



Protection of Bio-resources and Associated Knowledge against Bio-Piracy: A Critical Appraisal of Access-Control Mechanism in Biodiversity Management

Parimita Dash¹ and Debmita Mondal²

¹ Asst. Professor-II, School of Law, KIIT Deemed to be University, Bhubaneswar, India

² Asst. Professor-II, HNLU, Raipur, Chhattisgarh, India

parimita@kls.ac.in

Abstract. A core intellectual property politics at international level is the tug of war between biodiversity rich nation who complain that intellectual property regime promotes commercialization and exclusivity over their national resources and technology rich nations who term such access to biological resources and privatization of rights over inventions over such resources as bio-prospecting. India, with its remarkable biodiversity has been prone to bio-piracy in cases of neem, turmeric and many more. This chapter is an attempt to review the international legal norms relating to biodiversity and compare how access control and benefit sharing mechanisms has been implemented in specific to Indian legal regime.

The chapter introduces the challenges in protection of biodiversity in the first section. The second section highlights the necessity of appropriate legal tools for protection of biodiversity emphasizing its need not only for conservation, preservation but also for catering needs of modern society and generation of revenue for a nation. In the third section, an attempt has been made to focus on the salient features of Convention on Biodiversity, its Protocols, and the latest Kunming-Montreal Global Biodiversity Framework (GBF) as adopted in 2022. Indian position on access-control mechanisms and benefit sharing method for biodiversity management has been discussed with illustrative examples and incorporating prominent changes as introduced by Biological Diversity (Amendment) Act, 2023 in the last section.

Keywords: Biodiversity, Access-control, Benefit sharing, TRIPs, CBD, India.

1 Introduction

Biodiversity is a broad umbrella term referring to biological variety on earth which includes animals, plants, micro-organisms, etc.. The subtle balance in the rich biodiversity of the earth caters to many human needs like fresh water, food, medicines, clean air, stable climatic conditions, protection against natural calamities and many more. The importance of biodiversity can be highlighted through the example of mangrove trees who with the help of their living roots create barriers against soil erosion which otherwise might aggregate due to rising sea levels. [1]

© The Author(s) 2024

T. Pradhan et al. (eds.), *Proceedings of the NDIEAS-2024 International Symposium on New Dimensions and Ideas in Environmental Anthropology-2024 (NDIEAS 2024)*, Advances in Social Science, Education and Humanities Research 848,

https://doi.org/10.2991/978-2-38476-255-2_29

Since all species are interconnected in biodiversity, the dependence on one another is the law of nature and when some species are weakened or they become extinct, the whole diversity suffers harm. Often the misappropriation of the knowledge and genetic resources of farming and indigenous communities by individuals or institutions seeking exclusive monopoly control over these resources and knowledge results in cases of biopiracy which is the biggest roadblock to the success of biodiversity management. The alleged patenting of the already known usage and practices involving biological resources of a Nation which is considered as the rich traditional knowledge of the Nation leads to a scenario where the Nation is not only robbed of its resources and associated knowledge but also is made to pay a price for outsourcing the patented product which is a result of the research over its own resources & associated knowledge. This primarily happens due to three significant reasons. First the non-awareness regarding the commercial viability of such resources and the associated knowledge, and secondly the lack of appropriate infrastructure and skill to commercially process such resources and associated knowledge to generate revenue. The third and the most significant reason which causes this situation where the Nation having resources is put at a complete loss is the absence of a legal regime to regulate the access to such resources and associated knowledge and to negotiate to have better returns for the Nation and its people in any proposed commercial exploitation of its resources and the traditional knowledge involving such biological resources.

The absence of such a strong legal framework often leads to unauthorized commercial exploitation of the resources resulting in acts of biological theft which is commonly known as the phenomena of bio-piracy, where a technologically sound country targets the resources of another Country aiming at their undue commercial exploitation sharing no benefit accruing from such commercial exploitation with the nation from which such resources and associated knowledge are extracted. Similar cases of bio-piracy whether in the form of unauthorized patenting of the traditional knowledge regarding the healing properties of Turmeric or the patenting of the anti-fungal properties of the Neem, which is considered to be part of India's strong traditional knowledge system which also is often reflected in India's traditional medicine systems in the form of Siddha, Unani, Ayurveda etc. Hence these calls for a stringent and effective mechanism to protect not only the biological resources but also the associated knowledge of such biological resources.

