Ministry of Environment, Forest and Climate Change

National Biodiversity Authority, India

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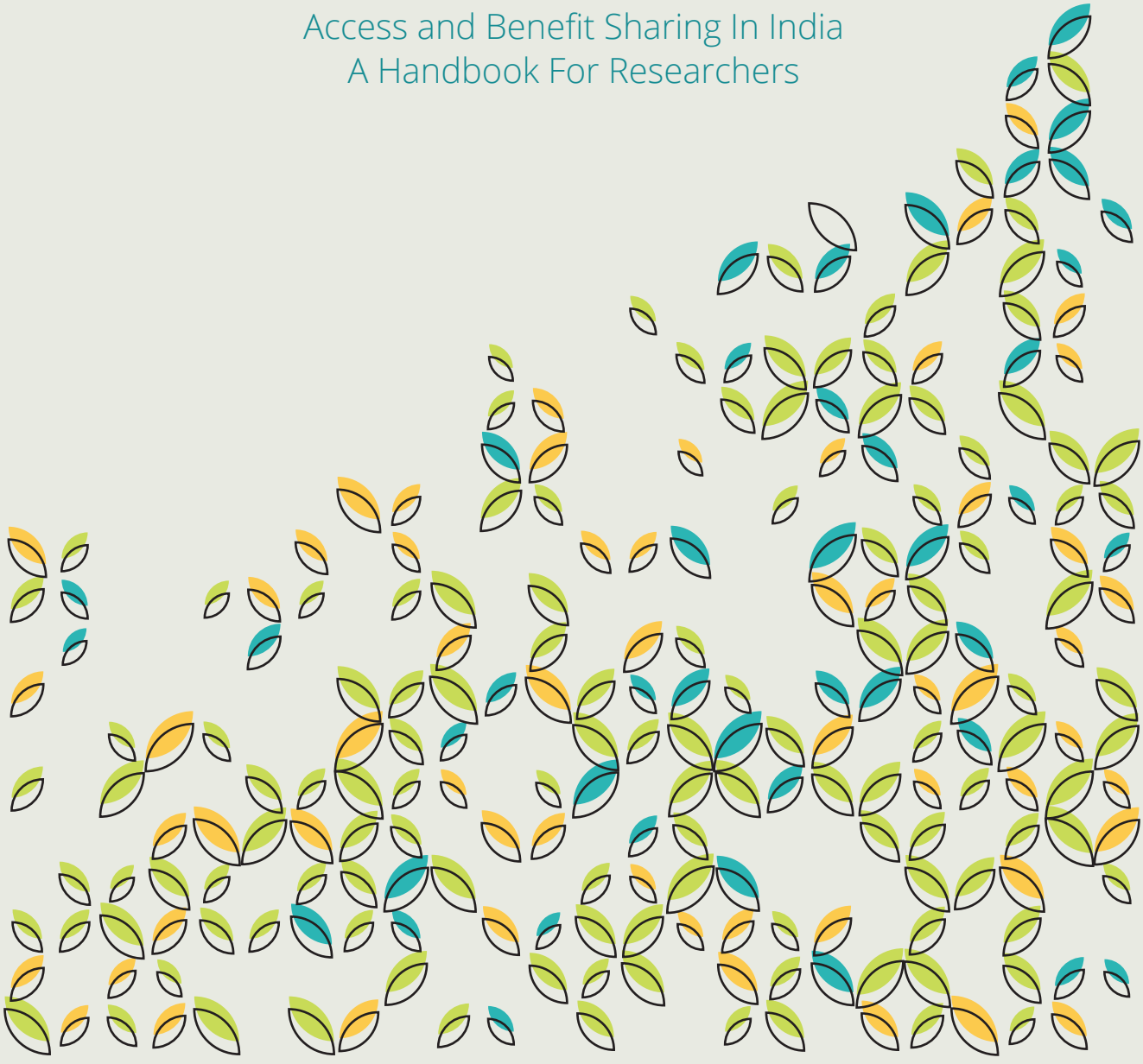
ABS

UNDP

UNDP-GEF PROJECT ON

'Strengthening Human Resources, Legal Frameworks, and Institutional Capacities to Implement the Nagoya Protocol' (Global ABS Project)

Access and Benefit Sharing In India
A Handbook For Researchers



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Disclaimer

The purpose of this document is mainly to guide the users in complying with the regulatory requirements under the Biological Diversity Act,2002. The contents of this document shall not be construed as any interpretation of law. This document cannot be quoted as a reference before any court of law.

All efforts have been made to ensure that the compliance procedures described in this document are accurate and consistent with all legal texts notified in the Gazette of India and other guidelines issued by the Ministry of Environment, Forest, Climate Change and the National Biodiversity Authority. In case of any conflict between this guidance document and the provisions of the Biological Diversity Act, 2002 or the Rules and Regulations made thereunder, the said provisions of the Act, Rules and Regulations will prevail over this document.

Users are also advised to refer to the bare Act of Biological Diversity Act, 2002, Rules made thereunder. Notifications in the Official Gazette published by Central Government and Guidelines/Clarifications/FAQ issued by the NBA from time to time for all their professional needs.

It may also be noted that compliance with the Biological Diversity Act, 2002 is in addition to other sector-related regulatory requirements and does not supersede regulations made for the protection of wildlife, forests or any other laws in the country.

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FOREWORD

Dr. V.B. Mathur
Chairperson, NBA

The Convention on Biological Diversity, adopted during the Earth Summit, 1992 held in Rio de Janeiro, Brazil is a collective and near universal commitment of the countries to conserve and sustainably use the biological diversity for the benefit of present and future generations. Of the three objectives of the Convention, namely conservation, sustainable use, and fair and equitable sharing of benefits arising from the utilization of biological resources and knowledge associated with them, the third one i.e., Access and Benefit Sharing (ABS) is the core objective, and is essential to achieve the first two.

The Convention's Nagoya Protocol on Access and Benefit Sharing establishes a clear framework, greater legal certainty and transparency towards the attainment of this core objective through access to genetic resources and associated traditional knowledge by companies and researchers, and for sharing of benefits arising from their use. India has been at the forefront in implementing the Convention and the Nagoya Protocol, because as a mega biodiverse country, India has vital stakes in realization of their objectives.

Government of India has enacted a progressive and robust legislative framework through Biological Diversity Act 2002 and Biological Diversity Rules, 2004, which includes provisions and procedures for access to resources subject to fair and equitable benefit sharing. The Guidelines on Access and Benefit Sharing Regulations, 2014 notified following the

Nagoya Protocol provided a further fillip to the ongoing implementation of access and benefit sharing measures by India.

UNDP-GEF Project on 'Strengthening Human Resources, Legal Frameworks, and Institutional Capacities to implement the Nagoya Protocol' (Global ABS Project) was implemented in India through UNDP and led by MoEFCC and hosted by NBA from the year 2017 to 2021. The project in India focused on niche area with an enhanced objective, which was to sensitize researchers and institutions (both academic and applied research) involved in research (commercial/non-commercial) on biological resources and associated knowledge.

UNDP partnered with the Premier National Law School of India University (NLSIU), Bengaluru who in turn tied-up with other law schools in the country in reaching out to and building capacities of the various stakeholder groups. This project reached out to over 1900 legal professionals drawn from the Law Schools spread across 16 States along with scientists from Indian Council of Forestry Research and Education (ICFRE) and Indian Council of Agricultural Research (ICAR) and build a cadre of master trainers is a testimony to the success of this project. The knowledge products developed under this project will be of immense use to various stakeholders and would contribute significantly in the conservation and management of biological resources in the country

Chennai
11 May, 2021

(Dr. V.B. Mathur)
Chairperson, NBA

MESSAGES

Dr. Ruchi Pant
Head, NRM &
Biodiversity

UNDP-GEF Project on 'Strengthening Human Resources, Legal Frameworks, and Institutional Capacities to implement the Nagoya Protocol' (Global ABS Project) aims at assisting 24 countries including India in the development and strengthening of their national ABS frameworks, human resources, and administrative capabilities to implement the Nagoya Protocol.

The Nagoya Protocol on Access and Benefit Sharing, a new International Treaty adopted under the auspices of the Convention on Biological Diversity in Nagoya, Japan in 2010, aims at fair and equitable sharing of benefits arising from the utilization of genetic resources. Towards this, the Protocol establishes a clear framework on how researchers and companies can obtain access to genetic resources and to traditional knowledge associated with genetic resources, and how benefits arising from the use of such material or knowledge will be shared.

The success of Nagoya Protocol would depend to a large extent on its effective implementation at the domestic level. As megadiverse country rich in biodiversity with a rapidly advancing biotechnology industry, India has much interest in ensuring effective implementation of the Protocol. In India, the Protocol is being implemented through the three-tiered institutional mechanism of the Biological Diversity Act 2002.

During the project implementation period, three knowledge products were developed viz.,

i. Access and Benefit Sharing in India: A Handbook for Researchers
ii. Monitoring Guidelines for Research Institutions to Promote Compliance with Access and Benefit Sharing under the Biological Diversity Act, 2002
iii. Ethical Code of Conduct on ABS for Researchers, Research Institutes and

These documents comprehensively address and simplifies the Access and Benefit Sharing procedures in the country with view to enhance compliance and shares our commitment to achieve the objectives of the Convention and the Protocol.

The UNDP is very pleased to partner MoEFCC, NBA and the other stakeholders to bring out this handbook. Global ABS Team deserves special recognition. I wish to place on record the unwavering support extended by Dr. V.B. Mathur, Chairperson, NBA towards finalizing this document.

(Dr. Ruchi Pant)
Head, NRM& Biodiversity

PREFACE AND ACKNOWLEDGEMENTS

Access and Benefit Sharing (ABS) refers to the process wherein genetic resources and associated traditional knowledge are legitimately accessed, and a fair share of the resultant benefits are shared with the holders or the country from where such resources and the knowledge originate. The UNDP-GEF Three Year Project "Strengthening human resources, legal frameworks, and institutional capacities to implement the Nagoya Protocol" (Global ABS Project) aimed at assisting 24 countries in the development and strengthening of their national ABS frameworks, human resources, and administrative capabilities to implement the Nagoya Protocol. In India, the project focused on enhancing capacities of academic and research institutions in the public and private sector accessing genetic resources to pursue research and transfer technology and better understand the legal provisions and guidelines related to ABS. One among the major objective of this project was the formulation of three knowledge products that could enhance the ABS implementation and understanding in the country, viz., (i) a Handbook on Access and Benefit Sharing for capacity development, (ii) an ethical code of conduct or guidelines for research on traditional knowledge and genetic resources, and (iii) a set of guidelines to develop a monitoring system for researchers to include due diligence. This document comprehends the the said three knowledge products developed under the Global ABS Project.

These knowledge products are the primary outcome of the two external consultancies engaged under this project. Dr. K. S. Varaparasad, Senior Consultant, focused on the development of the ethical code and monitoring guidelines while Dr. Prabha S. Nair,

Technical Consultant, elaborated the Handbook for Researchers. The development of these knowledge products was done through a series of consultative meetings with domain experts who represented the stakeholder groups belonging to the public and private sector and the academia. The zero draft of each of the knowledge products were continuously modified to ensure that the content developed had adequately addressed the capacity building and awareness raising concerns of the said stakeholder groups.

The authors acknowledge the contributions and initial coordination by Ms. Vidya Vijayaraghavan, UNDP Project Associate stationed at NBA towards the development of an initial zero draft encompassing different aspects of ABS. The knowledge products subsequently developed by the two consultants were reviewed by several experts from ICAR, IICT, DST and other experts from agriculture and forestry. The valuable inputs provided by Dr. Shashank Maurya, Former ADG, ICAR, Dr. Sunil Archak, ICAR- National Fellow and Principal Scientist, NBPGR, Dr. K Anitha, Principal Scientist, NBPGR Research Station, Hyderabad, Dr. N Sivaraj, Principal Scientist, NBPGR Research Station, Hyderabad and Dr. Pratibha Brahmi, Principal Scientist, NBPGR, New Delhi were of great help to refine the draft versions of the knowledge products.

UNDP and the authors are thankful to the National Biodiversity Authority, the NBPGR Research Station, Hyderabad and ICAR-NAARM, Hyderabad for their support by coordinating consultative meetings to review these knowledge products and sharing the knowledge of their in-house experts. We duly acknowledge the critical comments and extensive reviews by Dr. A. K. Goyal, Dr. R. V. Varma and Dr. Pushpakumar in fine tuning the draft to its current version.

The authors are particularly thankful to Dr. V. B Mathur, Chairman, NBA and Dr. Ruchi Pant, Head, NRM and Biodiversity, UNDP for their extensive support and the inspiration, leadership and guidance provided until the finalization of these knowledge products.

ACRONYMS AND ABBREVIATIONS

ABS	Access and Benefit Sharing
ABS-CH	Access and Benefit Sharing Clearing House
ABS Guidelines	Guidelines on Access to Biological Resources and Associated Knowledge and Benefit Sharing Regulations, 2014
BD Act	Biological Diversity Act, 2002
BD Rules	Biological Diversity Rules 2004
BMC	Biodiversity Management Committee
CBD	Convention on Biological Diversity, 1992
CoP	Conference of the Parties to the Convention on Biological Diversity
CSIR	Council for Scientific and Industrial Research, India
DACFW	Department of Agriculture and Cooperation and Farmers' Welfare
EPO	European Patent Office
GEF	Global Environment Facility
IP	Intellectual Property
IPRs	Intellectual Property Rights
IUPGR	International Undertaking on Plant Genetic Resources
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
LBF	Local Biodiversity Fund
MAT	Mutually agreed terms
MLS	Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agriculture
MoEF&CC	Ministry of Environment, Forest and Climate Change
NBA	National Biodiversity Authority
NBF	National Biodiversity Fund

NFP	National Focal Point
NGO	Non-Government Organization
NGT	National Green Tribunal
NP	Nagoya Protocol
PBR	People's Biodiversity Register
PIC	Prior informed consent
R&D	Research and Development
SBB	State Biodiversity Board
SBF	State Biodiversity Fund
SMTA	Standard Material Transfer Agreement
TBGRI	Tropical Botanical Garden and Research Institute
TRIPS Agreement	Agreement on the Trade Related Aspects of Intellectual Property Rights
UN	United Nations Organization
UNCBD	United Nations Convention on Biological Diversity
UNDP	United Nations Development program
UPOV	The International Union for the Protection of Plant Varieties
USPTO	United States Patent and Trademark Office

Part-1

ACCESS AND BENEFIT SHARING IN INDIA: A HANDBOOK FOR RESEARCHERS

A USER'S GUIDE

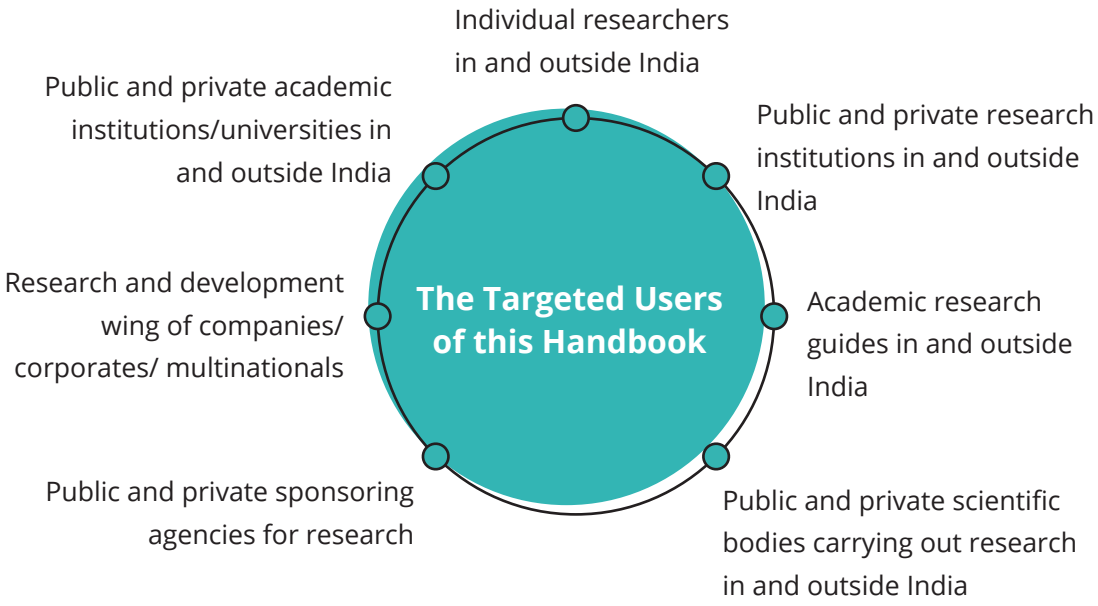
Context

This handbook starts with the premise that the concept of access and benefit sharing (ABS) is technically challenging and legally complex for the diverse global and local users of biological resources. ABS obligations are among the many regulatory obligations that these users of biological resources are expected to comply with. Although the concept of ABS is well known in the international arena, it is yet to be internalised in the working of the stakeholders concerned and secure greater compliance in India. The common understanding and awareness about the ABS among a majority of stakeholders and the general public is limited in India. Without adequate fundamental understanding of the concepts of ABS and the existing legal obligations and procedures, the entire process is, often, impacted by poorly informed decisions – on access, sharing of benefits and adherence to established procedures. Since all the stakeholders are vital in the development and implementation of ABS regime, wide scale awareness and capacity building efforts are required to make them all understand the importance of ABS and join hands in its implementation.

This handbook has been developed to address this need and help fill the gaps in knowledge about the ABS and the related processes. However, since the handbook cannot cover all the procedures relevant to all categories of stakeholders, bioscience researchers of all sectors are chosen as the key players who most often trigger ABS obligations through direct access and utilization of biological/ genetic resources. This handbook emphasizes the fact that despite the fast growing pace of the diverse disciples of bioscience and their historical culture of open access and sharing, the ABS has brought in a legal discipline of regulated access to biological/genetic resources and associated traditional knowledge and sharing of benefits arising from their utilization which the users of such resources ought to follow.

This handbook will enable bioscience researchers working on the biological resources occurring in or obtained from India and associated knowledge to connect to the ABS obligations as a research routine that would begin from the initial stages of research planning and proposal writing, intervene at different stages in the research process and might continue even after the completion of the research.

This handbook has been developed through intense consultations with the stakeholders, review and verification process among experts representing diverse fields of bioscience and the officials of the National Biodiversity Authority (NBA), Chennai. It tries to build on the prevailing rules and regulations and the evolving practices that are currently followed by the regulator and the different domain experts. However, this handbook does not aim to offer any legal interpretation of the provisions of the Biological Diversity Act, 2002 (BD Act). The handbook shall be used only as a guiding tool to understand the operative provisions of the BD Act and to personally assess the applicability of such provisions and legal obligations at varying levels of research and related activities. In short, it could be used as a basic reference material for research related ABS obligations while using biological resources occurring in or obtained from India and/or associated traditional knowledge. It will also be useful as a capacity building guide and training material for various awareness programmes.



Objectives of the Handbook

To provide clarity on the concept of ABS

To pomote basic understanding about the legal and institutional mechanism for ABS in India

To promote awareness about ABS related obligations associated with bioscience research

To promote awareness about the relevant provisions of the Biological Diversity Act, 2002 and related procedures

To enhance the capacity of researchers as major stakeholders

To secure greater compliance among bioscience researchers with the ABS process in India under the Biological Diversity Act, 2002

Scheme of Navigation

This handbook has been organised into six main chapters. Chapter 1 introduces the concept of access and benefit sharing (ABS) including its origin and development through international political and legal processes. Chapter 2 familiarises the readers with the legal and institutional mechanisms for ABS in India established under the Biological Diversity Act, 2002, Biological Diversity Rules, 2004 and ABS Regulations, 2014. Chapter 3 explains the legal obligations related to ABS prior to and while accessing biological resources occurring in or obtained from India and associated traditional knowledge for research. Chapter 4 describes the legal obligations after accessing biological resources occurring in or obtained from India and/or associated traditional knowledge, the processing of applications by the National Biodiversity Authority and a brief account of the provisions relating to offences and sanctions under the Biological Diversity Act, 2002 in the event of failure to comply with ABS obligations. Chapter 5 aims to facilitate practical understanding about ABS by providing step by step procedural requirements, addressing common myths about ABS process in India and a few practical exercises for better understanding of the legal provisions. Chapter 6 provides a set of ABS case studies from India.

Chapter 1

Understanding the Concept of Access and Benefit Sharing (ABS)

> Access and benefit-sharing (ABS) refers to the way in which genetic resources may be accessed, and how the benefits that result from their use are shared between the people or countries using the resources (users) and the people or countries that provide them (providers).
> Source: https://www.cbd.int/abs/infokit/brochure-en.pdf

ABS is the sum of two decoupled activities, a conditional access followed by an actual sharing of benefits upfront or at a later stage. "Access" to genetic or biological resources refers to the legitimate way in which a user obtains samples of biological resources for the purposes of research, industrial application or commercial use, in compliance with the procedures established under the concerned laws. "Benefit sharing" is a reciprocal obligation created on such users to pay back the providers a fair and equitable share of the benefits arising from the utilisation of biological resources so accessed. Here providers can be an individual or a group of individuals or a community or a country where the resources are physically present. Though there is no established formula to estimate what is "fair and equitable" sharing, it is internationally recognised as a form of compensation given to the provider who has been maintaining and conserving the resources accessed by the user based on mutually agreed terms.

Across the globe, the R&D and commercialization of biotechnology products are done under the close supervision of various regulatory agencies. Most of the regulatory agencies are generally involved in identification, regulation and mitigation of the risks associated with R&D, product development and commercialization through regular interventions at different stages of research and commercialization. In addition to dealing with environmental impacts of biotech research, such regulatory bodies also address the concerns of the consumers and occupational safety issues. Thus, regulations are not new to the bioscience sector and most of them are drafted in scientific and technical language that the researchers are familiar with.

Many of these regulations properly align with the R&D and commercialization routines of the biotechnology sector and do not project serious challenges in understanding the regulatory requirements or the legal processes involved. Nevertheless, the regulatory obligations created for ABS measures under the Convention on Biological Diversity (CBD), 1992 and its Nagoya Protocol are often perceived as unintelligible for different types of researchers in the bioscience sector. Such claims are also supported by reason of lack of uniform approaches towards ABS and the varying scope and coverage of regulated activities in different countries. Addressing these issues, the objective of this chapter is to provide relevant information on the concept of ABS as emerging from international politics and relevant international legal instruments.

Emergence of the Concept of Access and Benefit Sharing

It is convenient to look at the evolution and development of the concept of ABS, as it stands now, in three phases:

i. the historical phase of open access with no benefit sharing,
ii. introduction of ABS obligations through CBD, and
iii. growth of the concept of ABS through the Nagoya Protocol.

