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Ministry of Environment,  
Forest and Climate Change  
Government of India



# ***Biological Diversity Act 2002***

**Users' Guide to Access  
and Benefit Sharing**



**National Biodiversity Authority**



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## **FOREWORD**

The Biological Diversity Act, 2002 was enacted in India to address the ever increasing threat to biological diversity and to realise the objectives in the United Nation's Convention on Biological Diversity (CBD) 1992, which recognised the sovereign rights of the states over their biological resources. The Act provides guidance for conservation of biological diversity, sustainable use of its components and fair and equitable sharing of the benefits arising out of the use of biological resources, knowledge and for matters connected therewith or incidental thereto. As a Party to the CBD, India honours the commitment and strives to meet the international obligations under the Convention.

It is more than a decade after getting the BD Act & Rules in place. We have also taken considerable initiatives for institutionalizing Access and Benefit Sharing (ABS) mechanism in the country. But still there is acute lack of awareness on ABS provisions of the BD Act across all the stakeholders especially the users of bioresources like bioresources based industries and research scientists.

This book is a small attempt to fill up the gap and bring awareness among stakeholders. It will be of immense help not only to the biological resources users but also to other stakeholders like policy makers, State Biodiversity Boards (SBBs), Biodiversity Management Committees (BMCs) and Civil Society Organizations who are putting effort to institutionalize the ABS mechanism in India.

I would like to express my sincere gratitude to Dr. Shivendu K Srivastava, IFS (Retd.) for his sincere efforts to compile the text. I am also thankful to Shri. T. Rabikumar, IFS, Secretary NBA and the CEBPOL team members especially Dr. Rupam Mandal, Programme Manager for providing the generous support for bringing out this publication. I am also thankful to Ministry of Environment, Forest and Climate Change (MoEFCC), Government of India for encouragements and Norwegian Environment Agency (NEA), Norway & Norwegian Embassy, New Delhi for the financial support.

**B. Meenakumari**  
Chairperson  
National Biodiversity Authority



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*"The first law of ecology is that everything is related to everything else".*

*– Barry  
Commoner*

## **HOW TO USE THIS GUIDE**

The Users' Guide to Access and Benefit Sharing has been brought out by the National Biodiversity Authority (NBA) with the basic aim of familiarising users of biological resources of India with the provisions of the Biological Diversity Act. Readers will also get an overview of the functioning of the NBA, an institution established exclusively for the purpose of implementing the Biological Diversity Act. It is the central agency to advise the Government of India on all matters related to the conservation and sustainable use of biodiversity and an equitable sharing of the benefits arising from the use of biological resources and associated traditional knowledge. As a result, anybody dealing with the business of biodiversity in India in a way which the Biological Diversity Act impacts is directed to the NBA.

The NBA therefore becomes the centre point; yet at the state level and local level, a system was required to make the Biological Diversity Act operational over the length and breadth of the country. Therefore, State Biodiversity Boards (SBBs) have been set up in the States for sustainable management of biological resources in the field; and similarly, at the local level, Biodiversity Management Committees (BMCs) are being constituted with the specific aim of involving local institutions in the process.



Not all the provisions of the Biological Diversity Act have been elaborated in this guide. The aim is to familiarise users of biological resources with the broad outlines of the Act so that they are facilitated to enter the business of biodiversity.

It is advised that this booklet should not be used as reference in case of any dispute. In such cases, the original text in the legal documents and other supplementary circulars and guidelines issued by the Government of India and the NBA should be referred to. The intention here is to familiarise users in the simplest words with the functioning of the NBA, the SBBs and the BMCs.



# CHAPTER - 1

## ***INTRODUCTION***

### **Why conserve biodiversity and share its benefits?**

The worldwide stress given to the conservation of biodiversity is based on valid reasons. It is biodiversity which provides the life support system on Planet Earth – it helps in soil formation, recycles nutrients, cleans the air and water on earth, sustains the wetlands and trees and microorganisms that keep our ecosystems functioning and makes it suitable for all life forms to survive. Biodiversity also sustains the aesthetic aspirations of man.

We need to conserve biodiversity because it is the fountainhead of many foods and food additives, and most importantly, of medicines. Many drugs derived from natural products have already saved millions of lives, and many more are waiting to be discovered to make our future generations free from disease. Biodiversity is also the source of numerous products yielding economic benefits. Here too, the wild holds limitless potential to develop more economically productive items, including food for the world's growing population.

When the benefits arising out of the commercial use of biodiversity are considered, the principle of equitable sharing of benefits accruing from these resources and traditional knowledge associated with them is a natural corollary.





The basic principle is that benefits must be shared with the people who live within the ecosystems harbouring the biodiversity which is harnessed for economic profit. Why should the benefits be shared? One reason is that the indigenous and local communities that co-habit the biodiversity-rich regions of the world are dependent on biological resources for their sustenance and livelihood needs, and therefore the benefits accruing from biological resources and traditional knowledge associated with these resources need to be shared with them. It is argued that these communities should not be deprived of the potential benefits arising out of the commercial use of the resources that have traditionally been a source of sustenance for them unless they are provided with alternatives of livelihood opportunities.

Another telling argument is that the vast storehouse of traditional knowledge built up by generations of the indigenous and local communities is tapped by ethno-botanists without any acknowledgement, in order to develop a final product that benefits industry in some other corner of the world, and it would be an anomaly if there was no sharing of the ultimate benefits with the owners of this traditional knowledge.

It is therefore logical to talk about the sustainable use of the components of biodiversity and an equitable sharing of benefits arising from such use. The international conventions and agreements focusing on these aspects are discussed in the following sections.



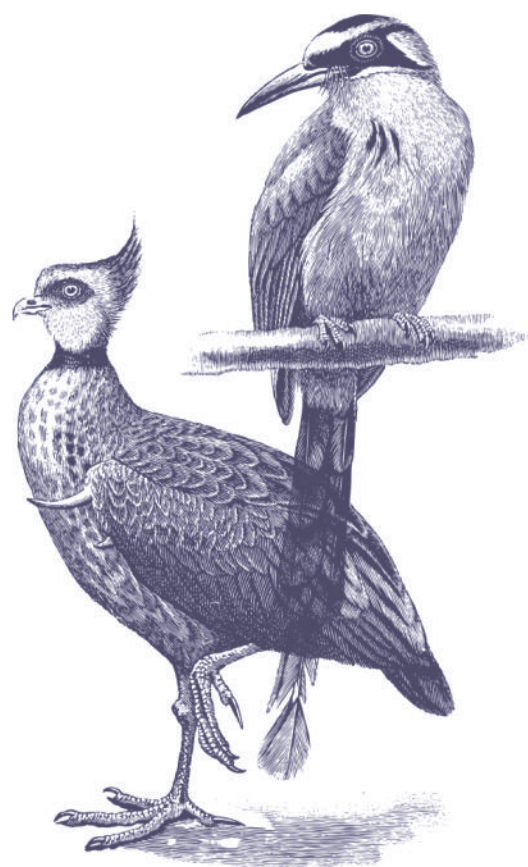


## The Biodiversity Scene in India

India is one of the 17 mega biodiversity countries of the world. It amounts to only 2.4 per cent of the total land area of the Earth, yet, accounts for 7 per cent to 8 per cent of the recorded species of the world - approximately 45,000 species of plants and 91,000 species of animals. It is also among the few countries that have developed a biogeographic classification for conservation planning, and has mapped biodiversity-rich areas within its territory.