2 Need for a legal regime for biodiversity protection

A need for having an effective legal regime to combat the cases of bio-piracy which India has seen over the past decade has been felt strongly which has led to the legislating of the Biological Diversity Act. 2002 incorporating the Access Control Mechanism. The backdrop behind the advent of such statutory provisions is discussed below.

2.1 Extinction of species

The major reason biodiversity laws are pertinent is that the earth is losing its rich natural heritage due to various factors like human need, technological evolution, industrialization, and overpopulation. Scientists have predicted that humans are causing a "sixth mass extinction" on Earth. The 2019 Global Assessment Report by the Intergovernmental Platform on Biodiversity and Ecosystem Services (IPBES) has reported that one million animal and plant species are threatened with extinction which is the highest number in human history [2]. The fear of extinction of biodiversity, thereby destabilizing the ecological balance in nature has led to conservation and reservation movements and organizations like the International Union for Conservation of Nature (IUCN) have maintained a "red list" of species which are threatened status of extinct since 1964.

2.2 Loss of natural habitat and conflict between humans and wild

Loss of Biodiversity has led to the loss of natural habitats of more than 1.9 million square km and this has led to wildlife invading nearby human habitats leading to human-wildlife conflicts in major cases and further loss of life and property.

2.3 Loss to economy

Biodiversity contributes to the economy through food, medicine, construction and building materials, tourism, scientific innovations, fashion, etc. Such sectoral contribution to the economy of a country is impacted when there is a loss of biodiversity in a region or country. Common drugs like Aspirin were originally extracted from the bark of willow trees and the benefits of Haldi for its antiseptic, and antifungal properties are globally known. To elaborate on the importance of biodiversity in its contribution to the economy, the Indian Budget where Rs 4,000 crore is allotted for deep ocean missions and particularly Rs. 436 crore was allotted towards Ocean Services, Modelling, Application, Resources and Technology (O-SMART) project whereby exploration of Indian Ocean Basin for gas hydrates will be facilitated is an example of Government's seriousness towards development of marine-based economy.[3]

3 International law relating to biodiversity protection

This segment of the paper will deal with the various international legal instruments which advocate for the protection of biological resources against unauthorized use and exploitation.

3.1 Convention on Biodiversity, 1993

The main objectives of conserving & preserving biological diversity, trying to ensure the sustainable use of these resources to meet sustainable development goals and providing for a mechanism of fair and equitable sharing of benefits arising out of the

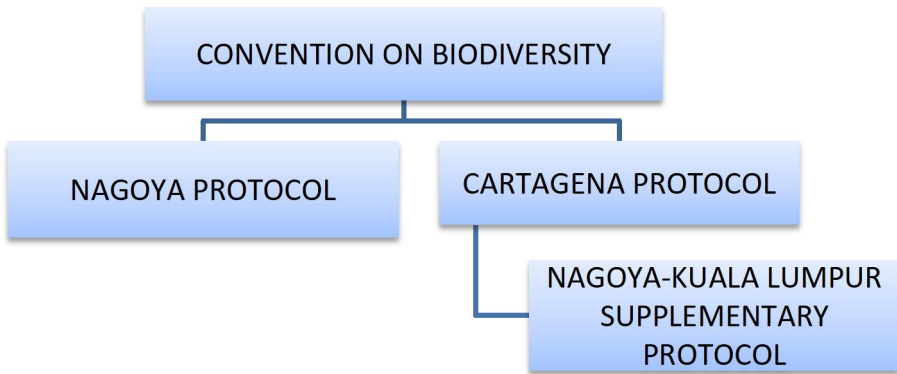
commercial exploitation of the biological/ genetic resources and the associated knowledge, the Convention on Biological Diversity (CBD) was entered in to in the year 1992 at the Rio Earth Summit.

This Convention is considered a landmark in the efforts of channelizing the focus towards safeguarding the biodiversity at large against not only climatic erosion and human-led erosion of the same but also to ensure the judicious use of the biological resources so that the optimum benefits can be accrued from their use and exploitation. This Convention is best known for deliberating for the first time on Nations having their sovereign rights over their biological resources available within their territorial limits, thereby replacing the Idea of Commons with the new order Idea of Sovereignty as far as fixing ownership over resources is concerned. This new idea of Sovereignty being exercised by the Nations empowered them to have laws in place to regulate the use and commercial exploitation of their resources. CBD is also considered a celebrated international legal instrument as this gave rise to a need to have Access and Benefit Sharing mechanisms in place for not only ensuring the optimum use of biological resources but also ensuring that the knowledge holders hold traditional knowledge over such resources.

