



**DRAFT GUIDELINES
ON
ACCESS AND BENEFIT SHARING**

UNDER THE BIOLOGICAL DIVERSITY ACT, 2002

PRESENTED TO

THE NATIONAL BIODIVERSITY AUTHORITY

PREPARED BY

YESHWANTH SHENOY
ADVOCATE



PLEASE SEND FEEDBACK TO:

MR. YESHWANTH SHENOY,
ADVOCATE,
ENTETELEGALE,
401, 4TH FLOOR, TRADE AVENUE
SUREN ROAD, ANDHERI (EAST),
MUMBAI 400093, INDIA.

E MAIL: yshenoy@entetelegale.com OR biojustice@gmail.com



DRAFT GUIDELINES ON ACCESS AND BENEFIT SHARING

I. Preliminary

1. Objectives

1.1 These Guidelines on Access and Benefit Sharing Regarding the Utilization of Biological Resources and knowledge associated thereto (hereinafter “the Guidelines”) provides an objective and non-discriminatory framework for granting approvals for access to Biological Resources and Knowledge associated thereto and the fair and equitable sharing of the benefits arising from their utilization, in conformity with the Biological Diversity Act 2002 (hereinafter “the Act”) and the Biological Diversity Rules 2004 (hereinafter “the Rules”).

1.2 The Guidelines lay out the conditions under which access to Biological Resources and Knowledge associated thereto shall be granted and under which the sharing of benefits arising out of the utilization of Biological Resources and Knowledge associated thereto shall be qualified as fair and equitable.

1.3 The CBD recognized the sovereign rights of States over the genetic resources within their jurisdiction and accordingly the Act requires that all Users of Biological Resources shall, unless otherwise provided in the Act, seek the consent of the State prior to access to Biological Resources.

2. Definitions

2.1 In these Guidelines, unless the context otherwise requires:

- a) *Access* means any access to the Biological Resources and/or knowledge associated thereto made under the Act
- b) *Net Profit* means profit after expenses have been deducted from gross revenue.
- c) *Provider* means any natural or legal person(s) which has the legal right of disposal over the Biological Resources and/or knowledge associated thereto being made available to the Users
- d) *User* means any natural or legal person(s) which has requested for Access to Biological Resources and/or knowledge associated thereto under the Act.

2.2 words and expressions used but not defined in these Guidelines and defined in the Act and/or Rules shall have the meaning respectively assigned to them in the Act and/or Rules.



II. User Obligations

3. User Obligations Prior to Access

3.1 The Users shall request for Access by using the appropriate Forms provided for in the Rules and shall, in addition to the details therein, disclose the following:

A. Biological Resources which are Plants, their parts or Genetic Material

- i. Whether cultivated or collected from natural areas
- ii. Whether BR procured from Private Land or Public Land
- iii. If Public Land, is it a protected Area, Forest, National Park etc
- iv. If the access is made directly from the source or there are Agents
- v. Whether the BR is endemic
- vi. Whether the BR is endangered species

B. Biological Resources which are Animals, their parts or Genetic Material

- i. Whether domesticated or wild
- ii. Whether BR procured from Private owners or from Public Land
- iii. If Public Land, is it a protected Area, Forest, National Park etc
- iv. If the access is made directly from the source or there are Agents
- v. Whether the BR is endemic
- vi. Whether the BR is endangered species

C. Biological Resources which are Micro organisms, their parts or Genetic Material

- i. Whether developed/maintained in controlled conditions or collected from natural areas
- ii. Whether BR procured from Private areas or Public areas
- iii. If Public Area, is it a protected Area, Forest, National Park etc
- iv. If the access is made directly from the source or there are Agents
- v. Whether the BR is endemic
- vi. Whether the BR is endangered species

D. Knowledge associated with Biological Resources

- i. Whether the knowledge is owned by individual, family, group, organisation or a community
- ii. What BR is associated with the knowledge?
- iii. What Benefit Sharing is proposed by the owners?



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3.2 The Users shall submit a report on the possible impact to environment that may be caused by their relevant activities prior to Access. The User shall continue to report changes to this report as and when the User identifies any such changes at any stage during or after the Access.

Provided that in the event, the User reports a possibility of any adverse impact on environment, the report shall also mention the ameliorative measures in place and precautions taken to cause no damage to the environment or Biological Diversity. Any Access falling within this proviso will require the approval of the NBA prior to access and in the event the report is made during or after the Access, the User shall ensure that it shall stop any and all activities of Access.

3.3 The users are encouraged to make an audio video recording of the negotiations with the Providers and in the event such a recording is made, a copy of the same shall be deposited with the concerned SBB or the NBA.

