

FREQUENTLY ASKED QUESTIONS ON THE BIOLOGICAL DIVERSITY ACT, 2002

1. What is Convention on Biological Diversity

The Convention on Biological Diversity (CBD) is a legally binding multilateral environmental agreement that has 194 contracting Parties (Countries) as its members with three objectives – conservation of biological diversity, sustainable use of the diversity and ensuring fair and equitable sharing of benefits of such use. It has entered into force on 29th December 1993.

2. How does CBD recognize the biological resources at country level?

The CBD provides sovereign rights over their biological resources, and requests countries would facilitate access to the genetic resources by other parties subject to national legislation and on mutually agreed terms. The CBD also provides for equitable sharing of benefits arising from the utilization of traditional knowledge, and practices, with holders of such knowledge. This has made it necessary for a legislation to be put in place, which lays down the framework for providing access, for determining the terms of such access and for ensuring the equitable sharing of benefits.

3. What is the status of India's biodiversity in comparison with the World?

India is one of the 17-mega biodiversity countries of the world. With only 2.4% of the land area, India already accounts for 7-8% of the recorded species of the world. Over 46,000 species of plants and 81,000 species of animals have been recorded in the country so far by the Botanical Survey of India and the Zoological Survey of India, respectively. India is an acknowledged centre of crop diversity, and harbors many wild relatives and breeds of domesticated animals and fish besides millions of microbial diversity, insects and other species. The ecosystem diversity of India is also unparalleled in comparison with other countries in the world.

4. We already have a number of Acts relating to forestry, wildlife etc. Why do we need this legislation on biodiversity?

The purpose of the Biodiversity Act is to realize equitable sharing of benefits arising out of the use of biological resources and associated knowledge. The main objectives of the Act are conservation, sustainable use and equitable benefit sharing out of the utilization of bioresources. The Act also covers the protection of traditional knowledge and equitable sharing of benefits arising out of the use of such knowledge.

5. What does the Biodiversity Act - 2002 primarily address?

The Biodiversity Act - 2002 primarily addresses issues of conservation, sustainable use of biological resources in the country, issue related to access to genetic resources and associated knowledge and fair and equitable sharing of benefits arising from utilization of biological resources to the country and its people.

6. What are the implementation structures of Biodiversity Act - 2002

The Act and the Rules are implemented in India through a decentralized system.

A three tiered structure has been established under the Act at the national, state and local levels.

At the local level, the Biodiversity Management Committees (BMCs) are to be established by institutions of local self-government for implementation of specific provisions of the Act and Rules.

At the state level, the State Biodiversity Boards (SBBs) are established to deal with all matters relating to implementation of the Act and the Rules.

At the national level, the National Biodiversity Authority (NBA) is established to deal with all matters relating to implementation of the Act and the Rules.

Each of these structure are required to be connected for decision making processes on various issues, including on issues of access and benefit sharing (ABS).

7. What are the mandates of the National Biodiversity Authority?

The National Biodiversity Authority is mandated to regulate use of India's biological resources; facilitates/ enable conservation action and provides advice to Central and State Governments on issues of conservation, sustainable use and access and benefit sharing.

8 .What is the legal status of NBA, SBBs and BMCs?

All of these institutions are statutory, autonomous bodies established under the Biological Diversity Act, 2002.

9. Is there any overlap in the functions of NBA and SBBs?

There is no overlap in the functions of NBA and SBBs on issues of ABS. Their domains and functions are very distinct from each other. All matters relating to requests by foreign individuals, companies or institutions and all matters relating to transfer of results of research to any foreigner, approvals for intellectual property protection where biological resources and associated knowledge are involved will be dealt with by NBA. All matters relating to access by Indians for commercial purposes will be under the purview of the concerned State Biodiversity Boards. However, the benefit sharing guidelines are to be issued by the NBA.

10. Will this legislation affect research by Indians in biological resources?

No. There is no requirement under the legislation for seeking permission for carrying out research, if it is carried out in India by Indians, as well as under collaborative research projects that have been drawn within the overall policy guidelines formulated by the Central Government vide notification S.O.1911(E) of Government of India. The only situations that would require permission of the NBA are: (i) when the results of any research which has made use of the country's biodiversity is sought to be commercialized, (ii) when the results of research are shared with a foreigner or foreign institution, and (iii) when a foreign institution/individual wants access to the country's biodiversity for undertaking research and (iv) when any intellectual property protection is sought on Indian biological resources.

11. Will this legislation impact collaborative research projects?

This legislation will not impact collaborative research projects. Section 5 exempts collaborative research projects from sections 3 and 4, provided these conform to the policy guidelines issued by the Central Government from time to time. Please refer to Notification S.O.1911(E) issued by Government of India on 8th November 2006 for this purpose.