Phase I - Open Access with No Benefit Sharing

Historically, biological resources were transferred across borders without restrictions. The Use of plant genetic resources for their food and medicinal value was the major driving force behind such initial transfers. Later, resource transfer became a very common aspect of species conservation. The first restriction to this open access regime was created by the introduction of plant breeders' rights with access and use restrictions created on new varieties of plants. The International Union for Protection of New Varieties of Plants (UPOV Convention) 1978 mandated that prior authorization of the breeder is required for the use of protected plant varieties for commercial production, offering for sale and marketing when done by others[1] . Considering the new access restrictions created for further developing new varieties using such protected varieties and their impact on food security, the international community, especially the developing countries, wanted to ensure

[1] Article 5, UPOV 1978

that plant genetic resources are maintained as a heritage of mankind with open access to them. With this intention, the FAO adopted the non-binding International Undertaking on Plant Genetic Resources (IUPGR popularly known as IU) in 1983 calling for free access to plant germplasm. However, the UPOV Member States did not agree to the principle of open access to protected varieties and later in 1988, an agreed interpretation was annexed to the IUPGR that open access did not mean access free of cost. This infused a sense of injustice to the developing and least developed countries that their plant genetic resources are open for free access while the protected /elite varieties developed using their native varieties are not freely available for further crop improvement.

Parallel to this were the discussions in the Uruguay Round of the Negotiations on the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) to bring in minimum standards for protection of biotechnological inventions. The developed countries argued for patent protection for all biotechnological inventions other than plants, animals and essentially biological processes. In addition to this, they further negotiated for protection of new varieties of plants through patents or *sui generis* plant breeders' legislations or a combination of the two. These claims later became part of the final text of the TRIPS Agreement in 1994[2]. Efforts to create new and different sets of property rights over biological materials augmented the sense of injustice pervaded among the developing countries. The intellectual property rights (IPR) sought over biological materials ensured monopoly rights over the resultant products of biotechnology enabling huge commercial returns. Developed countries had the technology to come up with inventions protected by IPR over biological materials while most of the biological resources were available in the developing countries. The developing countries were concerned that by letting their biological resources open for free access and allowing the products of biotechnology protected by IPR, no rewards would flow back to the countries or communities who have been actually conserving, maintaining and preserving the biological diversity and the traditional knowledge (TK) associated with it. These reasons contributed to the evolution of ABS as a political agenda eventually leading to the recognition of sovereign rights over genetic resources and the principle of access to genetic resources with informed consent and on mutually agreed terms for benefit sharing.

[2]Article 27.3(b) of the TRIPS Agreement

Phase II - Conditional Access with Prior Informed Consent and Mutually Agreed Terms for Benefit Sharing under the Convention on Biological Diversity

The Convention on Biological Diversity (CBD) negotiated parallel to the TRIPS Agreement and came into force in 1993 was a solution identified by the developing countries to address this inequity and unfairness. The countries almost universally recognises that genetic resources found within the territorial limits of each country are subject to its sovereign rights. Article 15 of the CBD provides that in exercise of such sovereign rights, countries have the authority to determine access to their genetic resources. The CBD further mandates that access to genetic resources shall be subject to prior informed consent (PIC) of the countries of origin and mutually agreed terms (MAT)[3]. Thus, the CBD framework has ended the notion of open access over biological materials for further utilization and enabled the countries to impose benefit sharing conditions before allowing others to access the resources. Regulation of access to genetic resources and fair and equitable benefit sharing arising from their utilization became the third objective of the CBD. This objective is considered as a mechanism that would support and promote the other two objectives of the CBD namely (i) conservation of biological diversity, and (ii) sustainable use of its components.

When the CBD came into force, its regulated access and benefit sharing system based on sovereign rights was found contrary to the principle of unrestricted access to plant genetic resources for food and agriculture under the ITPGRFA. Thus, the international community had come up with a special ABS regime called Multilateral System (MLS) under the International Treaty on Plant Genetic Resources (ITPGRFA/ the Treaty), 2001. The MLS creates a specialised ABS system within the ambit of sovereign rights over genetic resources through a standard material transfer agreement (SMTA) the terms of which are applicable only to the providers and recipients of germplasm from the different gene banks located across the globe. Under the MLS, Parties to the Treaty would provide facilitated access to plant genetic resources for food and agriculture listed in Annex I of the Treaty and the recipients would share the benefits arising out of the utilization of the materials received from the MLS with the Benefit Sharing Fund of the Treaty under the terms of the SMTA.

[3] Article 15 CBD

Phase III – Elaborate International Framework for ABS under the Nagoya Protocol to the CBD

To enhance the implementation of the benefit sharing objective of the CBD, the Nagoya Protocol on Access to Genetic Resources and Fair and Equitable Benefit Sharing Arising from their Utilization was negotiated with the Parties to the CBD in 2010. By this time, the term ABS had been widely recognized as a mechanism or process for operationalization of the third objective of the CBD and attained wider popularity. The scope of the CBD was further enhanced by the Nagoya Protocol with the specific inclusion of TK associated with genetic resources within the ABS framework[4]. Under the Nagoya Protocol, a PIC from the country of origin of the genetic resources is mandatory for accessing genetic resources[5]. It further mandates that in cases where local and indigenous communities have established rights over genetic resources, the countries must come up with measures to ensure their PIC or approval and involvement for accessing such genetic resources and associated traditional knowledge[6]. Depending on who holds the actual custody of genetic resources, PIC must be taken from local communities or the country of origin. Similarly, for accessing TK held by local and indigenous communities, domestic measures to ensure their PIC or approval and involvement are required under the Protocol[7]. The obligation to develop and sign MAT for benefit sharing is made equally applicable for genetic resources and TK[8] . It is notable that the MLS under the ITPGRFA is recognised as a specialized ABS regime under the Protocol and Parties to both instruments are bound to facilitate the operation of ITPGRFA-MLS within their territorial limits[9].

[4] Article 3, NP
[5] Ibid Article 6.1
[6] Ibid Article 6.2
[7] Ibid Article 7
[8] Ibid Article 5
[9] Ibid Preamble read with Article 4.4

Nagoya Protocol also mandates the countries where genetic resources are utilized, to put in place necessary measures to ensure compliance with the domestic access and benefit sharing legislation of the provider countries[10]. In order to monitor compliance by users, the user countries are also required to establish regulatory agencies that have functions relevant to the utilization of genetic resources as effective checkpoints[11]. Thus access, benefit sharing and compliance are the three pillars of the third objective of the CBD and are referred to as ABC of ABS. Annex to the Nagoya Protocol lists the different types of monetary and non-monetary benefits that can be shared in return for access to genetic resources and associated TK.

Table – Monetary and Non-monetary benefits listed under the Nagoya Protocol

Monetary benefits
Monetary benefits may include, but not be limited to: a. Access fees/fee per sample collected or otherwise acquired; b. Up-front payments; c. Milestone payments; d. Payment of royalties; e. Licence fees in case of commercialization; f. Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity; g. Salaries and preferential terms where mutually agreed; h. Research funding; i. Joint ventures; j. Joint ownership of relevant intellectual property rights.

[10] Ibid Article 17
[11] Ibid

Non- Monetary benefits

a. Sharing of research and development results;
b. Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the Party providing genetic resources;
c. Participation in product development;
d. Collaboration, cooperation and contribution in education and training;
e. Admittance to ex situ facilities of genetic resources and to databases;
f. Transfer to the provider of the genetic resources of knowledge and technology under fair and most favourable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity;
g. Strengthening capacities for technology transfer;
h. Institutional capacity-building;
i. Human and material resources to strengthen the capacities for the administration and enforcement of access regulations;
j. Training related to genetic resources with the full participation of countries providing genetic resources, and where possible, in such countries;
k. Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;
l. Contributions to the local economy;
m. Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in the Party providing genetic resources;
n. Institutional and professional relationships that can arise from access and benefit-sharing agreement and subsequent collaborative activities;
o. Food and livelihood security benefits;
p. Social recognition;
q. Joint ownership of relevant intellectual property rights.

Access and benefit sharing arrangements are in effect implemented through bilateral contractual obligations agreed between the user and the provider of genetic resources and associated TK. The provider may vary from the competent national authority of the country where the user plans to access the resources or the community or an individual depending upon the domestic law of the providing country. Notably, the CBD tries to introduce two critical terminologies with respect to the access point of genetic resources. One may access genetic resources from a "country of origin" or a "country providing genetic resources". Country of origin is the country which possesses the genetic resources in in situ conditions whereas a country providing genetic resources stands for the country supplying the resources collected from in situ sources or taken from ex situ sources. While complying with ABS laws/regulations, users are expected to comply with the laws of the country of origin and not the countries which are the immediate sources of genetic resources from where they are accessed[12] .

[12] With respect to International Agricultural Research Centres of the CGIAR, Under Article 15 of the Treaty, the IARCs should enter into agreement with the Governing Body of the Treaty with respect to the ex situ collections held by them under the following terms and conditions; (i) the PGRFA listed in Annex I of the Treaty shall be governed by the terms and conditions of the SMTA; (ii) With respect to the non-Annex I resources collected before the entry into force of the Treaty or materials assembled following SMTA will also be governed by the SMTA; and (iii) in the case of non-Annex-I resources received and conserved by the IARCs after the coming into force of the Treaty, access must be consistent with the mutually agreed terms entered into between the IARC concerned and the country of origin/country that has acquired the resource in accordance with the Convention. In short, all the Annex-I resources and the pre-Treaty collections or the collections obtained following SMTA and currently held by IARCs would be regulated by the SMTA.

Different countries implement the obligations emerging from the CBD and the Nagoya Protocol differently. Some countries regulate access to genetic resources only while countries like India legislate on the wider category of biological resources. ABS obligations in most of the countries are equally made applicable to nationals, foreigners, and other entities. Different countries follow different procedures for ABS. The ABS Clearing House (ABSCH) of the Nagoya Protocol provides country wise information on the measures adopted by different countries in furtherance of implementation of the Nagoya Protocol and ABS in their respective jurisdiction and serves as the best resource for researchers to identify ABS obligations in different jurisdictions. Countries are also mandated under the Protocol to designate a National Focal Point (NFP) on ABS which would provide information on the procedures regarding PIC and MAT for genetic resources and associated TK. In addition to this, countries are also required to constitute competent national authorities to grant access to genetic resources and associated TK and issue written evidence of MAT.

Under the Nagoya Protocol, Parties are required to make available to the ABS-CH, permits or its equivalents at the time of access as evidence that PIC and MAT are established. In the ABS-CH, such permits/equivalents will constitute the internationally recognised certificate of compliance by the user. The first IRCC was issued based on the access permit issued by India for a researcher affiliated with the University of Kent, the UK for accessing the ethno-medicinal knowledge of the Siddi community of Gujarat.

Source: https://www.cbd.int/doc/press/2015/pr-2015-10-07-abs-en.pdf

Research Community and ABS

The research and scientific community is one of the major users of biological resources and associated knowledge for the purpose of research and development. There may be individual researchers who work on their own or institutions or companies that have R&D wings/departments/divisions. Universities may engage in academic/non-commercial research on biological resources and may also have tie-ups for conducting commercial research with entities within or outside India. Most of the commercial activities aimed to tap the potential of biological resources begin with research. For instance, commercial development of a product from a biological resource requires extensive research activities. R&D on biological materials is often the first step in patenting a biotechnological invention. Usually, researchers come into direct contact with the point of access and may collect biological materials in person. Thus, research in many cases is the trigger point for utilization of genetic or biological resources and obligations for researchers are, therefore paramount in the ABS system. In practice, the success of the ABS process depends upon the commitment of the research community to comply with domestic ABS legislations creating legally binding obligations upon themselves or the subsequent actors in the value chain to share the benefits with country of origin and/or the local communities involved. It is, therefore, important that the scientific and research communities take a lead in applying for approvals before beginning their activities and follow all the procedures enshrined in national and international ABS laws.

Table 1
Provisions in the CBD relevant to research

Article	Details
Article 9. Ex situ Conservation	Each Contracting Party shall, as far as possible and as appropriate, and predominantly for the purpose of complementing in situ measures: Clause (b)- Establish and maintain facilities for ex situ conservation of and research on plants, animals and micro-organisms, preferably in the country of origin of genetic resources:

Article	Details
Article 12. Research and Training	The Contracting Parties, taking into account the special needs of developing countries, shall: Clause (b)- Promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, inter alia, in accordance with decisions of the Conference of the Parties taken in consequence of recommendations of the Subsidiary Body on Scientific, Technical and Technological Advice: and Clause (c)- In keeping with the provisions of Articles 16, 18 and 20, promote and cooperate in the use of scientific advances in biological diversity research in developing methods for conservation and sustainable use of biological resources.
Article 15. Access to Genetic Resources	Clause 6 Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties. Clause 7 Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.

Article	Details
Article 17. Exchange of Information	Clause 1 The Contracting Parties shall facilitate the exchange of information, from all publicly available sources, relevant to the conservation and sustainable use of biological diversity, taking into account the special needs of developing countries. Clause 2 Such exchange of information shall include exchange of results of technical, scientific and socio-economic research, as well as information on training and surveying programmes, specialized knowledge, indigenous and traditional knowledge as such and in combination with the technologies referred to in Article 16, paragraph 1. It shall also, where feasible, include repatriation of information.
Article 19. Handling of Biotechnology and Distribution of its Benefits	Clause 1 Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties.

Table 2
Provisions in the Nagoya Protocol relevant to research

Article	Details
Article 2. Use of Terms	The terms defined in Article 2 of the Convention shall apply to this Protocol. In addition, for the purposes of this Protocol: Cause (c) "Utilization of genetic resources" means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention.
Article 8. Special Considerations	In the development and implementation of its access and benefit-sharing legislation or regulatory requirements, each Party shall: Clause (a) Create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research

Article	Details
Article 17. Monitoring the Utilization of Genetic Resources	Clause 1 To support compliance, each Party shall take measures, as appropriate, to monitor and to enhance transparency about the utilization of genetic resources. Such measures shall include: Sub-clause (a) The designation of one or more checkpoints, as follows: Point (iv) Checkpoints must be effective and should have functions relevant to implementation of this subparagraph (a). They should be relevant to the utilization of genetic resources, or to the collection of relevant information at, inter alia, any stage of research, development, innovation, pre-commercialization or commercialization.
Article 22. Capacity	Clause 4 In support of the implementation of this Protocol, capacity-building and development may address, inter alia, the following key areas: Sub-clause (d) Capacity of countries to develop their endogenous research capabilities to add value to their own genetic resources. Clause 5 Measures in accordance with paragraphs 1 to 4 above may include, inter alia: Sub-clause (f) Bio-prospecting, associated research and taxonomic studies

Article	Details
Article 23. Technology Transfer, Collaboration and Cooperation	In accordance with Articles 15, 16, 18 and 19 of the Convention, the Parties shall collaborate and cooperate in technical and scientific research and development programmes, including biotechnological research activities, as a means to achieve the objective of this Protocol. The Parties undertake to promote and encourage access to technology by, and transfer of technology to, developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition, in order to enable the development and strengthening of a sound and viable technological and scientific base for the attainment of the objectives of the Convention and this Protocol. Where possible and appropriate such collaborative activities shall take place in and with a Party or the Parties providing genetic resources that is the country or are the countries of origin of such resources or a Party or Parties that have acquired the genetic resources in accordance with the Convention.

Article	Details
Annex **MONETARY AND NON-MONETARY BENEFITS**	Clause 1 Monetary benefits may include, but not be limited to: Sub-clause (h)- Research funding Clause 2 Non-monetary benefits may include, but not be limited to: Sub-clause (a) Sharing of research and development results Sub-clause (b) Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the Party providing genetic resources; Sub-clause (m) Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in the Party providing genetic resources

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Chapter 2

National Framework on ABS in India

India is rich in biological diversity and associated TK and is one of the mega diverse countries in the world. Access to biological or genetic resources in India was not regulated prior to 2002. At the time, biological resources occurring in or obtained from India and associated traditional knowledge were being utilized by a wide array of users particularly for research and development, commercialization, patenting, large scale exporting of resources outside India, etc. Obtaining consent of the providers of biological resources or their participation or involvement in determining the terms of access or sharing of any resulting benefits was unheard for many years. However, India always remained less tolerant to the inequity and unfairness created on account of access to genetic resources and associated traditional knowledge without sharing appropriate benefits in return. Soon after signing the CBD, India had to fight the infamous neem and turmeric cases involving misappropriation of TK on the biochemical properties of neem tree and turmeric plant through patenting in other countries.

Much before its domestic ABS framework was in place, Indian researchers had set an example of benefit sharing with the holders of TK in return for the use of their knowledge in research and commercial production of the plant-based tonic called Jeevani. The benefit sharing initiatives taken by the researchers for the use of TK of the Kani tribe in developing the anti-fatigue drug Jeevani is still considered a relevant and highly acclaimed ethical research practice internationally.

The Indian subcontinent, mega-diverse region with only 2.4% of the world's land area, accounts for 7-8% of all recorded species, including over 1,48,600 species of plants and animals. The country's diverse physical features and climatic conditions have resulted in a variety of ecosystems such as forests, wetlands, grasslands, desert, mangroves, coastal and marine ecosystems, which harbour and sustain high biodiversity and contribute to human well-being. Four of 35 globally identified biodiversity hotspots: The Himalayas, the Western Ghats, the North-East, and the Nicobar Islands, are in India.

Status of India's Rich Floral and Faunal Diversity

Taxonomic Group	No. of Taxa	Endemic species	Threatened species
Algae	7,357	1,924	NA
Bryophytes	2,748	629	c.80
Fungi	15,115	4,100	c.580
Pteridophytes	1,289	66	414
Gymnosperms	79	12	7
Angiosperms	18,386	4,303	1,700
Lichen	2,511	520	NA
Total Flora	**47,485**	**11,554**	**-**
Protozoans	3,525	640	NA
Invertebrates (including insects, spiders, ticks, mites, earthworms, crabs, molluscs, worms, sponges, marine inverte-brates)	90,986	26,782	135
Chordates, Cephalochordates and Urochordates	6,656	1,115	540
Fishes	3,364	482	228
Amphibia	414	287	75
Reptilia	584	220	54
Birds	1,340	81	89
Mammalia	427	45	94
Total Fauna	**1,01,167**	**28, 537**	**675**

Source: MOEFCC, 2019. Implementation of India's National Biodiversity Action Plan-An Overview. Ministry of Environment, Forest and Climate Change, Government of India.

Neem Patent Case

An European patent was granted in 1994 to the US company Warner Grace and the US Department of Agriculture for a method of controlling fungi in plants with neem oil formulation. Grant of the patent was challenged by an NGO in India and the International Federation for Organic Agriculture Movements. They were able to furnish evidence to the effect that the pesticidal properties of neem were known and used in India for centuries on plants and for dermatological uses in humans. The European Patent Office (EPO) revoked the patent on grounds of lack of novelty and inventive steps ten years later, in March 2005.

Turmeric Patent Case: In 1995, the United States Patent and Trademark Office (USPTO) awarded a patent (U.S. Patent 5,401,504) to the University of Mississippi Medical Centre on the wound healing properties of turmeric. The patent was challenged by the Council for Scientific and Industrial Research (CSIR), India on the ground that the wound healing property of turmeric is a matter of common knowledge among Indian households. Despite the difficulty to provide published information, CSIR managed to provide references for such use in different vernacular languages of India. This resulted in the revocation of the granted patent.

Source:

http://lup.lub.lu.se/luur download?func=downloadFile&recordOId=1555871&fileOId=1563800

Jeevani and Benefit Sharing with Kani Tribes

A team of researchers from the Jawaharlal Nehru Tropical Botanical Garden and Research Institute (TBGRI), Kerala came across the revitalizing effects of a local plant called Trichopus zeylanicus ssp travancoricus during one of their ethnobotanical expeditions guided by the Kani tribes of Kerala. The researchers were able to come up with a standardized herbal formulation which they named Jeevani, based on the active chemical compounds from the plant that could be safely used against stress and fatigue. In 1995, the technology for developing Jeevani was licensed to the Arya Vaidya Pharmacy, Coimbatore for commercial manufacturing. Recognizing the contribution of the TK from the Kani tribes, the TBGRI assisted the tribe in constituting a trust consisting of 9 tribal members that would receive a share of benefit that is due to TBGRI from the Arya Vaidya Pharmacy. The trust was formed with the objectives of (i) promoting welfare and development activities for Kani

people in Kerala; (ii) to prepare a biodiversity register to document the TK of the tribe; and (iii) to promote conservation and sustainable use of the Trichopus plant. The payment received by the trust was earmarked for developmental activities and insurance schemes to cover pregnant ladies and accidental deaths. This arrangement proved successful for a few years from 1997 until the expiration of the license given to Arya Vaidya Pharmacy.

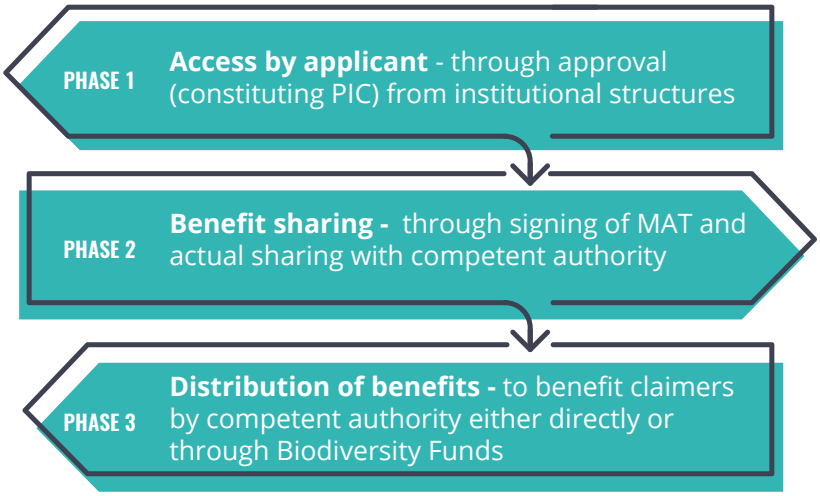
Source: WIPO Case Studies – Using Traditional Knowledge to Revive the Body and a Community available at https://wipo.int/ipadvantage/en/details.jsp?id=2599 (Last accessed on 19th April 2019)

The Biological Diversity Act, Rules and ABS Guidelines – A Brief Outline

Pursuant to its international commitment to the CBD, India enacted the Biological Diversity Act in 2002, after ten long years of consultative process. The objectives of the BD Act are identical to those of the CBD, viz., 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[13]. In 2004, the Biological Diversity Rules containing detailed procedural requirements and application forms for procuring approvals were brought into force. Later in 2014, Guidelines on Access to Biological Resources and Associated Knowledge and Benefits Sharing Regulations (ABS Guidelines)[14] were notified elaborating further on the procedural requirements for access and mandating the range of benefit sharing percentages that would be applicable for different activities regulated under the BD Act. The various notifications made under the BD Act from time to time based on the requirements emerging out of new developments nationally and internationally also adds to the law of the land on ABS. Having been enacted prior to the Nagoya Protocol, the BD Act and its related legal instruments govern primarily the biological resources found within the territory of India and thus has a wider scope than the Nagoya Protocol the application of which is confined to genetic resources. The Ministry of Environment, Forest and Climate Change (MoEFCC) is the national focal point and the NBA is the competent national authority in India on matters related to ABS.