Of the 34 global biodiversity hotspots, four are in India, represented by the Himalayas, the Western Ghats, the North-east region and the Nicobar Islands. Considering the outstanding universal value and exceptionally high levels of endemism in the Western Ghats, 39 sites in the States of Kerala, Karnataka, Tamil Nadu and Maharashtra have been included in the UNESCO World Heritage List in 2012.

Source: India's fifth National Report to the CBD (MoEF&CC), 2014 available at [www.cbd.int/doc/world/in/in-nr-05-en.pdf](http://www.cbd.int/doc/world/in/in-nr-05-en.pdf)





## Convention on Biological Diversity

The world's mindfulness about the need for conserving biodiversity has been alluded to in an earlier paragraph. This global concern led to the international treaty of the Convention on Biological Diversity<sup>1</sup>(CBD) of 1992 that was adopted in the 1992 Earth Summit held in Rio de Janeiro (Brazil) and came into force in 1993. The CBD enunciates the global commitment to biodiversity by laying down three main objectives: (1) Conservation of biological diversity (2) Sustainable use of its components and (3) Fair and equitable sharing of the benefits arising out of the utilisation of genetic resources.

The agreement recognises that (a) biodiversity is a global asset, (b) conservation of biodiversity is a common concern of humankind, and (c) the States have sovereign rights over their own biological resources. It also stresses that the knowledge, innovations and practices of indigenous and local communities relevant to biodiversity conservation and utilisation should be respected and that the traditional knowledge and the customary practices relating to the uses of biological resources should be protected. Another unique feature of this agreement is the provision of new and additional resources and proper funding and appropriate access to relevant technologies to meet the three main objectives. It also deals with the aspect of access to biological resources. It stresses that access, wherever granted, should be on mutually agreed terms and should be subject to prior informed consent of the Contracting Party providing such resources.

<sup>1</sup>Full text available at: [www.cbd.int/convention/text/](http://www.cbd.int/convention/text/)



The sovereign right of the States over their biological resources is well laid out, with the mandate that the States shall 'exploit their own resources pursuant to their own environmental policies', and 'the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.'

The CBD further maintains that wider application of traditional knowledge should be promoted with the approval and involvement of the holders of this knowledge and equitable sharing of benefits arising from the utilisation of this knowledge should be encouraged.

## Nagoya Protocol

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation (**Nagoya Protocol**<sup>2</sup> in short) is a supplementary agreement to the CBD with the aim of providing a legal framework for implementation of the CBD's objective of fair and equitable sharing of benefits accruing from the utilisation of genetic resources. This was the first time that a legally binding agreement was brought in to support the concept of benefit sharing.

### The Nagoya Protocol

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation was adopted in Nagoya (Japan) in 2010 and came into force on 12th October, 2014. India was among the first signatories to this agreement. The Nagoya Protocol was the basis for formulating the guidelines for access and benefit sharing. The guidelines (Guidelines on Access to Biological Resources and Associated Knowledge and Benefit Sharing Regulations 2014) were notified on 21st November, 2014 as regulations under the Biological Diversity Act.

<sup>2</sup>Full text available at: [www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf](http://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf)



This agreement generates incentives to conserve and sustainably use genetic resources, and offers greater legal certainty and transparency for both the resource providers and the resource users. It also helps to ensure benefit-sharing when genetic resources leave the country of origin. The benefit-sharing measures on the part of the resource user countries are to provide for the fair and equitable sharing of benefits arising from the utilisation of genetic resources with the resource provider countries. The sharing is subject to mutually agreed terms and the benefits may be monetary or non-monetary, such as royalties and the sharing of research results. Access to the genetic resources has to be subject to the prior informed consent or approval and involvement of indigenous and local communities based on fair and non-arbitrary rules and procedures.

The Protocol's objective also stresses appropriate transfer of relevant technologies and appropriate funding as a set of means to equitable benefit sharing that would promote the conservation of biological diversity and the sustainable use of its components.

Traditional knowledge associated with genetic resources is addressed in the Nagoya Protocol as an integral part. These measures for access and benefit sharing (ABS) have to be framed in accordance with domestic legislation regarding the established rights of indigenous and local communities over genetic resources. Additionally, these benefits ought to be directed towards the conservation of biological diversity and the sustainable use of its components.

*"Living wild species are like a library of books still unread.  
Our heedless destruction of them is akin to burning the  
library without ever having read its books".*

*- John Dingell*





## The Biological Diversity Act and the Institutional Setup for its Implementation

The Biological Diversity Act of 2002 was the result of decade-long deliberations and was enacted on 5th February, 2003. As a follow up, the Biological Diversity Rules came into force on 15th April, 2004 and the guiding principles for access and benefit sharing, known as the ABS Guidelines, came into force on 21st November, 2014. These guiding principles (Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations, 2014<sup>3</sup>) cover the different modes of sharing of benefits arising out of the commercial utilization of biological resources and associated traditional knowledge.

### Why this Act?

The worldwide interest in biodiversity, a wealth that lies mostly in tropical countries, forced these countries to formulate laws for conservation of biodiversity. Being a mega biodiversity country, India also enacted the Biological Diversity Act in 2002 with three core objectives:

- Conservation of biological diversity
- Sustainable use of the components of biodiversity
- Equitable sharing of the benefits arising out of the utilization of biological diversity and traditional knowledge associated

<sup>3</sup>Full text available at: [www.nbaindia.org/uploaded/pdf/Gazette\\_Notification\\_of\\_ABS\\_Guidelines.pdf](http://www.nbaindia.org/uploaded/pdf/Gazette_Notification_of_ABS_Guidelines.pdf)  
(English version on pages 11 to19).