India being a party to CBD has legislated its legislation for protecting biological resources and associated knowledge under the IPR framework. The legislation is Biological Diversity Act, 2002 and it has the same objectives as the main objectives of CBD providing for Conservation, sustainable development and fair and equitable sharing of benefits.

3.2 Protocols under CBD

The Convention on Biodiversity has two major protocols and a supplementary protocol under its wings:



Flowchart: Depicts Protocols and Supplementary Agreement under CBD

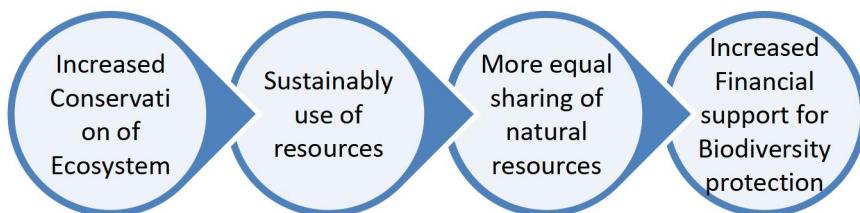
The “Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity” is an international agreement whose primary goal is to enhance legal certainty and transparency regarding benefits arising from the utilization of genetic

diversity.[4]There is an Access and Benefit-sharing Clearing-House (ABS Clearing-House) established through the Protocol as per requirements of the CBD Article 18 para 3 who look into the proper implementation of principles and obligations under the Nagoya Protocol providing a platform for users, providers of genetic diversity as well as associated traditional knowledge holders.

The 2nd protocol to the CBD is the "Cartagena Protocol on Biosafety to the Convention on Biological Diversity" whose primary objective is on "safe handling, transfer and use of living modified organisms (LMOs)" across jurisdictions have such bio-technological results may hurt bio-diversity as well as human health [5]. A supplementary agreement to this Cartegena Protocol was adopted named "Nagoya - Kuala Lumpur Supplementary Protocol on Liability and Redress" which addresses issues relating to liability where damage is suffered or likely to be suffered from handling, transfer or utilization of LMOs and it also highlights the response measures to be taken in such account. [6]

3.3 Kunming-Montreal Global Biodiversity Framework (GBF), 2022

The 15th meeting of the Conference of Parties (COP) under CBD has four major targets to be achieved by 2030 to "halt and reverse" the decline of biodiversity:



Picture: 4 major goals by 2030 under the Kunming-Montreal Global Biodiversity Framework.

Under these 4 major goals, there are 23 specific goals which have been identified by COP15 and a long-term goal to be achieved by 2050 is also agreed upon to ensure humans live in harmony with nature. [7] Though the framework is a non-legally binding instrument, it shows the commitments States are willing to explore to ensure conservation of Biodiversity.

3.4 Trade-Related Aspects of Intellectual Property Rights (TRIPs) Agreement, 1994 [8]

Article 27 (3) of the TRIPs Agreement allows members to exclude patenting of any innovation/ invention on plants and animals per se on grounds of public order and morality. It puts an obligation on the (member countries who through their domestic

laws including such exclusion of patenting of plants and animals) create such alternate domestic legal framework which can adequately protect the plant varieties and can promote research and development involving plants in line with the basic rationale behind Intellectual Property protection. Article 27 (3) however allows for patenting of microorganisms. Article 27(3) is important about private property rights relating to biodiversity.

There are examples where private proprietary rights in the form of patents have been claimed on what is associated with traditional knowledge belonging to particular communities over their genetic resources in their natural habitat. While the Western world has used terms like bio-prospecting, the East has criticized such moves as bio-theft or bio-piracy. India's fight against bio-piracy by filing objections against the patenting of properties of Neem and turmeric are classic example in this regard. In tune with CBD, a proper biodiversity management legal regime will strike a balance between private property rights like patents and the ABS mechanism of a country. The next section of this article highlights the Indian legal regime relating to Biodiversity Management.