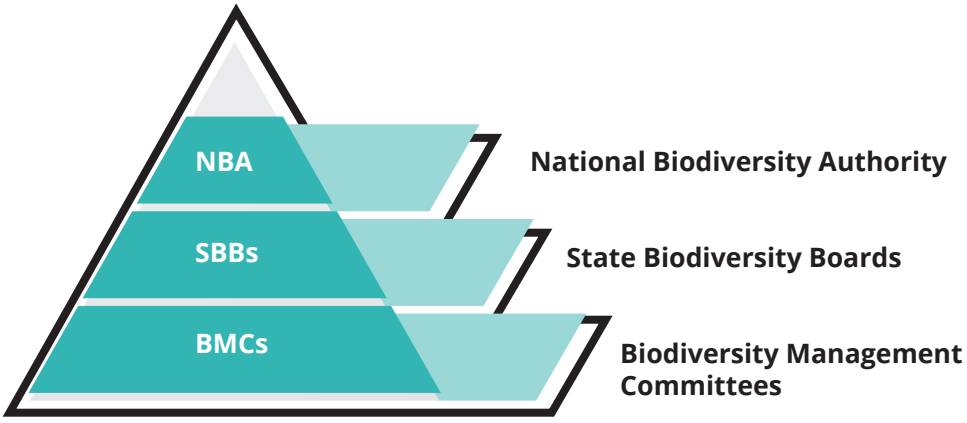
[13] Preamble, BD Act
[14] The ABS Guidelines 2014 are also called the ABS Regulations. However, this document, in all its different parts, refers to the said document as ABS Guidelines.

ABS Implementation in India



Phase I - Access

The ABS mechanism is implemented in India through a three-tier institutional structure. It comprises of the National Biodiversity Authority (NBA) at the central level, the State Biodiversity Boards (SBBs) at the state level and the Biodiversity Management Committees (BMCs) at the local body level. These three institutions are established as independent statutory bodies which carry out different functions and obligations under the BD Act related to all the three phases of ABS in India viz; access, benefit sharing and benefit distribution.



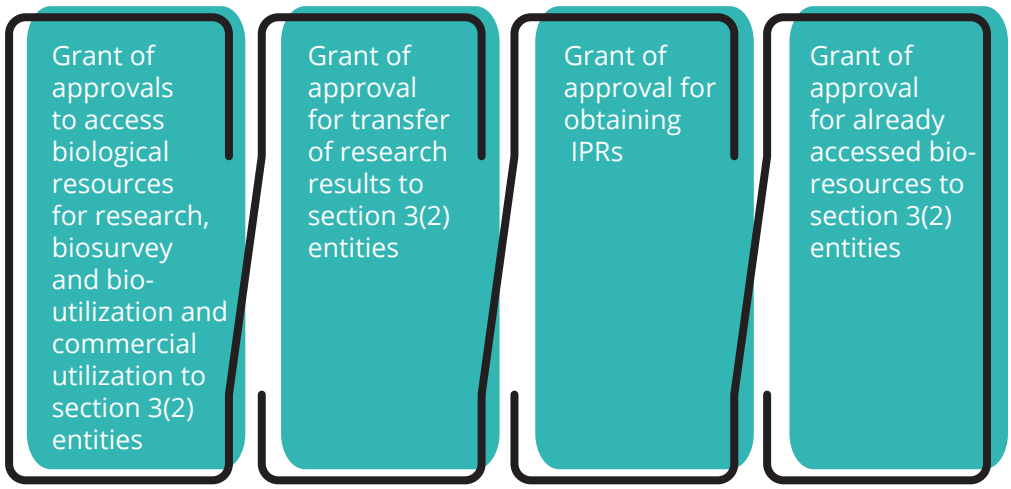
Institutional Structures

National Biodiversity Authority (NBA)[15]

NBA has been established under the MoEFCC with headquarters at Chennai. The Authority consists of a Chairperson, ten ex officio members and five non-official members. The ex officio members represent the Ministries/ Departments of Environment, Forest and Climate Change, Tribal Affairs, Agricultural Research and Education, Biotechnology, Ocean Development, Agriculture, Cooperation and Famers Welfare, Indian Systems of Medicine and Homoeopathy, Science and Technology, and Scientific and Industrial Research. The non-official members are appointed from amongst scientists and specialists having special knowledge or experience in matters relating to the three objectives of the BD Act, representatives of industry and conservers, creators and knowledge holders of biological resources. NBA is assisted in its functioning through constitution of various subject-specific expert committees namely; the Expert Committee on Agrobiodiversity; the Expert Committee on Medicinal Plants; the Expert Committee on ABS and the Expert Committee on Normally Traded Commodities, etc., on various aspects of ABS related to different kinds of biological resources.

Functions and Powers of NBA[16]

NBA is mandated to perform regulatory and advisory functions under the Act. Its regulatory functions include



[15] Section 8, BD Act
[16] Section 18, BD Act

The Act envisages prior permission from the NBA before carrying out all the activities specified above. The applicability of the regulatory jurisdiction of NBA is different for different types of natural and legal persons. These regulated activities would be discussed in detail in chapters 3 and 4 of this handbook.

Advisory Functions of NBA range from

- Advising the Central Government on matters related to achieving the three objectives of the Act
- Advising the State Governments in selection of biodiversity heritage sites and measures for their management

Opposition of IPR – The BD Act empowers the NBA to take necessary measures on behalf of the Central Government to oppose in other countries the grant of IPR on biological resources obtained from India or associated knowledge derived from India. It may also be noted that NBA could, without any specific authorization under the BD Act, file oppositions within India against the grant of patents as per the provisions of the Indian Patents Act, 1970.

State Biodiversity Boards[17] (SBBs)

The BD Act requires the State Governments to establish SBB in each State. Currently, 29 SBBs have been constituted in India. The SBB consists of a Chairperson, not more than five ex officio members and not more than five non-official members specialized on matters related to the three objectives of the BD Act. The role of a SBB in respect of a Union Territory is discharged by the NBA or any office authorized by NBA on its behalf, and for this purpose NBA has constituted Biodiversity Councils in all the 9 Union Territories vide a set of Office Memorandums dated 31st December 2019.

[17] Section 22 BD Act

Functions of SBBs: The functions of SBB are to

- Advise the State Government on matters related to the three objectives of the BD Act;
- Regulate (a) commercial utilization and (b) bio-survey and bio-utilization for commercial utilization of biological resources within the respective territorial limits of the concerned State;
- Other functions necessary to carry out the provisions of the Act.

Biodiversity Management Committees (BMCs)[18]

Biodiversity Management Committees are established at the level of local self-governments in rural and urban areas. Each BMC consists of a Chairperson and not more than six members nominated by the local body concerned. One third of such nominated members shall be women and not less than 18% of the BMC members should belong to the Scheduled Castes/Tribes.

BMCs are mainly constituted for promoting:

- Conservation, sustainable use and documentation of biological diversity
- Preservation of habitats
- Conservation of landraces, folk varieties and cultivars, domesticated stocks and breeds of animals and microorganisms
- Chronicling of knowledge relating to biological diversity.

NBA and the SBBs are mandated to consult the BMCs while taking any decision relating to the use of biological resources and associated knowledge occurring within the respective territorial jurisdiction of the BMCs. Through this consultation process, the BD Act ensures the participation or approval and involvement of the conservers and holders of the biological resources and/or associated TK in the determination of the conditions for ABS prior to access.

[18] Section 41 BD Act

Collection fee levied by BMCs

The BD Act specifically allows the BMCs to levy charges as collection fees on any person for accessing or collecting biological resources from their territorial limits for commercial purposes. This collection fee could be charged in addition to the monetary benefits determined by the NBA or the SBBs and any payment in this regard would not obviate the benefit sharing obligations of the person accessing or collecting the biological resources. Collection fee is charged for accessing biological resources for "commercial purposes", which is different from "commercial utilization", one of the regulated activities under the BD Act. BMCs could levy collection fee on section 3(2) and non-section 3(2) entities/ individuals, and all types of associations, organizations and corporate entities. The only criteria applicable for levy of collection fee are that:
- (i) the access/collection is for a biological resource as defined by the BD Act; and (ii) that such collection/ access should be for a commercial purpose.

Functions of BMCs: The main functions of BMCs are:

- Preparation of People's Biodiversity Register (PBR) in consultation with local people (PBRs contain comprehensive information on availability and knowledge of local biological resources, their medicinal and other uses and the TK associated with them);
- Advise NBA/SBB on matters referred to them for grant of approval for regulated activities;
- Maintain data about local vaids and practitioners using the biological resources;
- Maintenance of register with information about the details of access to biological resources and TK granted; details of collection fee levied; details of benefits derived; and the mode of their sharing;

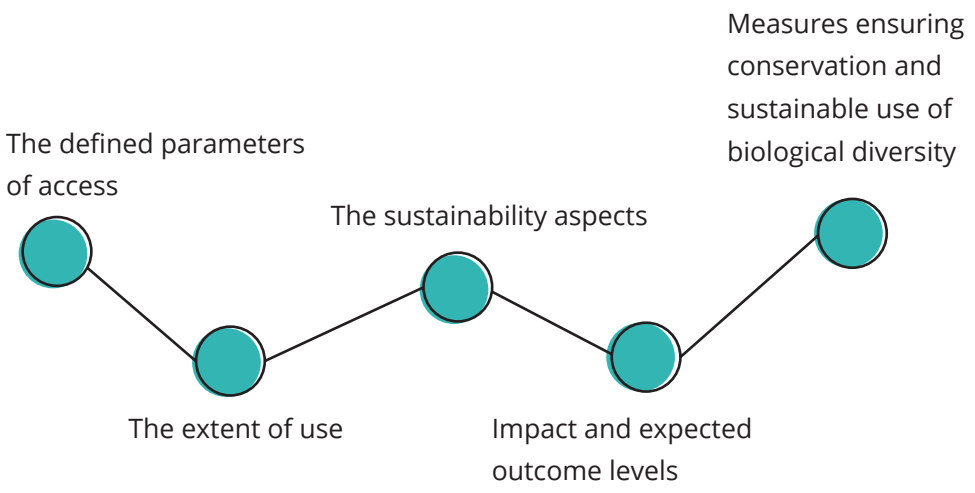
Phase II & III – Benefit Sharing and benefit distribution

In the second phase of the ABS process, benefit sharing implies actual sharing of the benefits by the applicant as mutually agreed with NBA or SBBs. Benefits ought to be shared in respect of the regulated activities. The quantum of benefits to be shared would be mutually agreed before access between the applicant, the benefit claimers and the local bodies concerned. It is the duty of the NBA to ensure that the mutually agreed terms and conditions secure fair and equitable benefit sharing. This would also mean that when benefit claimers are not identified, NBA could negotiate mutually agreed terms with the applicant. The BD Act defines fair and equitable benefit sharing to mean "sharing of benefits as determined by NBA in all or any of the following manner[19] : -

[19] Section 2(g) r/w section 21 BD Act

Criteria for Determining Fair and Equitable Benefit Sharing

As per the BD Rules, 2004, the primary factors in determining fair and equitable benefit sharing for a regulated activity are[20]



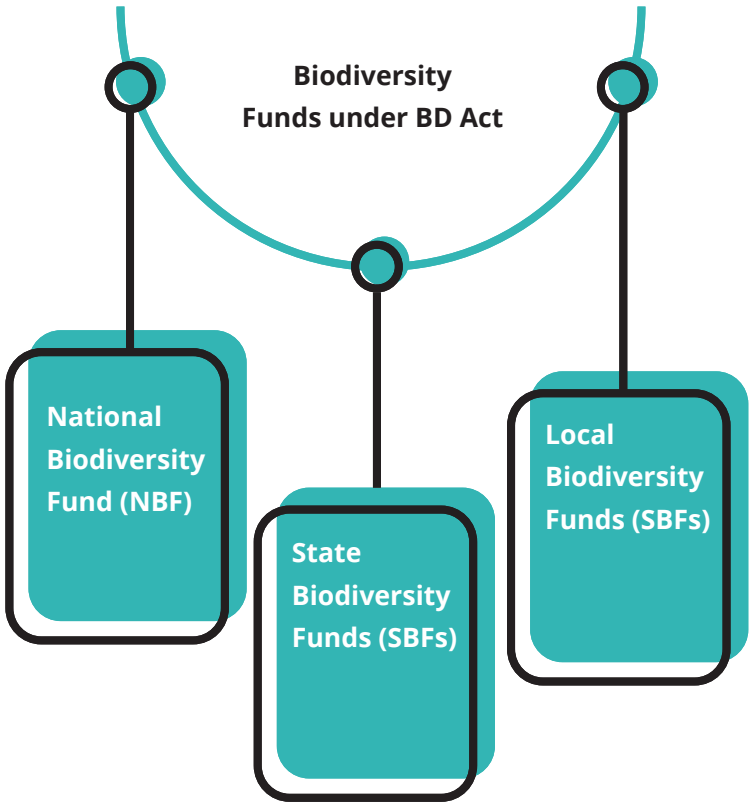
The ABS Guidelines, 2014 further provide that the considerations in determining fair and equitable benefit sharing would include[21] : -

- Commercial utilization of the biological resources
- Amount of investment already made for R&D
- Stages of R&D
- Potential market for the outcome of research
- Nature of technology applied
- Timelines and milestones from initiation of research to development of the product
- Risks involved in commercialization of the product
- Whether technologies/ products are developed for controlling epidemics or diseases and for mitigating environmental pollution affecting human/ animal/ plant health.

[20] Rule 20 (5), BD Rules
[21] Regulation 14, ABS Guidelines, 2014

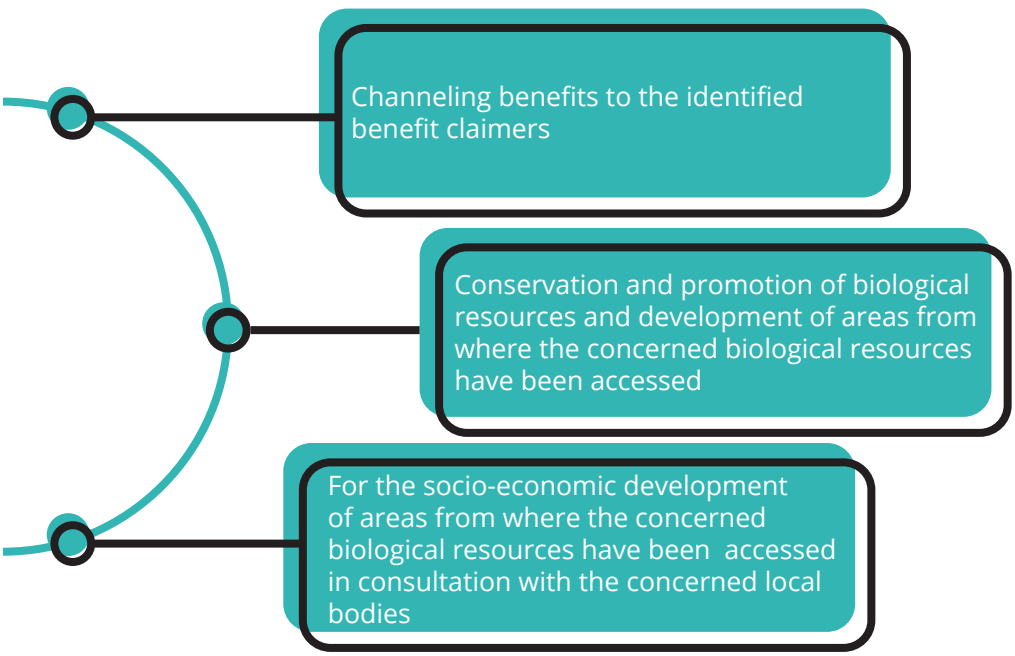
Application of Biodiversity Funds in Sharing and Distribution of Benefits

Biodiversity funds created under the Act at various levels play critical role in benefits sharing and benefits distribution. To facilitate benefit sharing at the three institutional levels, three types of biodiversity funds have been created under the BD Act - the National Biodiversity Fund (NBF) at the national level, the State Biodiversity Funds (SBFs) at the States' level and the Local Biodiversity Funds (LBFs) at the level of local bodies. The application fee and any share of monetary benefits from the applicants derived out of the regulated activities should be credited to the NBF and the concerned SBF. LBFs would receive monetary benefits from NBA or SBB in the form of grants. The different biodiversity funds are discussed below in detail.



National Biodiversity Fund[22]

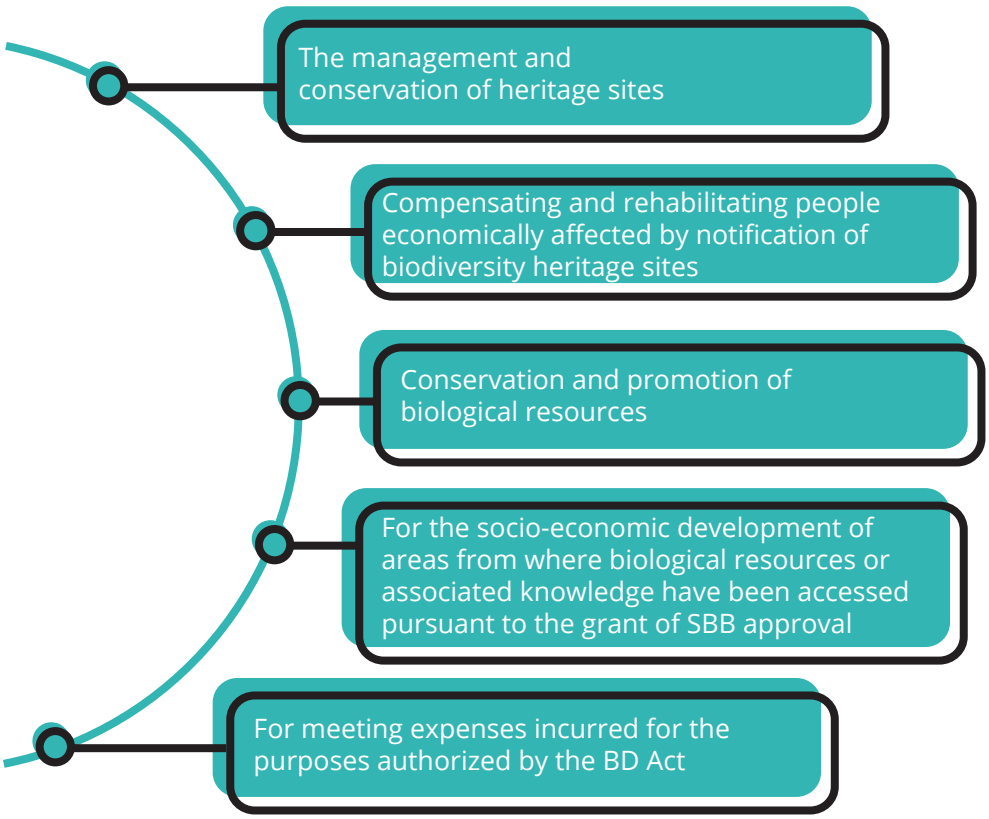
The applicant would deposit the application fee and any share of monetary benefit as mutually agreed with NBA in respect of the approval granted, in the NBF constituted as per the provisions of the BD Act. In cases where access to biological resources or associated knowledge is from a specific individual or group of individuals or an organization, NBA could request the applicant to pay directly to such identified benefit claimers in accordance with the MAT and in such a manner as decided by the NBA[23] in consultation with the applicant. Out of the benefit sharing amount received in the NBF, the NBA would retain 5% of such amount as administrative charges, half of which may be passed on to the concerned SBB too[24]. Rest of the monetary benefits would be used for:



[22] Section 27 BD Act
[23] Section 21(3) BD Act24
[24] Regulation 15, ABS Guidelines

State Biodiversity Fund (SBF)

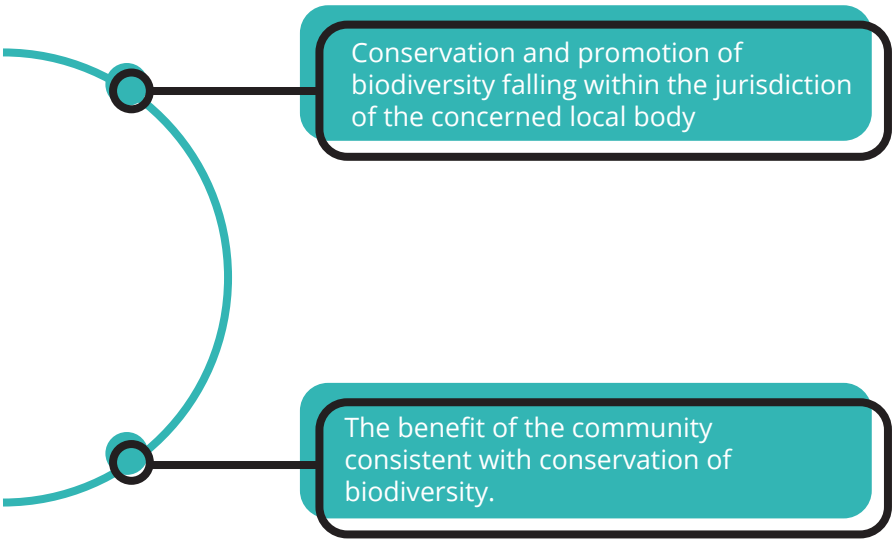
State Biodiversity Fund in each State would receive the grants and loans made by the concerned State Government and NBA and any other sum received by the SBB from other sources as decided by the State Government. The application fee and benefit sharing amount for the activities regulated by the SBB within its jurisdiction are also credited in the concerned SBF. The SBF is used for: -



The ABS Guidelines, 2014, allow the SBBs to retain 5% of the benefit sharing fee for administrative charges and to pass on the remaining share of benefits to the identified benefit claimers or the BMCs where the benefit claimers have not been identified. Further, where the benefit claimers are not identified, the Guidelines also direct the SBBs to use the benefit sharing amount to support conservation and sustainable use of biological resources and to promote livelihoods of local people from where the resources have been accessed.

Local Biodiversity Fund

The Local Biodiversity Fund is constituted by the local self-government to receive grants and loans made by the concerned State Government or the NBA or the concerned SBB; collection fee received from the applicants for accessing the biological resources from within its jurisdiction by the BMC; and any other sum received by the LBF as decided by the State Government. The management and custody of LBF is with the BMC. The fund is used for: -



Table

Matrix of activities regulated and benefit sharing obligations

Sl. No	**Regulated activity**	**Provision**	**Form in BD Rules**	**Who is regulated**	**From whom should prior approval be obtained?**	**Monetary benefit sharing applicable**
1	Research	Section 3	Form I	Only Non-Indians, non-resident Indians, non-Indian entities and Indian entities with non-Indian participation in share capital/ management	NBA	Benefit sharing NOT applicable For research on biological resources with high economic value, upfront payment needs to be made
2	Non-commercial research or research for emergency purposes outside India by Indian Researchers/ Government Institutions	Reg 13 of ABS Guidelines	Form B	Only Indians/ Indian government institutions	NBA	Benefit sharing NOT applicable
3	Bio-survey and bio-utilization for research	Section 3	Form I	Only Non-Indians, non-resident Indians, non-Indian entities and Indian entities with non-Indian participation in share capital/ managemen	NBA	Benefit sharing NOT applicable (upfront payment for biological resources with high economic value)

Sl. No	**Regulated activity**	**Provision**	**Form in BD Rules**	**Who is regulated**	**From whom should prior approval be obtained?**	**Monetary benefit sharing applicable**
4	Bio-survey and bio-utilization for commercial utilization	Section 3	Form I	Only Non-Indians and non-Indian entities covered under section 3(2)	NBA	On annual gross ex-factory sale of the product minus government taxes – 0.1% for companies upto Rs.1,00,00,000 0.2% for companies between Rs. 1,00,00,001 to 3,00,00,000 0.5% for companies above Rs. 300,00,000
		Section 7	Form I of the concerned SBB Rules	Only Indian and Indian entities not covered under section 3(2)	SBB	Same as above
5	Transfer of results of research to a person/entity under section 3(2)	Section 4	Form II	Both Non-Indian and non-Indian entities covered under section 3(2) and not covered under section 3(2)	NBA	Benefit sharing applicable 3%-5% of the monetary consideration

Sl. No	**Regulated activity**	**Provision**	**Form in BD Rules**	**Who is regulated**	**From whom should prior approval be obtained?**	**Monetary benefit sharing applicable**
6	Obtaining IPR	Section 6	Form III	Only Indians/ Indian government institutions	NBA	Benefit sharing applicable If applicant himself commercializes - 0.2-1.0% on the annual gross ex-factory sale minus government taxes When commercialised by a third party through assignment/ licensing – 3%-5% of the fee received and 2%-5% of the royalty received
7	Transfer of biological resource/ associated knowledge accessed to a third party	Section 20	Form IV	Both Non-Indian and non-Indian entities covered under section 3(2)	NBA	2%-5% of any amount and/or royalty received from the transferee

Chapter 3

Understanding the Legal Requirements for Accessing Biological Resources and Associated Knowledge for Research

Research on biological resources and associated knowledge, as discussed in the first chapter of this handbook, is the trigger point of many subsequent activities such as publication of research results, transfer of results of research, commercialization of research results, product development, obtaining IPR, licensing IPR, commercialization of final products, etc. Thus, all the regulated activities under the BD Act are relevant for research over biological resources and associated knowledge requiring careful consideration of persons and entities carrying out research. The first step in exploring the legal requirements for carrying out research would be to assess whether such proposed activity involves use of any 'biological resource' as defined by the BD Act or any knowledge associated with them. Knowledge associated with biological resources is also regulated under the BD Act. The meaning of the term 'research' under the BD Act is different from the common understanding of the term. "Bio-survey and bio-utilization", another regulated activity under the BD Act stands close to the common understanding of research. Hence, a researcher needs to carefully consider the scope of his activities vis-à-vis the BD Act while carrying out research and related activities on biological resources or using any associated knowledge.