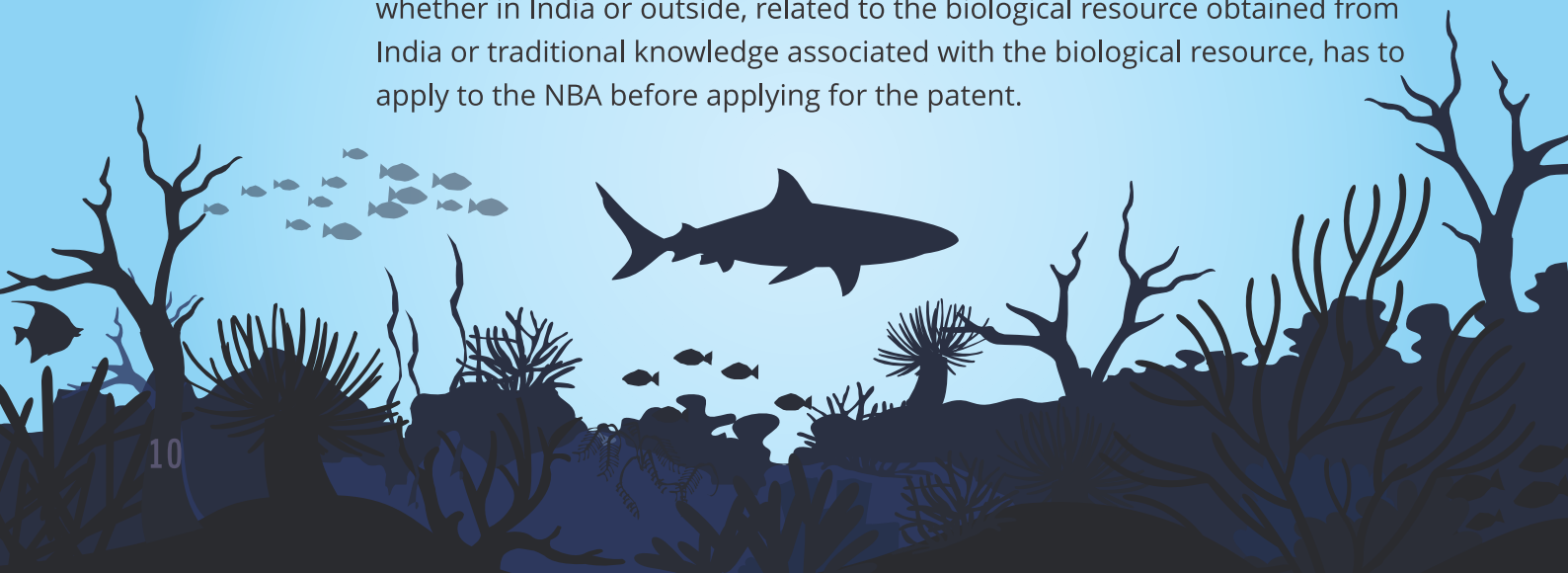
Here is an outline of the Biological Diversity Act:

### **Biological Diversity Act (2002)**

The objective of the Biological Diversity Act is to provide for conservation of biological diversity, sustainable use of its components and fair and equitable sharing of the benefits arising out of the use of biological resources and the traditional knowledge associated with these resources. This is in total conformity with the objective of the Convention on Biological Diversity, wherein the emphasis is on the conservation and sustainable use of the components of biodiversity and equitable sharing of benefits.

Biodiversity-based businesses should appreciate their dependency on biological resources and associated knowledge and should conform to the biodiversity laws, rules and regulations that present a binding legal framework. They should recognize that they will be able to benefit from their businesses only when supply of biological resources is sustained for the present and also for future prospects.

For implementation of the Biological Diversity Act, the Government of India established the National Biodiversity Authority (NBA) in 2003, with its headquarters in Chennai. Any person or entity intending to file a patent, whether in India or outside, related to the biological resource obtained from India or traditional knowledge associated with the biological resource, has to apply to the NBA before applying for the patent.





### **Does the Biological Diversity Act forbid granting of patents globally on biological resources obtained from India?**

No, it does not do so. The Biological Diversity Act does not prevent patents from being granted globally on biological resources obtained from India. It also does not forbid access to the biological resources or to the patents granted on biological resources within the country; it only regulates the access to and the grant of patents involving biological resources obtained from India in such a way as to ensure an equitable sharing of benefits that accrue from the commercial utilization of these resources. It also takes into consideration the aspects of conservation and sustainable use of the components of biodiversity.



India being a mega biodiversity country with vast resources, an elaborate set of institutional structures was needed to meet the objectives of the Biological Diversity Act. Therefore, in addition to the NBA, State Biodiversity Boards (SBBs) were created in each State of India and Biodiversity Management Committees (BMCs) were to be the entities at the local level under the Biological Diversity Act. These two establishments, along with the NBA, constitute a three-tier system of institutional support for the cause of biodiversity and present a well-organized institutional means that can regulate the activities mandated in the Biological Diversity Act.

The Biological Diversity Act clearly mandates that any person<sup>4</sup> referred to in Section 3(2) of this Act, who intends to access any biological resource (or traditional knowledge associated with the resource) occurring in India for research, or bio-survey or bio-utilization, or for commercial utilization, has to seek the prior approval of the NBA. For others, to undertake these activities prior approval from the concerned SBB is required, as the matter relating to access biological resources for commercial utilisation or for biosurvey and bioutilisation for commercial utilisation. On the other hand, such persons who want to access these biological resources purely for research purposes are free to do so – they do not need to seek approval from, or even inform any statutory body.

As regards the results of research related to India's biological resources, the publication of research papers or dissemination of knowledge at any seminar or workshop (subject to the condition that the publication is as per the guidelines issued by the Government of India) is free from these regulations. However, results of research cannot be transferred to any person or entity who is non-Indian, an NRI, or a body corporate having any non-Indian share in capital or management without the previous approval of the NBA.

<sup>4</sup>Any person who is (a) not a citizen of India, (b) a non-resident Indian as defined in the Income Tax Act, 1961, (c) a body corporate not registered in India, or (d) a body corporate registered in India, having any non-Indian participation in its share capital or management.





### **An open wealth:**

A vendor selling biological resources on the streets of Hyderabad (above), and plant parts he is selling in unprocessed form (left).



## Penal Clauses in the Biological Diversity Act

There are many regulatory provisions included in the Biological Diversity Act and the NBA functions as a regulatory body to meet the purposes of the Act. Violations of the provisions of this Act are cognizable offences and are non-bailable. It is therefore pertinent to briefly mention the penal clauses of this Act.

For undertaking biodiversity related activities in contravention of the regulations mentioned in the Biological Diversity Act, such as accessing a biological resource for research or for commercial utilization or for bio-survey and bio-utilization (applicable to the persons referred to in Section 3(2) of the Act), transferring the results of research, or applying for Intellectual Property Rights (IPRs) without approval of the NBA, the Act provides for terms of imprisonment up to five years and/ or fine up to Rs. 10 lakh. A fine also may be imposed in certain cases where damage is caused to biological diversity. Accessing biological resources for commercial utilization without prior intimation to the State Biodiversity Board, or undertaking any activity that is detrimental to the conservation and sustainable use of biodiversity or is contrary to the objectives of an equitable sharing of benefits can lead to imprisonment up to three years and / or a fine of up to Rs. 5 lakh.



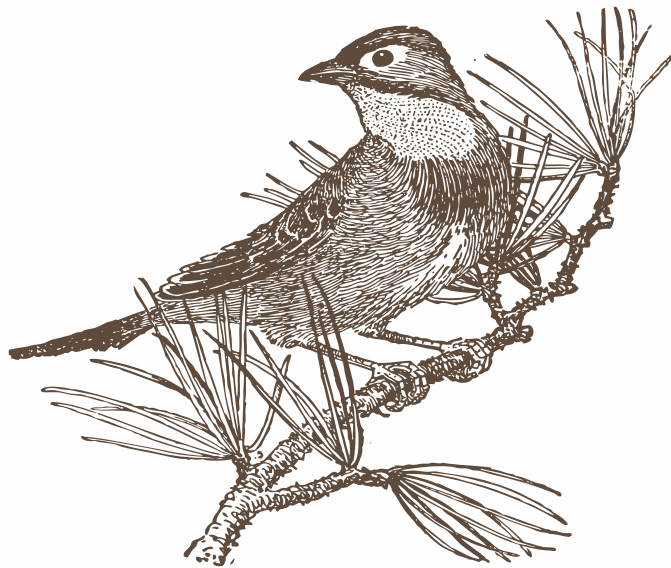
The NBA is also authorized to undertake physical inspection of any area in connection with the implementation of this Act. (References: Sections 55, 56 and 58 of Biological Diversity Act and Rule 12(xviii) of Biological Diversity Rules)

These penal provisions need not scare away researchers and other users of biodiversity, as there is an adequate and well-functioning set of institutional structures, comprising the NBA, the SBBs and BMCs, to ensure that the provisions of the Biological Diversity Act are easily followed. The way these three layers administer the Biological Diversity Act is discussed in the following sections.

