-nbsap-v2-en.pdf> (last visited on October 30, 2018).

⁶⁴ The Biodiversity Act of Bhutan, 2003, *available at*: <http://extwprlegs1.fao.org/docs/pdf/bhu69010.pdf> (last visited on October 30, 2018).

⁶⁵ Biodiversity Bill of Bhutan, 2016; *available at*: <http://www.nbc.gov.bt/wp-content/uploads/2016/03/Draft-Biodiversity-Bill-2016.pdf> (last visited on October 30, 2018).

⁶⁶ The Biological Diversity Act, 2002, India, *available at*: <http://extwprlegs1.fao.org/docs/pdf/ind40698.pdf> (last visited on November 03, 2018).

⁶⁷ The Biological Diversity Rules, 2004, India, *available at*: <http://extwprlegs1.fao.org/docs/pdf/ind53983.pdf> (last visited on November 03, 2018).

⁶⁸ Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014, India, *available at*: http://nbaindia.org/uploaded/pdf/Gazette_Notification_of_ABS_Guidelines.pdf (last visited on November 03, 2018).

⁶⁹ Bangladesh Biodiversity Act, 2017, *available at*: <http://www.ecolex.org/details/legislation/bangladesh/biodiversity-act-2017.html> (last visited on November 03, 2018).

resources. Bhutan, Bangladesh and India has already enacted the new legislation or amended the existing legislation in consonance of the Nagoya Protocol. Nepal, Maldives and Sri Lanka are in the process of formulating the national legislation, plans and strategy on the access and benefit sharing for commercial utilization of the genetic resources. Not only this, they have also extended affords through cultural integration, mutual cooperation and diplomatic negotiation to implement the legal instrument at regional level. The implantation measures provided under the CBD regime and Nagoya Protocol, however suffer from several drawbacks which could be detrimental to the achievement of the objective of the convention. Despite some drawbacks, the international regulation would be implemented and further developed in domestic jurisdiction for better commercial utilization of the genetic resources and associated traditional knowledge especially in South Asia. Further multilateral and bilateral negotiations will also offer some guidance to operationalize and implement the international regulation on the commercial utilization of genetic resources at national and regional level in South Asia.