The legal obligations regarding the regulated activities under the BD Act with respect to research can be broadly categorized into three: - (i) Obligations prior to access; (ii) obligations at the time of access; and (iii) obligations after access. Obligations prior to access mostly relate to the self-assessment each researcher must make in determining the applicability of the various provisions and benefit sharing obligations under the Act and to initiate the required procedural steps for compliance with the ABS obligations. Obligations at the time of access require the applicant to adhere to the terms and conditions imposed in collecting the biological resources or the associated knowledge. Since these obligations vary in accordance with the conditions imposed by NBA/SBB, we are not elaborating much on such conditions. The general guidance for researchers in this regard is to strictly comply with the terms and conditions of the approval as mutually agreed. After access, the applicant has to comply with a range of legal obligations that may emanate from the obligations to adhere to the terms and conditions of ABS; sharing of actual benefits with the authorities concerned; obtain necessary

approvals for carrying out other regulated activities upon change of intent or for carrying out subsequent activities if required as per the provisions of the BD Act. This chapter focuses on the legal obligations for accessing biological resources and associated knowledge for research.

Legal Obligations Prior to Access and Initiating Research Activities

Legal obligations prior to accessing biological resources and associated knowledge, in general, are elaborated under sections 3 and 7 of the BD Act. However, section 7 of the BD Act does not regulate research over biological resources undertaken by non-section 3(2) entities. Hence, this section describes only the legal obligations under section 3 for carrying out research over biological resources and associated knowledge.

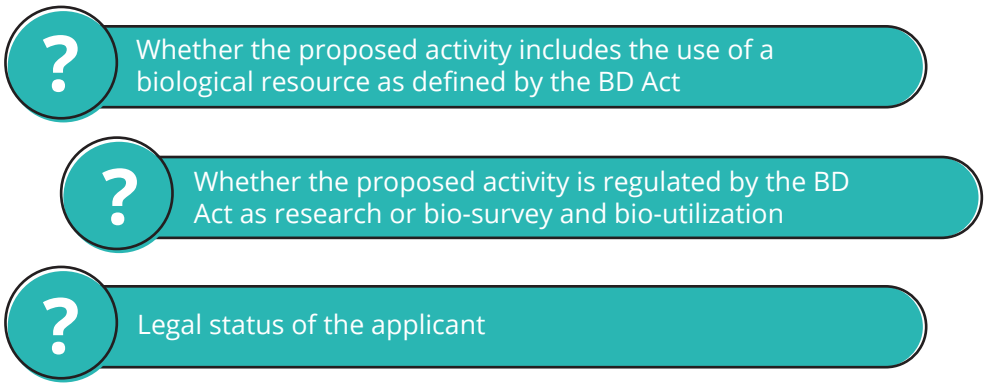
3. Certain persons not to undertake Biodiversity related activities without approval of National Biodiversity Authority—

i. No person referred to in sub-section (2) shall without previous approval of the National Biodiversity Authority, obtain any biological resource occurring in India or knowledge associated thereto for research or for commercial utilisation or for bio-survey and bio-utilisation.

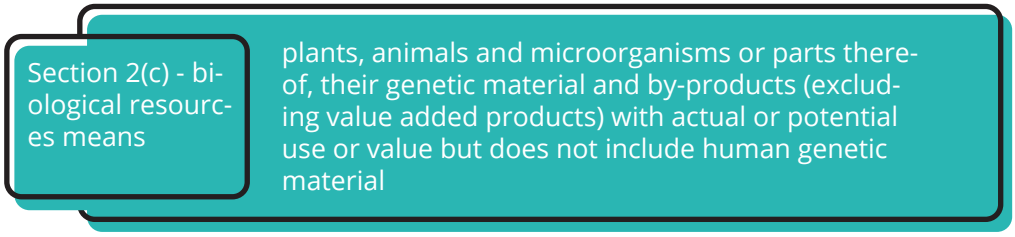
ii. The persons who shall be required to take the approval of the National Biodiversity Authority
under sub-section (1) are the following, namely: —
   a. a person who is not a citizen of India;
   b. a citizen of India, who is a non-resident as defined in clause (30) of section 2 of the Income-tax Act, 1961 (43 of 1961);
   c. (c) a body corporate, association or organisation—
      (i) not incorporated or registered in India; or
      (ii) incorporated or registered in India under any law for the time being in force which has any non- Indian participation in its share capital or management.

Under this section, legal obligations prior to accessing biological resources, are established in respect of three specific activities viz; research or bio-survey and bio-utilization or for commercial utilization. A person or entity may carry out commercial utilization of the biological resources without undertaking research or bio-survey and bio-utilization. Since this handbook is primarily intended for the use of researchers, the approach adopted here is to address commercial utilization as an activity after accessing biological resources for research.

The primary questions that decide the applicability of the BD Act to a researcher or an entity proposing to undertake research are



What constitutes a biological resource under the BD Act?



According to the definition provided by the BD Act, the diverse species of whole plants, animals and microbes would constitute biological resources. Similarly, the parts of these biotic components, their genetic materials and by-products are also considered biological resources under the BD Act. The definition of biological resources seems to lay emphasis on the physicality of biological materials.

The use value of these biological components can be actual or potential, thus covering the unknown uses or potential value of biological resources that may be revealed at a later point in time. If the proposed activity is intended to be done on the physical or genetic parts of a plant, animal or a microorganism, such activity is understood to involve the use of a biological resource.

O.A. Nos. 28/2013 and 17/2014 – Biodiversity Management Committee Vs. Western Coalfields Ltd., & Others in the National Green Tribunal (Central Zone)

This case is the first of its kind before the National Green Tribunal (NGT) of India that investigated the scope of the term "biological resource". The NGT considered the question whether coal is a biological resource falling within the scope of the BD Act.

The BMC of Eklehra (in Madhya Pradesh) filed these two applications seeking directions that coal was a 'biological resource' under the BD Act and the respondent coal companies were therefore bound to take prior approval from the Madhya Pradesh SBB to exploit the same to share the benefits. The BMC argued that the definition of biological resource as per section 2(c) of the BD Act covers fossil fuels within its rather broad purview. The SBB issued notices to the coal companies active in the state, and a petition was simultaneously filed in Bhopal before the Central Zone bench of the NGT seeking a favourable order interpreting coal as a biological resource under section 2(c) of the BD Act.

The NGT ruled that the definition of biological resource under the BD Act refers only to living organisms and their genetic materials. The NGT further laid down that any material lacking the genetic make-up or DNA (the functional units of heredity in the definition) cannot qualify as a genetic material and a biological resource.
This decision may be used by researchers to understand the existing legal interpretation of the term "biological resources".

The Act does not define the term 'by-product' neither does it give any examples of by-products. The NGT, while discussing the question whether coal is a biological resource, resorted to the dictionary definition of the term 'by-product' as an incidental or secondary product made in the manufacture or synthesis of something else. The NGT opined that by including by-products within the definition of biological resources, the BD Act seeks to cover only the by-products which plants, animals and microorganisms produce, the exploitation of which may threaten conservation of the very same resources that produce them. Gum, resins and honey are the illustrative examples of by-products given by the NGT in this case.

Associated Knowledge[25] forms part of ABS Regulations

The BD Act covers all kinds of biological resources be it wild or cultivated; of plant, animal, microbial or other origin; occurring in private or public lands or associated with any other natural resource such as water. There is no distinction in terms of their availability (whether abundant or scarce) in the territory of India or its commercial value in the market. The value of a biological resource may be actual and potential at the same time or in other words, a biological resource can have known or unknown uses at the same time. Associated knowledge on a biological resource is an example of the known use or value of a biological resource. The biochemical structure of an active component in a biological resource represents the scientific knowledge on a biological resource. By specifically including associated knowledge under access regulation as per section 3, the BD Act treats the scientific and associated knowledge over biological resources relevant for ABS purposes.

[25] The BD Act uses the term 'associated knowledge' while the ABS Guidelines uses the term "associated traditional knowledge. Hence the terms are used interchangeably without any change in its meaning or scope.

Biological resources and emerging technologies

The term "genetic material" present in the definition of biological resources under the BD Act is not defined any where in the Act while there is quite a lot of research done on genetic materials. The CBD defines 'biological resources' as "including genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity." The CBD further defines genetic resources as "genetic material of actual or potential value" and genetic material is in turn defined as "any material of plant, animal, microbial or other origin containing functional units of heredity". These definitions make it very clear that functional units of heredity assume much significance in a biological resource or a genetic resource. It may be noted that the decision of the NGT in the Western Coal Fields case has also taken the same view. The functional units of heredity, or DNA in other words, are expressed as sequences, which refer to the way in which nucleotides are present in a DNA. With the help of advanced techniques, it is possible to sequence the DNA and convert the gene sequence information in digital format. Using fabrication technologies, digitized gene sequence data could be used to synthesize genes in material form and come up with synthetic biological products. This issue is currently under discussion internationally to see whether the scope of ABS activities extend to these types of information. So, researchers are expected to update themselves on the latest legal and policy developments in this field and take proactive steps to ensure compliance while undertaking research with such technologies.

Exceptions to the term 'biological resources' under the BD Act

Human genetic material

The Act specifically excludes human genetic materials from the scope of the definition. The term "genetic material" is not defined in the BD Act and there is no guiding principle as to what constitutes a human genetic material. However, microorganisms or pathogens (including vectors of human diseases) found in human body would still be considered as biological resources.

Value added products

Value added products are excluded from the scope of the term "biological resources". Section 2(p) of the BD Act defines value added products as "products which may contain portions or extracts of plants and animals in unrecognizable and physically inseparable form". This definition does not enable a researcher to make a concrete judgement as to what constitutes a value-added product. In the business language, value addition refers to enhancement of the value of a product through different stages in development or production. Taking this logic, the value addition in a "value added product" as defined by the BD Act is creation of an end product having the presence of portions or extracts of plants and animals within it. The use of plural forms "portions" or "extracts" could mean that there must be more than one plant or animal in the form of extract or portion available in the product. Further, to qualify as a value-added product, the presence of the portions or extracts of such plants and animals must be unrecognizable and physically inseparable from the product. This implies that the presence of the plant and animal portions or extracts in a product should not enable a person to isolate the biological resources it contains. In short, a value-added product cannot serve as a source for accessing a biological resource wherein such biological resources could be further used for tapping its actual or potential value or uses. If the presence of plant or animal portions or extracts in a product facilitates further uses of such biological resources contained therein, such products will not qualify for exceptions under the BD Act.

What constitutes research under the BD Act

Section 2(m) - research means	study or systematic investigation of any biological resource or technological application, that uses biological systems, living organisms or derivatives thereof to make or modify products or processes for any use

As per the BD Act, research means study or a systematic investigation -

i. of a biological resource; or
ii. of a technological application using biological systems, living organisms or their derivatives; and aimed to make or modify products or processes for any use.

The second part of the definition is very similar to the definition of biotechnology under the CBD which reads "Biotechnology" means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use"[26] . Following this logic, research as per BD Act means study or systematic investigation on a biological resource or using biotechnology. The scope of this definition is very broad and will encompass all types of biological research within its purview. The latest advancement in the field of biotechnology is synthetic biology where research is being carried out using gene sequence data which are in the form of information sets without any physical genetic/biological material used in the research. However, synthetic biology would fall within the scope of "research" under the BD Act as a study or systematic investigation using biological systems aimed to make or modify products or processes for any use. The researchers should also note that there is no distinction made in the BD Act with respect to commercial or non-commercial research when we discuss the regulatory jurisdiction of NBA.

[26] Article 2 CBD23

The definition under the BD Act envisages research as an activity that would start only after accessing the biological resource. For carrying out the study or systematic investigation, the researcher should have had access to the biological resource first. Thus, the collection process as such would not amount to research under the BD Act while the collection of samples might very often be a fundamental part of research in many instances. (Can we add examples?) Though not as a part of research, the BD Act also regulates collection process under the heading of "bio-survey and bio-utilization".

Section 2(d) - bio-survey and bio-utilization means	Survey or collection of species, sub-species, genes, components and extracts of biological resource for any purpose and includes characterization, inventorization and bio-assay

The above definition emphasizes that the survey or collection could be for any purpose and thus, the scope of this term is much wider than basic research activities commonly understood by the research community. In short, "bio-survey and bio-utilization" can be for characterization, inventorization, bioassay, research (as per BD Act) or commercial utilization (as per BD Act) or for any other purpose which is not expressly specified by the BD Act. While considering the definition of research, a better approach for researchers would be to consider "bio-survey and bio-utilization" too as an additional aspect that needs to be looked into. This approach is also supported by regulation 1 of the ABS Regulations, which prescribes common procedures for access to biological resources and associated TK[27] for (i) research; and (ii) bio-survey and bio-utilization for research. It is very important for a researcher to understand that the approval granted for bio-survey and bio-utilization would not amount to an approval for research. Regulation 2 further clarifies that bio-survey and bio-utilization could also be a step towards commercial utilization and that separate permission would be required for these activities.

[27] It may be noted that though the ABS Guidelines, 2014 describe the procedure for accessing traditional knowledge instead of using the wider term associated knowledge under section 3 of the BD Act, nothing in the Guidelines would restrict the interpretation of associated knowledge only to include traditional knowledge.

Legal status of the person or entity undertaking research or bio-survey and bio-utilization

The legal status of the person (may include an individual and/or entity) undertaking the regulated activity is a very important aspect of ABS obligations under the BD Act. The legal status of the person seeking access determines the types of regulated activities for him/her/it and the competent authority before which he/she/it is required to apply.

Section 3 of the BD Act provides that for accessing biological resources or associated traditional knowledge for the purpose of research or commercial utilization or bio-survey and bio-utilization, the following categories of persons should take prior approval from NBA: -

a. A person who is not a citizen of India;
b. A non-resident Indian under section 2(30) of the Income Tax Act, 1961 (an Indian citizen or a person of Indian origin, not present in India for a period of 183 days in a financial year) where an Indian researcher on an exchange programme would be an ideal example;
c. A non-Indian entity (body corporate or association or organization); and
d. A body corporate, association or organization registered in India having any non-Indian participation in its share capital or management (even if it is a single share or a single person)

What kinds of activities are regulated under section 3

We can see that section 3 of the BD Act does not actually regulate research or bio-survey and bio-utilization. The regulated activity under section 3 is the process of "obtaining biological resources and knowledge associated therewith occurring in India". This implies that access for research and bio-survey and bio-utilization (including access for commercial utilization) are regulated. If access to biological resources or associated knowledge is for any other purpose, the regulatory jurisdiction of NBA will not be triggered. Let us consider an example where a researcher wants to conduct behavioral study of elephants in the Western Ghats.

All researchers would agree that this is biological research. Based on the definition of research, this is a systematic investigation on a biological resource. One may also argue that it forms part of bio-survey and bio-utilization under the logic that survey would include mere examination of behavior as per the Cambridge Dictionary. However, to be regulated under any of these heads, the research would be utilizing, at any stage in the research process, biological resources either directly or through application of biotechnology. In the given case, there is no utilization by "obtaining" the biological resources in the given behavioral study and it would not amount to a regulated activity.

Further, the regulatory powers of NBA under section 3 are applicable only in respect of biological resources "occurring in India" and the knowledge associated therewith. This does not mean that the researcher has to always access them from India for igniting the regulatory functions of NBA to come into play. The expression "occurring in India" means such resources are normally found within the territory of India in in situ conditions. The CBD defines in situ conditions as "conditions where genetic resources exist within ecosystems and natural habitats, and in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties". This interpretation foresees the possibility that the biological resources can also be found in ex situ conditions like collections of gene banks located in other countries. Even in such cases of access from other locations/countries, the researchers are expected to make a reasonable enquiry about the country of origin of biological resources. If found to have originated from India, prior approval from NBA would be mandatory for obtaining such biological resources for research or bio-survey and bio-utilization even from such ex situ locations in other countries.

Table
Legal Status and Regulated Activities

Section	Regulated Activities	Regulated Persons	Competent Authority	TK Regulated
Section 3	a. Research b. Bio-survey and bio-utilization (for research and commercial utilization) c. Commercial utilization	• Not a citizen of India • Non-resident Indian • A body corporate, association or organisation not registered in India • Indian entities with non-Indian participation	NBA	Yes
Section 7	a. Bio-survey and bio-utilization for commercial utilization b. Commercial utilization	• citizen of India • Indian entities without any non-Indian participation	SBBs	No

Exceptions created through notifications

The MoEFCC has issued two notifications under section 40 of the BD Act, which could have an impact on the scope of the biological resources and the activities regulated under the Act. Section 40 of the Act empowers the Central Government to issue notification to the effect that all or any of the provisions of BD Act would not apply to any items including biological resources normally traded as commodities. This section was utilized by the MoEFCC for (i) issuing a list of items normally traded as commodities and (ii) to provide for facilitated access to plant genetic resources for food and agriculture under the ITPGRFA. Researchers must consider these two notifications while assessing the applicability of the regulatory jurisdiction of NBA or SBBs in relation to the activities they are intending to carry out using biological resources or associated knowledge.

Notification of biological resources normally traded as commodities

The MoEFCC, on 7th April, 2016, issued a notification under section 40 of the BD Act listing 385 plants, specifying their different parts such as leaves, roots, fibres, stems, seeds, etc., and in some cases the whole plant as such to which the provisions of the BD Act will not apply. This list was further supplemented by the Ministry through another notification dated 7th November, 2017 with the addition of 36 more plants. All the plants listed are cultivated species although some could also be found in the wild. Based on their uses, these plant biological resources are categorized into 23 items, viz;

I. Cereals
II. Millets
III. Pulses
IV. Oil seeds
V. Fibre crops
VI. Forage crops
VII. Green manures
VIII. Sugar crops
IX. Narcotics
X. Cucurbits
XI. Cole crops
XII. Green/ leafy vegetables
XIII. Cruciferous vegetables
XIV. Bulb crops
XV. Tubers, Rhizomes and Pith
XVI. Root crops
XVII. Fruit crops
XVIII. Flower crops and ornamentals
XIX. Medicinal plants (including medicinal crops and aromatic plants)
XX. Spice crops
XXI. Plantation crops
XXII. Mushrooms
XXIII. Pulpwood

Exceptions created through notifications

The parts or whole of the plants corresponding to the items specified in the list are notified as biological resources normally traded as commodities. The notification provides that a biological resource listed under one item could also have uses under the other items and hence item categorization does not affect the normally traded status of the biological resources listed vis-à-vis their non-listed uses under other items. The notification further provides that when parts of these listed biological resources are normally traded as commodities, the provisions of the BD Act would not apply. Similarly, products that are derived from the items listed and traded as a matter of common practice would also be exempted on submission of evidence by the applicant that such products fall within common practice. For example, fruit of tomato is exempted as an item normally traded as commodities as per the notification. Tomato sauce is a product derived from tomato and traded as a matter of common practice. Hence, tomato sauce could also be treated as a product normally traded as a commodity and the burden to prove it as a common practice would lie with the person who is making the sauce. A person claiming an exemption under this notification should apply to the NBA or the SBB concerned depending upon the legal status of the claimant in the Form A (Annex 6) annexed to the notification. The objective of this notification is only to facilitate commodity trade within and across borders, and *it does not create any exception for any of the regulated activities. This notification, in its current state, does not have any impact on the scope of the regulated activities or on the coverage of biological resources under the BD Act as far as individuals and entities intending to carry out research or bio-survey and bio-utilization in India are concerned.* Though presently, the scope of this notification is narrow, the central Government has wider powers under section 40 to exempt any biological resources from the applicability of all or any of the provisions of the BD Act. This factor calls for the attention of researchers to appreciate the scope of any further notifications that might be issued on normally traded commodities.

Notification on facilitated access for plant genetic resources for food and agriculture

On 17th December 2014, the MoEFCC had issued a notification under section 40 of the BD Act to fulfill its obligations under the Multilateral System of the ITPGRFA to provide for facilitated access to plant genetic resources for food and agriculture listed in Annex I of the Treaty. This notification provides that it is for the Department of Agriculture, Cooperation and Farmers' Welfare (DAC & FW) under the Ministry of Agriculture and Farmers' Welfare to specify the crops listed in Annex I of the ITPGRFA, which are to be exempted from the applicability of access requirements under the BD Act. According to the notification, the specific activities exempted from the applicability of BD Act are

a. Obtaining Annex I plant genetic resources for the purpose of research, breeding and training – exempted from the applicability of section 3 of the BD Act

b. Transfer of results of research over Annex I plant genetic resources found in India by any person to any person/entity with a non-Indian element (persons/entities covered under section 3 as we have seen earlier in this chapter) – exempted from the applicability of section 4 of the BD Act

The notification further clarified that these exemptions would not be applicable when Annex I plant genetic resources are used for chemical, pharmaceutical and/or other non-food or feed industrial uses.

Following this, the DAC&FW under the Ministry of Agriculture had issued an office memorandum dated 16th February 2015 declaring that all the crops listed in Annex I are exempt from the application of sections 3 and 4 of the BD Act when used for research, breeding and training for food and agriculture. The DAC&FW further declared that the exempted crops would be governed by the 'Guidelines for the Implementation of ITPGRFA for Facilitated Access under the Multilateral System' issued by the Department vide office memorandum dated 30.07.2014. However, the introductory part of the Guidelines specifies that the facilitated access for Annex I plant genetic resources of the Treaty would currently

be available only towards 26563 identified accessions belonging to nine crops (barley, chickpea, finger millet, lentil, paddy, pearl millet, pigeon pea, sorghum and wheat). The Guidelines allow for further expansion of this list as and when warranted. Thus, currently, the multilateral system established in India covers only the 26563 specified accessions of Annex I crops as provided under the Guidelines. Considering the possibility of further inclusions that may be made by the DAC&FW towards the crops covered by facilitated access under MLS, the researchers are expected to check from time to time the presence of any other notifications in this regard issued by the MoEFCC as well as the Ministry of Agriculture.