### **Who implements the Biological Diversity Act?**

The National Biodiversity Authority established by the Government of India shall act on the implementation of this Act. Similarly at the state level, the State Governments shall establish State Biodiversity Boards in respective states and also Biodiversity Management Committees at local level for the sake of implementation of the provisions relevant to them.





## National Biodiversity Authority

As mentioned earlier, the National Biodiversity Authority is one of the three institutional means stipulated for the purpose of implementing the Biological Diversity Act, the other two being the State Biodiversity Boards and the Biodiversity Management Committees. At the national level, the NBA is the agency implementing the Biological Diversity Act. It is also designated as the Competent National Authority for access and benefit sharing as per the requirement of the Nagoya Protocol.

An eminent person from the field of biodiversity and ABS issues is appointed by Government of India as the Chairperson, who acts as the chief executive of the NBA. The institutional structure consists of ten official members representing relevant sectors (forests, tribal affairs, agricultural research, biotechnology, ocean development, Indian Systems of Medicine, scientific and industrial research and so on) and five non-official members from the field of conservation and sustainable use of biodiversity and ABS.

During a year, in the normal course, there are at least four meetings of the NBA. The issues brought up at any meeting are decided on by a majority of votes of the members present and voting. The responsibility for coordinating and convening the meetings of the NBA is borne by the Secretary, who is also responsible for other matters of importance assigned to him.





The main functions of NBA may be summarised as:

- To regulate access to biological resources occurring in India and the transfer of results of research related to biological resources and the traditional knowledge associated to these resources.
- To consider applications from researchers for prior approval before they apply for patents and to prescribe suitable terms for benefit sharing in the cases having future commercial prospects.
- To issue guidelines for access to biological resources occurring in India and the sharing of benefits arising from the commercial utilization of these resources and the associated traditional knowledge, and also to secure the equitable sharing of these benefits.
- To grant necessary approvals for biodiversity-related activities as per the provisions of Biological Diversity Act.
- To advise the Government of India on matters related to the three main objectives of the Biological Diversity Act and also advise the State Governments on certain issues.
- To give directions to the SBBs and the BMCs for effective implementation of the Biological Diversity Act and also to provide technical assistance and guidance to the SBBs and coordinate their activities.
- To take any measures necessary to oppose the grant of IPRs in any country outside India on any biological resource obtained from India or knowledge associated with such biological resource which is derived from India.
- The NBA is empowered to constitute a number of committees of experts who would examine the pros and cons of issues allocated and submit recommendations to assist the NBA in its functions under the Biological Diversity Act. Additionally, commissioning studies, sponsoring investigations and research, collecting and publishing technical and statistical data, manuals or codes relating to the three main objectives of the Biological Diversity Act are also part of the functions of the NBA.

(Reference: Sections 8, 13, 18, 19, 20 and 21 of the Biological Diversity Act)



## State Biodiversity Board

- The State Biodiversity Board is an institutional setup at the State level for implementation of certain activities specified in the Biological Diversity Act. It is mandated to comprise ten members, including five non-official experts, in addition to the Chairperson of the State Biodiversity Board. Its main functions are:
- To advise the State Government on issues related to biodiversity conservation, sustainable use of the components of biodiversity and sharing of benefits of the commercial utilization of biodiversity.
- To allow commercial utilization, bio-survey and bio-utilisation of any biological resources by Indian citizens, or prohibit or restrict these activities if, after enquiries, the SBB is of the opinion that the activities are detrimental to biodiversity or contrary to equitable benefit sharing.

(Reference: Sections 7, 23 and 24 of the Biological Diversity Act)

## Biodiversity Management Committee

The Biological Diversity Act envisages the constitution of Biodiversity Management Committees (BMCs) at the local level, with the principal objective that these institutions that are nearest to the habitat of biological resources will promote conservation, sustainable use and documentation of biological diversity. The other functions of BMCs are:

- Collection of fees from persons accessing or collecting any biological resources for commercial purposes
- Chronicling of knowledge relating to biological diversity



- Conservation of land races, folk varieties and cultivars
- Conservation of domesticated stocks and breeds of animals and microorganisms
- Preservation of habitats

Another provision in the Act is that BMCs will be consulted by the NBA and the SBB while taking decisions on the use of biological resources and knowledge associated with such resources occurring within the territorial jurisdiction of the BMC concerned.

(Reference: Section 41 of the Biological Diversity Act)



**Ashok Prajapati, a vaidya from Chhindwara in Madhya Pradesh.** A traditional healer in dermatology, he claims to have provided treatments worth Rupees 40 lakhs in the last 35 years. He is passing on his traditional knowledge to his son.



## **National Biodiversity Fund, State Biodiversity Fund and Local Biodiversity Fund**

For the purposes of channelling benefits accruing from the commercial utilization of biodiversity to the benefit claimers, a fund is constituted at the national level, termed as the National Biodiversity Fund. The fees and royalties received by the NBA, in addition to other grants or central allocations, are credited to this fund. The fund is used for biodiversity conservation and development, and also for the socio-economic development of areas from where the biological resources and associated knowledge are accessed for commercial utilization, in consultation with the local bodies concerned.

(Reference: Section 27 of the Biological Diversity Act)

Similar funds are constituted at the State and local levels, called State Biodiversity Fund and Local Biodiversity Fund respectively. These funds also are constituted broadly for the purposes stated for the National Biodiversity Fund, but have some additional objectives decided by the respective State Governments.

(Reference: Sections 32 and 43 of Biological Diversity Act)

## **Biological Diversity Rules 2004**

The Biological Diversity Rules came into effect on 14th April, 2004. The general functions of the National Biodiversity Authority and the administrative procedures, powers and duties are covered under these rules. The constitution and the functions of Biodiversity Management Committees at the level of local bodies in the States have also been elaborated in the rules. The procedures for applying to the NBA for accessing biological resources and associated knowledge, transfer of results of research, prior approval from the NBA for applying for Intellectual Property Rights, prior approval for transfer of accessed biological resources to a third party, and so on, form a major part of these rules. The criteria for equitable sharing of benefits are included in these rules too, and it is iterated that the formula for benefit sharing shall be determined on a case-by-case basis.





