



Frequently Asked Questions

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# **BIOLOGICAL RESOURCES AND RELATED LEGISLATION**



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### 1) WHAT ARE THE MAIN OBJECTIVES OF THE BIOLOGICAL DIVERSITY ACT, 2002 (BDA)?

The BDA came into force in the year 2002 and its main objectives are as follows:

- conservation and sustainable use of biological resources;
- to address issues related to access to biological resources; and
- to enable fair and equitable sharing of benefits arising from use and knowledge of such resources with the local communities.

### 2) WHO ARE THE BENEFIT CLAIMERS UNDER BDA?

The entities involved in the conservation of biological resources and who create, and holds knowledge and information relating to the use of biological resources, are the benefit claimers. The benefits could include monetary and non-monetary components, both.

### 3) WHAT IS THE PROCEDURE FOR EQUITABLE BENEFIT SHARING IN INDIA?

The National Biodiversity Authority (NBA) while granting approval for Intellectual Property Rights (IPR) application or transfer of biological resources or knowledge can determine equitable benefit sharing by giving effect to any of the following measures, namely:

- Grant of joint ownership of IPR to the NBA or to the benefit claimers;
- Transfer of technology;
- Locating the production or research and development sites in order to provide

better living conditions to the benefit claimers;

- Associating Indian scientists, benefit claimers and local people for Research & Development of the biological resources;
- Establishing venture capital fund for aiding benefit claimers and granting compensation to benefit claimers; and
- Payment of monetary compensation and other non-monetary benefits to the benefit claimers as the NBA may deem fit.

### 4) WHAT IS THE MODE AND HOW IS THE FAIR AND EQUITABLE BENEFIT SHARING (FEBS) DECIDED?

The NBA formulates the guidelines for benefit sharing which is then notified in the Official Gazette. The formula for benefit sharing is, however, subjective in nature and thus depends on case-to-case. The quantum of benefit is agreed mutually between the persons applying for approval from the NBA and the local bodies along with the benefit claimers. Further, 5 percent of the benefits is earmarked by the Authority towards administrative and service charges.

The applicant has an option to pay for benefit sharing ranging from 0.1 to 0.5 percent at the graded percentages of the annual gross ex-factory sale of the product which is worked out based on the annual gross ex-factory sale minus government taxes as given below:

Annual Gross Ex-Factory Sale of Product	Benefit Sharing Component
Up to Rupees	0.1 percent

1,00,00,000	
Rupees 1,00,00,001 up to 3,00,00,000	0.2 percent
Above Rupees 3,00,00,000	0.5 percent

- Where the applicant himself commercializes the process/ product/ innovation, the monetary sharing ranges from 0.2 to 1.0 percent based on sectoral approach, which is worked out on the annual gross ex-factory sale minus government taxes.
- Where the applicant assigns/licenses the process/product/innovation to a third party for commercialization, the monetary sharing ranges from 3.0 to 5.0 percent of the fee received (in any form including the license/assignee fee) and 2.0 to 5.0 percent of the royalty amount received annually from the assignee/licensee, based on sectoral approach.

One related case based on FEBS is of Divya Pharmacy vs Union of India wherein the High Court of Uttarakhand dismissed Divya Pharmacy’s (Petitioner) challenge to the FEBS determined by Uttarakhand State Biodiversity Board (Respondent) based on Sections 21(2)(f) and 21(4) of the BDA, since the biological resources were being utilized for commercial purposes, and thus petitioner was bound to share 0.1 - 0.5 percent of its annual sale since 2014 irrespective of being an Indian entity. A wider purposive interpretation of the Nagoya Protocol was adopted by the High Court in stating that both foreign and Indian entities

should abide by FEBS and share their benefits with local and indigenous communities.

## 5) WHAT STRUCTURE IS IMPLEMENTED TO REGULATE ACCESS TO BIOLOGICAL RESOURCES?

The BDA has implemented a three-tier structure of various levels to regulate the access to biological resources:

- At National Level: National Biodiversity Authority (NBA);
- At State Level: The State Diversity Boards (SDBs); and
- At Local Level: The Biodiversity Management Committees (BMCs).

## 6) WHO IS REQUIRED TO TAKE PRIOR APPROVAL OF THE NBA TO UNDERTAKE BIODIVERSITY RELATED ACTIVITIES?

As per Section 3 of the BDA, 2002, certain persons are not permitted to undertake biodiversity related activities or to obtain any biological resource occurring in India or knowledge associated thereto for research or for commercial utilisation or for bio-survey and bio-utilisation without prior approval of NBA, which are as follows:

- a person who is not a citizen of India;
- a citizen of India, who is a non-resident;
- a body corporate, association or organisation not incorporated or registered in India; or
- a body corporate, association or organisation 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.

Conclusively, on reading the above provision, it is clear that prior approval of NBA is mandatory for persons or entities who have a "foreign element" attached to it.

#### **7) WHICH TYPE OF ACTIVITIES OR USES OF BIOLOGICAL RESOURCES ARE EXEMPTED FROM THE BDA AND PRIOR NBA APPROVAL?**

The following activities and use of biological resources are exempted from the BDA and persons doing the same are not required to take prior permission from NBA:

- Use of Indian biological resources that are normally traded as commodities such as Pulses, Oilseeds, Fibre Crops, Forage Crops (for some species) and for no other purpose;
- Use of value-added products;
- Traditional uses of Indian biological resources or use in collaborative research projects between India and foreign institutions, publication of research papers, dissemination of knowledge in any seminar or workshop with conformity and due approval from Central Government;
- Uses of biological resources by the cultivators, framers, breeders, animal husbandries, poultry farming, live-stock keepers, beekeepers and traditional healers like vaid, hakims etc.;
- Use of completely exhausted biological resources i.e. bio-waste products;
- Any person making an application for any right under any law relating to protection

of plant varieties enacted by Parliament.