4 Law relating to access-control and benefit sharing mechanism in India

4.1 The Biological Diversity Act, 2002

As a member country of CBD and to comply with the chief objectives, India legislated its sui-generis law on regulating the access to its biological resources and the judicious use of these resources in the form of the Biological Diversity Act in the year of 2002. The Indian Law on this not only complies with the three basic objectives of the CBD but also goes a step ahead and comes with a very comprehensive framework of Access and Benefit Sharing, which is also considered as the USP of the Biological Diversity Act, 2002. This mechanism works in two sub-mechanisms under it. The first is the Access Control Mechanism and the other is the Benefit Sharing Mechanism. While the former is responsible for regulating access to the biological resources and associated knowledge available in India by both foreign and Indian stakeholders as per the stipulated provisions of the Act, the latter focuses on the aftermath of granting access by the appropriate authority over our resources in terms of facilitating a fair and equitable sharing of benefit between the concerned stakeholders involved in the process of generating such benefit, making this a mechanism safeguarding the interests of the knowledge holders who hold knowledge traditional/indigenous knowledge involving such resources.

4.2 The Biological Diversity (Amendment) Act, 2023

The BD Act 2002 was amended by the Parliament by passing the Biological Diversity (Amendment) Bill, 2023 on 1st August 2023. [9] The amended BD Act 2023 focuses on encouraging the use of indigenous medicines and goes on to rationalize the penalty provisions under the Act for wrongdoings by user

agencies.[10] The following analysis will be a comparative analysis of improvements brought to the existing BD Act 2002 by BD amended Act 2023.

4.3 Access control Mechanism under BD Act in India

The BD Act stipulates norms for access to biological resources and traditional knowledge in three ways:

(i) Access to biological resources and traditional knowledge to foreign citizens, companies and non-resident Indians (NRIs) based on 'prior approval of NBA'. [11]

Section 3: Access over biological resources and associated knowledge by foreign citizens, companies, NRIs etc. Only after prior approval of the NBA

Section 4: Transfer of research results obtained from conducting experiments over biological resources and associated knowledge available in India by any person can be made only after obtaining prior approval from the NBA regarding the same.

Section 5: Sections 3 and 4 are not to be made applicable to "Collaborative Research Projects" which are undertaken involving at least one party as Indian Govt. Or any stakeholder deriving power under Govt. Of India and where such project is undertaken as per the central gov't.'s guidelines issued to this effect.

Section 6: IPR can be filed over results obtained from conducting experiments over biological resources and associated knowledge available in India by any person can be made only after obtaining prior approval from the NBA regarding the same.

The 2023 amendment to the BD Act included the obligations under Sections 3, 4 and 6 for foreigner-controlled companies that are registered in India under the Companies Act, 2013.

(ii) As per section 7 of the Biological Diversity Act, Indian stakeholders in the form of citizens, companies, institutions, and organizations can see Access to the biological resources available in India only with a prior intimation to the concerned State Biodiversity Board (SBB) within whose territorial jurisdiction the resources and associated knowledge are extracted.

(iii) The Access Control Mechanism under the Biological Diversity Act, 2002 provides for an exemption in the form of a relaxation to the Local medicinal practitioners of an area where medicinal plants are found. As per section 5 of the Biological Diversity Act, 2002 these practitioners need not take any specific approval from NBA or SBB before having access to any medicinal plants to carry out their research in furtherance of their traditional medicinal practices. This clause acts like a safeguarding clause to acknowledge the contribution of the local traditional medicinal practitioners in the rich traditional medicinal knowledge systems in the form of Siddha, Unani, Ayurveda etc.

4.4 Benefit Sharing Mechanism under BD Act, 2002

As discussed earlier in the paper, the ABS (Access and Benefit Sharing mechanism) mechanism which is the major highlight of the Biological Diversity Act, of 2002 rests on two important pillars. One is the Access control mechanism, which has already been discussed in detail earlier in the paper. The other pillar is the Benefit Sharing Mechanism. Section 21 of the Biological Diversity Act, 2002 read along with

Rule 10 of the Biological Diversity Rules, 2004 gives us an idea that the National Biodiversity Authority is entrusted with the responsibility of ensuring the compliance of an effective benefit-sharing regime in all those cases where approval has been granted (under Section 3 of the BD Act, 2002) or an intimation has been provided (under Section 7 of the BD Act, 2002) in connection with the access over the biological resources and associated knowledge. The fair and equitable sharing of benefits which accrues from the commercial exploitation of biological resources and associated knowledge can be primarily done in two ways. The first one is the Monetary Benefit sharing while the other is the sharing of benefits in the form of capacity-building measures. Monetary sharing of benefits can again be done in two ways, either in the form of a one-time lump sum payment or through a continuous sharing of benefits in the form of royalties. A short brief, hereunder, has been provided highlighting the various modes in which the benefits can be shared among the concerned stakeholders under the Benefit Sharing Mechanism.