## **Guidelines on Access to Biological Resources and Associated Knowledge and Benefit Sharing Regulations 2014**

The approval accorded by the NBA for various activities under the Biological Diversity Act is in the shape of an agreement between the applicant and the NBA. This agreement comprises terms and conditions, including the mode of sharing benefits arising out of the activity, for which approval are accorded. For determining these terms and conditions as well as the benefit sharing, the NBA has notified suitable regulations as the Guidelines on Access to Biological Resources and Associated Knowledge and Benefit Sharing Regulations 2014.<sup>5</sup>

The 'Guidelines' describe the procedure for access to the biological resource, the modes of sharing benefits that are to be followed under various categories of approvals, and also the mode of sharing among the NBA, the State Biodiversity Boards, the Biodiversity Management Committees and the benefit claimers, as the case may be. The various options that may be offered for sharing of the monetary and non-monetary benefits, with mutually agreed terms between the applicant and the NBA, are also included in the Guidelines. There is also a unique provision for conducting non-commercial research or research for emergency purposes outside India by Indian researchers or Government institutions. Such approval may be granted without a written agreement.

The Guidelines act as a tool for realising benefit sharing under the Biological Diversity Act.

<sup>5</sup>Full text available at: [www.nbaindia.org/uploaded/pdf/Gazette\\_Notification\\_of\\_ABS\\_Guidelines.pdf](http://www.nbaindia.org/uploaded/pdf/Gazette_Notification_of_ABS_Guidelines.pdf)  
(English version on pages 11 to19)



## To whom is this Act relevant?

This Act is relevant to universities, research institutions, laboratories, manufacturers and traders associated with industries (chiefly pharmaceutical, cosmetic and chemical industries) based on biological resources, and other researchers. Any person who intends to access to biological resources obtained from India or intends to commercially utilize these resources as well as the associated traditional knowledge has to follow the provisions under this Act.

The provisions are different for Indian citizens and for persons who are not citizens of India or are NRIs. It also differentiates between an Indian company registered in India and a body corporate or organization either not registered in India or if registered in India, has non-Indian participation in its share capital or management.

From the perspective of benefit sharing, the Act is also relevant to the local bodies and the local communities who co-inhabit the biological resources and who harbour the associated traditional knowledge.

## CHAPTER - 2

### **HOW TO APPLY TO THE NBA**

The Biological Diversity Rules comprise the procedures for applying to the NBA for prior approval to undertake various activities pertaining to biological resources. For the benefit of users, these procedures are explained in the following sections.

#### **How to apply for access to biological resources for research, commercial utilization, bio-survey and bio-utilisation**

Any person or entity specified under Section 3(2) of the Biological Diversity Act will have to seek the NBA's approval for access to biological resources and/ or associated knowledge for research or for commercial utilization or for bio-survey and bio-utilisation. In other words, any person who is not a citizen of India or who is a non-resident Indian (NRI), or any corporate body that is not registered in India, or if registered, has any non-Indian share capital or participation in management, cannot access any biological resource and associated knowledge without the previous approval of the NBA.

The persons or entities mentioned above may apply for necessary approval from the NBA in a prescribed form (Form I<sup>6</sup> of the Biological Diversity Rules 2004) along with a fee of Rs. 10,000. The application fee may be paid either



<sup>6</sup>Full text available at:  
<http://nbaindia.org/content/26/59/1/forms.html>





**Form - I**  
Application  
Fee  
INR. 10000/-

### Form I - To access biological resource/knowledge to do

Study or systematic investigation of any biological resources

Study or systematic investigation of a technological application using biological systems, living organisms or their derivatives

Objective to make or modify products or processes for any use.

#### Research



End uses such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours, extracts

Use of genes for improving crops & live stock through genetic intervention

Does not include conventional breeding

Does not include traditional practices in use in agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping

#### Commercial Utilization



Conducting collection or survey of species, sub-species, genes or components /extracts of biological resources for any purpose

Also includes characterisation, inventorization and bio-assay

#### Bio Survey & Bio Utilization



#### Applicants

#### Individuals

#### Entities

Non - Indian

NRI

Entities regd / incorporated in country outside India

Entities regd / incorporated in India with non-Indian participation in share capital / management

Submit a copy of passport details

Submit a copy of the certificate of incorporation

Enclose a detailed proposal of the intended activity.





online or through a demand draft. The NBA may grant approval for access subject to certain terms and conditions, particularly relating to the conservation aspect and sharing of benefits in the light of future commercial prospects.

Before making a decision on the application, the NBA shall obtain comments from the local bodies concerned. If needed, some additional information may be sought from the applicant also. The approval is in the form of an agreement between the NBA and the applicant, and the NBA will periodically monitor compliance with the terms and conditions under which the approval was granted. The applicant will have to deposit a reference sample (voucher specimen) of the biological resource sought to be accessed with the repositories designated under Section 39 of the Biological Diversity Act.

The NBA will dispose of the application within a period of six months, and the time limit for processing the application shall commence only when the application is complete in all respects and the fee prescribed is received. If the application is rejected, reasons for rejection will be recorded. The applicant will be given an opportunity to be heard before such rejection. The approval for access, once granted, is liable to be revoked if there is non-compliance with any of the terms and conditions of the agreement signed on approval or there is a violation of the provisions of the Biological Diversity Act.

Indian citizens are not required to seek approval from the NBA to access biological resources for research purposes. However, to obtain any biological resource for commercial utilization or bio-survey or bio-utilisation, they will have to give prior intimation to the SBB concerned.

(Reference: Sections 3, 7, 19 and 24 of the Biological Diversity Act, Rule 14, 15 and 16 of Biological Diversity Rules and Regulations 1, 2 and 3 of the Guidelines)



## **How to apply for approval for transferring the results of research related to biological resources or associated knowledge**

Any person who intends to transfer the results of research relating to biological resources occurring in India to any person or entity specified under Section 3(2) of the Biological Diversity Act will have to seek previous approval of the NBA. (The section refers to any person who is not a citizen of India or who is a non-resident Indian, or any corporate body that is not registered in India, or if registered, has non-Indian share capital or participation in management.) The application for this purpose may be made in a prescribed form (Form II<sup>7</sup> of the Biological Diversity Rules 2004) along with a fee of Rs. 5,000. The application fee may be paid either online or through a demand draft.

The purpose here is to ensure that the results of research are not transferred to any person referred to in Section 3(2) of the Act without the NBA's prior approval, whether the transferor is an Indian citizen or a person referred to in Section 3(2) of the Act.

The NBA may grant approval for transfer of results of research subject to certain terms and conditions. The approval accorded is in the form of an agreement between the NBA and the applicant. The application has to be disposed of within a period of three months, and the time limit for processing the application shall commence only when the application is complete in all respects and the fee prescribed is received. If the application is rejected, reasons for rejection will be recorded. The applicant will be given an opportunity to be heard before such rejection.

(Reference: Section 4 of Biological Diversity Act, Rule 17 of Biological Diversity Rules and Regulations 6 and 7 of the Guidelines)

<sup>7</sup>Full text available at: <http://nbaindia.org/content/26/59/1/forms.html>



**Form - II**  
**Application**  
**Fee**  
**INR. 5000/-**

## **Form II - Transfer of the results of research**

Indian Citizen
Non - Indian
NRI
Entities regd. / incorporated in India
Entities not registered or incorporated in India

Non-Indian, NRI, Indian entity with non - Indian Participation in share capital or Management, Entity not registered or incorporated in India

- ▶ Transfer of research result should not involve transfer of any biological resource
- ▶ Absence of consideration in kind or cash in return for transfer of research result does not absolve the applicant from the obligation to file Form II application
- ▶ Publication of research papers or dissemination of knowledge in any seminar or workshop does not require prior approval of NBA.