4. User Obligations During and After Access

4.1 The Users shall after collecting the Biological Resources and Knowledge associated thereto, describe and record all relevant data and share the same with the nodal agency identified by NBA for the Purpose. Users shall respect customs, traditions and values of the Provider, if any during and after Access.

Provided that in the event of Knowledge associated with Biological Resources are accessed, the same shall be handled by the User in the manner requested by the Provider.

4.2 Users shall utilize Biological Resources and Knowledge associated thereto strictly for the purposes for which the Access was made obtained. Any change in the purpose shall be notified to NBA and NBA shall at its sole discretion allow such use or direct fresh application to be made under the Act.

4.3 Users shall conduct scientific study on the Accessed Biological Resources to ensure the conservation and sustainable use of the Biological Resources. The Users shall ensure that this knowledge shall be transferred free of cost to the Providers.

III. Provider Obligations

5. Provider Obligations

5.1 Once the Access is approved by the NBA, the Providers shall ensure that the Access is facilitated within the prescribed time.

5.2 If the Provider feels the need of professionals in assisting them with the negotiations with the Users, the Providers shall make a request for the same to the BMC, SBB or NBA and it shall be the responsibility of the BMC, SBB or the NBA as the case may be to provide the requested professionals to the Providers to assist them with the negotiations



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5.3 The Providers shall record the advantages and disadvantages as informed to them by the Users while negotiating the terms for the Access to Biological Resources and Knowledge associated thereto. In the event the Providers are not in a position to record the same, the User shall notify the concerned BMC, SBB or the NBA and the BMC, SBB or the NBA as the case may be shall ensure the presence of a suitably qualified person who shall record the negotiations under this Clause.

5.4 Providers shall ensure the conservation and sustainable use of the Biological Resources and if need be request the Users to conduct further studies under clause 4.3 after reporting their findings to the Users to ensure the conservation and sustainable use of the Biological Resources.

IV. NBA Approvals and Benefit Sharing principles

6.1 Where the Access to Biological Resources is obtained for Commercial utilization from Providers who are owners of the same, the User shall ensure that the Access ensures Sustainable Livelihoods¹ to the Providers. The User shall further share with the Providers its knowledge of best practices to ensure conservation and sustainable use of the Biological Resources.

6.2 Where the Access to Biological Resources is obtained for commercial utilization from local communities who collect the same from Public Land, the Users shall make fair payments² to the Providers and shall ensure ___% of the total price of the purchase towards welfare measures³ /NBF for the community. The User shall further share with the Providers its knowledge of best practices to ensure conservation and sustainable use of the Biological Resources.

6.3 Where the Access is made for Research Purposes, the User shall ensure effective participation of Providers, wherever possible or collaborate with any research institution (collaborative Research) identified by the NBA.

A. In case of non commercial research

- i. The research shall ensure the participation of at least one researcher from a research institute designated by NBA and all results of research shall be shared freely with the government research institutions and any know how for production shall be passed to non commercial producers free of any costs.
- ii. Any IP rights sought shall have the name of a government research institute designated for this purpose as one of the inventors or co owners of the IP.

¹ Sustainable Livelihoods For eg. Would mean direct procurement of the BR from the farmers through contract farming with a pre determined price for the produce and supply of the best seeds/insuring the produce etc. If the procurement is with the involvement of Agents, then a undertaking from the Agents about having paid the producers/farmers minimum wages for their labour etc.

² Fair payment means the payment fixed by the Government for such products (JFM's) or a minimum wage per day prescribed by the government

³ Welfare measures may be building community centers/infrastructure/scholarships etc for the community



B. In case of Collaborative Commercial Research

- i. Where the research is a Collaborative Research, any IP rights sought shall name the research institution involved as one of the inventors or co owners of the IP. Any know-how required for the production shall be transferred free of any costs if requested by the NBA for any use by government entities or if the products are required by the Government for Public good.
- ii. ___% of the Net Profit shall be paid to the National Biodiversity Fund and in the event of involvement of any community as Providers of the Biological Resources, the NBA may also direct the User to provide any of the non monetary benefit sharing measures provided for in Annexure I

C. In case of non Collaborative Commercial research

- i. Where results are shared

In cases where the results of a non collaborative commercial research is shared with any designated Government Research Facilities, the User shall pay to the NBF ___% of the Net Profit and the NBA shall also direct the User to provide any of the non monetary benefit sharing measures provided for in Annexure I

- ii. Where Results are not shared

In cases where the results of a non collaborative commercial research is not shared, the User shall pay to the NBF ___% of the Net Profit and the NBA shall also direct the User to provide any of the non monetary benefit sharing measures provided for in Annexure I

6.4 Where the NBA approval is sought for seeking any Intellectual Property Rights under sec 6 of the Act, the following benefit sharing shall be qualified as fair:

- i. Where the IP is for non commercial use

The User shall file an affidavit with the NBA stating that the IP is for non commercial use and the same shall be made available to the Government use free of cost. In the event the IP is later sought to be commercialized then sub clause (ii) of clause 6.4 shall be applicable.