- a. Grant of joint ownership of intellectual property rights to the NBA, or where benefit claimers are identified, to such benefit claimers;
- b. transfer of technology;
- c. to set up such research and development infrastructure which will be in furtherance of the development of the local people of that area which in turn will also provide employment opportunities for the skilled youth of such area.
- d. upfront payments in the form of one-time payments
- e. continuous sharing of benefits in the form of royalties.
- f. Capacity building measures such as creating capacity for the local people of that area to give them a better standard of living like building of school in that area, looking after the sanitation measures of that area etc.

India has signed the Nagoya Protocol in 2011 and ratified the same in 2012. [12] In virtue of its obligations under the Nagoya Protocol, India notified the ABS Rules in 2014. India is also a signatory to the Cartagena Protocol from 2003 and has established the India Biosafety Clearing House accordingly to act as an information exchange platform from India regarding LMOs. [13] The entire procedure as described in the Act has contributed substantially to facilitating an international regime of ABS on genetic resources and traditional knowledge.

An example of the ABS enforcement model in India is the case study of PepsiCo India Holdings Private Limited where the company paid a total of 3.7 million rupees to the Tamil Nadu Biodiversity Board for accessing "a species of exotic seaweed *Kappaphycus alvarezii* being cultivated by local communities in southern Tamil Nadu" [14]. However, questions remain where the negotiated and finalized monetary benefit tickled down to the end beneficiaries.

5 Conclusion and Suggestion

India is known for its rich biodiversity. It is also best known for its traditional knowledge in different domains. There are so many bioresources available in India which are exclusively native to India. It is often seen that such biological resources are nourished and preserved by the native communities of the place where such resources are found. It also observed that such native communities or tribes who contribute the most in the growth, propagation and preservation of these biological resources exclusively native to India, incorporate various usages of these biological resources in their day-to-day life adding significantly to the rich traditional knowledge system involving these resources which India boasts of. With such a rich biological diversity and associated traditional knowledge, India has been often a lucrative target in the past when it comes to appropriating these resources and associated knowledge in an unauthorized manner. That is the reason India has faced several cases of biological theft which is commonly called the cases of bio-piracy, already discussed in the paper. With the advent of the Convention on Biological Diversity in the year 1992, the Idea of State Sovereignty over all the resources (natural, mineral, biological etc.) available within the territory of a nation was introduced globally as against the earlier Idea of Openness which subjected all kinds of resources as a gift of nature to be used and exploited by the entire humankind without any state-specific regulations. This paved the way for the Nations to exercise their jurisdiction on the resources available within their territorial limits and make laws for the appropriate commercial and otherwise use of such resources thereby acting as a shield against the rampant cases of biological theft which many countries rich in biological resources and associated knowledge faced. India too joined the league and as a member country of the Convention on Biological Diversity (CBD) drafted its laws about the regulation of its biological resources and associated knowledge in the form of the Biological Diversity Act, of 2002. The provisions incorporated under the Biological Diversity Act, relating to safeguarding biological resources and associated knowledge against biological theft are considered regulatory and not prohibitory. According to these provisions, which also have been discussed in the paper, access to the biological resources and associated knowledge for research as well as for commercial exploitation by foreign as well as Indian entities is not prohibited rather it's well regulated by the statutory authorities under the Act so that the traditional knowledge holders in the form of benefits claimers get their due by a strong benefit sharing mechanism in exchange of their contribution in preserving the biological resources and the traditional knowledge involving such biological resource which will in turn not only accelerate the research and innovation involving bio resources but also in long run contribute in the Nation's development by promoting the interests of its native people. However, there is always scope for improvement in a system as the system needs to evolve with time and the evolving needs of the people to whom such a system caters. In the same way, the Access Control mechanism also needs to be more proactive while taking up the cases of benefit sharing in terms of the identification of appropriate benefit claimers from a traditional/indigenous community. Often it is seen that the appropriate identification of the benefit claimers