## How to apply for approval to obtain Intellectual Property Rights for inventions based on any research or information on a biological resource obtained from India

Any person, whether an Indian citizen or a person referred to in Section 3(2) of the Act, who intends to apply for Intellectual Property Rights for an invention based on any research or information on a biological resource obtained from India, will have to seek prior approval from the NBA. This approval will have to be obtained for filing applications for any Intellectual Property Rights in India or outside. The application for this purpose may be made in a prescribed form (Form III<sup>8</sup> of the Biological Diversity Rules 2004) along with a fee of Rs. 500. The application fee may be paid either online or through a demand draft.

Before making a decision on the application, the NBA shall consult the local bodies in areas from where the associated traditional knowledge used in the research, if any, is accessed. If needed, some additional information may be sought from the applicant and also from other agencies. The NBA may grant approval for obtaining Intellectual Property Rights subject to certain terms and conditions. These conditions would normally include levying of a benefit sharing fee, or royalty, or both, depending upon whether the applicant commercializes her/his innovation by herself/himself or licenses it to a third party. The sharing of benefits will be in accordance with the Guidelines of 21st November, 2014.<sup>9</sup>

The approval is in the form of an agreement between the NBA and the applicant. The NBA will dispose of the application within a period of ninety days, and the time for processing the application shall commence only when the application is complete in all respects and the fee prescribed is received. If the application is rejected, reasons for rejection will be recorded. The applicant will be given an opportunity to be heard before such rejection.

(Reference: Section 6 of Biological Diversity Act, Rule 18 of Biological Diversity Rules and Regulations 8, 9 and 10 of the Guidelines)

<sup>8</sup>Full text available at: <http://nbaindia.org/content/26/59/1/forms.html>

<sup>9</sup>Full text available at: [www.nbaindia.org/uploaded/pdf/Gazette\\_Notification\\_of\\_ABS\\_Guidelines.pdf](http://www.nbaindia.org/uploaded/pdf/Gazette_Notification_of_ABS_Guidelines.pdf)  
(English version on pages 11 to19).





## Form III – To apply for IPR

Form - III  
Application  
Fee  
INR. 500/-



### When to Apply:

- ▶ To apply under Form III, the invention must be based on any research or information on a biological resource.
- ▶ The biological resources used in the invention must have been obtained from India
- ▶ Form III application must be filed before filing the patent application in India or outside.
- ▶ Permission of NBA shall be obtained prior to the grant of IPR.
- ▶ Approval will be granted to obtain IPR only in the countries specified in the application.
- ▶ NBA is mandated to dispose of the application within a period of 90 days from the date of receipt as far as possible.



## **How to apply for approval for transfer of biological resources and/ or associated knowledge already accessed**

Persons or entities who have secured the NBA's approval to access biological resources occurring in India or knowledge associated to these resources are required to apply afresh to the NBA if they intend to transfer the very biological resource or associated knowledge that is the subject matter of the previous approval. Without this successive approval, the biological resource or the associated knowledge cannot be transferred to any third party.

An application for this purpose may be made to the NBA in a prescribed form (Form IV<sup>10</sup> of Biological Diversity Rules 2004) along with a fee of Rs. 10,000. The application fee may be paid either online or through a demand draft.

Before making a decision on the application, the NBA may make necessary enquiries, seek some additional information, and consult an experts committee constituted for the purpose. The NBA will dispose of the application within a period of six months, and the time for processing the application shall commence only when the application is complete in all respects and the fee prescribed is received. In case the application is rejected, reasons for rejection will be recorded and the applicant will be given an opportunity to be heard before such rejection.

The necessary approval for third party transfer shall be granted subject to certain terms and conditions. The approval is in the form of an agreement between the NBA and the applicant.

(Reference: Section 20 of Biological Diversity Act, Rule 19 of Biological Diversity Rules and Regulations 11 and 12 of the Guidelines).

<sup>10</sup>Full text available at: <http://nbaindia.org/content/26/59/1/forms.html>



## Form IV - Transfer of biological resource/ associated knowledge

Applicant - A person / entity who had already obtained the biological resource/knowledge under Form I

**Form - IV**  
**Application**  
**Fee**  
**INR.10000/-**

Entities not regd. or  
Incorporated in India

Non - Indian  
NRI

Indian entity with  
non-Indian  
Participation

Transferring  
BR / TK

↓

Indian Citizen

Non - Indian

NRI

Entities regd. / Incorporated in India

Entities not registered or  
incorporated in India

▶ Any person / entity which had already accessed any biological resource/ associated knowledge under Form I should obtain prior approval before transferring the same to any person/entity



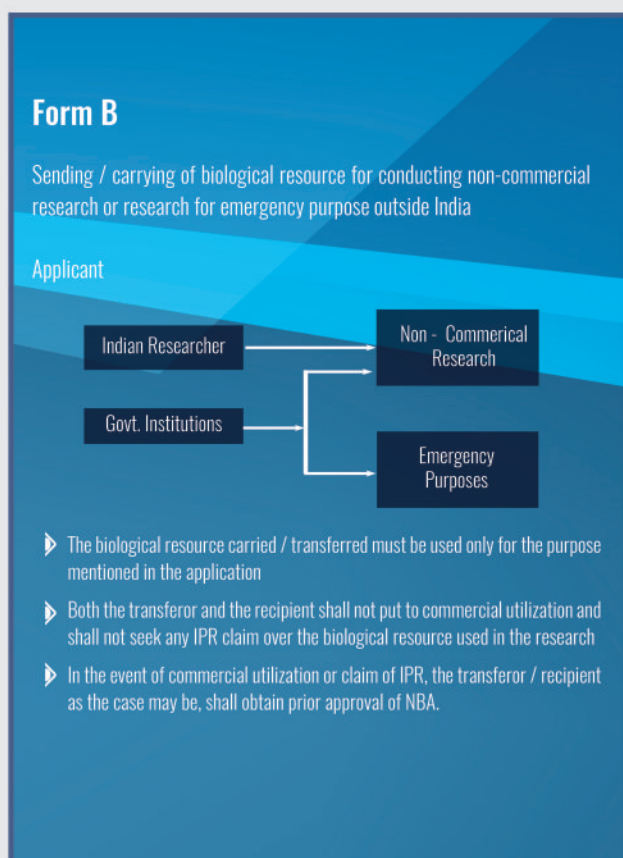
## How to apply for sending biological resources outside India for non-commercial research or for emergency purposes

If any biological resource occurring in India is intended to be carried by a researcher or to be sent outside India for basic (non-commercial) research, or if any Government Institution intends to do so for an emergency purpose like studies to avert epidemics etc., prior approval has to be obtained from NBA. The application for this purpose may be made in a prescribed form (Form B annexed to the ABS Guidelines, 2014). The biological resources so transferred have to be used only for the purpose mentioned in the

application. The results of research shall not be utilized for any commercial gain or for any research, and no claim for Intellectual Property Rights may be made. However, if any commercial gain or claim for IPR is envisaged, the transferor or the recipient of the biological resource has to seek prior approval from NBA. The biological resource so transferred shall not be shared or any of its part left behind outside India without approval of the NBA.