The Special case of international collaborative research projects

Section 5 of the BD Act makes exception to certain types of collaborative research projects from the applicability of sections 3 (access for research, bio-survey and bio-utilization and commercial utilization) and 4 (transfer of results of research to persons and entities regulated under section 3) of the Act even though such projects involve transfer or exchange of biological resources or information associated with them. In order to be entitled for such exemption under section 5, a collaborative research project

a. Must be between institutions, including government sponsored institutions of India and such other institutions in other countries;
b. Should conform to the policy guidelines issued by the Central Government; and
c. Should be approved by the concerned Ministry in India.

Researchers must note that collaborative research projects exempted under the BD Act do not exclusively cover all types of collaborative research projects that are very common in the biotechnology research sector. The MoEFCC has issued guidelines for international collaborative research projects under section 5 of the BD Act. In order to claim exemption under this provision, the researchers should fill up the proforma for collaborative research projects at the time of writing the research proposal and obtain the approval of the concerned ministry in the formats prescribed on the NBA website. A copy of such approval must be sent to NBA in the required format as a proof that the research conforms to the policy guidelines issued by the MoEFCC.

The Guidelines for International Collaborative Research Projects involving transfer or exchange of biological resources or information is available at: http://nbaindia.org/uploaded/pdf/notification/7%20%20collaborative%20guidelines.pdf

The special case of sending or carrying biological resources outside India for non-commercial research or research for emergency purposes

Regulation 13 of the ABS Guidelines envisages two special situations where Indian researchers or Indian governmental institutions would have to carry or send biological resources occurring in India outside India for research purposes. The application shall be filed under Form B (Annex 7). The table below illustrates the conditions to be satisfied for this purpose:

Who can send	**Purposes allowed**
Government institutions only	Urgent studies to avert emergencies like epidemics
Government institutions and Indian researchers	Basic research other than collaborative research under section 5 of the BD Act

The BD Act {section 39(3)} requires that any person discovering a new taxon shall notify the repository concerned designated under the BD Act and deposit its voucher specimens in the concerned depository depending on the category of the newly discovered resource. This provision is applicable to all irrespective of whether they are regulated or not under the BD Act.

The International Bacteriological Code of Nomenclature, under Rules 27 and 30, requires mandatory deposition of novel microbial species in at least two Internationally recognized culture collections, one in the country of origin and the other in a foreign country for publication of a new taxon. Though not a statutory obligation under the Act, the NBA requires Indian scientists and researchers to give prior intimation of deposition under Form C (Annex 8) of new microorganisms isolated from India in the repositories located in other countries in support of their proposed publication in the journal.

Procedure for obtaining approvals from NBA for activities regulated under section 3[28]

For carrying out research or bio-survey and bio-utilization regulated under section 3 of the BD Act, the researchers falling within the scope of section 3(2) of the BD Act should file an application before NBA in Form I prescribed under the Biological Diversity Rules, 2004 along with an application fee of Rs. 10,000/-. NBA is mandated to decide the application within six months of the date of receipt of the application in consultation with the local bodies concerned. The successful processing of an application in time depends on the correctness and adequacy of the information furnished in the application or sought by NBA at any stage of processing the application. The approval granted by NBA would be in the form of an agreement. Though the approval granted by NBA would generally contain a benefit sharing component, there is no monetary benefit sharing obligation in respect of research or bio-survey and bio-utilization. This does not preclude the possibility of sharing non-monetary benefits with NBA.

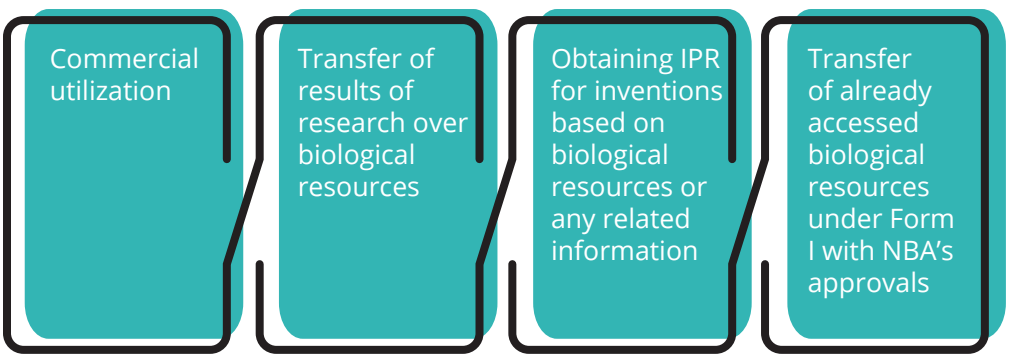
Concerned State Biodiversity Rules may be referred to verify regulation of access for the purpose of bio-survey and bio-utilisation for commercial utilisation and in such cases, the prescribed procedures need to be followed.

[28] Article 2 CBD23

Chapter 4

Regulated Activities Subsequent to Access

The BD Act stipulates a set of legal obligations related to some activities over biological resources accessed for undertaking research or bio-survey and bio-utilization. It was made clear in the last chapter that researchers would require separate approval for undertaking research despite the approval accorded for obtaining biological resources for bio-survey and bio-utilization. When there is a change of intent with respect to the use of the biological resources accessed for research, approval from NBA would be required. These types of obligations are imposed through MAT between the researcher and NBA necessitating strict adherence to such terms. Similarly, each of the activities subsequent to research regulated under the BD Act requires separate approval for legally carrying them out. The following are the activities subsequent to research regulated under the Act:



Except for commercial utilization, NBA would be the sole competent authority for according approvals for the above activities. This chapter focuses on the legal obligations related to each of the above activities.

Commercial utilization

Section 2(d) - bio-survey and bio-utilization means

End uses of biological resources for commercial utilization such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours, extracts and genes used for improving crops and livestock through genetic intervention, but does not include conventional breeding or traditional practices in use in any agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping.

Commercial utilization under the BD Act refers to end uses of biological resources for commercial utilization. The term "commercial utilization" that appears again in the definition seems to carry the common understanding of the term, i.e., commercial production aimed at sale in the market. Such commercial production may be for end uses of biological resources such as drugs, enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours, extracts, etc., or genetic improvement of crops and livestock. Thus, commercial utilization could mean commercial production of end use products using biological resources and it also extends to genetic improvement done in plants and animals with a commercial motive (The end uses also include genetically improved crops and livestock). The two exceptions provided in the definition, viz., conventional breeding and traditional practices, broadly relate to different agricultural and farming activities alone while the Act does not define them. The genetic improvement in crops and livestock through conventional breeding will not amount to commercial utilization irrespective of the legal status of the person engaged in such activity. The term "conventional breeding" has proved to be confusing for many of the researchers of the agricultural sector as they employ genetic intervention techniques over biological resources in the breeding process and later multiply such new varieties using conventional breeding methods popular in the sector. In such cases, the multiplication process intended for commercial production even if done with conventional breeding techniques would not be considered as an exemption. A differentiation between breeding and multiplication for commercial production needs to be made while assessing the applicability of the ABS obligations for commercial utilization vis-à-vis conventional breeding. Similarly, traditional

practices in use in any agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping are also exempted from the definition of commercial utilization.

Primary considerations in determining commercial utilization

(i) Whether the intended activity involves the use of a "biological resource"?
(ii) Whether the intended activity is aimed at commercial production of end products such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours, extracts and crops or livestock improved through genetic intervention.

There are four possibilities under the BD Act for a person/entity to engage in commercial utilization.

i. Engage directly in commercial utilization
ii. Engage in commercial utilization subsequent to research
iii. Engage in commercial utilization subsequent to obtaining IPR after research
iv. Engage in commercial utilization subsequent to bio-survey and bio-utilization for commercial utilization

All these contexts would require different approvals under the BD Act. This pre-supposes that required permission for research or bio-survey and bio-utilization for commercial utilization has been obtained by the person/entity intending to do commercial utilization. In this handbook, we consider commercial utilization as an activity a researcher might intend to do during or after the completion of his/her/its research. However, the procedures elaborated below are equally applicable to the other three contexts of commercial utilization.

The competent regulatory authority for commercial utilization varies depending upon the legal status of the person/entity engaged in commercial utilization. NBA would act as the regulatory authority for persons/entities specified in section 3(2) of the BD Act, viz., non-Indians, non-resident Indians and entities with non-Indian participation in share capital or management.

Approval for commercial utilization from NBA

The detailed procedures for obtaining biological resources for commercial utilization are similar to access procedures in respect of research as explained in Chapter 3 and are provided under Rule 14 of the Biological Diversity Rules, 2004. A person/entity covered under section 3(2) of the BD Act intending to access biological resources for commercial utilization should make an application in Form I prescribed by the Biological Diversity Rules along with an application fee of INR. 10,000/-. The processing and disposal of application for commercial utilization of biological resources and associated knowledge would be considered by NBA in the same manner in respect of an application for research. NBA, on receipt of an application for commercial utilization, is required to dispose it off, in consultation with the local bodies concerned, within six months from the date of receipt. However, the pendency of an application beyond this timeframe may result from an incomplete application or the delay from the applicant to furnish additional documents or information required by NBA in time. The delay in generating MAT for the approval, which includes the benefit sharing component could also affect the early disposal of the application within six months from the date of its receipt by the NBA.

Approval for commercial utilization from SBBs

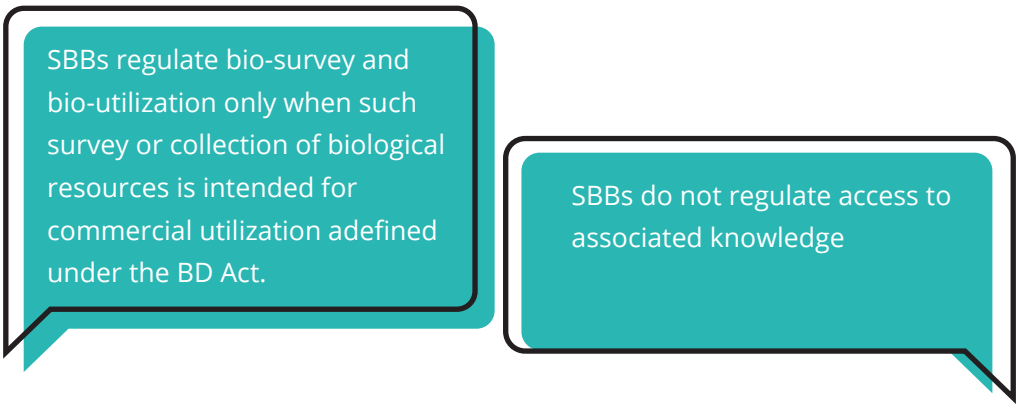
Section 7 of the BD Act provides that prior intimation to the concerned SBB is required for accessing biological resources for commercial utilization or bio-survey and bio-utilization for commercial utilization when undertaken by

a. Indian citizens; and
b. Body corporates or associations or organizations registered in India without non-Indian participation in share capital or management

Section 7 exempts from its applicability, the local people and communities within the jurisdiction of SBBs concerned, when they access biological resources for the

regulated activities. Such communities may include growers and cultivators of biodiversity and vaids and hakims who have been practicing indigenous medicines. However, if they access biological resources establishing a body corporate or association, the exemption would not be available for such bodies.

Since Indian entities with non-Indian participation must apply before NBA, the Indian entities without any non-Indian participation in share capital or management need to apply before the SBB concerned. The jurisdiction of the SBB is determined based on the area from where a person is planning to access the biological resource. If the resources are purchased from the market, the researcher is expected to put reasonable efforts to identify the State where the biological resource is naturally grown and approach the SBB concerned to comply with the ABS obligations. Under the BD Act, research is not a regulated activity for Indian entities without any non-Indian participation in share capital or management.



Benefit Sharing Obligations for Commercial Utilization

The ABS Guidelines envisage benefit sharing obligations for different actors in the supply chain of biological resources. When the applicant accesses biological resources from a trader or manufacturer of biological resources (for example, manufacturer of an extract), the Form I application for commercial utilization or bio-survey and bio-utilization (before NBA) shall be accompanied by Form 'A' provided under the ABS Guidelines. Form 'A' is a self-disclosure Form to be signed by the person/entity from whom the applicant would be accessing the biological resources. Such person/entity could be a trader or a company or a manufacturer who might operate at different levels in the supply chain. Form 'A' requires

disclosure by the concerned intermediary of the common and scientific names of the biological resources to be accessed, the parts of the biological resources, which are traded, the purpose for which the resources are traded, the source/ location (including the details of local bodies/BMCs, if available) of procurement by the intermediary concerned, quantity available with the intermediary, the SBB whose jurisdiction is applicable in respect of the biological resources and the prospective buyers of the biological resources. The applications made before the SBB must be in the formats prescribed by the State Biodiversity Rules concerned. The ABS Guidelines stipulate specific benefit sharing obligations for these types of intermediary actors in the supply chain. The procedural and benefit sharing obligations in this regard are equally pertinent for the applications before the NBA and the SBBs for commercial utilization or bio-survey and bio-utilization for commercial utilization.

Monetary Benefit Sharing Obligations for Commercial Utilization/ Bio-survey and Bio-utilization for Commercial Utilization

Benefit sharing obligations when purchased from intermediaries

An applicant intending to assess the biological resources for commercial utilization or bio-survey and bio-utilization for commercial utilization may purchase the same from the intermediaries. In such cases, the intermediaries concerned may or may not enter into benefit sharing negotiations with the different types of local people (joint forest management committees, forest dwellers, tribal cultivators, gram sabha, etc.) from whom they directly purchase the biological resources. The ABS Guidelines envisage different monetary benefit obligations as given in the table below for the applicant as well as the intermediaries in the value chain in respect of the biological resources purchased from the local people:

Person/ entity to share benefits	Context	Competent authority	Monetary benefit sharing component
Trader	Direct purchase of biological resources from local people without prior benefit sharing negotiations	NBA/SBB	1.0 – 3.0 percent of purchase price

Person/ entity to share benefits	Context	Competent authority	Monetary benefit sharing component
Manufacturer	Direct purchase of biological resources from local people without prior benefit sharing negotiations	NBA/SBB	3.0 – 5.0 percent of purchase price
Subsequent trader	Purchase from the first trader who directly purchased the biological resources from local people without benefit sharing negotiations	NBA/SBB	1.0 - 3.0 percent of the purchase price (upon proof of benefit sharing with immediate seller, buyer need to pay only the percentage amount corresponding to the difference)
Subsequent manufacturer	Purchase from the first trader who directly purchased the resources from local people without benefit sharing negotiations	NBA/SBB	3.0 – 5.0 percent of purchase price (upon proof of benefit sharing with immediate seller, buyer need to pay only the percentage amount corresponding to the difference)
Applicant	Purchase from trader who has negotiated prior benefit sharing with the local people	NBA/SBB	Not less than 3% of the purchase price
	Purchase from manufacturer who has negotiated prior benefit sharing with the local people	NBA/SBB	Not less than 5% of the purchase price

The ABS Guidelines under regulation 4 provides an alternative option to the applicant for commercial utilization/ bio-survey and bio-utilization for commercial utilization to pay benefit sharing ranging from 0.1 to 0.5 percent of the annual ex-factory sale (annual gross ex-factory sale minus government taxes) of the product out of commercial utilization in a graded manner as follows:

Annual gross ex-factory sale of the product	Benefit sharing component
Up to rupees 1,00,00,000	0.1%
Rupees 1,00,00,001 - 3,00,00,000	0.2%
Above rupees 3,00,00,000	0.5%

When an applicant accesses biological resources with high economic value (sandal wood, red sanders, etc.) or their derivatives, NBA/SBB may demand an upfront payment of not less than 5% on the auction or sale amount.

Transfer of Results of Research

Researchers may transfer the results of their research over biological resources to others with or without any compensation in return. The transfer of the results of any research relating to any biological resources found in the territory of India or obtained from India by any person to a person or entity covered under section 3(2) is regulated by NBA under section 4 of the BD Act. In short, the transferor may be any person including Indians, non-Indians, non-resident Indians, and all types of entities irrespective of the non-Indian element in share capital or management whereas the transfer must be to a non-Indian, non-resident Indian, non-Indian entity or Indian entity with non-Indian participation in share capital or management covered under section 3(2). It may be noted that if the transfer is to an Indian or an Indian entity regulated by section 7, no permission is required. Prior approval from NBA is mandatory for transferring the results of research to a section 3(2) entity irrespective of any monetary benefits that may or may not accrue to the person transferring the result. However, NBA's regulatory approval is not required for

(i) transferring results of research emerging from collaborative research projects conforming to the provisions of section 5 of the BD Act; and
(ii) transferring results of research related to the specified accessions of the nine crops notified by the DAC&FW belonging to Annex I of the ITPGRFA. (Exception will not be applicable, if these biological resources are used for chemical, pharmaceutical, non-food/feed purposes).

The BD Act further provides that the scope of transfer under section 4 would not include publication of research papers as per the guidelines issued by the central government or dissemination of knowledge in any seminar or workshop. The Central Government has not issued any guidelines in this regard till date under the BD Act and hence, the existing practice is to exempt publication of research papers from the scope of transfer of research results. However, the efforts are on for framing the guidelines.

The transfer of research results may sometimes involve transfer of biological resources as such. In some cases, transfer of the research results would be equivalent to transfer of the biological resources as such. Publication of gene sequence in a journal or deposition of the gene sequence data in a repository as a requirement for publication is equivalent to facilitating indirect or virtual access to biological resources. It would be ethical as well as advisable in such cases to consult NBA on such aspects before carrying out such transfer. The discussions in the previous chapter regarding the special case of international collaborative research projects are also relevant under this head.

Procedure for transferring the results of research is provided under rule 17 of the Biological Diversity Rules, 2004 and regulation 6 of the ABS Guidelines. Any person intending to transfer the results of research relating to biological resources found in the territory of India or obtained from India shall apply in Form II under the BD Rules along with an application fee of Rs. 5,000/- (Rupees five thousand). Where applicants are persons or entities covered under section 3(2) of the BD Act, evidence must be submitted to the effect that biological resources used for research have been accessed with prior approval from NBA under section 3 of the BD Act. The applicants must also provide complete information on the potential commercial value of the results of the research as known to them. NBA must dispose off such applications within a period of three months from the date of receipt of the application. Prior approval from NBA would be in the form of an

agreement which would specify among other terms, a mutually agreed benefit sharing component in respect of the transfer.

For transferring the result of research, the applicant is required to pay the monetary and/or non-monetary benefits to the National Biodiversity Fund as mutually agreed between him/her and the NBA. In the event of any monetary benefits received by the applicant for such transfer, 3.0 to 5.0 percent of such monetary consideration shall be shared with NBA (Reg. 7).

Obtaining IPR for Inventions Based on Biological Resources or any Related Information

Obtaining IPR for products or processes emerging from research over biological resources is very common among researchers and the BD Act seeks to regulate this activity under section 6, by way of requiring prior approval from NBA and levy of benefit sharing obligations. Before applying for IPR for inventions using biological resources or any information associated therewith, the researchers should be aware that

1. The obligation to take prior approval from NBA to obtain IPR is applicable equally to persons and entities covered under section 3 and section 7. Exemption granted to local people and vaids and hakims under section 7 for carrying out commercial utilization or bio-survey and bio-utilization for commercial utilization will not extend to obtaining of IPR under section
2. The obligation to take prior approval from NBA is applicable in respect of inventions based on any research or information on a biological resource obtained from India. The current practice limits the applicability of this obligation to patents and plant varieties. Information on a biological resource could be scientific information or traditional associated knowledge.

3. The obligation to take prior approval from NBA for obtaining patents is equally applicable for patents sought within and outside India.
4. The obligation to take prior approval for securing breeders' rights (protection of plant varieties) is applicable only when sought outside India. Prior approval is not required when protection is sought under the law relating to protection of plant varieties enacted by the Indian Parliament.
5. Under the strict language of law, researchers should obtain prior permission from NBA for assessing the biological resources even before seeking patent protection within and outside India and plant variety protection outside India.

However, in the case of patents, the Act provides that prior approval needs to be obtained any time before the grant of patents. This is a way to ensure that the priority of the applicants for their patent application is not lost on account of this regulatory requirement. It is important to note that this exemption is not available for obtaining plant variety protection outside India.

Application for prior approval to obtain IPR must be filed in Form III prescribed under the BD Rules, 2004 and accompanied by a fee of Rs. 500/- (Rupees five hundred). When a Form III application is filed by a person or entity under section 3(2) of the BD Act, the applicant should submit evidence of prior approval for accessing biological resources and/or associated knowledge specified in Form III (regulation 8 of ABS Guidelines). An application filed for the grant of prior approval from NBA for obtaining IPR needs to be disposed within 90 days from the date of receipt of such application.

The benefit sharing obligations in respect of Form III applications for obtaining IPR arise when the IPR obtained is commercialized and monetary or non-monetary benefits or both as mutually agreed are payable to the NBA. When the applicant himself commercializes the process/ product/innovation, the monetary benefit sharing component shall be in the range of 0.2 to 1.0% of the annual gross ex-factory sale price minus government taxes. When the IPR is being commercialized by a third-party, the benefit sharing component shall be in the range of 3.0 to 5.0% of the fee received (licensing/assignment) and in the range of 2.0 to 5.0% of the royalty amount received annually from the licensee/assignee. (regulation 9 of ABS Guidelines).

The ABS Regulations impose further obligations on Form III applicants in the event of commercialization of IPR. For persons and entities within the scope of section 7, the Regulations stipulate that prior intimation needs to be given to the concerned SBB(s) if further access to the biological resources is required for commercialization of IPR. In short, for non-section 3(2) entities commercialization of IPR requiring further access to biological resources would warrant prior intimation/completion of procedural requirements of the concerned SBB(s). Similarly, for section 3(2) entities, if further access to biological resources is required for commercialization of the IPR received, an application in Form I under section 3 of the Act would be required for approval prior to the access to biological resources (regulation 10 of ABS Guidelines).

Transfer of Already Accessed Biological Resources under Form I with NBA's Approval

Section 20 of the BD Act describes the obligations in the event of third-party transfer of the biological resources accessed in accordance with section 3 of the BD Act for any of the three regulated activities. The applicability of this section is confined to section 3(2) persons/entities who have accessed biological resources following NBA's approval for research or bio-survey and bio-utilization or commercial utilization. This provision is not applicable to non-section 3(2) entities. Prior approval of NBA is required for transferring the accessed biological resources to any person or entity who is not a party to the mutually agreed terms (the approval) including transfer to a person/entity not falling within the purview of section 3(2). A person or entity intending to do such transfer to a third party for research or commercial utilization shall apply to NBA in Form IV prescribed by the BD Rules, 2004 along with a fee of rupees ten thousand (Regulation 11 of ABS Guidelines). NBA would take decision on the matter in due consultation with the expert committee on ABS. If the biological resources are intended to be transferred to a section 3(2) person/entity for research, commercial utilization or bio-survey and bio-utilization, such transferee should obtain approval from NBA for obtaining the biological resources under section 3 of the Act.