Collaborative research projects that have commercial utilization as a component however, need to seek prior permission of NBA since the exemption covers only research collaboration and not commercialization.

12. Do Indian researchers require approval for obtaining biological resource for research purposes?

The Indian researchers neither require prior approval nor need to give prior intimation to SBB for obtaining biological resource for conducting research in India.

In case the results are used for commercial purposes, prior intimation to the State Biodiversity Board is required under Section 7 of the Biological Diversity Act 2002.

13. How will the Act check biopiracy?

To check misappropriation of Indian biological resources, the Act provides that access to Indian biological resources and associated knowledge are subject to terms and conditions, which secure equitable sharing of benefits. Further, it would be required to obtain the approval of the National Biodiversity Authority before seeking any IPR based on biological material and associated knowledge obtained from India.

14. Does the legislation provide for any exemptions?

The legislation provides for the following exemptions

- a. Exemption to local people and communities of the area for free access to use biological resources within India
- b. Exemptions to growers and cultivators of biodiversity and to Vaidis and Hakims to use biological resources.
- c. Exemption through notification of normally traded commodities from the purview of the Act only when used as commodity
- d. Exemption for collaborative research through government sponsored or government approved institutions subject to overall policy guidelines and approval of the Central Government and conforms to the central government guidelines.

15. Why value added products have been excluded from the definition of biological resources?

The intention of the Act is not to cover value added products of biological resources. Though the biological resources by definition do not include value added products, an explicit exemption has been mentioned to allay the fears of Indian industry so that export of value added products is not hampered.

16. What is implied by value added product?

Value added product implies products containing portions/extracts of plants and animals in unrecognizable and physically inseparable form.

17. When a normally traded commodity is used for the purpose other than commodity trade is there a need to get prior approval of NBA.

Yes. When they are utilized for research and development by certain individuals under section 3 of the Act and for alternate/ commercial uses they need to get prior approval from NBA, as the exemption is only for purposes of commodity trade.

18. Does the Indian industry need prior approval of the SBB?

Under Section 7 of the Biological Diversity Act, 2002 the Indian industry is required to give prior intimation to the concerned SBB about obtaining the biological resources for commercial utilization. The SBB will have the power to prohibit or restrict any such activity, which violates the objectives of conservation, sustainable use and equitable sharing of benefits.

19. Whether the legislation on biodiversity would come in the way of development of industry and would it jeopardize trade?

The Act does not come in the way of development of the industry. It provides for use of biological resources in a manner that fulfills obligation of ethics and equity in conservation, sustainable use and sharing of benefit arising from utilization of bioresources and associated knowledge thereto.

20. India has several practitioners of Indian systems of medicines who use herbs etc, for medicine and healthcare. Will such use be affected by the legislation?

The Act does not aim at banning the use of medicinal plants by vaidas and hakims and for traditional practices. They will continue to have free access to resources and knowledge. An explicit provision to this effect has been made under Section 7 of Biological Diversity Act 2002.

21. Will this legislation affect the use of bio-resources by local people?

No. An explicit exemption has been made in section 7 for local people and communities, including growers and cultivators of biodiversity, and vaidas and hakims. Moreover commercial utilization has been defined in section 2, which also specifically excludes traditional practices and use in agriculture, horticulture, poultry, dairy farming, animal husbandry etc.

22. How the concept of prior informed consent (PIC) with the concerned local people be formalized?

The provision of mandatory consultation of BMCs by the NBA and SBBs would ensure formalization of PIC by the communities and the involvement of BMCs in the decision making process.

23. Does the legislation provide for protection of TK?

The Act covers the traditional knowledge in the preamble itself. It also provides for issues related to traditional knowledge under the umbrella of associated knowledge within various provisions of the Biological Diversity Act, 2002. Rules, 2004.

24. How is NBA promoting creation of BMCs?

NBA has issued a set of guidelines for the establishment and operationalization of BMCs. It also provides financial support for establishment of BMCs. Working close with the Ministry of Panchayat Raj, NBA has facilitated issuance of a direction from Ministry of Panchayat Raj (Ref No: N – 11011/9/2013 – POL – II of 10th April 2013) that requests all local bodies to establish the BMCs.

On a regular basis, NBA and SBBs are organizing orientation, capacity building and awareness programmes for BMCs.

25. Who are the benefit claimers?

The benefit claimers are conservers of biological resources, creators and holders of knowledge and information relating to the uses of biological resources.

26. What kinds of benefits are envisaged under the benefit sharing arrangement approved by the NBA?

The benefits could include monetary and non-monetary components. Examples could include grant of joint ownership of IPRs, transfer of technology, association of Indian Scientists in R&D, setting up of venture capital fund etc.