The NBA will dispose of the application within a period of 45 days and after NBA's approval but before transferring the biological resource, the applicant shall deposit voucher specimens in the designated repositories.

(Reference: Regulation 13 of the Guidelines)







## How to file an appeal against a decision of the NBA

The Biological Diversity Act has a provision of appeal against any determination of benefit sharing or order made by the NBA or State Biodiversity Boards. The appeal may be filed by an aggrieved party within a period of thirty days from the date of communication of the orders. The National Green Tribunal (NGT)<sup>11</sup> has the appellate jurisdiction for this purpose since 2010, the year when the NGT came into existence. Prior to the establishment of the NGT the High Courts had the appellate jurisdiction for appeal under the Biological Diversity Act.

Further, there is a provision for seeking a review of a decision of the NGT, and finally any person aggrieved by the decision of the NGT may appeal to the Supreme Court within the time limit of 90 days.

(Reference: Sections 52 and 52A of Biological Diversity Act)

*"Each species is a masterpiece, a creation assembled with extreme care and genius."*

**- Edward O. Wilson**



<sup>11</sup>The National Green Tribunal was established under the National Green Tribunal Act, 2010 to handle the expeditious disposal of the cases pertaining to environmental issues. Text of this Act available at: [www.moef.nic.in/downloads/public-information/NGT-fin.pdf](http://www.moef.nic.in/downloads/public-information/NGT-fin.pdf)







## CHAPTER - 3

*"The more you know about a species, the more you understand about how better to help protect them".*

*- Alan Clark*



### **ACTIVITIES EXEMPTED FROM THE PURVIEW OF THE BIOLOGICAL DIVERSITY ACT**

Certain activities are exempted from the purview of the Biological Diversity Act and the users of biological resource need not approach the National Biodiversity Authority for any approval to carry out such activities. These activities are summarised in the following paragraphs:

1. Traditional agricultural practices: For accessing biological resources occurring in India or associated knowledge for commercial use in manufacturing, for research and for filing Intellectual Property Rights, with or without genetic intervention, or even for transferring the results of research, necessary approval is required from the NBA under the Biological Diversity Act. However, for the use of biological resources in conventional breeding or traditional practices in agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping, no approval is required from the NBA.

(Reference: Section 2(f) of the Biological Diversity Act)





2. Publication of research papers: The results of research relating to biological resources occurring in India cannot be transferred to any person referred to in Section 3(2) of the Act without necessary approval from the NBA. However, publication of research papers or presentations in a seminar or workshop is exempted if such publication is as per the guidelines issued by the Government of India.

(Reference: Explanation of Section 4 of the Biological Diversity Act)

3. Access to or transfer of biological resources under collaborative research projects: Accessing biological resources or transfer or exchange of biological resources or associated knowledge between institutions within and outside India are exempted from the purview of the Biological Diversity Act if the research involved is under a collaborative research project approved by the Government of India and conforms to the Guidelines dated 8th November, 2006<sup>12</sup> issued by the Government of India.

However, previous approval of the NBA shall be required if the research project has any component of seeking Intellectual Property Rights and commercial utilization.

(Reference: Section 5 of the Biological Diversity Act)

4. Rights under any law relating to the Protection of Plant Varieties Act: For those applying for certain types of protection under the Protection of Plant Varieties and Farmers' Rights (PPVFR) Act 2001, no permission is required under the Biological Diversity Act. However, the PPVFR Act also has a provision for benefit sharing, and the Protection of Plant Varieties and Farmers' Rights Authority is required to endorse a copy of the rights granted under the PPVFR Act to the NBA.

(Reference: Sections 6(3) and 6(4) of the Biological Diversity Act)

<sup>12</sup>Available at: [www.nbaindia.org/uploaded/pdf/notification/7%20%20collaborative%20guidelines.pdf](http://www.nbaindia.org/uploaded/pdf/notification/7%20%20collaborative%20guidelines.pdf)  
(English version on pages 4 to 6).





5. Local communities, cultivators of biodiversity and vaid and hakims: No biological resource can be obtained by an Indian citizen or a body corporate for commercial gains without giving prior intimation to the State Biodiversity Board concerned. The local communities, growers and cultivators of biodiversity and local health practitioners (vaid and hakims, practicing indigenous medicine) are exempted from this provision.

(Reference: Sections 7 and 24 of the Biological Diversity Act)

6. Biological resources normally traded as commodities: In consultation with the NBA, the Government of India (Ministry of Environment, Forest and Climate Change) may notify a list of the biological resources that are normally traded as commodities.<sup>13</sup> The products that are derived from the items listed when traded as a matter of common practice shall also be treated as normally traded as commodities. The biological resources and items included in this list will be exempted from the purview of the Biological Diversity Act as long as they are traded as commodities. In case these biological resources or items are used for research, bio-survey and bio-utilization or for obtaining IPR, approval of the NBA shall be required. The Department of Agriculture, Cooperation and Farmers' Welfare, Government of India, also specifies certain food crops and forages covered under the Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) that are exempted from the purview of the Biological Diversity Act (Section 3 and 4) for the purpose of utilization and conservation for research, breeding and training for food and agriculture. However, for obtaining IPR on these plant genetic resources, the NBA's approval is required.

(Reference: Section 40 of Biological Diversity Act and Government of India, Ministry of Environment, Forest and Climate Change Notification dated 17th December, 2014)<sup>14</sup>

<sup>13</sup>The current list available at:

[http://nbaindia.org/uploaded/pdf/Notification\\_of\\_Normally\\_Traded\\_Commodities\\_dt\\_7\\_April\\_2016.pdf](http://nbaindia.org/uploaded/pdf/Notification_of_Normally_Traded_Commodities_dt_7_April_2016.pdf)

(English version on pages 22 to 37)

<sup>14</sup>Full text available at:

[http://nbaindia.org/uploaded/pdf/Gazette\\_Notification\\_on\\_exemption\\_of\\_crops\\_listed\\_in%20the\\_Annex-I\\_of\\_the\\_ITPGRFA.pdf](http://nbaindia.org/uploaded/pdf/Gazette_Notification_on_exemption_of_crops_listed_in%20the_Annex-I_of_the_ITPGRFA.pdf)

(English version on page 2).



7. Accessing value added products: 'Value-added products' as defined in the Act do not attract the provisions of the Act, and therefore accessing value-added products is an activity exempted from the purview of the Biological Diversity Act.

(Reference: Sections 2(c) and 2(p) of Biological Diversity Act)



**Alternative medicine vs. modern medicine:** Plant parts in raw form (left), and processed and packaged herbal products on sale (right). If some of these products could provide a lead to modern medicine, manifold commercial gain could accrue to the local communities who are merely wage earners.