receives a setback because of the improper management of databases regarding the details of such traditional communities because of which the proceeds from a benefit sharing agreement even though reaches the National Biodiversity Authority, the apex authority for the management and regulation of Access Control Mechanism under the Biological Diversity Act, 2002, the disbursement of such proceeds whether in terms of monetary gains or terms of capacity building measures is not appropriately done among the benefit claimer often leaving them deprived of their dues. Hence better involvement of the officials of the Biodiversity Management Committee, the grass root authority under the Biological Diversity Act, 2002, who is responsible for being in direct interaction with the local people of an area from where the resources and associated knowledge are extracted, is the need of the hour in creating and managing the database of the local people and all of their traditional and indigenous knowledge involving India's resources. This will not only help in easy access to such details as and when a requirement of identification of benefit claimers comes in connection with a benefit-sharing agreement between NBA/SBB and any foreign/ Indian stakeholders but will also significantly contribute to the maintenance of the Traditional Knowledge Digital Library (TMDL), a Govt. of India's initiative towards safeguarding our resources and the associated traditional knowledge against unauthorized appropriation leading to biological theft commonly known as bio-piracy. Even though with scope for betterment, the implementation of the Access-Control Mechanism in India under the Biological Diversity Act, of 2002 has proved to be an effective framework in biodiversity management by protecting not only the biological resources but also the traditional & indigenous knowledge associated with such biological resources against their misappropriation resulting in India becoming victims to the cases of bio-piracy.

References

1. Esme Stallard, What is biodiversity and how are we protecting it? BBC NEWS, <https://www.bbc.com/news/explainers-60823267>, 21 April 2023.
2. Why Biodiversity Matters, United Nations Climate Change, <https://unfccc.int/news/why-biodiversity-matters>, 10 September 2021.
3. Akshit Sangomla, Union Budget 2021-22: Finance Minister launches Rs 4,000 crore deep ocean mission, DOWN TO EARTH, <https://www.downtoearth.org.in/news/environment/union-budget-2021-22-finance-minister-launches-rs-4-000-crore-deep-ocean-mission-75308>, Published: Monday 01 February 2021
4. The Nagoya Protocol on Access and Benefit-sharing, <https://www.cbd.int/abs/>.
5. The Cartagena Protocol on Biosafety to the Convention on Biological Diversity, <https://bch.cbd.int/protocol>.
6. The Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety, <https://bch.cbd.int/protocol/supplementary/>.
7. Kunming-Montreal Global Biodiversity Framework, <https://www.cbd.int/gbf/>
8. TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, (1994) [hereinafter TRIPS Agreement].

9. The Biological Diversity (Amendment) Act, 2023, Ministry of Environment, Forest and Climate Change, GOI, <https://moef.gov.in/moef/biological-diversity-amendment-act-2023/index.html>
10. Amitabh Sinha, What is the Biodiversity Act? What changes have the Lok Sabha cleared in the law?, available at: <https://indianexpress.com/article/explained/explained-law/biodiversity-act-amendment-lok-sabha-8863004/>, last updated: July 28, 2023
11. The Biological Diversity (Amendment) Act, 2023 No. 10 Of 2023; The section 3 of the principal BD Act, in sub-section (2), in clause (c), for sub-clause (ii), the following sub-clause was substituted, namely: — “(ii) incorporated or registered in India under any law for the time being in force, which is controlled by a foreigner within the meaning of clause (27) of section 2 of the Companies Act, 2013.”
12. Convention on Biological Diversity (CBD), MoEF, GOI, available at: <https://moef.gov.in/moef/division/environment-divisions/conservation-and-survey-cs/convention-on-biological-diversity-cbd/index.html>.
13. INDIA Biosafety Clearing House, available at: <https://geacindia.gov.in/india-bch.aspx>
14. Aathira Perinchery, Bioresource access and benefit-sharing: How far have we come in India?, MONGABAY, available at: <https://india.mongabay.com/2020/04/india-bioresource-access-and-benefit-sharing-how-far-have-we-come/>, last updated: April 9, 2020.

Open Access This chapter is licensed under the terms of the Creative Commons Attribution-NonCommercial 4.0 International License (<http://creativecommons.org/licenses/by-nc/4.0/>), which permits any noncommercial use, sharing, adaptation, distribution and reproduction in any medium or format, as long as you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons license and indicate if changes were made.

The images or other third party material in this chapter are included in the chapter's Creative Commons license, unless indicated otherwise in a credit line to the material. If material is not included in the chapter's Creative Commons license and your intended use is not permitted by statutory regulation or exceeds the permitted use, you will need to obtain permission directly from the copyright holder.