The applicant shall share with NBA such benefits mutually agreed between NBA and the applicant in respect of the third-party transfer of biological resources. Throughout the term of the third-party transfer agreement with NBA, the applicant is required to pay, based on a sectoral approach, any amount and/or royalty received from the transferee in the range of 2.0 % to 5.0%. NBA would impose upfront payment as mutually agreed with the applicant for transfer of biological resources with high economic value (Regulation 12 ABS Guidelines).

Processing of Applications by NBA (Regulation 16 of ABS Regulations)

Applications filed before the NBA shall be complete and the statutory processing time specified in respect of applications under different forms would start only from the date of receipt of the application with complete information. NBA maintains the confidentiality of all the data submitted along with the application. With respect to Form I applications, NBA would consider whether the biological resource is

- cultivated or domesticated or wild;
- rare or endemic or endangered or threatened species;
- accessed directly through the primary collectors living in natural habitat or obtained through intermediaries like traders;
- developed or maintained under ex situ conditions;
- of high value/ importance to livelihoods of local communities;
- restricted under the Act or any other law for time being in force;
- exempted under section 40 of the Act;
- included in the crops listed under Annex I to the ITPGRFA, to which India is a contracting Party;
- included in the Appendices of the Convention on International Trade on Endangered Species (CITES).

The decision of NBA on Form I and Form IV applications would be always in consultation with SBBs and BMCs within whose jurisdiction the biological resources or the associated knowledge or both referred to in the applications, are found.
On receipt of applications under Form I to Form IV and Form B, after enquiries and in consultation with the SBBs and local bodies concerned, and also wherever required, in consultation with the expert committee on ABS, NBA would either approve or reject an application. When an application is rejected, the reasons for rejection would be recorded in writing after providing the applicant an opportunity of being heard.

Approval granted by the NBA would be in the form of written agreement duly signed by an authorised officer of the NBA, the applicant and others, as applicable. However, the approval granted for the purposes of conducting non-commercial research or research for emergency purposes outside India by Indian researchers/ Government institutions under Regulation 13 will be effected without any written agreement.

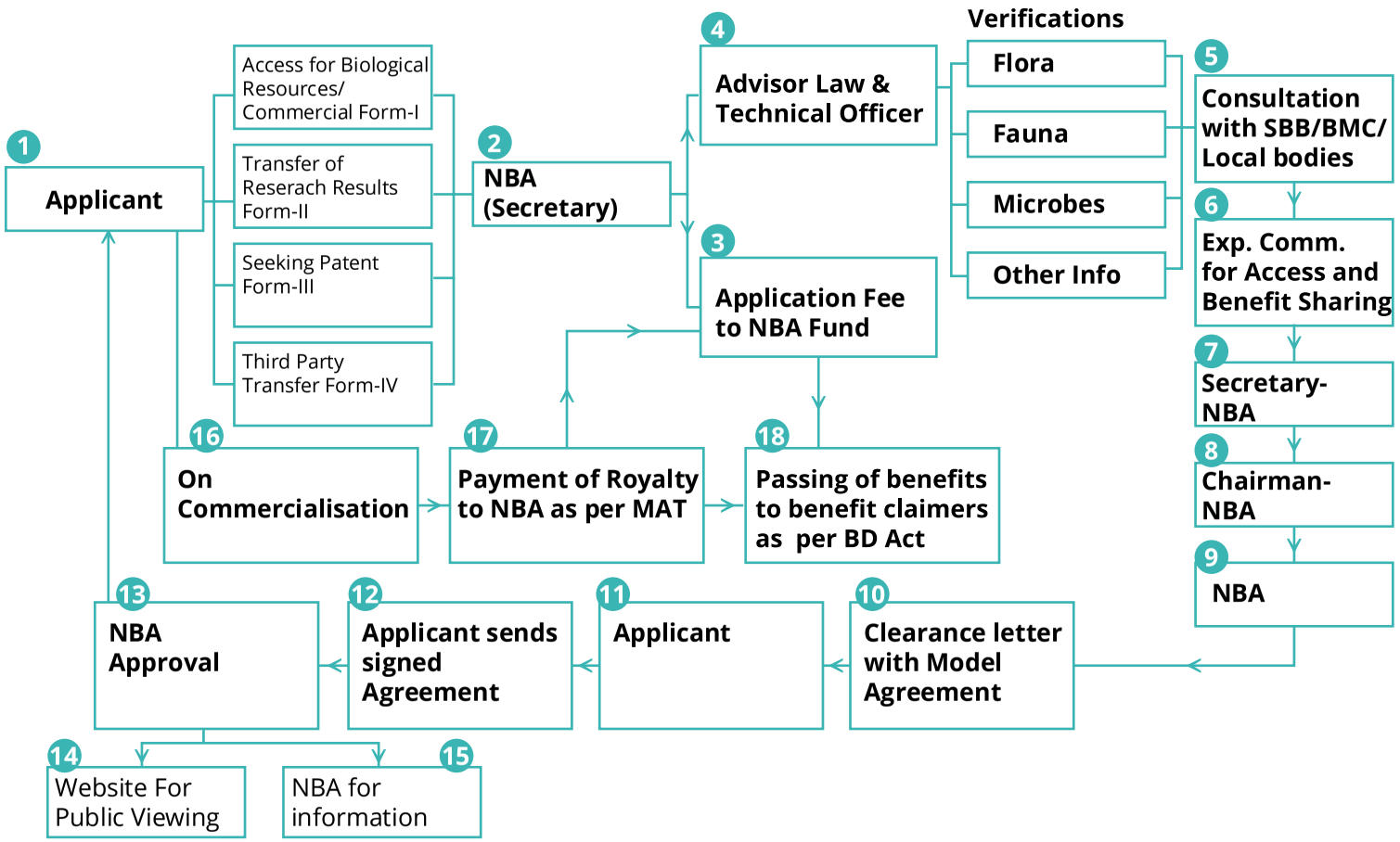
Grounds for Rejection of Application for Access[29]

Access requests related to biological resources would be rejected by NBA if

a. the request for access is for any endangered taxa;
b. the request for access is for any endemic and rare species;
c. the request for access may likely to result in adverse effect on the livelihoods of the local people;
d. the request to access may result in adverse environmental impact which may be difficult to control and mitigate;
e. the request for access may cause genetic erosion or affecting the ecosystem function;
f. use of resources for purposes contrary to national interest and other related international agreements entered into by India.

[26] Rule 16, BD Rules

Schematic Presentation of Processing of Applications under Biological DIversity Act, 2002 and Rules 2004



Grounds for Revocation of Access[30]

Based on any complaint or on its own volition, NBA may withdraw the approval granted for access by revoking the written agreement entered with the applicant based on any of the following grounds:

a. that there is a reasonable case to believe that the person/entity to whom access was granted has violated any of the provisions of the Act or the condition on which the approval was granted;
b. that the person who has been granted approval has failed to comply with the terms of the agreement;
c. on failure to comply with any of the conditions of access granted;
d. n account of overriding public interest or for protection of environment and conservation of biological diversity.
e. A copy of the revocation order would be sent to the concerned SBB(s) and the BMC(s) for prohibition of access. Along with this, the SBB or BMC concerned may be directed to assess the damage, if any, caused due to the access based on which steps could be taken to recover such damage.

Withdrawal of Application[31]

An applicant could request NBA for withdrawal of his application any time after filing but before the grant of approval and in such cases, NBA would close the application. After filing an application, when the applicant fails to respond to the queries of NBA within a stipulated time, such application would be deemed to have been withdrawn and the NBA would initiate steps to close such application. In any of the cases above where the application is withdrawn, the applicant might revive the application by making a fresh application along with the requisite fee.

[30] Rule 15, BD Rules
[31] Reg.16(12), ABS Guidelines 2014

Redressal of Grievances on Account of Benefit Sharing Determination by NBA/SBB (Section 52A of the BD Act)

A person aggrieved by the determination of benefit sharing order or any other order by the NBA/SBB under the BD Act could prefer an appeal to the National Green Tribunal (NGT) in accordance with the provisions of the National Green Tribunal Act, 2010. The applicants or the BMCs and/or local bodies concerned or any individual or group of individuals or community could file appeals under this section. The benefit sharing determination or other orders of NBA/SBBs and the decision of the NGT in any appeal as specified above are executable as decrees of a civil court.

Offences and Sanctions under the BD Act

Offences under the BD Act can be classified into (i) Offences specifically mentioned under section 55 of the BD Act; and (ii) Contraventions of orders/directions made by the Central Government/State Governments or NBA/SBBs (other offences) mentioned under section 56 of the BD Act.

Offences and Sanctions under Section 55 of the BD Act

Whoever contravenes or attempts to contravene or abets the contravention of the provisions of sections 3, 4, 6 and 7 or an order made under section 24(2) of the BD Act shall be liable for criminal sanctions under section 55 of the BD Act. In respect of the activities regulated by NBA under section 3, 4 and 6, the Act prescribes punishment with imprisonment for a term, which may extend up to five years or fine, which may extend to rupees ten lakh or with both. When the damage caused exceeds rupees ten lakh, the fine would be commensurate with the extent of damage caused. For offences related to section 7 and any order made under section 24(2) (prohibition or restriction by SBB of any activity contrary or detrimental to the objectives of the BD Act), the BD Act provides for punishment of imprisonment that may extend to three years or fine which may extend up to rupees five lakh or with both.

Other Offences (section 56)

Contravention of any direction or order made by the Central Government, the State Government, NBA, or the SBBs for which no punishment has been separately provided by the BD Act is punishable with fine that may extend to one lakh rupees for first time offenders, and rupees two lakh for second and subsequent offenders. In case of continuous contraventions, the court can impose additional fine up to rupees two lakh every day during which the default continues.

The offences under Section 56 of the BD Act are

a. non-bailable (bail cannot be claimed as a matter of right and the authorized person/police cannot release the accused on bail. Need to apply for bail before the court);
b. Cognizable (A police officer/the authorized person has the authority to arrest the accused without warrant); and
c. Actionable in a court of law only upon a complaint made by: -
d. The Central Government or any authority or officer authorized in this behalf by that Government; OR
e. Any benefit claimer (before approaching the court, such benefit claimers should give thirty days' notice to the Central Government or any of its authorized officers regarding the offence and the intention to make a complaint)

Application forms for access to biological resources or associated knowledge or both, guidelines for filling them and form of agreements, are available on the NBA's website: www.nbaindia.org

Step by Step Procedure for Users Intending to Access Biological Resources/ Associated Knowledge for Research in India

This section aims to explain to the targeted stakeholders, the steps that must be taken while accessing biological resources for research purposes. This offers basic information of the stages of the process and appropriate instructions for action. However, since each case involving access to biological resource and/or associated knowledge is different, the suggested steps may have to be customized to each specific research situation.

The targeted stakeholders should note that failure to comply with the provisions of the BD Act and the Rules, Regulations and Guidelines and the notifications issued under it would result in repercussions on their research and development and would lead to legal obstacles. The procedures for obtaining an approval from the NBA may initially appear as an additional burden for research projects. However, if the procedures are understood well, the researchers may opt for filing online applications for necessary approvals at NBA's website.

Thus, the step by step procedural requirements under ABS mechanism elaborated below may be considered by the researchers intending to use biological resources for their research.

Step-by-Step Procedural Requirements under ABS Mechanism

Stages	Step by Step Procedure	Things to Do	Useful Tips
Planning	✓ Check whether the research you intend to undertake is subject to benefit sharing under the BD Act? ✓ Check whether you/your institution/ company is within the regulated ambit of the BD Act? ✓ Check which authority you are required to intimate/ get the prior approval from ✓ Make a schedule of timelines for obtaining prior approval for access from the concerned authority	✓ Check whether the research to be undertaken is covered under section 2(m) of the BD Act ✓ Check whether the research is covered within the scope of "collaborative research" as envisaged under section 5 of the BD Act ✓ Check the Biological Diversity Rules, 2004, the concerned State Biodiversity Rules and the ABS Regulations to find out the authority which will regulate your activity.	✓ Go through the access procedures and other requirements as laid down in the BD Act, Rules, ABS Guidelines ✓ If you are an Indian or Indian entity and have an option regarding accessing the biological resource from more than one state, choose a SBB in which you have already established contact with the authorities and the Board which has a track record of facilitating access within a reasonable timeline.

Stages	Step by Step Procedure	Things to Do	Useful Tips
Preparation	✓ Contact a knowledgeable person who has adequate knowledge about the working of access and benefit sharing regime for advice on applicability of the provisions of the BD Act on your research and on you/your company/ institution ✓ Contact the concerned authority – either the National Biodiversity Authority or the concerned State Biodiversity Board to confirm the applicability of the provisions of the BD Act on your research and on you/your company/ institution. ✓ If there is no response, contact the National Focal Point on ABS ✓ Apply for seeking prior approval: submit the necessary information to the competent authority and	✓ Check if you need to get approval from any other authority for access to the said resources/associated knowledge ✓ Cost of application processing fee must be borne by the applicant ✓ Check if your research partners are also legally bound by the requirements for access under the law and if yes, have they complied with the requirements	✓ Apply for access as early as possible ✓ The process may be time consuming; follow up with the concerned Authority and negotiate deadlines for completing the procedure ✓ Do not presume that the activity falls outside the scope of the BD Act since the scope of research under the BD Act is broad. ✓ Always cross check with the concerned authorities and/or legal persons

Stages	Step by Step Procedure	Things to Do	Useful Tips
Approval process	✓ After getting the clearance letter from the Authority regarding approval, check whether the proposed terms in the form of an Access and Benefit Sharing agreement are to your satisfaction ✓ If not, start negotiating benefit sharing and agree to a final amount agreeable to both the parties ✓ Adhere to the agreed terms of research proposed, if not, inform the concerned Authority again and renegotiate benefit sharing, if necessary	✓ Respect and follow any restrictions or limitations imposed by the Authority on the access requirements	

Stages	Step by Step Procedure	Things to Do	Useful Tips
Post approval obligations	✓ All further research activities should be covered within the scope of the ABS Agreement. If not, the same should be informed to the concerned Authority ✓ In case there is a change of intent, i.e., if the research transforms into: • A commercial activity falling within the scope of commercial utilization (defined under section 2(f) of the Act) • If there is an intention to transfer the results of research to a section 3(2) entity • If there is an intention to obtain a patent/ plant variety protection over the results of research • If the accessed resources obtained are intended to be transferred to a third party Inform the Authority concerned immediately for revision of the agreement conditions	✓ Submit a status report annually as required under the ABS agreement ✓ Ensure that all the information and facts given to the Authority are true and verified ✓ Ensure that the required approvals are obtained in case of change of intent or for carrying out other regulated activities subsequent to access	

Common Myths About Research Under the ABS System

Sl. No	Common myths	Reality under law
1.	BD Act is an Act to prevent biopiracy by foreigners	Preventing biopiracy is one of the objectives of the BD Act. The core objectives of the Act are conservation of biological resources, sustainable use of its components and fair and equitable sharing of benefits arising out of such use. The BD Act has provisions that are applicable to both Indians as well as persons who are not a citizen of India. On similar lines, there are different provisions for a company that is Indian or that has any non-Indian participation in its share capital or management.
2.	Research is not regulated under BD Act	Research on biological resources and associated knowledge obtained or occurring from India is regulated in India
3.	Approval can be obtained at any stage of access and usage of biological resources	"Prior approval" is mandatory for doing an activity regulated under the BD Act.
4.	Approval for one activity is an approval for all subsequent activities	Separate approval would be required in respect of each type of regulated activity on the biological resources.
5.	Any and all activities done for research undertaken by Indian/ Indian entities {non-section 3(2)} with the biological resources / associated knowledge are exempted	Research is exempted for Indians/Indian entities under the BD Act. However, if an Indian/ Indian entity carries BR outside India for non-commercial research or research for emergency purposes, then a prior approval has to be procured under Form 'B' from NBA
6.	Only commercial research is regulated and academic/non-commercial research are exempted	BD Act does not distinguish between commercial and non-commercial research.

7.	BD Act discourages research and development	BD Act does not restrict research activities. It only regulates research on BR and or AK so that there is no exploitation. Further, BD Act aims to pay back a fair and equitable share of benefits derived from commercial use to the local people or community who deserve to be rewarded for their efforts and knowledge.
8.	There is no need to obtain prior approval for a research activities, if done outside India	If the biological resource intended for use is originating from India, irrespective of where the research is conducted, prior approval would be required even if sourced from locations other than India.
9.	All collaborative research projects are exempted under the BD Act	Only the collaborative research projects that fulfill all the requirements of section 5 of the BD Act will be exempted and not all projects which are executed through collaborations.
10.	Research on biological resources that are widely available are not regulated	BD Act does not make any classification between widely available resources and scarcely available resources when it comes to regulating activities on biological resources. Research on any biological resource occurring in India is regulated for the section 3(2) persons/entities.
11.	Research that aids conservation and sustainability of the BR is exempted	Research conducted on any biological resources occurring in India is regulated under the BD Act, irrespective of whether the research is beneficial for conservation and sustainability of biological resources.
12.	Research done by government bodies are exempted	The research by government bodies are exempted only in cases where the persons involved in research are Indians/Indian entities. If the Government institution or body sponsors a non-Indian person or entity or collaborates with a non-Indian entity, it is still regulated under the BD Act
13.	Research if done by a non-Indian person/entity through an Indian acting as an agent in India is exempted	Research done by a section 3(2) persons/ entities whether directly or indirectly is regulated under the BD Act. A non-Indian entity/person will not be exempted just because an Indian is involved.
14.	If the research is done with a biological resource that was obtained from India prior to BD Act and Rules, it is exempted	If the research continues after the commencement of the BD Act, approval needs to be procured for the continued activity although the access of the biological resource is done prior to 2004 when the BD Rules came into place.

Practical Exercises for Better Understanding

Use the checklist provided in Annex I to answer the questions.

Case Study I - Research from biological resources obtained from India

ABC International Inc., is a multinational company with its wholly owned subsidiary, ABS India Ltd., registered in Mumbai, India under the Companies Act of India. ABC International Inc., is a world-renowned cosmetic company that develops, manufactures and markets herbal based cosmetics utilizing the biological resources from various countries across the globe including India. Currently, the research team of ABS India Ltd., found that Waltheria indica has properties of removing tan from the outer layer of skin. In furtherance to this, extract of W. indica is produced. Appreciating the efforts, ABC International Inc., decided to establish a high-class laboratory at the ABS India Ltd., and is ready to invest $1 million on research for developing a fairness cream from W. indica collected from Madhya Pradesh. ABS International is unaware of legal requirements in India and approaches you for expert advice.

Under these circumstances, consider the following questions:

a. Do you think ABC International Inc., needs to obtain approval under the BD Act, 2002 considering it is going to access only extracts and not the biological resources per se?
b. Can ABC International Inc., obtain approval through its wholly owned subsidiary – ABS India Ltd., since the resources are accessed through the subsidiary?
c. Should ABS India Ltd., obtain prior approval from the concerned State Biodiversity Board since the biological resources have been accessed locally and its research lab is set up there? If so, which SBB should it approach?
d. Can ABS India Ltd., transfer the research results to its parent company ABS International Inc., without requiring any approval considering that it is transferring the results of its research – i.e., to its own parent company? State reasons.

Case Study II – Traditional/associated knowledge

KLM is a trust established under the Indian Trusts Act, 1882. It is a non-profit organisation focused on making ayurveda, appropriately integrated with modern medicine, the treatment of choice for select chronic diseases and non-communicable diseases. This is a sister organisation of KLM Research and Development Labs India Ltd (KLM Ltd) incorporated and registered in India. CDF Ltd, a leading pharmaceutical company in Germany sponsored the research study of KLM Ltd., to undertake a study on the effects of traditional ayurveda interventions on greasy mild acne prone skin. One of the conditions of the sponsorer was that the research results should be transferred to CDF on the completion of study. During the study, it was discovered by KLM Ltd., that there is a medicinal paste – Thaila made from selected plants having medicinal properties, mentioned in ayurveda texts references, that has been used to make an external facial application. This could be used in developing an advanced acne ointment for long term relief from acne prone skin.

Under these circumstances, consider the following questions:

a. Do you think KLM being an Indian trust started for conducting a non-commercial activity needs to obtain approval under the BD Act, 2002?
b. Is it permitted for KLM to access the knowledge available in the ayurveda texts and conduct research?
c. Should KLM obtain approval for transferring results of research to CDF Ltd., considering that it is being fully sponsored for the study and the results will not be jointly owned by KLM after the completion of study?
d. Should CDF Ltd., obtain prior approval under the BD Act, 2002 for procuring the results of research from KLM?

Case Study III – Commercial utilisation

ABC Pvt. Ltd., is a private company registered under the Companies Act in India with its manufacturing unit in Chennai. It does not have any foreign participation and is an Indian company. It is involved in manufacturing, supplying and exporting of seafood products such as fish meal, dry fish, fish oil, squid liver powder and squid liver paste. All their products are used only for animal or poultry feed. The company has been traditionally engaging in fishing and processing of fishes for the past 45 years and has grown from a small-scale company to an export company over the years. The company is of the opinion that they do not require permission for accessing fishes and manufacturing the products since it is exempted under traditional practices in use. Further the company claims that even if they are regulated, they are not obligated to pay benefits since they are already sharing benefits to the community by creating employment and providing social services/benefits to villagers.

Under these circumstances, consider the following questions.

a. Is the activity carried out by ABC company regulated under the BD Act, 2002?
b. If yes, who is the concerned authority that regulates it and under which provisions of the BD Act should the company apply?
c. What is your opinion on the exemption claimed by the company under traditional practices in use?
d. Do you think since the company is already sharing a lot of benefits to the community, they must be exempted from the benefit sharing mechanism under the BD Act?

Case Study IV – Transfer of research results and IPR

PQR is a public limited company incorporated in India having foreign shareholding in its share capital. The company obtained the culture from a government institution, collected from the backwaters in Kerala. The company received a grant for research from a government research institution in India under a 'Technology Initiative Scheme'. Under this, the company intends to conduct research and isolate useful strains. Subsequently, the company wants to transfer the isolated strain and the research results to a foreign company STU Inc., incorporated in Italy for further research and product development and also for obtaining a joint patent outside India in the future.

Under these circumstances, answer the following questions:

a. Do you think PQR Ltd., should obtain approval for collecting backwaters under the BD Act, 2002? If so, from which authority and under which provisions?
b. Should PQR Ltd., take approval to transfer the results of research to STU Inc., under the BD Act, 2002? If so, from which authority and under which provisions?
c. Should STU Inc., obtain approval for obtaining the research results from PQR Ltd., and then go for a product development?
d. Should PQR Ltd., and/or STU Inc., obtain prior approval under the BD Act, 2002 for obtaining patents outside India?
e. Assuming that PQR Ltd., requires approval to conduct research and to transfer the research results, should PQR Ltd., obtain two separate approvals and sign two different ABS agreements?
f. PQR company argues that considering that the resources were obtained from wild and it's a resource available in abundance, no approval is required under the BD Act? What would your advice be for PQR Ltd?

Case study V – Form B – Sending biological resources outside India for emergency purpose or otherwise

"X", an Indian citizen, is a research associate from a leading research institute in Bangalore, who completed his doctoral studies on centipede biogeography. Getting to know his work, the Royal Society, London offers to fund a study on centipede specimens at the Natural History Museum, London. "X" will be working under one Professor. "Y" at the Royal Society London. For this purpose, "X" is required to take dead specimens of centipedes within a limited time period of two months.