## CHAPTER - 4

*"We won't have a society if we destroy the environment."*

*- Margaret Mead*



### **CASE STUDIES**

A brief account of some of the approvals accorded by the NBA is given in the following pages for the benefit of users of biological resources who intend to apply to the NBA for various approvals. These approvals involve upfront payments and non-monetary benefits that are the modes of benefit sharing determined on a case-by-case basis, transfer of results of research, prior approval for obtaining IPR in India as well as in other countries. An example of a case having no benefit sharing for academic research has also been included.

#### **An Indian industry agrees for an upfront payment (Application in Form I)**

Based on a Memorandum of Understanding with the University of Pune, a well-known Indian industry agreed to fund a research project involving algal strain. The various steps in the proposed research activity ranged from collection of microalgae, its isolation, identification, characterization to documentation and scaling up. A professor of the university was authorised to collect the samples. Based on the MoU, the industry was to own the strains collected as well as any IP rights originating from any developments using the strains. The industry, being an Indian company with non-Indian participation in its shareholding, filed an application in Form I before NBA to access green algae and cyanobacteria from sea water from the marine areas in the states of Gujarat, Maharashtra and Goa and the Union Territory region of Diu.



Consent was obtained from the State Biodiversity Boards concerned and the application was placed before the Experts Committee which recommended prior approval with upfront payment to the NBA. Upfront payment is one of the modes of benefit sharing provided under Section 21 of the Biological Diversity Act to be determined on a case-to-case basis. It was mutually agreed by the Parties that an upfront payment of Rupees 5.90 lakhs would be given to the National Biodiversity Fund. Subsequently the Indian industry made the upfront payment to the National Biodiversity Fund.

#### **An MNC agrees for an upfront payment (Application in Form I)**

NBA received an application in December, 2012 from a world-renowned cosmetics manufacturing company registered in India, with non-Indian participation in its share capital and management, to collect seven biological resources including neem, brahmi, bhringaraj and amla from different suppliers in Karnataka and Kerala. The purpose of access was to do research on the properties of the said resources for cosmetic purposes, especially hair care. The application was filed in Form I and based on the recommendation of the Experts Committee on Benefit Sharing, the company agreed to make an upfront payment of Rupees 4.27 lakhs to the National Biodiversity Fund. The amount was paid in December, 2015 and the agreement was signed in January, 2016. The company is bound to obtain separate permission for commercial utilization of the biological resources which are already accessed or which are yet to be accessed for the purpose of commercializing any resultant product of the research specified in the application.

#### **Approval for academic research involving no benefit sharing (Application in Form I)**

NBA granted permission under Section 3 of the Biological Diversity Act to a research scholar from a UK-based University for accessing the ethno-medicinal knowledge of the Siddi Community in Gujarat for research purposes. The terms mutually agreed and signed by the researcher and the NBA restricted the applicant from obtaining any IPR based on the accessed biological resources/ traditional knowledge without NBA's prior approval. The applicant was also restricted from transferring or parting with the accessed biological resources/ traditional knowledge without the prior approval of NBA. The applicant is under





the obligation of submitting a report of the outcome of the research work to the NBA. There is no benefit sharing obligation upon the applicant, as the research is of academic nature.

#### **A Sate Agricultural University accorded approval for transfer of results of research (Application in Form II)**

A State Agricultural University from Tamil Nadu filed an application in Form II for transferring the results of its research relating to a protein of Bt to an Indian seeds research company, with non-Indian participation in its share capital and management, for the purpose of generation of insect-resistant crop plants. After consulting the SBB, Tamil Nadu, the NBA granted approval for transferring the research results with the following conditions: (i) transfer should be confined only to the transfer of research results and not of biological resources, and (ii) the State Agricultural University should pay 3 per cent of the monetary benefits received from the seeds research company to the National Biodiversity Fund.

#### **Approval for obtaining IPR in India as well as in other countries (Application in Form III)**

An Ayurveda doctor hailing from Pune, Maharashtra, applied to the NBA in Form III for permission to seek a patent for an invention relating to a process for preparation of an Ayurvedic antidote for snake venom comprising four medicinal plants, viz., *Erythina indica*, *Eugenia jambolana*, *Mangifera indica* and *Jasminum sambac*. The four countries where the applicant proposed to file patent applications were India, Uganda, Tanzania and Kenya. The application was approved by the NBA with the following mutually agreed terms: (i) the applicant would obtain prior approval of NBA for obtaining IPR in any country other than those mentioned in the application, (ii) the applicant would pay to the National Biodiversity Fund a royalty of 2 per cent of the gross sales or gross revenue of the product derived from the accessed biological resources, and (iii) NBA could direct the applicant to share non-monetary benefits like grant of joint patent ownership with NBA/ benefit claimers, transfer of technology, location of production and R&D for the betterment of the living standards of the benefit claimers, association for Indian scientists and local people in the R&D units etc.



**A primary stakeholder in benefit sharing:** Gulbasiya Devi Markam from Singrauli district (Madhya Pradesh) runs a state-owned cooperative society for collection of local biological resources. She hires a truck to transport collected resources to the state capital to sell to the processing centre of M.P. State Minor Forest Produce (T&D) Cooperative Federation.

*“A tree is equal to ten sons. The ten gifts of the tree are - Oxygen, Water, Soil, Food, Cloth, Energy, Shelter, Medicine, Fodder and Shade. And what a son! He wants care and water but for five years, and wants no milk, no nurse.*

*– The Upanishads*



## CHAPTER - 5

*“Biodiversity starts in the distant past and it points toward the future.”*

*– Frans Lanting*

### **CONCLUSION**

Users of biological resources and the people involved in the business of biodiversity would have heard of the Biological Diversity Act, which mandates approval from the NBA or SBB in various situations and for various purposes. This elementary booklet demystifies the process of approaching the NBA, and highlights the basic features and functions of the organization.

Not all provisions under the Biological Diversity Act have been covered in this booklet. For instance, many important aspects like controlling risks associated with the use of living organisms modified by biotechnology, registration of the knowledge of local people relating to biodiversity, power of the Government of India to notify threatened species, and so on, have not been touched upon here. The idea was to keep the text here concise and focussed, as the aim is to impart to the users a working knowledge of the provisions of the Biological Diversity Act and the functions of the NBA.

Referring frequently to the links and internet resources will be helpful for better comprehension of the underlying issues.

*“The activist is not the man who says the river is dirty.  
The activist is the man who cleans up the river.”*

*– Ross Perot*

## About CEBPOL

Government of India in collaboration with the Norwegian Government has established "Centre for Biodiversity Policy and Law (CEBPOL)" at the National Biodiversity Authority (NBA), an autonomous and statutory body of the Ministry of Environment, Forest and Climate Change towards strengthening of expertise in Biodiversity Policy and Law in India. This programme is executed by the NBA in collaboration with Norwegian Environment Agency through the Royal Norwegian Embassy, New Delhi, India.

The Centre aims to provide advice and support to the Governments of India and Norway on Biodiversity Policy and Law related issues including complex negotiations on Access and Benefit Sharing and Traditional Knowledge as well as governance issues relating to biodiversity at the National and International level. The Centre proposes to help NBA in the effective implementation of International agreements on conservation, sustainable use and the associated access and benefit sharing components of it.



# CEBPOL

Center for Biodiversity Policy and Law

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