27. How will the beneficiaries of benefits be identified?

Under Rule 22 (6) of the Biological Diversity Rules, 2004, the BMCs main function is to prepare the People's Biodiversity Register (PBRs). These registers are used, where available, to identify the BMCs where from the biological resources are accessed and benefits will be provided to the Local Biodiversity Funds (LBFs) maintained by BMCs.

28. To whom will the monetary benefits be given?

In cases where specific individuals or group of individuals are identified, the monetary benefits will be paid directly to the Local Biodiversity Fund to be used by the Biodiversity Management Committee (BMC).

29. How will the benefits be shared?

The National Biodiversity Authority has issued a set of guidelines on Biodiversity Management Committees. Details of managing the local Biodiversity Fund can be found in the document "Guidelines for BMCs" on NBA's website.

30. What is a PBR?

People's Biodiversity Register (PBR) is a legal document that contains details of biological resources occurring within a BMC and contains associated knowledge as well. The PBR acts as a source of inventory of biological resources and knowledge and for benefit sharing purposes under the ABS component.

31. Who prepares a PBR?

Under Rule 22 (6) of Biological Diversity Rules, 2004, the BMC needs to develop PBR.

32. Are there are guidelines available for preparing a PBR?

Yes, the National Biodiversity Authority issued a set of guidelines on developing a PBR in 2009 which was subsequently revised in 2013 based on wide consultations and experiences gained in developing a PBR.

33. How to develop the PBR?

Detailed Guidance on how to develop a PBR and the formats can be downloaded from <http://nbaindia.org/content/105/30/1/pbr.html>

34. How will PBR promote the objectives of the Act?

PBR contains information about the biological resources and associated knowledge at BMC level. This information is critical for conservation, sustainably monitoring of biological resources at local level. A PBR also helps in identification of a beneficiary with whom benefits can be shared when an ABS agreement becomes operational.

35. How does NBA & SBB help preparation of PBR?

NBA, through SBBs, provide financial assistance for preparation of PBRs. Details of such support and guidelines can be accessed from <http://nbaindia.org/gallery/284/36/2/publications.html>

36. Is there any overlap between Biological Diversity Act and Protection of Plant Varieties and Farmers' Rights Act?

There is no overlap between Biological Diversity Act and Protection of Plant Varieties and Farmer's Rights Act (PPV&FRA). The scope and objectives of these two legislations are different. In order to harmonise both the legislations, an exemption has been provided under Section 6 (3) of the Biodiversity Act for applicants seeking protection under the PPV&FRA.

37. Why an exemption has been provided in Section 6 (3) of the Biological Diversity Act for applicants seeking protection under the PPV&FRA.

This has been done to harmonise the two legislations and to avoid overlap of procedural requirements. The purport of Section 6(3) is to ensure that before grant of IPRs, it becomes possible to realize equitable sharing of benefits arising out of the use of biological resources and knowledge. As the PPV&FRA also has a provision for benefit sharing, an exemption has been provided in the Biological Diversity Act for applicants seeking protection under the

PPV&FRA. The Authority under the PPV&FRA legislation would be required to endorse a copy of the rights granted under this Act to the NBA.

38. Is there any overlap between the Biological Diversity Act and Patents (second Amendment) Act 2002?

There is no overlap between these two legislations. The scope and objectives of the two legislations are different. The patent applicant should disclose the source and geographical origin of the biological material when used in an invention. Further, non-disclosure or wrongful disclosure of source of biological material and any associated knowledge will result in opposition to the grant of patent or revocation of the patent.

39. How does the approval process for IPR work under the Biological Diversity Act?

Section 6(1) provides that prior approval of NBA is necessary before applying for any kind of IPRs in India and outside based on any research or information on a biological resource obtained from India. However, in case of patents, permission of the NBA may be obtained after application is made but before sealing of the patent.

40. What is the concept of Biodiversity Heritage sites? How are they different from Protected Areas?

Section 37 provides for designating Biodiversity Heritage Sites (BHS). These are areas of biodiversity importance, which harbour rich biodiversity, wild relatives of crops, or areas, which lie outside the protected area network. The purpose is not to cover the already designated protected areas such as national parks and wildlife sanctuaries.

41. Who will initiate the process of declaring a BHS?

An application for designating a BHS shall originate from BMCs.

42. How does the Act address the concern relating to threatened species?

Section 38 provides for notifying threatened species by the SBBs and prohibits or regulates their collection.

43. What is the rationale behind establishing repositories?

Section 39 provides for designating of institutions for different categories of biological resources. 15 institutions have been notified by the Government of India under the Biological Diversity Act for keeping different categories of biological resources for safe custody and posterity. These deposits made under Section 39 relate to ABS applications only.