- ii. Where IP is for commercial use

The User shall pay to the NBF ___% of the Net Profit and the NBA shall also direct the User to provide any of the non monetary benefit sharing measures provided for in Annexure I



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6.5 Where the Access is made for knowledge associated with Biological resources

The Benefit Sharing shall be in accordance with the terms and conditions negotiated between the Users and Providers and the NBA shall interfere only in the event of a gross inadequacies to the disadvantage of the Providers is found in the negotiated terms. The Benefit sharing may have a monetary part and any non monetary benefits that may be listed in Annexure I of these Guidelines or any legislation/mechanism made on TK.

6.6 The NBA while determining the mode for the sharing of benefits shall consider the short, medium and long term interests of all stakeholders involved. NBA acknowledges that some modes of benefit sharing may become effective immediately, whereas others become effective only in the distant future due to the period of time needed for the benefits to arise.

7. Certification of Compliance

The NBA shall develop a system of certification and a certification mark will be provided for by the NBA that shall certify the compliance with the Act and highlight the fair and equitable benefit sharing.



Annexure I – Non Monetary Benefit Sharing⁴

- a) Sharing of research and development results;
- b) Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities
- 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 to facilitate abilities of indigenous and local communities to conserve and sustainably use their genetic resources;
- 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 providing Parties
- 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 India
- n) Institutional and professional relationships that can arise from an 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.
- r) Collaboration in education and training;
- s) Collaboration in scientific research and development programs;
- t) Participation in product development;
- u) Joint ventures;
- v) Co-authorship of publications.
- w) Admittance to *ex situ* facilities of genetic resources and to databases;
- x) Admittance to taxonomic, biochemical, ecological, horticultural and other information and data;
- y) Transfer of knowledge and technology, 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.

⁴ This list contains the non monetary benefits identified and set out in Bonn Guidelines



EXPLANATORY NOTE ON THE DRAFT ABS GUIDELINES

The Convention on Biological Diversity (CBD) was signed in June 1992 with the main goals of conservation of biodiversity, sustainable use of the components of biodiversity and the sharing of benefits arising from the commercial and other utilization of genetic resources in a fair and equitable way. Thereafter, many of the signatories introduced national legislation to implement the CBD. However, there was a great confusion on the process of obtaining access to genetic resources and the standards of fair and equitable benefit-sharing and as a result many of the countries where the national legislations were introduced to implement CBD suffered and research in these countries suffered.

During the Conference of Parties (COP) VI, the Bonn guidelines on access to genetic resources and the fair and equitable sharing of the benefits arising from their utilization (the Bonn Guidelines) was adopted and the guidelines were intended to assist Parties, Governments and other stakeholders when establishing legislative, administrative or policy measures on access and benefit-sharing and/or when negotiating contractual arrangements for access and benefit-sharing.

India signed the CBD on 5th June 1992 and ratified it on the 18th February 1994 and in 2002 enacted the Biological Diversity Act (the Act) to implement and achieve the goals of CBD. The National Biodiversity Authority (NBA) was established at the National Level, the State Biodiversity Boards at the state level and the Biodiversity Management Committees at the local level.

India faced the same uncertainty on the issues of Access and Benefit Sharing and the effects were felt on the research sector. Some multi-national companies even placed voluntary moratorium on research related to Biological Resources until the issue is cleared by clear legislation/government notification. It is natural for the industry to take such steps because without a certainty on the input cost, it would be next to impossible for the industry to decide on the feasibility of research or the pricing of the Product. Since industry would be the buyers, it is extremely important to give this certainty, without which the market will be devoid of buyers and



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it will hurt the local people who are the sellers. Therefore, it would be a win-win situation for both the industry (which will act as buyers) and the local people (which will act as sellers) to formulate a definitive process for access of Biological Resources and knowledge associated thereto and formulate a clear cut policy standard on fair and equitable benefit sharing.

The Act requires the NBA to dispose of all Access Applications within six months from the date of application. As regards the transfer of research results and IPR are concerned, the time limit prescribed by the Act is three months from the date of application. Considering the rich biodiversity available in India and the potential of the research professionals the burden on the NBA can be considerably high and this would compel strong systems to be put in place to effectively implement the Act.