#### **8) WHAT ARE THE VALUE-ADDED PRODUCTS AND WHY ARE THESE EXCLUDED FROM THE DEFINITION OF BIOLOGICAL RESOURCES?**

The value-added products are those products which are extracted as portion or extract (like alcoholic extract or aqueous extract) from the plants or animals in a physical inseparable and unrecognizable form. The reason for exempting the value-added products from the definition of biological resources is to remove the fear of the Indian industry, so that export of value-added products can be carried out smoothly without getting hampered.

#### **9) WHAT IS ACCESS AND BENEFIT SHARING?**

Access and Benefit Sharing (ABS) ensures that the benefits obtained from the use of biological resources are shared in a fair and equitable manner with the indigenous individuals or local communities who are well-versed with the traditional knowledge and use of the biological resources.

#### **10) DOES INDIA PRACTICE ABS?**

Yes, India became a signatory to the Nagoya Protocol of Convention on Biological Diversity (CBD) in 2014 which explicitly dealt with ABS. The ABS Guidelines were also enacted by the Indian legislature which lays down several regulations including payments. An Applicant has to make payment in return for commercial use of a genetic resource out of which 95 percent of the payment must reach the indigenous and local communities, among others. The NBA also has the authority to

determine the equitable benefit sharing arising from the use of biological resources.

**11)CAN INVENTIONS RELATED TO BIOLOGICAL MATERIAL BE PATENTED IN INDIA?**

Yes, the inventions having biological material can be patented in India. The Applicant should sufficiently disclose the source and geographical origin of the biological material. Further, the Applicant also needs to submit an approval obtained from NBA in case the biological material is obtained from India.

**12)WHAT IS THE PROCEDURE FOR OBTAINING NBA APPROVAL FOR IPR?**

Section 6(1) of the BDA, 2002 provides that prior approval of NBA is necessary before applying for any kind of IPR, related to biological material, in India or outside India on relevant Form of the Biological Diversity Rules, 2004. However, in case of specific IPR i.e. patent application filing, permission from NBA may be obtained after filing or acceptance of patent application but before grant of patent by the Patent Office. Further, the NBA is required dispose of such application for permission made to it within a period of ninety days from the date of receipt thereof.

**13)DO INDIAN RESEARCHERS REQUIRE APPROVAL FOR OBTAINING BIOLOGICAL RESOURCE FOR RESEARCH PURPOSES?**

The Indian researchers neither require prior approval from any authority nor they need to give any prior intimation to SBB for obtaining

biological resource for conducting research in India.

In case the results obtained through the research is used for commercial purposes, prior intimation to the SBB is required under Section 7 of the BDA.

**14)WHAT ARE THE PENALTIES THAT MAY BE IMPOSED IN CONTRAVENTION TO BDA?**

It is significant to note that all offences made under the BDA are cognizable and non-bailable. The followings are the penalties against the contravention of below said Sections of BDA:

Section	Cause	Penalty
55(1)	Contravention of Sections 3 or 4 or 6 of the BDA. These Sections related to persons undertaking biodiversity related activities without approval of the NBA, the results of research not to be transferred without approval of NBA and application for IPR not to be made without approval of NBA.	Imprisonment up to 5 years or fine up to Rs. 10 lakhs or both. When damage exceeds 10 lakhs, the fine may be commensurate with the damage caused.
55(2)	Contravention of Section 7 of the BDA, related to	Imprisonment up to 3 years or fine up to Rs. 5

	prior intimation to State Biodiversity Board for obtaining biological resources.	lakhs or both.
56	Contravention of directions/ orders of Central Government, State Government, NBA and SBBs.	If no penalty is prescribed in any other provision of the Act, then Rs. 1 lakh for 1st default, Rs. 2 lakhs for 2nd default and an additional 2 lakhs per day for continuous default.
57	For offences committed by companies in contravention of the BDA.	Every person who was in charge or had the responsibility of the company at the time of the commission of the offence will be proceeded against and punished accordingly.

**15)WHAT ARE THE PROVISIONS UNDER THE PATENTS ACT, 1970, THROUGH WHICH THIRD PARTY CAN INITIATE PROCEEDINGS AGAINST THE GRANT OF PATENT OR GRANTED PATENT, USING BIOLOGICAL RESOURCES?**

The following proceedings can be initiated under the Patents Act, 1970:

- Refusal of Grant: As per Indian Patents Act 1970, contravention of provisions related to biodiversity provisions, leads to refusal of patent under Section 15 of the Patents Act, 1970;
- Opposition Proceedings: If the complete specification does not disclose or wrongly mentions the source and geographical origin of biological material used for the invention, then pre- grant opposition or post-grant opposition proceedings can be initiated under Sections 25(1) and 25(2) of the Patents Act, 1970, respectively;
- Revocation of Patent: Non-Disclosure or wrong disclosure of the source and geographical origin of biological material used for the invention, is one of the grounds of revocation proceedings in the Patents Act, 1970, before the Patent Office.

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