Under these circumstances, answer the following questions:

a. Is 'X' restricted/regulated under any of the provisions of the BD Act, 2002 and its related laws/regulations? If yes, what is the procedure?
b. Can 'X' send the specimens outside India without prior permission since the specimen is dead?
c. Are there any legal obligations for Prof. 'Y' under the BD Act, 2002?
d. Should 'X' obtain prior approval to transfer the biological resources under Form IV? State reasons.

Case VI – Export of biological resources

'XYZ' is a non-profit research organisation in India that has a collaborative research project called "DTMP- drought tolerant maize project" with ABC Ltd., which is a biotechnology company in Thailand. Under a SMTA, 'XYZ' wants to export maize bred in-lines to ABC Ltd., for evaluation. The objective is to develop a drought tolerant maize for smallholder farmers in Asia by crossing drought tolerant African maize developed by XYZ with ABC developed varieties by applying genetic mapping technology. The documents indicate that the maize germplasm is non-transgenic and no Indian germplasm have been involved. The transit is about 50 entries with 20 seeds in each packet. Once the inbred lines are identified, it will be imported into India and multiplied here for distributing the seed materials to farmers. This is done under a SMTA.

Under these circumstances, answer the following questions:

a. Does the transfer of inbred maize lines from 'XYZ' to ABC Ltd., under the SMTA covered under the BD Act, 2002? State reasons
b. Whether sending inbred lines for evaluation amounts to transfer of research results by 'XYZ' to ABC ltd?
c. Assuming that the activity of sending inbred lines is not within the purview of BD Act, 2002, what are the possible precautions that must be taken to ensure that there is no exploitation of resources for purposes other than those stated in the SMTA
d. Is export and import of biological resources regulated under the BD Act, 2002?
e. Considering that the inbred lines sent by XYZ to ABC Ltd., will be imported into India again for multiplication, whether it requires approval under the BD Act, 2002?

Part-2

ETHICAL CODE OF CONDUCT ON ABS FOR RESEARCHERS, RESEARCH INSTITUTES AND ORGANIZATIONS

Introduction

The objective of this ethical code of conduct is to promote legitimate access on a sustainable basis to the biological resources occurring in India and fair and equitable benefit sharing aris-ing from their utilization through research and related activities. The broader principles of ethical practices outlined herein do not suggest any professional standards for conducting re-search by the users of biological resources. However, they are set out in a way that individual researchers can easily follow. Further, research institutions, organizations and the diverse private bioscience research sectors can build upon these broad principles to formulate their own sector specific best practices to promote access and benefit sharing. Such sector specific best practices can extend to acquisition and utilization of biological resources and associated knowledge for research, commercialization of research results and/or licensing of technolo-gies by the researchers in their organizational or institutional set up.

This ethical code of conduct is developed within the scope and implementation of Biological Diversity Act, 2002 and the Rules and Regulations framed thereunder. This ethical code of conduct has been formulated after consultations with a wide range of stakeholders. It is ex-pected that this model code of conduct would be further deliberated upon in the respective (or varying/diverse) disciplines of the bioscience sectors for further customization, if necessary and adoption with emphasis on development of a transparent policy on access, benefit shar-ing and utilization of biological resources and associated knowledge.

This ethical code of conduct is applicable to (hereinafter referred as "Users"):

i. Individual researchers including Indians, non-Indians and non-resident Indians who are using or intending to use biological resources and/or associated knowledge,
ii. Research institutions, organizations and public and private entities (irrespective of their place of operation) utilizing biological resources occurring in or obtained from India, and
iii. Gene banks/ex situ collection centres, repositories, government departments and re-search organizations serving as providers of biological resources to the third parties.

Ethical Code of Conduct on Access and Benefit Sharing

The broad principles contained in this ethical code of conduct on ABS go much beyond the legal obligations contained in the Biological Diversity Act and suggest operational proce-dures the researchers must follow before, during and after accessing any biological resources occurring in or obtained from India and/or associated knowledge for carrying out research. The ethical practices suggested under this code of conduct on ABS include, but not limited to:

1. Compliance with relevant national and international Acts/laws on access and benefit sharing, the users shall:

   b. honour in letter and spirit, all the national and international laws and regulations relevant to use of biological resources and associated knowledge.
   c. make themselves aware and keep updated about the international and national conventions and laws relevant to the use of biological resources and associated knowledge that support conservation, sustainable use and equitable sharing of benefits arising out of such use.
   d. Comply with the provisions of applicable permits or approvals and other agree-ments SMTAs/MOUs/MOAs that are entered into with the provider(s) within the country.
   e. in case of any ambiguity, not to interpret the domestic access and benefit sharing regulations on their own and seek clarifications from the competent national au-thorities having territorial jurisdiction over the area from where biological resources and/or associated knowledge are sought to be accessed. and
   f. check the applicability of various domestic ABS laws across the globe through the ABS Clearing House Mechanism (ABS-CH) under the Nagoya Protocol before accessing biological/genetic resources for research or commercial utilization.
   g. proactively follow best practices when domestic access and benefit sharing laws are not in place.

2. Acquisition

Keeping in view the multifarious uses of biological resources, the diverse sources from where they are available and benefit sharing practices in collaboration with different partners, the users shall -

a. agree to develop the best practices for acquisition, benefit sharing and utilization of biological resources by the institutions and organizations to guide the researchers.
b. examine the available documentation of source and geographical origin to confirm the applicable laws for acquisition of biological resources.
c. assess the obligations in respect of the use and transfer of biological resources under the national laws of the providing country and the country where the bi-ological resources and/or associated knowledge are proposed to be used, in-cluding the terms of use of ex situ collection centres.
d. identify the responsibilities for acquisition of biological resources and associ-ated knowledge at institutional and individual levels.
e. follow the legal and institutional procedures to obtain permits and Prior In-formed Consent (PIC) and Mutually Agreed Terms (MAT).
f. obtain the required permits and approvals from different competent authorities.
g. acquire biological resources as per the existing laws and act in accordance with the terms of approvals/permits.
h. follow sustainable collection practices that would prevent biodiversity loss.
i. indulge in collection practices that would build trust in providers and provid-ing countries.
j. do not engage in collection practices that would cause any negative impact on the livelihood of local communities who rely on the biological resources sought to be accessed.
k. at institutional level, specify the records and data to be maintained on acquisi-tion (passport data of the biological resources collected including the date of collection and acquisition, wherever possible, even if acquired prior to CBD).

k. at institutional level, specify the records and data to be maintained on acquisi-tion (passport data of the biological resources collected including the date of collection and acquisition, wherever possible, even if acquired prior to CBD).
l. collect the details of the source/origin from where the biological resources would have possibly arrived in the market, if acquired from the market.
m. develop institutional policy for acquisition of biological resources from in situ and ex situ sources including for acquisition of associated organisms .

3. Utilization

Utilization of biological resources can cover a broad range of activities such as basic re-search, characterization, evaluation, sequencing, development of new products or processes and their commercialization. With respect to utilization of biological resources and/or associated knowledge, the user insti-tutes shall:

a. develop an institutional mechanism for acquisition, utilization of biological resources and associated knowledge and implementation of access and benefit sharing mechanism.
b. introduce appropriate counselling/guidance/support measures in relation to legal and technical ABS implementation issues.
c. require that submission of a statement of utilization of biological resources is mandatory for approval of new projects.
d. advise the principal investigators to be aware of the legal requirements for acquisition and utilization of biological resources and associated knowledge and emphasize the need for compliance by all the research staff. Appropriate checklists may be developed to ensure adherence with the legal, contractual and procedural requirements regarding access to and utilization of biological resources and associated knowledge.

e. advise the research staff to carefully consider the permissible uses of gene se-quence information under the approvals/permits obtained and agreements signed. The researchers may be advised to renegotiate with the providers and competent authorities or obtain fresh permits, if required when utilization goes beyond the original agreements or in case of any change of intent.
f. monitor the utilization of acquired biological resources and direct the re-searchers to revisit the communities, if required to share the progress.
g. ensure that the contribution of the communities is appropriately acknowl-edged in the final or project closure report and relevant publications.
h. ensure linkage mechanism on access and benefit sharing commitments if re-search is to be continued through another project within or outside the coun-try.
i. ensure and extend all necessary support to commercialize the technologies developed through appropriate committees such as institute technology man-agement unit or institute technology management committee in fixing the value of commercialization and sharing mechanisms.
j. provide adequate support to the researchers undergoing regulatory processes involved in ABS implementation through appropriate guidance and speedy two-way communication with the competent authorities and regulatory bod-ies, whenever required.
k. establish appropriate internal procedures to deal with violations (e.g., how to stop continuing violation) or inappropriate utilization. Internal mechanisms should also address follow up and reporting obligations after the completion of research in cases where the developed technology is transferred to third parties for commercialization.
l. ensure awareness among researchers on the implications of research publica-tions through print and electronic media including submission of online data-bases, gene banks or data repositories.

4. Traditional Knowledge

Traditional knowledge refers to the knowledge, innovations, and practices of indigenous and local communities around the world. Traditional Knowledge associated with biological re-sources has its own value and is commercially viable to various applications in the different bioscience sectors. Biological resources and associated traditional knowledge are interlinked and traditional knowledge is an integral part of the biological resources being accessed. Con-sidering that the associated traditional knowledge has its own value and existence, the princi-ples and obligations contained in this ethical code of conduct on the acquisition of biological resources are also applicable to the traditional knowledge associated with biological re-sources.

Fair and equitable sharing of benefits arising out of the utilization of traditional knowledge associated with biological resources is a legalized ethical obligation to recognize the contributions of traditional associated knowledge holders in conserving, maintaining, and preserving the biological diversity. To appreciate this obligation, the researchers shall identi-fy the possible ways in which their research could be directly beneficial to the local people and communities as early as possible even at the time of conceiving a research idea. This eth-ical obligation shall be properly addressed and, wherever possible fulfilled, even in the ab-sence of any legal obligation to share benefits of utilization of associated traditional knowledge.

5. Benefit Sharing

Benefits generated out of the utilization of biological resources and associated knowledge may be monetary, non-monetary or a combination of both. Hence, benefit sharing negotia-tions shall ensure that the benefits flow primarily and directly to reward and promote conser-vation considering local circumstances, community needs, are fair and equitable and the ac-tivities that support sustainable use of biological resources. The users shall

a. agree to allow retrospective claims, wherever feasible.
b. show respect to community resources including associated traditional knowledge.

c. engage only in such activities that would enhance the reputation of the user and the relationships with communities as well.
d. consider contributing even non-monetary benefits liberally to the communi-ties providing biological resources and associated traditional knowledge.
e. while providing biological resources, ensure that appropriate MTAs or SMTAs are signed with subsequent users, and protect the interests of the ac-tual providers of the biological resources and associated knowledge.
f. notify subsequent users about the obligations to comply with access and bene-fit sharing laws of the country of origin of the biological resources they pro-vide.

6. Curation and Data Management

Curation and data management is a very significant aspect of record keeping in relation to the acquisition and utilization of biological resources at institutional level, relevant to effective implementation of ABS obligations at all levels. Data authenticity shall be monitored, and appropriate mechanisms be developed for reliability and easy access. The users shall :

a. record the terms and conditions imposed by the providers and competent national authorities in a central database accessible to relevant authorities for monitoring or review of ABS implementation.
b. record the information relevant to ABS in annual reports and progress reports.
c. generate awareness among the financial staff so that appropriate budget heads are created in the financial management system to record sharing of benefits.
d. record the flow of bioresources within and outside the institute including third party supplies in compliance with applicable laws and procedures.

e. record information on use of samples acquired such as availability and/or disposal of remaining samples, whether completely exhausted or transformed while developing technology for use, etc.
f. maintain databases on the genetic/biological resources held at the institute along with passport data and details of resource transfer/sharing within or outside the institute.
g. ensure that the passport data contains details of the original contributor of biological resources and the exact location of collection with latitude and lon-gitude data.
h. maintain relevant records of access, use, transfer, and disposal of biological resources for at least 25 years after utilization and technology development.
i. retain the identity of the specimen utilized and link it to all other identification numbers generated during use to maintain alternate identities for the same sample or specimen. This obligation is applicable in transfers and exchanges of all biological resources between and among colleagues, institutions, and organizations within and outside India. This obligation would coexist with all the legalrequirements regarding transfer and exchange of biological resources and research results based on them.
j. conduct internal audit on implementation of access and benefit sharing obli-gations arising out of the access and use of biological resources and associat-ed knowledge.

7. Policies, Internal Mechanisms and Staff Training

Many of the national level organisations have IPR policy and implementation mechanism. However, ABS policy and implementation is yet to be developed. The user insti-tutes/organizations should develop and declare ABS policy both at the organisation (e.g., IC-AR, CSIR and DBT.) and at the institute level that addresses issues on ABS such as new collections and acquisitions of BR, managing the collections, managing the compliance with MAT, exchange and loan of genetic resources including DNA, DSI and tissues, research including collaborations within and outside the country, data management and documentation regarding acquisition, utilization and transfer of biological resources, identification of inter-nal monitoring agencies for ABS compliance, etc. Such measures may also be developed at the level of universities and private labs. The policies should address in detail sector specific issues and concerns.

Appropriate linkages should be established among applicable policies within institutes and organizations. Organization level IPR policies should integrate ABS and data management policies related to access and use of biological resources and associated knowledge.

Legal and technical experts working with or assisting the competent national and state level authorities shall be accessible to researchers for consultation prior or during or after comple-tion of research projects. Valuation of biological resource based technologies is a very specialized subject requiring engagement of experts and the institutes may constitute committees comprising technical and legal experts on access and benefit sharing to guide the researchers on valuation. New committees may be constituted for access and benefit sharing, if required.

There are chances of conflict of ideas between the researchers and the competent authority concerned regarding the applicability of ABS provisions of the domestic laws. In such situations, the researcher is expected to follow the directions given by the concerned authority if planning to access the biological resources prior to initiating any legal action. This will ensure the researcher's legitimate compliance with the existing regulatory practices and the in-terpretations such authorities normally follow which could be contested at any later stage before the court of law having competent jurisdiction.

International and industry collaborations are very common in bioscience research. Due diligence must be exercised to identify the various legal obligations emerging at different stages of collaborative research. The collaborating partners must be informed and involved, if necessary, in ABS compliance at different identified levels of research and related activities.

Staff training strategy on ABS may be developed. Resources may be drawn from both tech-nical and legal areas. Special efforts could be extended to develop sector and organisation/institute specific training and study materials. National guidelines, detailing domestic laws and institute policy on ABS should be part of the curricula.

Part-3

MONITORING GUIDELINES FOR RESEARCH INSTITUTIONS TO PROMOTE COMPLIANCE WITH ACCESS AND BENEFIT SHARING REGULATIONS UNDER THE BIOLOGICAL DIVERSITY ACT, 2002

Objective

This document aims to provide guidance to the research organisations and institutes including State, Central and private universities on the measures that could be adopted to monitor compliance by their researchers/scientists/employees undertaking research on biological resources and associated knowledge with the legal and procedural requirements for access and benefit sharing (ABS) in India. It is expected that such organizations and institutes including universities would internalize the spirit of these ABS Regulations and create effective and proactive measures and mechanisms for monitor-ing compliance with the ABS process in India within their respective domains. Private research insti-tutes and laboratories are also encouraged to develop their own internal monitoring mechanisms taking insight from this document.

General Principles

1. Monitoring should be conducted in a phased manner at different stages like prior to, during and after the completion of research and at the stage of applying for intellectual property rights (IPR) and commercializing any such IPR granted including commercialization of any product, process and technology developed with the help of research.
2. The objective of monitoring compliance shall be primarily aimed to secure greater compli-ance with the provisions of the Biological Diversity Act, 2002 and the Rules and the Regula-tions made/issued thereunder.
3. The institutional measures/mechanisms developed for monitoring compliance should en-sure that monetary benefits, if any, generated out of the utilization of biological resources and associated knowledge are actually shared in a fair and equitable manner with the local people and communities conserving and holding such resources and knowledge in accord-ance with the applicable law.
4. The institutional measures/ mechanisms developed for monitoring compliance should en-sure that, wherever possible, non-monetary benefits arising out of the utilization of biologi-cal resources and associated knowledge will directly benefit the local people and communi-ties holding biological resources and associated traditional knowledge.

5. Annex I to this document contains a checklist that researchers/scientists/ institutions/ pri-vate research laboratories can make use of in assessing their ABS obligations under the BD Act. Research institutes and organisations including private entities engaged in bioscience research could encourage the scientists/researchers working with them to use the checklist prior to, during and after the completion of the research activities they are engaged in.
6. The monitoring measures created at institutional/organisational level for compliance with ABS obligations should be less bureaucratic and user friendly.
7. Research organizations should develop appropriate ethical code of conduct for researchers and scientists/employees that would support compliance with the ABS obligations under the BD Act.
8. Research Organizations like ICAR,CSIR,ICMR etc., can direct the Institutes under them to give appropriate training on ABS compliance. University Grants Commission may direct the uni-versities through their Vice Chancellors to include BD Act as part of the curriculum/ course work for PG and PhD students
9. Research organisations should direct the institutes/universities governed by them to make a module on the various provisions of the BD Act, Rules and Regulations as a compulsory part of the curriculum/course work for PG and PhD students and the researchers and scientists working in research institutes should be given appropriate training on ABS compliance.

Guidelines for Research Organizations (e.g., ICAR, CSIR, DBT, DST and UGC)

1. Research organizations may develop "ABS Implementation Guidelines" as a reference tool appli-cable to the institutes/universities and researchers governed by them (e.g., like IPR guidelines of ICAR). ABS compliance may be stated as part of research integrity at all levels.
2. Critical mass of human resource needs to be trained on ABS Regulations and implementation for researchers.
3. Financial resources generated and distributed to the providers of the biological resources and associated knowledge be approved as a sub-head as part of Financial Management System of the organization to the relevant institutes/universities.
4. Appropriate guidance may be provided to the relevant institutes including ICAR to incorporate a section in their annual reports/newsletters on ABS compliance.
5. Incentive mechanisms to promote ABS compliance in research institutes may be introduced by the governing bodies of such research organizations on annual basis, giving more weightage to sharing of the benefits generated with the communities providing biological resources and associated knowledge.
6. The respective bureaus of ICAR (e.g., NBPGR, NBFGR) may be requested to develop a central database to highlight the existence of hotspots, use of bioresources, details of communities holding associated knowledge and conserving biological resources and benefits sharing mecha-nisms, efforts being made towards bioresources conservation from the financial resources gen-erated.
7. The existing internal compliance mechanisms such as approvals for release of varieties by Cen-tral Variety Release Committee or State Variety Release Committee, registration of bio-pesticides by Central Insecticide Board and Registration Committee, or approval for filing of pa-tent applications, should also include a component on ABS implementation.

8. In collaborative research projects involving non-Indian participation as per section 3 (2) of the BD Act, clear guidelines may be issued based on the policy guidelines issued by the Central Gov-ernment under section 5 of the Biological Diversity Act. While developing such guidance docu-ments, due attention shall be paid to the status of Indians staying outside India for more than 182 days or non-Indians doing research in India as part of exchange programmes.
9. Guidelines may be issued to the effect that all the publications based on biological resources shall contain the details of original source such as the providers' name and geographical loca-tion, with due acknowledgement.
10. Data (safety data and effectiveness/usefulness data) developed by the Institutes on biological resources should have links to the original source from where those have been collected.
11. Genomic sequence and digital sequence information derived from the biological resources col-lected shall have link to the original provider and associated ABS obligations.

Monitoring guidelines for research institutes/universities (e.g., ICAR-IIRR, CSIR-IICT, TNAU and AMITY)

1. Selected members of relevant committees shall be trained in ABS implementation to provide guidance at the institute level (e.g., in ICAR-PME, ITMC, ITMU, IRC, AKMU and IPR). One of these officials may be given additional responsibility as ABS Compliance Officer at the institute level.
2. Appropriate instructions may be issued to the project/principal investigators to find out the ap-plicability of ABS laws within and outside India with respect to their research projects by making use of the ABS Clearing House Mechanism (ABS-CHM) of the Nagoya Protocol.
3. Approaches and guidelines for acquisition, utilization, curation and data management, collabo-rations and sharing of bioresources may be developed at the institute/university level (e.g., ac-quisition of seed from the forests or communities, fish from different marine zones/inland water bodies or communities, microbes from soil or insects and from secondary source such as Bu-reaus and Culture Collection Centres). Such guidelines may also address acquisition from trad-ers/markets to record information on source or origin of biological resources.
4. Collection guidelines promoting sustainability may be issued by the institutes and universities.
5. Based on existing national laws, specific guidelines may be issued on acquisition of and benefit sharing from biological resources from outside India in compliance with the provider country legislations.
6. While formulating policies and guidelines, due consultation with NBA may be done for clarity on legal provisions for ABS compliance.

Annex - I

Question	Approval required if you answer	Explanations
Access for research and bio-survey and bio-utilization		Section 3
1.Whether the biological resource required is a human genetic materi-al?	If NO, approval from NBA is required.	If YES, you are exempted - hu-man genetic material is not a biological resource as per the definition under the BD Act.
3.Whether the biological resource sought to be accessed constitutes a "value added product" as defined under sec-tion 2(p)?	If NO, approval from NBA is required	If YES, you are exempted – approval is not required for accessing value added products
4.Does the biological re-source you plan to work on belong to a plant genetic resource for food and agricul-ture coming under the 26563 accessions of the nine crops notified by the Ministry of Agricul-ture for implementing the MLS of	If NO, approval from NBA is required for access and transfer. Also, if you propose to use such resources for any activity other than research, breeding and training, approval from NBA would be required.	If YES, exempted from ABS obligations for access under section 3 and transfer of research results under section 4. The biological resources can be accessed and transferred using standard material transfer agreement. However, you are required to apply to NBA for obtaining patent in India or outside and for plant variety protection outside India.
5. Do you /your compa-ny/ institute belong to the list of per-sons/entities specified under section 3 (2) of the BD Act?	If YES, approval from NBA is required	If you are not an entity within the purview of section 3(2) of the BD Act, you can undertake research and bio-survey and bio-utilization without any ap-proval from NBA. Research and bio-survey and bio-utilization for research are not regulated by SBBs.

Question	Approval required if you answer	Explanations
6. Is there any non-Indian participation (even a single share/ person) in the share capital or management of your company?	If NO, approval of NBA is not required.	If YES, approval from NBA is required. Even if the non-Indian element is in the form of a single person or a single share NBA will assume regulatory powers over entities for accessing biological resources.
7. Whether your proposed activity constitutes re-search under section 2(m) or bio-survey and bio-utilization under section 2(d) of the BD Act	If YES, approval from NBA is required	For deciding whether your activity is regulated by NBA, all the questions from 1-6 need to be considered.
Commercial utilization and bio-survey and bio-utilization		Section 3 and 7
8. Questions 1-4	Answers as applicable to Q.1-4	Consider all the questions from 1-4 to decide whether you are covered under the regulatory provisions of the BD Act.
1. Whether you want to engage in an ac-tivity that falls within the scope of bio-survey and bio-utilization, aimed at commercial utilization, as per section 2(d) of the BD Act?	If YES, you need to take ap-proval from SBB	Bio-survey and bio-utilization for commercial utilization when undertaken by persons/entities under section 7 of the Act are regulated by the SBB from whose jurisdiction you want to acquire the biological resources
Whether you want to engage in an activity that falls within the scope of commercial utilization as per sec-tion 2(f) of the BD Act?	If YES, you need to obtain approval from NBA or SBB depending on your legal status (whether you are a section 3(2) or non-section 3(2) entity)	Commercial utilization of biological resources is a regulated activity for all types of persons and entities. However, the competent regulatory authority would be different depending on the legal status under section 3(2) and section 7.