44. In case of research of Human stem cell for obtaining patent does NBA's prior approval needed?

As per the provisions of BD Act human genetic material is excluded from the definition of biological resources and prior approval of NBA is not needed.

45. If a company multiplies seeds or vegetatively produced planting materials in India from a variety that has been developed outside India do they need any documents/or approvals from the National Biodiversity Authority to export the seeds or vegetatively produced planting materials again as it is their material (including possible agreements with third parties)? What steps a company needs to take with regard to the NBA?

If the biological resources used by the company in India does not contain any Indian germplasm* (biological resource) in their development or multiplication or production or research, then it will not come within the ambit of the NBA.

If the biological resources handled, researched, developed, multiplied, produced etc., contain any strain of an Indian germplasm (biological resource) then prior approval of NBA is required under Section 3 of the Act, for companies covered by the section.

For companies not covered section 3, who undertake activities as above, prior intimation has to be given to the concerned State Biodiversity Board (SBB) as per Section 7.

For application to NBA in above mentioned scenario, please refer to Rule 14 of the Biological Diversity Rules 2004 and Form I thereunder. It is available on our website www.nbaindia.org.

* Indian germplasm is any plant genetic material that originated in Indian Territory or has been introduced and/or adapted to Indian Agro-ecologies where they have developed distinctive properties.

46. Do companies need to apply for transfer approval when sending samples from seed lots (of varieties that are for sale in India/APAC) produced in India, for testing to confirm purity and identity, to a laboratory outside India?

If the company in question is covered under Section 3 of the Act, then the company will have to apply for prior approval of NBA for access to the biological resources for research (which includes testing for confirming purity and identity) or bio-utilization.

If the company is sending the biological resources to a laboratory outside India for research purpose, the criteria is whether the control and ownership of accessed biological resources rests with the company in India or with the entity outside. In either of the cases, the permission for transfer on Form I need to be taken.

If there is no transfer of the biological resource and the same is being sent only for the purpose of carrying out some research or tests for and on behalf of the company, prior approval applied under Form I is sufficient. In this case, the control over the biological resource is retained by the company. (applicant under Form I)

If there is substantial transfer of the accessed biological resource from the company which has applied under Form I to another entity, then the applicant has to obtain the permission of the NBA under Section 20 of the Act read with Rule 19 of the Rule and Form IV therein. In this case, the significant control over the biological resource is transferred to a third party.

47. Do companies need to apply for transfer approval when sending samples of company-owned material for genotyping outside India (results to be used in the Indian breeding program)?

It is important to first note that the Act does not recognize a category called 'company-owned material', when dealing with biological resources.

Answers to the above question explain this question also.

48. Do companies need to apply for transfer approval if India is used as a hub to produce plants for other affiliates, starting with company owned material from outside India with end products that need to be exported again (e.g production of double haploids in a lab in India).

If all material from outside India used to produce the plants in India by a company, then no approval of the NBA is required for the export of the end products. This is subject to the opinion given in point (Question no. 1).

49. Do companies need to apply for transfer approval when exporting company owned material from India to produce new material and bring back to India?

If the material is an Indian biological resource or contains Indian germplasm (biological resource) then companies covered under Section 3 would need to apply under Form 1 for the prior approval of the NBA.

Again as in question 2 if there is substantial transfer of the biological resource to a third party, Form IV application also needs to be submitted for approval.

50. Do companies need to apply for approval of transfer of research results when sharing data from disease or other performance tests done on their locations in India with company owned germplasm, with colleagues of other affiliated outside of India?

If the biological resources used for the research are occurring in or obtained from India, then an approval is required for transferring the results of research relating to such biological resources under Section 4 read with Rule 17 of the BD Rules and apply in Form II therein.

51. Section 4 makes reference to 'any biological resources occurring in India', would that also include any breeding material from a (multinational) breeding company that originates from (a) Indian commercial varieties or from (b) international varieties/germplasm?

It would include breeding materials which are Indian whether commercial or local, and in case of international varieties, which contain any Indian germplasm.

52. Is it correct that applying for PBR in India is exempted, but applying for PBR outside of India is not? Section 6(4) mentions the exemption of PBR under the protection of Plant Varieties and Farmers' Rights Act, 2001: does this really exclude PBR in other countries or is this mentioned as an example?

The section gives the PBR exemption only if the PBR is granted under Indian law i.e., Plant Varieties Protection and Farmers Rights' Act, 2001.

53. Can molecular marker assisted breeding/selection be considered as 'Conventional Breeding' (as this is mentioned under Commercial utilization).

Molecular marker aided selection is not yet considered as conventional breeding.