The Draft Guidelines on Access and Benefit Sharing (ABS Guidelines) is a first step taken by the NBA to put in an objective system in place to deal with the approval system for access and benefit sharing. This explanatory note endeavors to explain the clauses of the draft guidelines.

The ABS Guidelines is divided into four parts:

- I. Preliminary
- II. User Obligations
- III. Provider Obligations
- IV. NBA Approvals and Benefit Sharing Principles

Part I has clause 1 explaining the objectives of the ABS Guidelines and clause 2 which has a few definitions which are in addition to the definitions available in the Act and the Rules.

Part II deals with User Obligations both before and after the Access. Clause 3 requires certain additional information (information other than what is disclosed in the application formats). The information provided under this is critical to the disposal of an application. If the access is sought for a Biological Resources which is cultivated/domesticated, it would imply that there may not



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be a threat to the resource as the use will be sustainable and in these cases the application should be disposed off immediately under the standard benefit sharing formula defined in Part IV of the ABS Guidelines.

The main goal of the CBD and the Act is to ensure conservation and sustainable use and the primary concern of NBA should be to ensure this and if a case demonstrates conservation and sustainable use, then the question of equitable benefit sharing has to be taken into consideration and the same should be disposed off in accordance with the defined criteria. The additional information sought for in clause 3 will take care of this responsibility of NBA at the same time ensuring speedy disposal of applications in an objective manner giving certainty as well.

Clause 4 requires a sample of the accessed Biological Resource and the general data to be deposited with a nodal agency thereby ensuring that the data is available with the State.

Part III deals with the Provider Obligations and ensures protection to this class which is generally considered weaker side in case of negotiations across the table. Clause 5 ensures professional help, if any, required by the providers before, during or after negotiations. It also ensures recording of the pros and cons related to access thereby allowing the providers to take a well informed decision.

Part IV deals with the NBA approvals and Benefit Sharing Principles. Clauses 6.1 & 6.2 deals with cases of access to Biological Resources for commercial utilization, the benefit sharing shall be in the form of ensuring Sustainable livelihoods to the Providers in case the Biological Resource is cultivated/domesticated. In the event of the Biological Resource being collected from a public land, then as a part of benefit sharing, the user in addition of ensuring sustainable livelihood of the Provider, will also have to deposit a certain amount to the National Biodiversity Fund.

Clause 6.3 provides the benefit sharing principles in case the access is for research purposes. The research in this case has been divided as non commercial research and commercial research.



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Commercial research has further been divided into collaborative and non-collaborative research. The non-collaborative research has further been divided as cases where the results of research are shared and where they are not shared and accordingly for each of these classes the benefit sharing formula is prescribed.

Clause 6.4 deals with the benefit sharing principles where the application is made to seek NBA approval before seeking any Intellectual Property Rights. Clause 6.5 deals with NBA's role in interfering with the benefit sharing formula agreed to between the Users and Providers.

Clause 7 deals with a system of certification wherein it is planned that NBA will allow the use of certain certification marks in case where the User has followed the guidelines and ensured fair and equitable benefit sharing with the providers.

The Annexure contains a list of non monetary benefit sharing as identified in the Bonn Guidelines.



ABOUT THE AUTHOR



Mr. Yeshwanth Shenoy is a practicing lawyer and is an expert on Biodiversity Law and is the Legal Consultant to the National Biodiversity Authority, a Regulatory Authority under the Government of India. He started his career as a trial lawyer and practiced as a counsel in High Court of Bombay and High Court of Kerala. His exposure to the corporate world as an In house Counsel was through Larsen and Toubro (the largest engineering and construction conglomerate in India), British Telecom (the UK based Telecom giant) and Computer Associates (US based IT management software giant).

Mr. Shenoy has an LL.M in Intellectual Property Laws from a joint program of WIPO (World Intellectual Property Organization) and Turin University, Italy. He also has a Masters in Law in Commercial and Consumer Laws with International Business Transaction from Mumbai University. He has done specialization courses in International Trade Law and European Business and Competition Law for which he was granted a scholarship by the Italian Foreign Ministry and University Institute of European Studies. Mr. Shenoy also briefly interned at the United Nations Interregional Crime and Justice Research Institute in Italy where he worked on issues relating to International Security and Terrorism.

He has also authored books on Company Law and Biodiversity law and is a regular contributor of articles to various Law Journals. He has presented papers on varied subjects in national and international conferences. He is also a visiting faculty at the K.C.Law College, Mumbai.