Question	Approval required if you answer	Explanations
12. Are you making use of only conventional breeding techniques or traditional practices in agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping for improving crops or livestock for commercial production?	If NO, you are required to take approval from NBA/SBB depending on your legal status	If YES, you are exempted. Conventional breeding and tra-ditional practices in the fields mentioned are exempted from the definition of commercial utilization. Irrespective of your legal status, if you are engaged in conventional breeding or traditional practices in the fields referred here, the Act will not regulate access for com-mercial utilization.
13. Whether you/ your company belong to person/entity listed under section 3(2) of the BD Act?	If Yes, you require approval from NBA.	If NO, you require approval from SBB. Commercial utilization of biological resources is a regulated activity for all types of persons and entities. How-ever, the competent authority would differ depending on the legal status of the per-son/entity covered under sec-tion 3(2) and section 7.
14. Are you a local *vaid* or *hakim* practicing traditional medicine or do you represent local people or community such as growers or cultivators of biodiversity?	If NO, you need approval from SBB	If YES, you need not apply to SBBs for commercial utilization or bio-survey and bio-utilization for commercial utili-zation of biological resources. However, if you establish a commercial establishment for your practice, the SBB can regulate your activities based on the concerned State Biodi-versity Rules.

Question	Approval required if you answer	Explanations
15. Does your research fall within the purview of collaborative research projects exempted un-der section 5 of the BD Act and approved by the Ministry con-cerned?	If NO, you would require ap-proval of NBA. (need approval for research, commercial utilization, bio-survey and bio-utilization when accessed by section 3(2) enti-ties and transfer of research results to section 3(2) entities when done by any person)	If YES, you are exempted from obtaining approval of NBA for access (section 3) and transfer of research results under sec-tion 4.
Transfer of research results		
16. Do you want to trans-fer your research re-sults to any of the per-sons/ entities specified under section 3(2)	If YES, you would need approval from NBA	If you want to transfer your research results to a person or entity other than those listed in section 3(2), you will not need any approval under section 4 for such transfer.
17. Are you a section 3(2) entity propos-ing to transfer the re-sults of your research over biological resources occurring in or obtained from India to an non-section 3(2) entity?	If NO, you would need approval from NBA under section 4 for transfer of research results	Section 4 does not regulate transfer of results of research by non-section 3(2) persons or entities or transfer by section 3(2) persons or entities to non-section 3(2) persons or entities. It regulates transfer of results of research to section 3(2) persons or entities.
18. Are you receiving any monetary or non-monetary considera-tion for transfer of your research results?	The answer is irrelevant, for any transfer of research results to a section 3(2) person or entity, you would require approval from NBA	The type or quantum of benefits are not determining factors for transfer of research results to section 3(2) persons or entities

Question	Approval required if you answer	Explanations
19. Does the transfer of re-search results involve transfer of biological re-sources to a person or en-tity listed under section 3(2)?	If YES, the transferee should obtain approval under section 3 from NBA for accessing biological resources	If transfer does not involve biological resource, the transferee need not take approval from NBA.
20. If you are a section 3(2) person/ entity, have you obtained NBA's approval for accessing the biological resource which was used for re-search?	All section 3(2) persons/ entities transferring results of research on biological resources occurring in or obtained from India must ensure that they have obtained BRs with the prior approval from NBA under section 3 for carrying out their research	If NO, it would amount to violation of the BD Act
21. If you plan to publish your results of re-search, is there any condition in your ac-cess agreement related to publication	If YES, adhere to the terms of the agreement. Those terms and conditions should not be in contravention of the guidelines issued by the Central Government under section 4 of the BD Act.	If NO, you are free to publish keeping in view compliance to the guidelines issued by the Central Government under section 4 of the BD Act.
22. Is your research a col-laborative research project under section 5 of the BD Act and ap-proved by the con-cerned Ministry?	If No, approval from NBA would be required for transfer of results of research involving biological resources	(If YES, approval for transfer of research results not required)

Question	Approval required if you answer	Explanations
For obtaining IPR for inventions based on research or information on biological resources		Section 6
23. Have you developed your invention based on re-search or information on a biological resource ob-tained from India	If YES, you would need prior approval from NBA for obtaining IPR	(The obligation is not applicable for any other form of IPR)
24. Are you planning to apply for patent pro-tection within and/or outside India	If YES, you would need prior approval from NBA before applying for patent in any country	The obligation is same if you apply for patent in India or any other country. Permission should be taken to obtain IPR for all countries where you want a patent.
25. Are you planning to ob-tain plant variety pro-tection only in India	If NO, you would need prior approval from NBA before ob-taining plant variety protection in other countries. (obligation applicable only when plant variety protection is sought outside India)	If you are applying in India, you are not required to get prior approval for the protection in India. But for other countries where you plan to apply, prior approval is required.
26. If you are a section 3(2) person/ entity, have you sought NBA's ap-proval for accessing the biological resources used in your invention or for developing new plant variety	All section 3(2) entities should ensure that the biological resources used for developing the invention or the new plant variety have been obtained in accordance with section 3 of the BD Act	If NO, it will amount to violation of section 3 of the BD Act.
27. Have you applied for NBA's approval before seeking patent or plant va-riety rights?	If not applied for NBA's approval, check the status of the patent/ plant variety application and take measures to obtain NBA approval before the grant of these IPR	The grant of these IPR before obtaining the approval of NBA would amount to violation which cannot be rectified later.

Question	Approval required if you answer	Explanations
28. Would you further re-quire biological re-sources to commercial-ize your IPR	If YES, file appropriate application before NBA/SBB for access to biological resources	The initial permission you secured to do research will not act as a blanket approval for further acquisition
29. Do you plan to apply for patents/ plant vari-ety protection in other countries which are not specified in your Form III application under section 6	If YES, take steps to amend the MAT under the approval granted by NBA under section 6 to include the additional countries where protection is sought	If IPR is granted in such countries which are not mentioned in your application, it will amount to violation of section 6 of the BD Act which cannot be rectified later.
Transfer of biological resources accessed under Form I (section 3)		Section 20
30. Have you already ac-cessed biological re-sources with approval from NBA under sec-tion 3?	If YES, you can apply for approval of NBA to transfer such biological resources to a third party whether Indian or non-Indian	If you are a non-section 3(2) entity, you don't need any permission for transfer of biological resources as such transfer to a section 3 person /entity would require filing of an access (section 3) application by the latter to NBA for legitimising such transfers .
31. Are you planning to transfer the already ac-cessed resources to a person/entity under section 3(2)?	If YES, check whether the transferee has obtained NBA's approval under section 3 to access biological resources from you	If the transferee has not obtained NBA'a approval for accessing the biological resource, it would amount to violation and you would be abetting the violation which is a punishable offence
32. Are you planning to trans-fer the biological re-sources to an Indian or an entity falling within the scope of section 7 of the Act	If YES, (Apply to NBA in Form IV for the transfer)	If the transferee is a section 3(2) person or entity, check whether the transferee has obtained NBA's approval under section 3 to access biological resources from you

Question	Approval required if you answer	Explanations
33. Are you a government institution proposing to send biological re-sources outside India for research to avert emergencies	If YES, Apply in Form 'B' under Regula-tion 13 of ABS Regulations , 2014	If NO, you are not authorised to undertake this activity
34. Are you an Indian researcher or an Indian government institution intending to carry /send biological re-sources outside India for non-commercial re-search	If YES Apply in Form 'B' under Regula-tion 13 of ABS Guidelines	Only individual researchers and government institutions are authorised to undertake this activity. Must refrain from do-ing this if you are a commercial entity.
35. Are you an Indian re-searcher/ scientist wish-ing to deposit novel microorganisms isolat-ed from India for publi-cation in a journal?	If YES, (Apply in Form 'C')	This is not a statutory require-ment. However, NBA pre-scribes doing this.

Annex - I
Checklist of Obligations

Question	Approval required if you answer	Explanations
Access for research and bio-survey and bio-utilization		Section 3
1.Whether the biological resource required is a human genetic materi-al?	If NO, approval from NBA is required.	If YES, you are exempted - hu-man genetic material is not a biological resource as per the definition under the BD Act.
3.Whether the biological resource sought to be accessed constitutes a "value added product" as defined under sec-tion 2(p)?	If NO, approval from NBA is required	If YES, you are exempted – approval is not required for accessing value added products
4.Does the biological re-source you plan to work on belong to a plant genetic resource for food and agricul-ture coming under the 26563 accessions of the nine crops notified by the Ministry of Agricul-ture for implementing the MLS of	If NO, approval from NBA is required for access and transfer. Also, if you propose to use such resources for any activity other than research, breeding and training, approval from NBA would be required.	If YES, exempted from ABS obligations for access under section 3 and transfer of research results under section 4. The biological resources can be accessed and transferred using standard material transfer agreement. However, you are required to apply to NBA for obtaining patent in India or outside and for plant variety protection outside India.
5. Do you /your compa-ny/ institute belong to the list of per-sons/entities specified under section 3 (2) of the BD Act?	If YES, approval from NBA is required	If you are not an entity within the purview of section 3(2) of the BD Act, you can undertake research and bio-survey and bio-utilization without any ap-proval from NBA. Research and bio-survey and bio-utilization for research are not regulated by SBBs.

Question	Approval required if you answer	Explanations
6. Is there any non-Indian participation (even a single share/ person) in the share capital or management of your company?	If NO, approval of NBA is not required.	If YES, approval from NBA is required. Even if the non-Indian element is in the form of a single person or a single share NBA will assume regulatory powers over entities for accessing biological resources.
7. Whether your proposed activity constitutes re-search under section 2(m) or bio-survey and bio-utilization under section 2(d) of the BD Act	If YES, approval from NBA is required	For deciding whether your activity is regulated by NBA, all the questions from 1-6 need to be considered.
Commercial utilization and bio-survey and bio-utilization		Section 3 and 7
8. Questions 1-4	Answers as applicable to Q.1-4	Consider all the questions from 1-4 to decide whether you are covered under the regulatory provisions of the BD Act.
1. Whether you want to engage in an ac-tivity that falls within the scope of bio-survey and bio-utilization, aimed at commercial utilization, as per section 2(d) of the BD Act?	If YES, you need to take ap-proval from SBB	Bio-survey and bio-utilization for commercial utilization when undertaken by persons/entities under section 7 of the Act are regulated by the SBB from whose jurisdiction you want to acquire the biological resources
Whether you want to engage in an activity that falls within the scope of commercial utilization as per sec-tion 2(f) of the BD Act?	If YES, you need to obtain approval from NBA or SBB depending on your legal status (whether you are a section 3(2) or non-section 3(2) entity)	Commercial utilization of biological resources is a regulated activity for all types of persons and entities. However, the competent regulatory authority would be different depending on the legal status under section 3(2) and section 7.

Question	Approval required if you answer	Explanations
12. Are you making use of only conventional breeding techniques or traditional practices in agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping for improving crops or livestock for commercial production?	If NO, you are required to take approval from NBA/SBB depending on your legal status	If YES, you are exempted. Conventional breeding and tra-ditional practices in the fields mentioned are exempted from the definition of commercial utilization. Irrespective of your legal status, if you are engaged in conventional breeding or traditional practices in the fields referred here, the Act will not regulate access for com-mercial utilization.
13. Whether you/ your company belong to person/entity listed under section 3(2) of the BD Act?	If Yes, you require approval from NBA.	If NO, you require approval from SBB. Commercial utilization of biological resources is a regulated activity for all types of persons and entities. How-ever, the competent authority would differ depending on the legal status of the per-son/entity covered under sec-tion 3(2) and section 7.
14. Are you a local *vaid* or *hakim* practicing traditional medicine or do you represent local people or community such as growers or cultivators of biodiversity?	If NO, you need approval from SBB	If YES, you need not apply to SBBs for commercial utilization or bio-survey and bio-utilization for commercial utili-zation of biological resources. However, if you establish a commercial establishment for your practice, the SBB can regulate your activities based on the concerned State Biodi-versity Rules.

Question	Approval required if you answer	Explanations
15. Does your research fall within the purview of collaborative research projects exempted un-der section 5 of the BD Act and approved by the Ministry con-cerned?	If NO, you would require ap-proval of NBA. (need approval for research, commercial utilization, bio-survey and bio-utilization when accessed by section 3(2) enti-ties and transfer of research results to section 3(2) entities when done by any person)	If YES, you are exempted from obtaining approval of NBA for access (section 3) and transfer of research results under sec-tion 4.
Transfer of research results		
16. Do you want to trans-fer your research re-sults to any of the per-sons/ entities specified under section 3(2)	If YES, you would need approval from NBA	If you want to transfer your research results to a person or entity other than those listed in section 3(2), you will not need any approval under section 4 for such transfer.
17. Are you a section 3(2) entity propos-ing to transfer the re-sults of your research over biological resources occurring in or obtained from India to an non-section 3(2) entity?	If NO, you would need approval from NBA under section 4 for transfer of research results	Section 4 does not regulate transfer of results of research by non-section 3(2) persons or entities or transfer by section 3(2) persons or entities to non-section 3(2) persons or entities. It regulates transfer of results of research to section 3(2) persons or entities.
18. Are you receiving any monetary or non-monetary considera-tion for transfer of your research results?	The answer is irrelevant, for any transfer of research results to a section 3(2) person or entity, you would require approval from NBA	The type or quantum of benefits are not determining factors for transfer of research results to section 3(2) persons or entities

Question	Approval required if you answer	Explanations
19. Does the transfer of re-search results involve transfer of biological re-sources to a person or en-tity listed under section 3(2)?	If YES, the transferee should obtain approval under section 3 from NBA for accessing biological resources	If transfer does not involve biological resource, the transferee need not take approval from NBA.
20. If you are a section 3(2) person/entity, have you obtained NBA's approval for accessing the biological resource which was used for re-search?	All section 3(2) persons/ entities transferring results of research on biological resources occurring in or obtained from India must ensure that they have obtained BRs with the prior approval from NBA under section 3 for carrying out their research	If NO, it would amount to violation of the BD Act
21. If you plan to publish your results of re-search, is there any condition in your ac-cess agreement related to publication	If YES, adhere to the terms of the agreement. Those terms and conditions should not be in contravention of the guidelines issued by the Central Government under section 4 of the BD Act.	If NO, you are free to publish keeping in view compliance to the guidelines issued by the Central Government under section 4 of the BD Act.
22. Is your research a col-laborative research project under section 5 of the BD Act and ap-proved by the con-cerned Ministry?	If No, approval from NBA would be required for transfer of results of research involving biological resources	(If YES, approval for transfer of research results not required)

Question	Approval required if you answer	Explanations
For obtaining IPR for inventions based on research or information on biological resources		Section 6
23. Have you developed your invention based on re-search or information on a biological resource ob-tained from India	If YES, you would need prior approval from NBA for obtaining IPR	(The obligation is not applicable for any other form of IPR)
24. Are you planning to apply for patent pro-tection within and/or outside India	If YES, you would need prior approval from NBA before applying for patent in any country	The obligation is same if you apply for patent in India or any other country. Permission should be taken to obtain IPR for all countries where you want a patent.
25. Are you planning to ob-tain plant variety pro-tection only in India	If NO, you would need prior approval from NBA before ob-taining plant variety protection in other countries. (obligation applicable only when plant variety protection is sought outside India)	If you are applying in India, you are not required to get prior approval for the protection in India. But for other countries where you plan to apply, prior approval is required.
26. If you are a section 3(2) person/ entity, have you sought NBA's ap-proval for accessing the biological resources used in your invention or for developing new plant variety	All section 3(2) entities should ensure that the biological resources used for developing the invention or the new plant variety have been obtained in accordance with section 3 of the BD Act	If NO, it will amount to violation of section 3 of the BD Act.
27. Have you applied for NBA's approval before seeking patent or plant va-riety rights?	If not applied for NBA's approval, check the status of the patent/ plant variety application and take measures to obtain NBA approval before the grant of these IPR	The grant of these IPR before obtaining the approval of NBA would amount to violation which cannot be rectified later.

Question	Approval required if you answer	Explanations
28. Would you further re-quire biological re-sources to commercial-ize your IPR	If YES, file appropriate application before NBA/SBB for access to biological resources	The initial permission you secured to do research will not act as a blanket approval for further acquisition
29. Do you plan to apply for patents/ plant vari-ety protection in other countries which are not specified in your Form III application under section 6	If YES, take steps to amend the MAT under the approval granted by NBA under section 6 to include the additional countries where protection is sought	If IPR is granted in such countries which are not mentioned in your application, it will amount to violation of section 6 of the BD Act which cannot be rectified later.
Transfer of biological resources accessed under Form I (section 3)		Section 20
30. Have you already ac-cessed biological re-sources with approval from NBA under sec-tion 3?	If YES, you can apply for approval of NBA to transfer such biological resources to a third party whether Indian or non-Indian	If you are a non-section 3(2) entity, you don't need any permission for transfer of biological resources as such transfer to a section 3 person /entity would require filing of an access (section 3) application by the latter to NBA for legitimising such transfers .
31. Are you planning to transfer the already ac-cessed resources to a person/entity under section 3(2)?	If YES, check whether the transferee has obtained NBA's approval under section 3 to access biological resources from you	If the transferee has not obtained NBA'a approval for accessing the biological resource, it would amount to violation and you would be abetting the violation which is a punishable offence
32. Are you planning to trans-fer the biological re-sources to an Indian or an entity falling within the scope of section 7 of the Act	If YES, (Apply to NBA in Form IV for the transfer)	If the transferee is a section 3(2) person or entity, check whether the transferee has obtained NBA's approval under section 3 to access biological resources from you

Question	Approval required if you answer	Explanations
33. Are you a government institution proposing to send biological re-sources outside India for research to avert emergencies	If YES, Apply in Form 'B' under Regula-tion 13 of ABS Regulations , 2014	If NO, you are not authorised to undertake this activity
34. Are you an Indian researcher or an Indian government institution intending to carry /send biological re-sources outside India for non-commercial re-search	If YES Apply in Form 'B' under Regula-tion 13 of ABS Guidelines	Only individual researchers and government institutions are authorised to undertake this activity. Must refrain from do-ing this if you are a commercial entity.
35. Are you an Indian re-searcher/ scientist wish-ing to deposit novel microorganisms isolat-ed from India for publi-cation in a journal?	If YES, (Apply in Form 'C')	This is not a statutory require-ment. However, NBA pre-scribes doing this.

Glossary of Terms

(This glossary does not cover the terms which are defined in the handbook)

Biological diversity – Variability among living organisms from all sources including, inter alia, terrestrial, marine, and other aquatic ecosystems and the ecological complexes of which they are a part; this includes diversity within species, between species, and of ecosystems.

Biotechnology – Any technological application that uses biological systems, living organisms, or derivatives thereof to make or modify products or process them for specific use.

Compliance - Compliance is either a state of being in accordance with established guidelines, specifications, or legislation or the process of becoming so.

Country of origin – The country which possesses those genetic resources in or under in situ conditions.

Country providing genetic resources – The country supplying genetic resources collected from in situ sources, including populations of both wild and domesticated species or taken from ex situ sources which may or may not have originated in that country.

Derivatives – A product including information developed, or part taken, or extracted from a biological or genetic resource, e.g., varieties, strains or breeds, blood, proteins, oils, resins, gums, genes, seeds, spores, bark, wood, leaf matter, or formulae; includes products incorporating material or formulae as above.

Ex-situ conservation – The conservation of components of biological diversity outside their natural habitats (e.g., in gene banks).

Genetic diversity – The variety of genes within a particular species, variety, or breed.

Genetic material – The Convention on Biological Diversity defines genetic materials as materials of actual or potential value containing functional units of heredity.

Genetic resources – All genetic materials of actual or potential value
In-situ conservation – The conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties

Intellectual property (IP) – Refers to creations of the mind: inventions, literary and artistic work, and symbols, names, images, and designs used in commerce; intellectual property may be divided into two categories: industrial property, which includes inventions (patents), trademarks, industrial designs, and geographic indications of source; and copyright, which includes literary and artistic work such as novels, poems, plays, films, musical work, artistic work such as drawings, paintings, photographs, sculptures, and architectural designs; rights related to copyright include those of performing artists in their performances, producers of phonograms in their recordings, and broadcasters in their radio and television programmes.

Intellectual property rights (IPRs) – The legal protection given to persons over their creative endeavours; usually gives the creator an exclusive right over the use of his/her creation or discovery for a certain period of time; IPRs also refer to the recognition that the inventor should be granted a reward such as exclusive rights to use it or to earn royalties from renting out its use.

Internationally recognized certificate of compliance: The Nagoya Protocol establishes that domestic access permits that are made available to the Protocol's Clearing-House shall constitute "internationally recognized certificates of compliance". All Parties with users in their jurisdiction must recognize such certificates as evidence of acquisition in accordance with applicable rule of the genetic resource covered.

International Union for the Protection of New Varieties of Plant (UPOV) – An intergovernmental organisation established by the International Convention for the Protection of New Varieties of Plants, UPOV's mission is to provide and promote effective systems of plant variety protection. Its aim is to encourage the

development of new varieties of plants for the benefit of society. The Convention was adopted in 1961 and revised as deemed necessary in 1972, 1978, and 1991. The objective of the Convention is the protection of new varieties of plants through intellectual property rights.

Invention – Section 2 (l) of the Patent Amendment Act of India refers to new invention as any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of a patent application with complete specification; i.e., the subject matter has not fallen in the public domain, or does not form part of the state-of-the-art.

Patent – A form of intellectual property protection available for inventions, whether products or processes, that are new, involve an (non-obvious) inventive step, and are useful or capable of industrial application; a patent is a legal grant by the State to an inventor allowing the right to exclude others from making, using, exercising, and marketing his/her invention within its geographic territory for a stipulated duration in lieu of disclosing the invention in a patent specification.

Plant variety – A plant grouping within a single botanical taxon of the lowest known rank, defined by the reproducible expression of its distinguishing and other genetic characteristics

Prior art – The existing knowledge base before the invention was discovered, or before the invention was disclosed by filing a patent application

Sovereign rights – Rights which appertain to independent sovereign states to legislate, manage, exploit, and control access to their natural resources; they include the right to determine the property regimes applicable to those resources, what rights of ownership can be entertained, and how ownership is established.

Sovereignty – The power of the State to independently regulate its own internal and external affairs; it is not ownership; it is the power to regulate ownership.

Sui generis – one of its own kind

Sustainable use – The use of components of biological diversity in a way and at a rate that does not lead to the long-term decline of biological diversity, thereby maintaining its potential to meet the needs and aspirations of present and future generations.

Traditional Knowledge (TK) – There is currently no generally accepted definition of TK at an international level. WIPO defines it as "knowledge, know-how, skills and practices that are developed, sustained and passed on from generation to generation within a community, often forming part of its cultural or spiritual identity." It also notes that "TK in the narrow sense refers to knowledge as such, in particular the knowledge resulting from intellectual activity in a traditional context, and includes know-how, practices, skills, and innovations." (http://www.wipo.int/tk/en/tk/). The Nagoya Protocol covers TK associated with Genetic Resources not TK as a separate element.

Utilization (of genetic resources) – to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention (definition from the Nagoya Protocol).